CONTENTS

Appendix 1

Scope of work

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Scope of work (from original scope)

1 Guidance title

Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children.

1.1 Short title

Obesity

2 Background

a) The National Institute for Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Primary Care (NCC–PC) to work with the Health Development Agency (HDA) and develop guidance, for use in the NHS in England and Wales, on the prevention, identification, assessment, treatment and weight management of overweight and obesity in adults and children. This follows referral of the topic by the Department of Health and Welsh Assembly Government (see Annex). The guidance will provide recommendations for good practice that are based on the best available evidence of effectiveness, including cost effectiveness. The term 'guidance', rather than 'guideline' is used to reflect the broad nature of the task. The guidance has two key components. First, a guideline providing recommendations on the clinical management of overweight and obesity in the NHS will be developed through the NICE guideline development process. Second, advice on the prevention of overweight and obesity will be issued and will apply in both NHS and non-NHS settings.

b) The joint Institute and HDA guidance will support the implementation of National Service Frameworks (NSFs) (including those for Coronary Heart Disease, Diabetes, and the NHS Cancer Plan) in those aspects of care and prevention where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The guidelines and technology appraisals published by the Institute after an NSF has been issued will update the Framework. The guidance will also support the implementation of the Priorities and Planning Framework 2003–6 and the new General Practitioner (GP) contract.

3 The need for the guidance

a) Obesity and overweight (pre-obese) are conditions in which weight gain has reached the point where it poses significant risks to health. Obesity is more than a lifestyle disorder. It may be considered as a disease and a risk factor for other diseases (for example, type 2 diabetes). In adults, the body mass index (BMI) is frequently used as a measure of overweight and obesity, with overweight being defined as a BMI 25-29.9 and obesity as a BMI ≥ 30. Epidemiological surveys of England indicate that the prevalence of overweight and obesity in adults has nearly trebled during the last 20 years. In 1980, 8% of adult women and 6% of adult men were classified as obese; by 2002 this had increased to 23% of women and 22% of men, with a further 43% of men and 34% of women being overweight. Therefore, around two-thirds of men and women, almost 24 million adults, were either overweight or obese in 2002. The Welsh Health Survey, undertaken in 1998, found that 1 in 6 adults in Wales were obese (nearly 15% of men and 17% of women). Compared with 1985 levels, obesity in Wales had doubled among men and increased by half among women by 1998. The prevalence of obesity differs according to age, socio-economic group and ethnic group. The National Audit Office (NAO) (2001) found that obesity:

- increases with age
- is more prevalent among lower socio-economic and lower income groups, with a particularly strong social class gradient among women
- is more prevalent among certain ethnic groups, particularly among African-Caribbean and Pakistani women (from Joint Health Surveys Unit, 2001)
- is a problem across all regions in England but shows some important regional variations.

In children, the prevalence of obesity is also rising. In England in 2002, over 16% of boys and girls aged 2–15 years were obese compared with 10% of males and around 12% of females in 1995 (defined as a BMI above the 95th percentile) (Health Survey for England [HSE] 2002). Around a further 14% of males and females were estimated to be overweight (defined as a BMI between the 85th and 95th percentiles) compared with around 13% of males and females in 1995. There are inequalities in the prevalence of obesity. The HSE (2002) found that obesity was more common in children, particularly girls, from lower social groups and the National Diet and Nutrition Survey (NDNS) (1997) of young people found that obesity was more common among Asian groups and children living in Wales.

Obesity occurs as a result of consuming more calories than are expended for daily energy needs. In adults, obesity is associated with an increased risk of diseases that are a major cause of morbidity and mortality, notably type 2 diabetes, coronary heart disease, hypertension, many cancers and osteoarthritis. In children and teenagers, the associated morbidities include hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction, and exacerbation of existing conditions such as asthma. However, the persistence of obesity into adulthood is the most important concern; the risk of persistence increases with increasing age of the child and severity of obesity.

Obesity imposes a considerable economic burden. The National Audit Office (NAO) (2001), estimated that in 1998 obesity directly cost the NHS at least £0.5 billion, while the indirect cost of obesity on the wider economy was around £2 billion a year.

b) There is evidence of variability in the management of overweight and obese people in the NHS. The NAO (2001) identified no central guidance on management of obesity and, at local level, only 28% of Health Authorities had taken action to address obesity as a health problem. It was also noted that primary care played an important role in the management of obesity but that GPs and practice nurses used a wide range of different methods to manage overweight and obese patients and many were uncertain as to which interventions were most effective. The NAO also highlighted the need for joint working with different agencies to facilitate cross-government initiatives to prevent obesity at both national and local level and the need to consider the broader environment in terms of its potential to support behavioural change. As the key representative for health within Local Strategic Partnerships, Primary Care Trusts (PCTs) in England and Local Health Boards in Wales have a role to play which goes beyond the clinical setting and extends into the wider community through work in schools, workplaces and neighbourhoods.

c) National guidance is needed on the prevention of obesity and the identification, evaluation, and management of overweight and obese adults and children. The NAO (2001) noted that most general practices surveyed said they would find a national guideline for overweight and obesity useful. The reasons for needing guidance in this area are:
    - the rising prevalence of obesity and attendant rise in prevalence of diseases associated with obesity
    - the evidence of wide variations in care provided to adults and children with obesity, notably in primary care, and
    - the evidence that certain interventions can prevent excess weight gain, overweight and obesity .

4 The guidance

a) The guideline development process is described in detail in two booklets that are available from the NICE website (see 'Further information'). *The Guideline Development Process – An Overview for Stakeholders, the Public and the NHS* describes how organisations can become involved in the development of a guideline. *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers* provides advice on the technical aspects of guideline development.

b) This document is the scope. It defines exactly what this guidance will (and will not) examine, and what the guidance developers will consider. The scope is based on the referral from the Department of Health and Welsh Assembly Government (see Annex).

c) The areas that will be addressed by the guidance are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) This guideline will cover adults and children aged 2 years or older in following two categories: overweight or obese. This includes adults and children with established comorbidities, and those with or without risk factors for other medical conditions.

The following special groups will be considered, where there is good evidence of effectiveness of interventions targeted at these groups:
    - Black and minority ethnic groups
    - lower socio-economic groups
    - vulnerable groups, including older people and women of child-bearing age.

b) Currently a healthy weight (defined as being neither obese nor overweight), in order to support them in maintaining a healthy weight.

4.1.2 Groups that will not be covered

a) Children aged less than 2 years.

b) The medical management of related medical conditions. However, links will be made to other appropriate NICE guidance, such as that for type 2 diabetes and eating disorders.

4.2 Healthcare settings

a) The guidance will cover the care provided by NHS healthcare professionals working with overweight and obese adults and children in primary, secondary and, where appropriate, tertiary care (Specialised Morbid Obesity Services). The guidance will address areas that require collaboration between primary, secondary and tertiary care.
b) The HDA has a remit to work with a wide range of organisations and agencies – not just in the NHS but within national and local government, the voluntary and academic sectors and the private sector.

4.3 Areas that will be covered

The guidance will cover the following areas:

4.3.1 Clinical management of overweight and obesity in adults and children aged 2 years or older

a) The identification of overweight and obesity in adults and children in primary and secondary care. This will include advice on the following,
   i. The best way to discuss weight in the clinical setting.
   ii. The role of BMI and waist circumference as a method of measuring overweight and obesity, including an appropriate definition of overweight and obesity.
   iii. The role of serial measurements of height and weight in the clinical setting.
b) The assessment of overweight and obesity in adults and children in primary and secondary care. This will include advice on the following.
   i. Assessment of any weight-related comorbidities (for example, diabetes, coronary heart disease), including the adult's or child's clinical need to lose weight.
   ii. Assessment of risk factors strongly associated with overweight and obesity.
   iii. Determining the adult's or child's readiness and motivation to try to lose weight.
   iv. Consideration of lifestyle factors that are likely to explain why energy imbalance has occurred, including weight control history, usual dietary habits and physical activity levels.
c) The management of overweight and obesity in adults and children in primary and secondary care. This will include advice on the following.
   i. How practitioners should develop goals and treatment strategies with the adult or child with overweight or obesity (and their parent/family as appropriate). This will include, as appropriate, the goal of weight maintenance as well as weight loss.
   ii. The role of non-pharmacological interventions. Where there is good evidence of effectiveness, the following interventions will be considered:

- dietary advice including the role of low-fat, low-carbohydrate and very low-energy diets, the role of meal replacements and the role of ‘slimming clubs’
- physical activity
- psychological therapies
- professionally organised alternative therapies[1]

iii The role of pharmacological interventions. This will be limited to orlistat and sibutramine. These are currently the only anti-obesity drugs listed in the *British National Formulary* and available on prescription. The guidance will update the current NICE technology appraisals for these agents and when the guidance has been published the technology appraisals will be withdrawn.

- National Institute for Clinical Excellence (2001). *Guidance on the Use of Orlistat for the Treatment of Obesity in Adults*
- National Institute for Clinical Excellence (2001). *Guidance on the Use of Sibutramine for the Treatment of Obesity in Adults*

Note that guidance recommendations will fall within licensed indications: exceptionally, and only where clearly supported by evidence, can use outside a licensed indication be recommended. The guidance will assume that prescribers will use the Summary of Product Characteristics to inform their decisions for individual patients.

d) Morbid obesity in adults (BMI > 40) and children will be discussed in sufficient detail to inform primary and secondary care practitioners on best practice for referral to tertiary care (Specialised Morbid Obesity Services) and to identify key aspects of care for people with morbid obesity in tertiary centres. The following aspects of care will be considered.

i. The identification of morbid obesity in adults and children in primary and secondary care.

ii The criteria that should be used to determine when adults and children with morbid obesity should be referred to tertiary care.

iii. The assessment of morbid obesity in adults and children in tertiary care, including a health risk assessment based on presence of comorbidities.

iv. The management of morbid obesity in adults and children in tertiary care, including the role of an integral management approach aimed at weight loss and weight maintenance. The role of surgical treatment of morbid obesity will be addressed. The guidance will update the NICE technology appraisal on the use of surgery; when the guidance has been published the technology appraisal will be withdrawn.

- National Institute for Clinical Excellence (2002). *Guidance on the Use of Surgery to Aid Weight Reduction for People with Morbid Obesity*

4.3.2 The prevention of overweight and obesity in adults and children aged 2 years or older, who are currently of a healthy weight

a) The role of primary prevention approaches intended to support adults and children in maintaining a healthy weight. These approaches will be aimed mainly outside the clinical setting and will include advice on the following.

i. Raising awareness of what constitutes a healthy weight range and the need to stay within such a range.
ii. Identifying adults and children who should participate in prevention programmes based on their risk factors for obesity and readiness and opportunities to change their behaviour.
ii. Maintaining energy balance in adults and children of a healthy weight through a healthy diet and physical activity.
iv. Developing local strategies to prevent obesity and support weight maintenance in adults and children of a healthy weight. These will focus on multi-faceted interventions including:
   - community-based services including those to which individuals are referred from primary care services
   - broader environmental interventions in the community
   - interventions in workplaces
   - interventions in schools
   - interventions targeted at children aged 2–5 years
   - interventions targeted at black and minority ethnic groups, at vulnerable groups and at individuals at vulnerable life stages.

4.4 Areas that will not be covered

The guidance will not cover the following areas of clinical practice.

a) Population-based screening programmes for overweight or obesity.
b) Complementary therapy approaches to the treatment of overweight and obesity that are not included in the definition of 'professionally organised alternative therapies'.
c) Eating disorders, including binge-eating disorder.
d) In adults and children, the prevention or management of comorbidities (for example, type 2 diabetes) associated with overweight or obesity.
e) In children, the diagnosis and management of childhood syndromes (for example, Prader–Willi syndrome) or childhood diseases (for example, hypothyroidism) that lead to obesity.
f) In terms of prevention of overweight and obesity, the guidance will contribute to the evidence base leading to subsequent recommendations in national Government or European policies, including fiscal policy, food labelling policy and food advertising and promotion. The guidance is intended to support local practice whereas national or 'upstream' action will be addressed in the context of wider work such as the forthcoming Food and Health Action Plan.

4.5 Status

4.5.1 Scope

This is the final version of the scope.

4.5.2 Guidance

The development of the guidance recommendations will begin in September 2004.

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[1] These are defined as: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy (House of Lords, 2000).

5 Further information

Information on the guideline development process is provided in:

- *The Guideline Development Process – An overview for Stakeholders, the Public and the NHS*

- *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers*

These booklets are available as PDF files from the NICE website (www.nice.org.uk). Information on the progress of the guideline will also be available from the website.

Annex – Referral from the Department of Health and Welsh Assembly Government

The Department of Health and Welsh Assembly Government asked the Institute:

"In consultation with the Health Development Agency, to prepare clinical guidance for the NHS in England and Wales for the prevention of obesity and for the identification, evaluation, and management of overweight and obese patients including the maintenance of weight loss. The guidance should:

- promote the best use of available NHS resources including workforce
- include a definition of obesity, standards for identification and evaluation, and guidance on effective methods of management and treatment, in primary care and other appropriate settings
- give appropriate emphasis to exercise, dietary approaches, group and individual behaviour modification, and to the scope for collaborative working between the NHS and other agencies
- make links to other appropriate NICE guidance."

Appendix 2

Questions and parameters

Key questions: public health

Raising awareness of what constitutes a healthy weight range and the need to stay within such a range

What is the effectiveness of public health interventions and the media to increase awareness of importance of staying a healthy weight?

What is the effectiveness of public health interventions and the media to increase awareness of behaviours associated with maintenance of a healthy weight (diet and activity)?

How can interventions best engage population/target groups?

Is an increase in awareness translated into action?

Sub-questions:

- Does the impact vary by gender, age, ethnicity, religious practices or social group.
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?

Identifying adults and children who should participate in prevention programmes based on their risk factors for obesity and readiness and opportunities to change their behaviour

What is the effectiveness of public health interventions to identify individuals who would benefit from participation in prevention/public health interventions to manage weight?

What are the existing UK and non-UK guidelines/recommendation in relation to identifying individuals who would benefit from participation in prevention/public health interventions to manage weight?

Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- What is the most effective source of delivery?
- What is the most effective mode of delivery?
- To what extent are public health interventions effective in identifying individuals for referral to/from primary care (clinical or non clinical setting)?
- Is there any negative impact?

Maintaining energy balance in adults and children of a healthy weight through a healthy diet and physical activity

What are the factors helping individuals to maintain energy balance/prevent overweight and obesity?

What are the factors helping individuals to increase their activity levels to an extent which will help maintain energy balance/prevent overweight and obesity?

What are the factors helping individuals to improve their diet in such a way to help maintain energy balance/prevent overweight and obesity?

Consideration of the above should be given for 'at risk' groups.
Sub-questions:

- Does this vary by gender, age, ethnicity, religious practices or social group?
- Do factors vary whether individuals previously lost weight?
- How is impact sustained?
- Is there any negative impact? (i.e. consider the flip side of healthy eating/physical activity health promotion messages – increased parental control and anxiety over eating/ link with eating disorders/parents displacing their own concerns over eating to their children)
- What was helpful/unhelpful?

Community-based services including those to which individuals are referred from primary care services

What is the effectiveness of interventions through community based public health services in terms of helping individuals/populations maintain a healthy weight/prevent overweight or obesity?
What is the effectiveness of interventions through community-based public health services in terms of helping individuals/populations improve behaviours associated with maintenance of a healthy weight (diet and activity)?

What strategies are effective in engaging a broad range of organisations and encouraging partnerships?
Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?
- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Broader environmental interventions in the community

What is the effectiveness of broader environmental interventions in terms of helping individuals/populations maintain a healthy weight/prevent overweight or obesity?
What is the effectiveness of broader environmental interventions in terms of helping individuals/populations improve behaviours associated with maintenance of a healthy weight (diet and activity)?
What strategies are effective in engaging a broad range of organisations and encouraging partnerships?
Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?
- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Interventions in workplaces

What is the effectiveness of workplace interventions in terms of helping individuals/populations to maintain a healthy weight/prevent overweight or obesity?
What is the effectiveness of workplace interventions in terms of helping individuals/populations improving behaviours associated with maintenance of a healthy weight (diet and activity)?
What strategies are effective in attracting workplaces to invest in the health and activity of their workforce?
Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?
- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Interventions in schools

What is the effectiveness of school interventions in terms of helping individuals/populations maintain a healthy weight/prevent overweight or obesity?
What is the effectiveness of school interventions in terms of helping individuals/populations to improve behaviours associated with maintenance of a healthy weight (diet and activity)?
What strategies are effective in engaging schools to undertake interventions?
What are the essential elements of a ‘whole schools approach’?
Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?

- Is the mode of delivery important?
- Is there any negative impact?
- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Interventions targeted at children aged 2–5 years

What is the effectiveness of interventions targeted at 2–5-year-olds, and their families/carers, in terms of helping children maintain a healthy weight/preventing overweight or obesity?

What is the effectiveness of interventions targeted at 2–5-year-olds, and their families/carers, in terms of helping children to improve behaviours associated with maintenance of a healthy weight (diet and activity)?

What strategies (identified in 8.1 or 8.2) are most effective in terms of participation and retention and which factors contribute to this success?

Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?
- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Interventions targeted at black and minority ethnic groups, at vulnerable groups and at individuals at vulnerable life-stages

What is the effectiveness of interventions to help vulnerable groups maintain a healthy weight/prevent overweight or obesity?

What is the effectiveness of interventions to help vulnerable groups improve behaviours associated with maintenance of a healthy weight (diet and activity)?

What strategies (identified in 9.1 or 9.2) are most effective in terms of participation and retention and which factors contribute to this success?

Sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?

- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Interventions to manage overweight and obesity in non-clinical settings

What is the effectiveness of interventions in non-clinical settings (i.e. community-based and including commercial and self management) to help manage overweight or obesity?

What is the effectiveness of interventions in non-clinical settings (i.e. community-based and including commercial and self management) to help overweight and obese groups improve behaviours (diet and activity) associated with weight loss?

What non-clinical (i.e. community-based) strategies are associated with the maintenance of weight loss and continuation of improved behaviours (diet and activity) among overweight and obese individuals?

Additional questions on exercise referral in children

- What is the effectiveness of exercise referral programmes for children to help manage overweight or obesity?
- What is the effectiveness of exercise referral programmes for children to help increase physical activity to an extent that may aid the management of overweight and obesity?

General sub-questions:

- Does effectiveness vary by gender, age, ethnicity, religious practices or social group?
- Do recommendations vary whether individuals have previously lost weight?
- Is the source of delivery important?
- Is the mode of delivery important?
- Is there any negative impact?
- Does cost have an impact on effectiveness? (e.g. cost of attending slimming group compared with free group)
- What strategies are effective in engaging a broad range of organisations and encouraging partnerships?

Key questions: clinical management

NOTE: not all the ***Key clinical questions (KCQs)*** appear as individual reviews in the full guidance as some were used as background papers for the GuidelineDevelopment Group (GDG) and some were addressed using expert opinion of the GDG and co-optees. These questions are clearly identified in the Notes section of the table.

NEED TO CONSIDER ‘WHAT EFFECT WILL THIS HAVE IN PRACTICE’ – ELABORATE ON CARE PATHWAY
i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional***)saying ‘But what should I do?’

	Adult	Child	Inclusion/exclusion	Notes
Identification				
1.1.1	What classifications of overweight and obesity should be used for body mass index (BMI), waist circumference or bioimpedance?	What classifications of overweight and obesity should be used for BMI, waist circumference, or bioimpedance? Which charts should be used for BMI?	Classification as specified in Key References.[2] Classification from recognised authorities and organisations including the World Health Organization (WHO), Department of Health (DoH) Expert reviews	STATUS: done
1.1.2	How do BMI, waist circumference and bioimpedance correlate with morbidity and mortality?	How do BMI, waist circumference and bioimpedance correlate with morbidity and mortality?	Systematic reviews and expert narrative reviews	STATUS: not KCQ. Background information.
1.1.3	Do BMI, waist circumference and bioimpedance correlate with morbidity and mortality in different ethnic groups?	Do BMI, waist circumference and bioimpedance correlate with morbidity and mortality in different ethnic groups?	Systematic reviews Primary studies carried out in the UK Primary studies carried out in the country of	STATUS: done

NEED TO CONSIDER ‘WHAT EFFECT WILL THIS HAVE IN PRACTICE’ – ELABORATE ON CARE PATHWAY
i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional*)**saying ‘But what should I do?’

	Adult	Child	Inclusion/exclusion origin	Notes
1.2.1	What test(s) in addition to BMI should be used to assess the degree of obesity?	What test(s) in addition to BMI should be used to assess the degree of obesity? And are different test(s) appropriate for different ages/lifestage? Should measurements of other family members, including siblings, parents be considered?	Systematic reviews Primary studies	STATUS: done
1.3.1	Is there evidence that ‘opportunistic identification’ of people who are overweight/obese leads to improved health outcomes?	Is there evidence that ‘opportunistic identification’ of people who are overweight/obese leads to improved health outcomes?		STATUS: done
1.3.2	What standards of equipment (e.g. type of scales) and methods (e.g. how to measure waist) should be used?	What standards of equipment (e.g. type of scales) and methods (e.g. how to measure waist) should be used?	Defined standards Expert opinion	STATUS: not evidence based KCQ.
Initial assessment				
2.1.1	What are the common weight-related comorbidities and how do they impact on the health of the individual, both now and in the future?	What are the common weight-related comorbidities and how do they impact on the health of the individual, both as a child and in the future as an adult?	Systematic reviews or expert narrative reviews	STATUS: background information
2.1.2	What factors should be considered in the *initial clinical assessment* of people who are overweight/obese?	What factors should be considered in the *initial clinical assessment* of children who are overweight/obese?	Systematic reviews or expert narrative reviews Supplemented by pragmatic randomised	STATUS: done

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[2] Key references are: National Health and Medical Research Council (NHMRC) guidelines (adult and child), National Institutes of Health (NIH) guidelines (adult), and Scottish Intercollegiate Guidelines Network (SIGN) guidelines (child) and other World Health Organization (WHO) expert papers.

NEED TO CONSIDER 'WHAT EFFECT WILL THIS HAVE IN PRACTICE' – ELABORATE ON CARE PATHWAY
i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional)***saying 'But what should I do?'

	Adult	Child	Inclusion/exclusion	Notes
			controlled trials (RCTs) in the UK	
2.2.1	How should an individual's readiness and motivation to change be assessed?	How should a child's and/or parent's readiness and motivation to change be assessed? Does this affect the choice/target of intervention?	RCTs of different methods of assessment. Process of care. Brief interventions review. Stages of change. Counterweight Rollnick. Pragmatic RCTs.	STATUS: lack of theory based evidence in obesity. Currently review being undertaken by Centre for Public Health Education (CPHE) on behaviour change
2.2.2	Is there evidence that delivering a brief intervention in primary care and other general clinical settings leads to improved outcomes for adults who are overweight and obese?		RCTs of brief interventions.	STATUS: done.
Further assessment				
2.3.1	What factors should be considered in the *further* clinical assessment of people who are overweight/obese?	What factors should be considered in the *further* clinical assessment of children who are overweight/obese?	Systematic reviews or expert narrative reviews.	STATUS: done
2.4.1	When should people who are overweight/obese be referred to other services (not including tertiary obesity services)?	When should children who are overweight/obese be referred to other services (not including tertiary obesity services)?	Audits and current practice reports. Expert opinion. Other guidelines.	STATUS: done.

NEED TO CONSIDER 'WHAT EFFECT WILL THIS HAVE IN PRACTICE' – ELABORATE ON CARE PATHWAY
i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional)***saying 'But what should I do?'

	Adult	Child	Inclusion/exclusion	Notes
Management (general)[3]				
3.1.1		Who should any intervention be targeted at? Child? Parent? Family? Child and parent? Does this affect the choice of intervention?		STATUS: done
3.2.1	How should the individual and the HCP develop goals and strategies for weight loss and/or weight maintenance and other goals as appropriate?	How should the child and the parent and HCP develop goals and strategies for weight loss and/or weight maintenance and other goals as appropriate?	RCTs of different strategies.	STATUS: lack of theory based evidence in obesity. Currently review being undertaken by CPHE on behaviour change
3.2.2	What outcomes should be set and how should they be measured?	What outcomes should be set and how should they be measured?		STATUS: lack of theory based evidence in obesity. Currently review being undertaken by CPHE on behaviour change
3.3.1	What is the role of dietary information in weight loss and/or maintenance and other specified outcomes in adults?	What is the role of dietary information (food intake, nutrition, eating habits) in weight loss and/or maintenance and other	RCTs	STATUS: done

NEED TO CONSIDER 'WHAT EFFECT WILL THIS HAVE IN PRACTICE' – ELABORATE ON CARE PATHWAY
i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional)***saying 'But what should I do?'

	Adult	Child	Inclusion/exclusion	Notes
		specified outcomes in children and their families?		
3.3.2	What is the role of physical activity in weight loss and/or maintenance and other specified outcomes in adults?	What is the role of physical activity (increased physical activity, decreased sedentary activity) in weight loss and/or maintenance and other specified outcomes in children and their families?	RCTs	STATUS: done
3.3.3	What is the role of behaviour change strategies in weight loss and/or maintenance and other specified outcomes in adults?	What is the role of behaviour change strategies in weight loss and/or maintenance and other specified outcomes in children and their families?	RCTs	STATUS: done
3.3.4	What is the role of professionally organised therapies in weight loss and/or maintenance and other specified outcomes in adults?	What is the role of professionally organised therapies in weight loss and/or maintenance and other specified outcomes in children and their families?	RCTs	STATUS: done
3.3.5	What is the role of combined interventions (for example diet and physical activity) in weight loss and/or maintenance and other specified outcomes in adults?	What is the role of combined interventions (for example diet and physical activity) in weight loss and/or maintenance and other specified outcomes in children and their families?	RCTs	STATUS done
3.3.6	What is the role of orlistat and sibutramine in the management of overweight/obesity in adults?	What is the role of orlistat and sibutramine in the management of overweight/obesity in children?	RCTs only	STATUS done
3.4.1	What should happen if agreed goals are not achieved as assessed by both the	What should happen if agreed goals are not achieved, as assessed by both the	RCTs if available Audits and current	STATUS: lack of theory based

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[3] Throughout evidence of effectiveness will be used to drive recommendations on who/where/when.

NEED TO CONSIDER 'WHAT EFFECT WILL THIS HAVE IN PRACTICE' – ELABORATE ON CARE PATHWAY i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional)***saying 'But what should I do?'				
	Adult	Child	Inclusion/exclusion	Notes
	individual and/or the HCP?	child and/or parent and/or the HCP?	practice reports. Expert opinion.	evidence in obesity. Currently review being undertaken by CPHE on behaviour change
3.5.1		What are the harms associated with intervention in children? Specifically does intervention cause/promote eating disorders or anxiety in children who are identified as overweight/obese?	RCT evidence. Cohort studies. Expert opinion.	STATUS: done
3.6.1	When should an adult with severe obesity be referred to specialist services?	When should a child with severe obesity be referred to specialist services?		STATUS: done using expert opinion
Severe obesity				
4.1.1	How should severe obesity be defined in adults?	How should severe obesity be defined in children?	Key references and expert opinion.	STATUS: done
4.2.1	What biological factors need to be considered as potential causes of severe obesity?	What biological factors need to be considered as potential causes of severe obesity?	Systematic reviews and expert narrative reviews.	STATUS: done using expert opinion
4.3.1	What factors should be considered in the clinical assessment of people who are severely obese?	What factors should be considered in the clinical assessment of children who are severely obese?	Systematic reviews or expert narrative reviews.	STATUS: done using expert opinion
4.4.1	How should severe obesity be managed in tertiary care, including an integrated management approach?	What special consideration should be given to a child with severe obesity, including an integrated management	RCTs of different service configurations, for example specialist	STATUS: done using expert opinion

NEED TO CONSIDER 'WHAT EFFECT WILL THIS HAVE IN PRACTICE' – ELABORATE ON CARE PATHWAY
i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional)***saying 'But what should I do?'

	Adult	Child	Inclusion/exclusion	Notes
		approach to care?	clinics, integrated clinics.	
4.5.1	What is the role of surgical interventions in the management of severe obesity in adults?	What is the role of surgical interventions in the management of severe obesity in children?		STATUS: done
Models of care				
5.1.1	Who is the most appropriate HCP to undertake any of the above?	Who is the most appropriate HCP to undertake any of the above?	RCTs of different HCPs delivering intervention.	STATUS: done
5.1.2	What is the most appropriate setting to undertake any of the above?	What is the most appropriate setting to undertake any of the above?	RCTs of different service configurations.	STATUS: done
5.1.3	What are the barriers (individual/HCP/family/carer/other) to the management of weight in the clinical setting?	What are the barriers/motivations (individual/HCP/family/carer/other) to the management of weight in the clinical setting? (See previous questions on motivation to change for individuals)	Qualitative studies identifying barriers/motivation to management of overweight/obesity (focus groups, interviews, surveys, etc.). Barriers to be identified by participants themselves, not presupposed by researchers Population generalisable to UK.	STATUS: done
5.1.4	What are the key skills/core	What are the-key skills/core	Key documents from	STATUS: done

NEED TO CONSIDER 'WHAT EFFECT WILL THIS HAVE IN PRACTICE' – ELABORATE ON CARE PATHWAY i.e. How will the questions and their answers (therefore recommendations) help the HCP ***(Health care professional)***saying 'But what should I do?'				
	Adult	Child	Inclusion/exclusion	Notes
	competencies/attributes-of HCPs in the assessment and management of people who are overweight/obese?	competencies/attributes-of HCPs in the assessment and management of children who are overweight/obese?	professional organisations.	
5.1.5	What organisational or professional interventions are effective in improving the management of overweight/obesity in the clinical setting?	What organisational or professional interventions are effective in improving the management of overweight/obesity in the clinical setting?	RCTs of effectiveness (Effective Practice and Organisation of Care EPOC quality criteria).	STATUS: done

Review parameters: public health

Study year and type

- Rapid review to include search for interventions and evaluations and also cohort, qualitative and survey studies for corroborative evidence.

- In line with NICE methodology, if sufficient high quality, up-to-date evidence is found for a specific question, older studies and/or those using weaker designs will not be examined.

- English language papers only will be included.

- Papers not held at the British Library will be excluded.

Evidence of effectiveness

- Weight outcomes – include all RCTs and all controlled clinical (non-randomised) trials (CCTs) from 1990. To ensure that any key data published pre 1990 is not overlooked, an additional search of the Cochrane Trial database 1966–89 to be undertaken and any relevant RCTs included. In addition, where systematic reviews (published 1995 onwards) are identified, any included RCTs published before 1990 to be considered in rapid review. For topic areas with limited or no RCT/CCT evidence we will use the best available evidence.

- Intermediate outcomes (i.e. physical activity and diet) – include systematic review evidence from 1995 plus more recent RCTs and CCTs where available. For topic areas with limited or no systematic reviews, RCT/CCTs we will use the best available evidence.

- Cost outcomes – as intermediate outcomes (NB: this criteria for rapid reviews; additional search on costs likely to be undertaken).

- Changes in knowledge, attitudes and awareness *alone* will not be considered within the main body of reviews but will be considered in a separate ‘mini review’. This restriction is due to time constraints.

Cohort studies
(NB: of particular relevance to review addressing *The Determinants of Weight gain and Weight Maintenance*)

- Prospective cohorts of at least 12 months duration that assessed factors potentially associated with weight gain or weight control in adults and/or children who were not all obese at baseline and reported a weight outcome at baseline and follow-up included.

- There are no structured reporting requirements for observational longitudinal studies. Tooth et al. (2005) have recently developed and tested a checklist.

Corroborative evidence

- Evidence from UK to be included in all reviews. Relevance of evidence from outside UK to considered by question though ability to include constrained by time limitations.

Length of follow-up

- Minimum requirement for studies of effectiveness is at least one data point before and one after the intervention.

- Minimum time period of 3 months between baseline and repeat measures for interventions.

Treatment of systematic reviews

- To avoid ‘double counting’, where more than one systematic review is available to answer a question, the ‘best systematic review’ will be included. The ‘best’ will invariably be the most recent but older reviews will be included if better quality than more recent reviews. The excluded review(s) will be checked to ensure all appropriate studies included.

‘Unpicking’ individual studies within systematic reviews

- The need to ‘unpick’ the ‘best’ available systematic review to its individual study components should be considered on a ‘case-by-case’ basis.

- Where a review is judged to be of high quality and meets the NICE inclusion criteria, there is no need to unpick the review down to the components of individual studies. However, where the reviewers are in some doubt as to the quality of the review, or there are concerns about the lack of intervention detail presented within the review, then the review should be unpicked.

- The outcome measures and follow up time are critical in determining the need to unpick a review (i.e. a review that includes two different studies, one with a 2-week follow-up time and the other with 4-month follow-up should be unpicked).

- The benefits of 'unpicking' a review should be carefully balanced against time constraints.

Combining systematic reviews and individual studies

- Where a systematic review and a more recent individual study are identified, the approach should be to update the review rather than treating the review and study separately. However, how reviews and individual studies are combined should be the judgement of reviewers.

- NICE technical team to advise where there is some doubt as to how specific review(s) and studies should be combined.

Grading systematic reviews

- The grade of review should be based on the study type for which the conclusions are primarily based (i.e. if a review included five RCTs and fifteen CCTs but overall conclusions predominantly based on CCT evidence, then grade should be as a review of CCTs not as a review of RCTs).

Critical appraisal tools

- There is not currently a NICE appraisal tool for non-randomised controlled studies. Agreed that reviewers should use relevant EPOC forms as where NICE tools are not currently available.

Intention to treat

- To use the Cochrane Handbook definition of intention to treat (ITT) (see section 8.4; http://www.cochrane.dk/cochrane/handbook/hbook.htm).
- Contrary to current NICE guidelines, where RCTs do not include ITT the *quality* of the study should be downgraded, not the study type.
- It was agreed that the lack of ITT is a quality issue and not a design issue and that the current NICE methodology handbook is incorrect in implying that RCTs without ITT should be 'downgraded' to non-RCTs.

Review parameters: clinical management

Generic parameters applied for intervention studies are as below.
In summary, reviews included:

- Systematic reviews from 1995 and single studies (predominantly RCTs and non-randomised trials). No time restriction was applied for the Adult reviews, but Child reviews were limited to studies published since 1985.
- Studies which reported outcome measures of weight change (in kg for adults, and using any appropriate measure for children).
- Studies with at least 12-months follow-up for adults, and 6 months for children.

Where specific parameters were applied, the details are reported in the evidence review.

Appendix 3

The effectiveness of public health interventions to identify individuals who would benefit from participation in prevention/public health interventions to manage weight

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EVIDENCE SUMMARY TABLES

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EVIDENCE TABLE 1: IDENTIFYING ADULTS AND CHILDREN WHO SHOULD PARTICIPATE IN PREVENTION PROGRAMMES BASED ON THEIR RISK FACTORS FOR OBESITY AND READINESS AND OPPORTUNITIES TO CHANGE THEIR BEHAVIOUR

SUMMARY

Evidence for identification of individuals at risk of overweight and obesity:
Eight observational longitudinal studies, one retrospective cohort study and one ongoing prospective study were found providing evidence of interventions or potential interventions to identify those at risk of overweight and obesity. Eight studies examined interventions with children (or studies tracing from childhood to adulthood) and two studies examined interventions with adults. All studies had some confounders. Only one study (Metcalf 2002) was carried out in the UK.

Children
Eight moderate quality studies (Barba 2001; Freedman 2001; Maffeis 2001; Freedman 2002; Guo 2002; He 2002; Metcalf 2002; Toschke 2004) examined interventions to identify children at risk of overweight and obesity.
Two studies (Guo and He) found that growth and probability charts were useful tools to identify those who are at risk of becoming overweight and obese in adulthood. One small UK-based study (Metcalf) determined that accelerometers were a well-tolerated effective way to identify the habitually inactive child (mean age 4.8 years) who may be at risk of future obesity.
Of the four studies measuring anthropometric variables, one (Maffeis) concluded that measurement of waist circumference at 8 years may be a promising index to predict overweight at puberty, and two linked studies (Freedman; Freedman) concluded that a measurement of height could be used to identify more accurately children who are likely to become overweight adults, although this may only be true for those children already overweight. The fourth study (Toschke) concluded that although weight gain from birth to 24 months was the best predictor of overweight at school entry, a positive predictive value of 19% implied that 81% of children with large infant weight gain would receive an unnecessary intervention if action were taken.
A further study (Barba 2001), in which anthropometric variables were measured and lifestyle factors such as diet and physical activity (by self-reported responses to a questionnaire) were examined, concluded that large-scale involvement of primary schools in screening programmes could identify those children at risk of being overweight and obese in adulthood and for whom strategies to prevent overweight and obesity would be most effective.

Adults
Two studies with some confounders (St Jeor 1997; Kroke 2002); examined interventions to identify adults at risk of overweight and obesity. The large ($n = 18001$) study (Kroke 2002) evaluating the influence of recent weight changes on subsequent weight changes concluded that the data indicated a need for a thorough weight history assessment to identify those most likely to gain weight.

The smaller (*n* = 385) study (St Jeor 1997) studied natural weight changes to develop a weight classification system that could identify weight maintainers, gainers and losers. The authors concluded that a criterion of a 5 lb (2.3 kg) weight change to identify departures from weight maintenance should initiate early interventions and weight monitoring as strategies to prevent weight gain.

Cost-effectiveness data

No cost-effectiveness studies were found.

EVIDENCE TABLE 1: IDENTIFYING ADULTS AND CHILDREN WHO SHOULD PARTICIPATE IN PREVENTION PROGRAMMES BASED ON THEIR RISK FACTORS FOR OBESITY AND READINESS AND OPPORTUNITIES TO CHANGE THEIR BEHAVIOUR

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								

CHILDREN

Toschke 2004	Retrospective cohort study	3	+	German school children participating in the obligatory school entry health examination in 1999–2000. City and rural participants from six different areas in Bavaria, Germany. *n* = 6862 Age range 5.0–6.9 years. Full data available *n* = 4235 children and used for analysis.	**Aim:** To assess the best anthropometric predictor from birth to 2 years for later overweight. Measurements taken from paediatric preventive health care examinations at 6, 12 and 24 months, and at the school entry examination. Weight, kg, length in cm, body mass index (BMI) and ponderal index (kg/m^3) were all calculated and differences between	Retrospective study, but data used from 6 months to between 5.0 and 6.9 years.	Final sample consisted of only those with all measures (4235/6862 [62%]) Weight gain >9764 g from birth to 24 months was the best predictor of overweight at school entry, compared with length gain, BMI gain, or ponderal index gain. Two-year interval better predictor than shorter intervals. The odds ratio for overweight at school entry associated with weight gain greater than 9764 g was 5.7 (95% confidence interval [CI] 4.5, 7.1). This contrasts with a corresponding low positive likelihood ratio of 2.39 (95% CI	Only subjects with all measures included in sample. Bavaria, Germany. Probably generalisable to the UK. Cites Euro-growth study which doesn't find difference in growth patterns among populations of European infants.

				No socio-economic data reported.	measures at the ages above were compared by receiver operating characteristic curves and predictive values. Unclear who delivered although all measures taken at standard 'well-child' check-ups or school entry examination. No power calculation provided. International Obesity Task Force (IOTF) BMI classifications used.		2.20, 2.59) and a positive predictive value of 19% (95% CI 17, 21), suggesting that only one of five children with a large weight gain in the first 2 years is overweight at school entry indicating poor predictability in the general population. The authors concluded that the results imply that 81% of children with large infant weight gain would undergo an unnecessary intervention, with potential adverse effects if intervention was based on large early weight gain.	
Freedman 2002	Observational Longitudinal Study	3	+	Subjects (*n* = 1055 of a possible 4043) from Louisiana, USA. Biracial (one-third black) community of approximately 43,000 residents. Included city and surrounding rural populations. Mean age at baseline	**Aim:** To determine whether childhood height is related to adult adiposity and whether the association is independent of childhood levels of BMI and triceps skinfold thickness. Anthropometric measures (height,	Mean follow-up: 18 years	Only those with both measurements included in analysis (*n* = 1055). Compared with children whose heights were below the gender- and age-specific median, a child with a height-for-age above the 95th percentile was approximately 2.5 times as likely to have a BMI ≥30 kg/m^2 and approximately five times as likely to have a skinfold thickness sum >90th	**Providers of intervention:** Bogalusa Heart Study. Only those with both measurements included in analysis (26.1% or original sample). Only examined 2–8-year-olds. Possibly only children who are already

				7 ± 1years Mean age at follow-up 24 ± 3 years 62% female 33% black From Bogalusa Heart Study – community-based study of cardiovascular disease risk factors among children and young adults.	weight and triceps skinfold thickness) taken at age 2–8 years (1973–82) and re-measured at adulthood, >18 years (1985–96). Longitudinal relations of childhood height to relative weight and skinfold thicknesses in adulthood examined. No power calculation provided. Probably Higher Education researcher delivered, but not stated. BMI-for-age percentiles calculated using a modification of the 'LMS technique'.		percentile in adulthood. Although height and adiposity among childhood were associated (*r* = 0.29) among children, the observed longitudinal relations persisted after controlling for BMI and the triceps skinfold thickness in childhood. Height in children ≥9 years was not related to adult adiposity. The authors concluded that it is possible that information on height could be used to identify more accurately children who are likely to be obese in later life. It is possible that tall, overweight children could be targeted with specific interventions aimed at preventing the development of adult obesity. Examines differences in height with the same BMI. Second checker.	overweight. Louisiana, USA – probably generalisable to the UK.
Guo 2002	Observational longitudinal study	3	+	Cohort of 166 males and 181 females* from the Fels longitudinal study, Ohio, USA 100% white	Study of the new Centers for Disease Studies (CDC) BMI charts and definitions of adult overweight and obesity to predict adult overweight and	On-going longitudinal study. Data used from birth to 35 years	The sensitivity and specificity of the chosen cut-off (50th percentile for overweight and 72nd percentile for obesity) were excellent for predicting overweight and obesity at 35 years of age from BMI values at 18 years of	Part of the (US) Fels Longitudinal study. US White subjects only for this study but the CDC charts were developed from data on

				Data collected from birth onwards. Many participants were from families where all members were enrolled in the study. No socio-economic data reported. Part of long-term large longitudinal study (Fels longitudinal study) (1929 – still ongoing. Serial multidisciplinary study, longest running in the World. Now part of Lifespan Health Research Center at Wright State University, Dayton, OH, USA.)	obesity. Update of previous report (1994) on use of CDC BMI-for-age growth charts to identify those who are likely to be overweight at 35 years. Logistic models were fitted to relate adult overweight and obesity to childhood and adolescent BMI values at each age (collected at 3-month intervals for the first year, 6-month intervals thereafter to age 18 years and every 2 years thereafter) No power calculation given. Probably Higher Education researcher delivered but not stated. BMI for overweight and obesity follow		age. The sensitivity and specificity at 3, 8 and 13 years of age were lower than those at 18 years of age for the chosen cut-off, and they were lower in the males than in the females. The authors concluded that this cut-off could facilitate public health screening programmes by detecting children and adolescents with a high probability of being overweight or obese at 35 years of age.	white and black children and adolescents at all ages, plus Mexican American from age 2 to 6 years. Sampling strategy unclear. US – probably generalisable to UK *'because of missed measurement at various ages, data are missing for some participants at some ages; thus at any age or for any age group, the number of participants varies and therefore differs slightly from the total number of participants.'

					definitions of WHO, National Heart, Lung and Blood Institute, the National institutes of Health and the US Department of Health and Human Services.			
He 2002	Longitudinal Growth Study	3	+	Healthy grade school children born in Gothenburg and surrounding areas in Sweden. *n* = 3650 Sample size for each gender varied between 582 and 1857 for various ages; at 18 years: Males *n* = 1849 Females *n* = 1801 No socio-economic data reported.	**Aim:** to develop a probability chart of adult overweight based on childhood BMI values and to evaluate BMI change during the BMI rebound period during childhood in different populations with the use of risk function curves. Weight and height values obtained from birth to 18 years. No power calculation provided. Delivered by four trained Higher Education investigators and two school nurses. IOTF BMI	Approx. 18 years Data were collected between April and November 1992 (97% of children born between 1973 and 1975).	A probability chart for reaching a BMI >23 kg/m^2 at 18 years was constructed for boys and girls. For example, a BMI of 18 kg/m^2 at 4 years of age is associated with a 0.70 probability of attaining a BMI >23 kg/m^2 at 18 years in boys: a BMI of 16 kg/m^2 at 4 years of age leads to a 0.40 probability of having a BMI >23 kg/m^2 at 18 years in girls. Children with an obvious BMI rebound before 8 years of age have a high risk of being overweight at 18 years of age. The authors concluded that probability charts for adult overweight developed in this study will provide a useful tool for paediatricians to identify those children who are at a high risk of becoming overweight in adulthood so that clinical intervention can be started as	Data were collected retrospectively from birth register and doctors and nurses notes. Some subjects excluded due to lack of presence of all measurements. Sampling strategy unclear (although exclusion criteria are stated, the number of children who did not meet the exclusion criteria and for each specified criterion is not confirmed). Sweden – probably generalisable to the UK.

					classifications used.		early as possible.	
Metcalf 2002	Observational longitudinal Study	3	+	Healthy children recruited at school entry from a random, stratified sample of schools in Plymouth, UK *n* = 100 Mean age 4.8 years. ‘Schools representing all socioeconomic groups.’ Part of ‘EarlyBird’ prospective cohort study monitoring effects of lifestyle on the metabolic status of healthy children.	Aim: To establish the range of physical activity (PA) undertaken by contemporary children; and to assess the feasibility of using activity monitors to screen for the habitually inactive child. Each child fitted with a CSA (computer science and applications) activity monitor to be worn, on the hip, during waking hours for 7 consecutive days (5 school days and both weekend days). This monitor is both lightweight and tamperproof. Records time and sums changes in acceleration for each 1 min interval, from which are displayed the timing, intensity, and duration of the child’s PA. Data	Not known – only baseline data available	82/100 children (37 boys and 45 girls) provided data for at least 4 weekdays and both weekend days and were included in the analysis. The authors concluded that accelerometers singled out habitually inactive children, most of them girls, who did little, whether at school or over the weekend. Accelerometers are of potential value in identifying, from an early age, children at risk of becoming obese. Accelerometer is well tolerated and generates quality data from >80% of children. Fourteen of the 16 children recording the lowest quintile of weekend activity were girls. Children who were inactive during the week were also inactive at the weekend. The authors also concluded that the activity monitor could prove an important tool for ‘assessment’ if schools are to take back responsibility for physical as well as academic education.	Providers of intervention: EarlyBird Research Centre (supported by a grant from the NHS Executive SW and by Roche Pharmaceuticals, the Henry Smith Foundation, the Child Growth Foundation, Eli Lilly, the London Law Trust and the EarlyBird Diabetes Trust). Analysis did not include all of starting sample. No confounders discussed.

					downloaded to PC and analysed according to week/weekend day and gender. No power calculation provided. Higher Education Researcher and research nurse delivered. Test–retest correlation (for CSA monitor output) over 12 months of *r* = 0.47 (<0.001)			
Barba 2001	Ongoing prospective study	3	+	All children of the II Circolo Didattico Primary School in Avellino, Italy were invited to participate; 509 (66.4%) accepted. Data here are from a preliminary analysis of 363 subjects for whom computerised data was available. Age: Males 8.7	Aim: to evaluate dietary habits and anthropometric factors in a sample of school children aged 6–12 years living in Southern Italy in the framework of an ongoing prospective study aimed and childhood obesity prevention. BRAVO project – part of an education programme on	N/a	Data from baseline: *n* = 363 (62% of eligible sample of this age group). The authors propose a strategy of evaluating dietary habits and anthropometric factors aiming at the identification of children in whom preventive strategies would be more effective. Data were pooled for boys and girls. For any age class, a considerable large proportion of children, almost 50%, had BMI above the age-specific centile	Part of a larger research project that includes an educational programme on nutrition for the teachers. Analysis does not take into account all of eligible sample. May be largely focussed on identification of childhood obesity as a risk factor for adulthood obesity.

				± 1.4 years; Females 8.86 ± 1.3 years Male *n* = 181 Female *n* = 182 No socio-economic data provided.	nutrition for the schoolchildren and their families. All participants underwent brief medical examination during which detailed anthropometry (including height and weight) were measured. Used standard balance beam with attached ruler. Children were examined by a trained dietitian under the supervision of a physician, within the school premises. A detailed questionnaire on medical history, lifestyle and dietary habits was filled in at home by the parents and checked during the visit. Prevalence of obesity was estimated according to the		that predicts the risk of being overweight in adult life. Among those at risk, many children – ranging from 20 to 30% across age-classes – were above the percentile curve that predicts the risk of overt obesity in adult life. Only half the sample (52.9%) regularly practised PA (as assessed by a questionnaire response), which was more common among girls in comparison to boys (56 vs. 44%, chi-square = 5.614, $p < 0.05$). Fruit intake appeared to be poor (10–20% ate fruit every day) whilst daily consumption of high-energy snacks was rather common among children (45%). The authors concluded that their data, though preliminary, suggest that the large-scale involvement of primary schools in screening programmes could represent an effective preventive strategy against the increased risk of childhood obesity. The study focused on the risk of children being overweight or obese in adult life, thus aiming at the identification of children in whom preventive strategies, involving	Southern Italy – probably generalisable to the UK. Screening in primary schools to identify those at risk of overweight and obesity.

					standard definition adopted by the IOTF. No power calculation provided.		targeted changes in dietary habits and lifestyle, would be more effective.	
Freedman 2001	Observational longitudinal study	3	+	Subjects (*n* = 105, of a possible 272) from Louisiana, USA. Biracial (one-third black) community of approximately 43,000 residents. Included city and surrounding rural populations. Age = 5 years in 1973 (beginning of study). From Bogalusa Heart Study – community-based study of cardiovascular disease risk factors among children and young adults. Sample demographics and socio-economic data not reported.	**Aim:** To examine whether the relation of adiposity rebound increases the risk for overweight in adulthood and whether this relation is independent of childhood BMI levels. Seven cross-sectional studies of children conducted during school years between 1973 and 1991. Total number of children studied in this analysis *n* = 105 comprising 5-year-olds who were examined in 1973, and were eligible for re-examination in 1974, 1975, 1976 and in 1987–91 (as 19–23-year-olds). Subjects had been examined at age 5 years, re-examined	14–18-year follow-up	105/272 subjects included in analysis (only those with sufficient data). Subjects who experienced rebound (age at which minimum BMI occurred – 'age_{min}") at ≤5 years were, on average, 4–5 kg/m^2 heavier in early adulthood than were subjects whose age_{min} was >7 years. Age_{min}, however, was also correlated with childhood BMI levels (r ~ –0.5), and age_{min} provided no additional information on adult overweight if the BMI level at age 7 years (or 8 years) was known. In contrast, childhood height, which was also correlated with age_{min} (r = –0.47), was independently related to adult BMI. Among relatively heavy (BMI = 16.0 kg/m^2) 5-year-olds, a child with a height of 120 cm was estimated to be 1.2 kg/m^2 heavier in adulthood than would a 104-cm tall child. **Conclusion:** Although an early BMI rebound was related to higher levels of	Small study sample (*n* = 105). Total sample and sampling frame have not been reported (although it is likely that this data has been reported in an earlier and/or companion study). USA – probably generalisable to the UK. The importance of childhood height needs to be examined in other longitudinal studies and research is needed to determine the possible mechanisms.

					at ages 19–23 years and had at least two (of three possible) measurements at ages 6, 7 and 8 years. No power calculation provided. Probably higher education researcher delivered, but not stated. No validation of measures discussed.		relative weight in adulthood, this association was not independent of childhood BMI levels. The relation of childhood height to adult BMI needs to be confirmed in other cohorts, but it is possible that childhood height may help identify children who are likely to become overweight adults. It is possible that childhood height could provide a simple tool in more accurately predicting which children are likely to become overweight adults.	
Maffeis 2001	Observational longitudinal study	3	+	Healthy pre-pubertal children recruited through questionnaires distributed to teachers at public and private primary schools in Italy. *n* = 112 Age = 8.7 ± 0.9 years Female = 58 Male = 54 100% White Response rate not stated.	**Aim:** To identify in a group of 8-year-old prepubertal children the anthropometric parameter with the highest prediction power of overweight, measured 4 years later. Four-year study with baseline and 4 year measurement of weight and body composition Measurements of	Baseline and 4 years	100% provided data at follow up. RelBMI (relative body mass index; %) at baseline showed significant correlation with waist circumference ($r = 0.89$; $p < 0.001$). Partial correlation analysis showed waist circumference had significant independent association with relBMI at follow-up, when basal BMI controlled for ($r = 0.23$, $p < 0.02$). Waist circumference measured at age 8 years is the best predictor of overweight (relBMI) at age 12 ($r^2 = 0.64$; $p < 0.001$). Each	All White children. No full description of recruitment. Parental BMI self-reported One of the funders Nestle Italiana Spa. Italy – probably generalisable to UK

					weight, height, skinfold thicknesses and waist circumference taken (on standardised equipment) at baseline and follow up at the hospital, and self-reported weight and height of the parents taken at baseline. No power calculation provided. Delivered by paediatricians in project laboratory at hospital.		centimetre increase of waist circumference at age 8 years doubles risk of having relBMI >120% at age 12 years. The authors concluded that the results of this study showed that waist circumference measured at the age of 8 years, which is simple to perform and easy to reproduce, may be a promising index to assess adiposity as well as to predict overweight at puberty.	

ADULTS

Kroke 2002	Observational longitudinal study	3	+	General population (those in the EPIC-Potsdam study, Germany), *n* = 18001 Males *n* = 6689; mean age 52 (range 24–69) years. Females *n* = 11312; mean age 49 (range 19–70) years Women: 57.36% with college or university degree. Men: 68.56% with college or university degree Sample selected from *n* = 27,548 in EPIC Potsdam study, after excluding those who did not respond to follow-up in 2000, those who smoked, those	**Aim:** To evaluate the influence of recent weight changes (weight gain, loss and cycling) on subsequent weight changes. Baseline information on lifestyle and health-related variables obtained from interviews. Baseline anthropometric measurements of body height and weight. Subjects questioned as to whether or not weight loss/gain was intended, to distinguish weight cyclers. Follow-up – self-assessment questionnaires for assessment of body weight and incident diseases. No power calculation provided.	2 years	Polytomous logistic regression (using stable weight group as the reference category and adjusting for potential confounders) demonstrated that weight cycling before baseline was strongest predictor of subsequent large weight gain (≥2 kg) with odds ratio (OR) 4.84 (95% confidence interval (CI) 3.34–7.02) in men. In women, prior weight loss was strongest predictor of subsequent large weight gain (OR 4.77; 95% CI 3.63–6.03) followed by weight cycling (OR 3.02; 95% CI 2.15–4.25). The authors concluded that these data indicate the need for thorough weight history assessment to identify those who are most likely to gain weight.	The subjects' weight-change variable derived from the difference between measured weight at baseline and self-reported weight at follow-up. This was otherwise a high quality study. Some subjects excluded from analyses due to lack of data. Germany – probably generalisable to the UK.

				with illness and pregnant women, and those with missing data. Providers of intervention: EPIC Potsdam Study.	Measurements taken by ‘trained personnel’, possibly Higher Education researchers. No validation of measure discussed.			
St Jeor 1997	Observational longitudinal study	3	+	USA, healthy subjects, including normal and overweight men and women. *n* = 508, mean age 44.1 ± 14.1 years. Of 385 included in analyses, 180 women (92 normal weight, 88 obese) and 205 men (105 normal weight, 100 obese). No socio-economic data reported.	**Aim:** To study natural weight changes and to develop a weight classification system that can identify weight maintainers, gainers and losers. Series of body composition measurements (done ‘according to established protocol’) taken annually in a clinic. Measures analysed to determine maintainers, losers and gainers (defined by changes in weight of ± 5 lbs [2.3 kg]) during the 5 years. No power calculation	5 years (1985–90).	Recruitment and response rate: 385/508 = 76% 46% maintainers, 34% gainers, 20% losers over total 4-year interval. Subjects more likely to become gainers over successively longer time periods ($p < 0.05$) for 4 years against 1 or 2. Only 22% were gainers in any given 1-year period. The authors concluded that weight changes of greater than ± 5 lb (2.3 kg) can classify a person as a weight maintainer, gainer or loser. Although annual weight changes were used in this study, a weight change of more than 5lb (2.3 kg) between any two points in time may suggest non-maintenance of weight or weight instability that needs further evaluation. The criterion of a 5 lb (2.3 kg)	Relationships of Energy, Nutrition, and Obesity to Cardiovascular Disease Study. Motivated, generally healthy population. Biased towards working men and women. Selection of ± 5 lb (2.3 kg) choice slightly arbitrary. Analysis did not include non-completers. USA – probably generalisable to UK.

					provided. Probably Higher Education researcher delivered, but not stated.		weight change to define departures from weight maintenance at any point should initiate early interventions and weight monitoring as strategies to prevent weight gain.	

Evidence of corroboration (external validity)								
Evidence of salience – is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Metcalf 2002	Observational longitudinal study	3	+	Healthy children recruited at school entry from a random, stratified sample of schools in Plymouth , UK *n* = 100 Mean age 4.8 years. ‘Random stratified sample of Plymouth schools representing all socioeconomic groups’. Part of ‘EarlyBird’ prospective cohort study monitoring effects of lifestyle on the metabolic status of healthy children.	See above.	See above.	See above.	See above.
Evidence for implementation – will it work in the UK?								

First author	Study design	Research type	Research quality	Study Population	Research question and design	Length of follow-up	Main results	Confounders/comments
Evidence of cost-effectiveness								
First author	**Study design**	**Research Type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Cost-effectiveness summary: No cost-effectiveness studies found								

EVIDENCE TABLE 2: EXISTING UK AND NON-UK GUIDELINES/RECOMMENDATIONS IN RELATION TO IDENTIFYING INDIVIDUALS WHO WOULD BENEFIT FROM PARTICIPATION IN PREVENTION/PUBLIC HEALTH INTERVENTIONS TO MANAGE WEIGHT

SUMMARY

For the purposes of this review a clinical or practice guideline was defined as a document that aimed to identify, summarise and evaluate the best evidence and/or most current data about the prevention, management and/or identification of overweight or obesity or the prospective risk of developing overweight or obesity. Clinical guidelines were based on or likely to be based on a systematic review of the current research evidence.

Public/policy statements and recommendations were defined as documents that aimed to provide advice on or recommendations for the prevention, management and/or identification of overweight or obesity or the prospective risk of developing overweight or obesity. Public/policy statements and recommendations are likely to have been developed based on consensus agreement by an expert panel.

Guidance from UK guidelines/recommendations

No usable UK guidelines were identified.[4]

Evidence from four UK recommendations, all for children only, suggests that there is currently no consensus available for the screening of children for unhealthy weight gain. One policy statement (UK National Screening Committee, 2005), based on expert consensus opinion, recommended that screening should not be offered while the evidence from a briefing paper prepared by the Child Growth Foundation (2004) firmly recommended universal serial BMI monitoring for children at least until the end of primary school. One further report (House of Commons Select Committee on Health, 2004), supported the guidance suggested by the Child Growth Foundation and suggested that BMI measures should be recorded annually for school-aged children. Evidence underpinning the identified recommendations is not available or is of lower-level quality. Recently published guidance for Primary Care Trusts (Department of Health 2006 [4663]) recommends measurement of BMI in reception and year 6 children on an annual basis for the purpose of population monitoring. The guidance discourages giving out BMI to children or parents.

Quality assessment of UK guidance

According to the AGREE instrument for the appraisal of guidelines (see paper 9.3a, section 3.3.2) only three publications would be recommended (Child Growth Foundation 2004; UK National Screening Committee 2005; Department of Health 2006), two with provisos (UK National Screening Committee; Department of Health).

Guidance from non-UK guidelines/recommendations
Of the 11 identified guidance documents, overall evidence from nine non-UK recommendations suggests that periodic monitoring of weight status and BMI and waist circumference measurements should be routinely provided. One US-based practice guideline (US Preventive Services Task Force 2003) did not support screening for asymptomatic adults and one recommendation statement from Canada (Douketis 1999) concluded that there was insufficient evidence to recommend for or against BMI measurement in the periodic health examination of the general public.

Clinical practice guidelines
Five clinical practice, evidence-based guidelines were identified, of which four recommended recurrent screening for weight gain. Three of these were from the USA, one from Canada and one from Australia. Of the US-based recommendations, one (Institute for Clinical Systems Improvement 2004) recommended that height, weight and BMI measurements be taken annually for mature adolescents and adults, one (Expert Panel on the Identification, Evaluation and Treatment of Overweight in Adults, 1998) recommended that adults who are not overweight or who have no history of overweight should be screened for weight, BMI and weight circumference every 2 years, and one (US Preventive Services Task Force 2003) firmly recommended against screening for obesity for asymptomatic adults. The Canadian guideline (Registered Nurses' Association of Ontario 2005), based on expert opinion, advocated the inclusion of monitoring and surveillance data on nutrition, PA and measures of adiposity for children in public health policies. The Australian guideline (National Health & Medical Research Council 2003) recommended recurrent measurement of height and weight in a nationally representative sample of children and adolescents. Supporting evidence for clinical practice guidelines was obtained from controlled comparative studies, observational data and expert judgement from clinical experience.

Recommendation statements
Two recommendation statements, one US-based and one from Canada, proposed conflicting advice. The Canadian evidence-based statement (Douketis 1999) concluded that there was insufficient evidence to recommend for or against BMI measurement in the periodic health examination of the general public, while the US-based statement (Holcomb 2004), proposed an algorithm to determine a child's BMI at health visits. It recommended that good nutrition and exercise should be encouraged at health visits if a child's BMI <75th percentile and weight management advice should be provided if a child's BMI measurement is <85th percentile but >75th. No supporting evidence for the US statement is available and the frequency for health visits is not indicated.

Policy statements

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[4] The results from the only UK clinical practice guideline for adults (Scottish Intercollegiate Guidelines Network 1996 [26]) cannot be included in the guidance summary. Robin Harbour, Quality & Information Director SIGN, confirmed that the link to the evidence in this guideline is not available and that it is currently under review to be updated or withdrawn (by telephone 9 August 2005). SIGN have advised us not to use it. SIGN Guidance for Children (2003 [25]) considered, but excluded it as it discusses identification of overweight and obesity only.

Three policy statements all supported serial assessments for weight monitoring. Two US-based statements recommended recurrent measurement of BMI, one of which (Krebs, 2003) recommended annual routine assessments to calculate and plot BMI measurements for children and the assessment of eating and activity patterns for excessive weight gain relative to linear growth. The other US-based statement (Nawaz, 2001) recommended periodic BMI measurement for all adults, independent of weight or BMI, along with consistent counselling about healthful dietary and PA patterns from primary care practitioners. There are no apparent links to supporting evidence for either of these statements. One evidence-based collaborative policy statement from Canada (Dietitians of Canada, Canadian Paediatric Society, The College of Family Physicians of Canada, Community Health Nurses Association of Canada, 2004) suggested that repeated height and weight measurements be part of scheduled well-baby and well-child health visits and that health maintenance visits for children be organised according to a child's immunisation schedule. Continued growth monitoring on an annual basis at primary care visits for older children and adolescents was also recommended. These recommendations were based on expert opinion only. BMI-for-age screening from age 2 years onwards to track and predict future risk of being overweight was also advised.

Taskforce report
One taskforce report from Australia (National Obesity Taskforce Secretariat 2003) recommended, as part of its national action agenda, regular tracking of height and weight status in the community as well as monitoring of knowledge, attitudes, intentions, behaviours and other indicators of healthy eating and active living. The recommendation from this report is not evidence-based.

Quality assessment of non-UK guidance
According to the AGREE appraisal criteria all five clinical practice guidelines would be strongly recommended. One guideline counsels against screening for adults (US Preventive Services Task Force 2003). The remaining four guidelines recommend screening for children (Registered Nurses' Association of Ontario 2005), children and adolescents (National Health & Medical Research Council, Australia, 2003), mature adolescents and adults (Institute for Clinical Systems Improvement, ICSI, USA, 2004) and adults (Expert Panel on the Identification, Evaluation and Treatment of Overweight in Adults, USA, 1998).

The five recommendation and policy statements are broadly recommended with provisos although one (Holcomb, 2004) is an identification algorithm only for children and adolescents and would not be recommended as a guideline. One recommendation document concludes that there is insufficient evidence for screening of adults (Douketis, 1999). The remainder recommend screening for children and adolescents (Holcomb, 2004), screening for adults (Nawaz, 2001), or monitoring for children (Krebs 2003; Dieticians of Canada,2004).

The taskforce report (National Obesity Taskforce Secretariat 2003) advises monitoring for children and their families but would not be recommended for use according to the AGREE criteria.

Cost-effectiveness data
No cost-effectiveness data were found.

EVIDENCE TABLE 2

UK GUIDELINES/RECOMMENDATIONS

First author	Guideline design/AGREE grading	Country of origin	Guideline topic Screening or monitoring Adults and/or children	Guidance/recommendation	Comments
Department of Health 2006 [4663]	Guideline. Recommend with provisos. Scope and purpose 100% Stakeholder involvement 63% **Rigour of development 36%** Clarity and presentation 75% Applicability 75% Editorial independence 63%	UK	Monitoring. Children.	The guidance recommends measurement of BMI in reception and year 6 children on an annual basis for the purpose of population monitoring. The guidance discourages giving out BMI to children or parents.	

UK National Screening Committee 2005	Policy statement **Recommend with provisos – policy statement, not guidelines** Scope and purpose 100% Stakeholder involvement 56% **Rigour of development 33%** Clarity and presentation 81% Applicability 50% Editorial independence 25%	All UK.	Screening Children	Screening should not be offered [to children].[1]	The NSC received the report of a consensus conference held at Coventry on 29 July 2000 and agreed that there is not enough evidence, at this time, to recommend screening for obesity. [1] Child Growth Foundation Seminar on the Epidemic of Obesity in Childhood – RCP London, 29–30 July 2000. The original conference consensus report states three main reasons for rejecting screening (see Appendix C – supporting information).
House of Commons Select Committee on Health 2004	Report **Would not recommend** Scope and purpose 50% Stakeholder involvement 25% **Rigour of**	All UK.	Monitoring. Population-wide (recommendation refers to children).	Throughout their time at school, children should have their BMI measured annually at school, perhaps by the school nurse, a health visitor or other appropriate health professional. Where appropriate, BMI measurement could be carried out alongside other health care interventions that are delivered at school, for example inoculation programmes.	Paragraph 369. No apparent link to evidence.

	development 25% Clarity and presentation 50% Applicability 25% Editorial independence 25%				
Child Growth Foundation, 2004	Briefing paper **Recommend** Scope and purpose 100% Stakeholder involvement 58% **Rigour of development 72%** Clarity & presentation 100% Applicability 100% Editorial independence 25%	All UK.	Monitoring. Children.	Universal serial BMI assessments must be recommended. Although those children at most risk of becoming obese can easily be targeted, only universal assessment will pick up the child who is in a healthy BMI range today but has been/may still be insidiously putting on weight and be obese 'tomorrow'. Monitoring should be implemented at a frequency* reasonably to allow a trend of significant unhealthy weight gain to be identified from birth and at any age thereafter. BMI monitoring should be the standard measure.[1] *A protocol outlining frequency is included in this briefing paper and recommends monitoring yearly through primary school (up to year 6)	Briefing paper prepared by pressure group [Guideline Development Group advice] for the clinical Guideline Development Group. [1] Hall D, Elliman D. *Health for All Children*. 4th Edn. Oxford: Oxford University Press, 2003.

NON-UK GUIDELINES/RECOMMENDATIONS

First author	Guideline design/AGREE grading	Country of origin	Guideline topic Screening or monitoring Adults and/or children	Guidance/recommendation	Comments

Registered Nurses' Association of Ontario 2005	Clinical practice guideline **Strongly recommend** Scope and purpose 75% Stakeholder involvement 69% **Rigour of development 96%** Clarity and presentation 100% Applicability 75% Editorial independence 100%	Canada	Screening and advice. Children.	Nurses advocate for healthy public policies that include monitoring and surveillance data at the population level regarding nutrition, PA and measures of adiposity including obesity and overweight status.[1]	Level of evidence IV. [1]Raine KD. *Overweight and obesity in Canada: a population health perspective*. Ottawa: Canadian Institute for Health Information, 2004.
Institute for Clinical Systems Improvement 2004	Clinical practice guideline **Strongly recommend** Scope and purpose 75% Stakeholder involvement 63% **Rigour of**	USA	Screening and advice. Mature adolescents and adults.	Measure height, weight and calculate BMI preferably annually for screening and as needed for management. A BMI calculation is worthwhile in the growing patient because it provides a reference point for future comparison. Subsequent observations establish a relative trajectory for this index of obesity.[1]	Supporting evidence is of classes D (cross-sectional study, case series, case report), R (consensus statement, consensus report, narrative review). [1]Barlow SE, Dietz WH. Obesity evaluation and treatment: expert committee recommendations. *Pediatrics* 1998;102:E29. (Class R).

	development 50% Clarity and presentation 100% Applicability 50% Editorial independence 100%				Algorithm 1 is currently being updated. It is anticipated that revisions will be completed by the end of September 2005. The Insitute for Clinical Systems Improvement (ICSI) will forward updated revisions as soon as they are available.
US Preventive Services Task Force 2003 US Preventive Services Task Force 2003	Clinical practice guideline **Strongly recommend** Scope and purpose 58% Stakeholder involvement 50% **Rigour of development 68%** Clarity and presentation 81% Applicability 50% Editorial independence 63%	USA	Screening and advice. Adults.	The USPSTF recommends against routinely providing [the service] (screening for obesity in adults) to asymptomatic patients. *The USPTF found at least fair evidence*[1] *that [the service] is ineffective or that harms outweigh benefits.*	[1]Fair evidence is sufficient to determine the effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalisability to routine practice; or indirect nature of the evidence on health outcomes. No apparent link to evidence.
Expert Panel on the Identification,	Clinical practice guideline	USA	Screening and advice. Adults.	Patients should receive periodic monitoring of their weight, BMI* and waist circumference. Patients who are not overweight or have no	*Only apparent evidence available is that linked to the recommendation for the

Evaluation and Treatment of Overweight in Adults 1998 National Institutes of Health 2000	***Strongly recommend*** Scope and purpose 83% Stakeholder involvement 44% **Rigour of development 79%** Clarity and presentation 81% Applicability 58% Editorial independence 63%			history of overweight should be screened for weight gain every 2 years. While this time span is not evidence-based, it is believed to be a reasonable compromise between the need to identify weight gain at an early stage and the need to limit the time, effort and cost of repeated measurements. *Practitioners should use the BMI to assess overweight and obesity.	measurement of BMI to assess overweight and obesity in the clinical setting. Evidence category C (evidence is from outcomes of uncontrolled or nonrandomised trials or from observational studies). Epidemiological and observational studies have shown that BMI provides an acceptable approximation of total body fat for the majority of patients. Because there are no published studies that compare the effectiveness of different measures for evaluating changes in body fat during weight reduction, the panel bases its recommendation on expert judgment from clinical experience. No apparent link to evidence.
National Health & Medical Research Council 2003	Clinical practice guideline **Strongly recommend** Scope and purpose 67%	Australia	Screening and advice. Children and adolescents.	The prevalence of overweight and obesity in children and adolescents in Australia is high enough to warrant both intervention and preventive action. Height and weight should be measured recurrently in a nationally representative sample of children and adolescents.	Evidence level III-2 evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case–control studies, or interrupted time series with a control group.

	Stakeholder involvement 50% **Rigour of development 82%** Clarity and presentation 75% Applicability 50% Editorial independence 100%				No apparent link to evidence.
Douketis 1999	Recommendation **Recommend with provisos** Scope and purpose 67% Stakeholder involvement 44% **Rigour of development 64%** Clarity and presentation 69% Applicability 50% Editorial independence	Canada	Screening and advice. Adults.	Because of lack of evidence supporting long-term effectiveness of weight-reduction interventions, there is insufficient evidence to recommend for or against BMI measurement in the periodic health examination of the general population (C).*	*C Grade There is poor evidence relating to the inclusion or exclusion of a condition or manoeuvre in a periodic health examination, but recommendations can be made on other grounds. (See Appendix C – supporting information for evidence.)

	100%				
Holcomb 2004	Proposal for recommendations **Would not recommend as guideline – Algorithm for identification only** Scope and purpose 58% Stakeholder involvement 25% **Rigour of development 25%** Clarity and presentation 63% Applicability 50% Editorial independence 25%	USA	Algorithm for screening and identification. Children and adolescents.	Proposed identification and management algorithm for overweight and obese children. Determine child's BMI at each visit. If BMI is <75th percentile, continue to encourage good nutrition and exercise to parents and child. If BMI is <85th percentile but >75th percentile, instruct parents and child regarding weight management, diet, and exercise. Advise on limiting television to no more than 2 hours/day. Reassess the child annually.*	*No direct evidence linked to proposed algorithm. Supporting evidence may be Best Practice Group. *Best Practices in the Diagnosis and Treatment of Childhood Obesity*. Kansas: Metropolitan Health Council, 2003. Centers for Disease Control. BMI for Children and Teens. http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-for-age.htm
Krebs 2003	Policy statement **Recommend with provisos – as position statement only** Scope and purpose 50%	USA	Monitoring Children	Calculate and plot BMI once per year in all children and adolescents. Use change in BMI to identify rate of excessive weight gain relative to linear growth. Routine assessments of eating and activity patterns in children and recognition of excessive weight gain relative to linear growth are	*Miller LA, Grunwald G, Johnson SL, Krebs NF. Disease severity at time of referral for pediatric failure to thrive and obesity: time for a paradigm shift? *Journal of Pediatrics* 2002;141:121–124.

	Stakeholder involvement 44% **Rigour of development 32%** Clarity and presentation 63% Applicability 67% Editorial independence 25%			essential throughout childhood. The CDC and Prevention percentile grids for BMI are important tools for anticipatory guidance and discussion of longitudinal tracking of a child's BMI.*	
Nawaz 2001]	Policy statement ***Recommend with provisos*** Scope and purpose 50% Stakeholder involvement 25% **Rigour of development 36%** Clarity and presentation 63% Applicability 50% Editorial independence 25%	USA	Screening and advice. Adults	Independent of weight or BMI, all adult patients should consistently receive counselling about healthful dietary and PA patterns in the context of primary care. Periodic measurement of BMI is recommended for all adults. Although an emphasis on health-promoting behaviours may be preferred to an emphasis on weight per se, weight monitoring is considered useful to both clinician and patient in gauging the adequacy of behavioural interventions.	No apparent link to evidence.

Dietitians of Canada, Canadian Paediatric Society, The College of Family Physicians of Canada, Community Health Nurses Association of Canada 2004	Collaborative policy statement **Recommend with provisos** Scope and purpose 67% Stakeholder involvement 50% **Rigour of development 50%** Clarity and presentation 63% Applicability 50% Editorial independence 100%	Canada	Monitoring. Assessment and monitoring growth (growth charts). Infants and children.	Serial measurements of recumbent length (birth to ages two or three) or height (age ≥2 years), weight and head circumference (birth to age 2 years) should be part of scheduled well-baby and well-child health visits in order to identify infants and children with disturbances in rates of weight gain or physical growth. Although the ideal number of health maintenance visits for children has not been established, current recommendations are that they be organised according to the immunization schedule with additional visits within the first month and also at 4, 6, 9, 12, 18, 24 months and 4–6 years. The frequency for monitoring older children and adolescents is unknown; however, it seems reasonable to continue monitoring growth on an annual basis at primary care visits for the early identification and referral of a child whose growth appears abnormal. To yield accurate measurements, weights and measures should be obtained using calibrated, well-maintained quality equipment and standardised measurement techniques. An individual child's measurements should be recorded in the data table of a consistent growth chart appropriate for age and gender, and then plotted to identify any disturbances in height or weight gain. BMI-for-age is recommended to screen children from age 2 years onwards to identify those who may be at risk for conditions and illnesses related to excess body fat. BMI-for-age provides a reference of overweight for older children and	I recommendation (i.e. based on 'expert opinion' as there is insufficient evidence in quantity or quality to make a recommendation; however, other factors may influence decision-making). (Canadian Task Force on the Periodic Health Examination. *The Canadian Guide to Clinical Preventive Health Care*. Ottawa: Supply and Services Canada, 1994; Saunders NR, Shouldice M. Health maintenance visits: a critical review. In: Feldman W, ed. *Evidence-based Pediatrics. Hamilton*: B.C. Decker Inc., 2000). B recommendation, (i.e. there is fair evidence to recommend this action). (World Health Organization. Physical status: the use and interpretation of anthropometry. Report of a WHO Expert Committee. *World Health Organization Technical Report Series* 1995; 834; Henry JJ. Routine growth monitoring and assessment of growth disorders. *Journal of Pediatric Health Care*

				adolescents that was previously not available. It is consistent with adult BMI, so it can be used continuously from age 2 years to adulthood and can therefore track body size throughout the lifecycle. In addition, BMI-for-age is also a predictor of health risks and future risk of being overweight. A Canadian Pediatric Nutrition Surveillance System should be developed for organised and ongoing collection of anthropometric measurements to follow growth and nutritional status of Canadian children and describe trends in key indicators of their nutritional status.	1992;6(5 Pt 2):291–301; US Department of Health and Human Services, Maternal and Child Health Bureau. Using the CDC growth charts: accurately weighing and measuring: equipment http://depts.washington.edu/ growth [accessed November 2003]). B recommendation, (i.e. there is fair evidence to recommend this action) (Whitaker RC, Wright JA, Pepe MS, Seider KD, Dietz WH. Predicting obesity in young adulthood from childhood and parental obesity. *New England Journal of Medicine* 1997;337(13):869–873). This recommendation is not graded.
National Obesity Taskforce Secretariat 2003	Report **Would not recommend** Scope and purpose 67% Stakeholder involvement 44%	Australia	Monitoring. Adults and children (families).	The NOTS national action agenda recommends improved regular tracking of height and weight status in the community as well as monitoring of knowledge, attitudes, intentions, behaviours and other indicators relating to healthy eating and active living; scope and develop specifications for national nutrition and PA monitoring and surveillance systems; design a comprehensive, regular, coordinated monitoring system for height and weight status (particularly of young	No supporting evidence available.

	Rigour of development 25% Clarity and presentation 50% Applicability 33% Editorial independence 63%			people) and a series of validated indicators of key behaviours and environments related to healthy eating and active living.	

SEARCH STRATEGIES

1. exp obesity/
2. (obes: or overweight or weight gain: or weight change: or weight retention or BMI).mp.
3. (risk factor: or “high risk:”).mp.
4. (stage: of change: or readiness for change: or behavio:r change: or attitude: to change: or intention to change: or motivat: to change).mp
5. exp Health Promotion/
6. Health Education/
7. health promotion.ti,ab.
8. health education.ti,ab.
9. Public Health/
10. primary prevent:.mp.
11. preventive health services/ or “early intervention(education)”/ or school health services/
12. exp mass screening/
13. (identif: or target: or detect: or locat: or predispos:).mp.
14. (alcohol: or apnea or arteriosclerosis or atherosclerosis or arthriti: or asthma: or brain or cancer: or carcinoma: or cardiovascular disease: or coronary: or cystic fibrosis or dementia or diabet: or fracture: or growth hormone: or haemodialysis or heart disease: or hypercholesterol: or hypertens: or insulin or metabolic syndrome or myocard: or osteoarthritis or osteoporosis or PCOS or polycystic ovar: syndrome or pressure ulcer: or thrombosis or varicose vein: or venous thrombosis).mp.
15. or/1-2
16. or/3-4
17. or/5-13
18. and/15-17
19. 18 not 14
20. Animals/
21. Human/
22. 20 not (20 and 21)
23. 19 not 22
24. limit 23 to (english language and yr=”1990 – 2005”)

For guidelines and recommendations the McMaster guidelines search filter was used

guidelines.pt.
practice guidelines.pt.
exp guidelines/
health planning guidelines/
or/1-4

Data sources

The following information sources were searched for interventions:

MEDLINE
HealthPromis
Centre for Reviews and Dissemination, York: www.york.ac.uk/inst/crd
EPPI-Centre - http://eppi.ioe.ac.uk/
NCCHTA (National Coordinating Centre for Health Technology Assessment) - http://www.ncchta.org.uk
New Zealand Health Technology Assessment (NZHTA): www.nzhta.chmeds.ac.nz/
Google + Google Scholar: www.google.co.uk
NRR(National Research Register): www.nrr.nhs.uk/
CRISP(Computer Retrieval of Information on Scientific Projects): www.crisp.cit.nih.gov/

The following information sources were searched for guidelines:

MEDLINE
HealthPromis
Eguidelines: www.eguidelines.co.uk
National Guideline Clearing House (NGC): www.guideline.gov
NeLH guidelines finder: www.libraries.nelh.nhs.uk/guidelinesFinder
SIGN Guidelines: www.sign.ac.uk
New Zealand Guidelines Group (NZGG): www.nzgg.org.nz
Google + Google Scholar: www.google.co.uk

The electronic search strategies were developed in Medline and adapted for use with the other information sources.

EXCLUDED REFERENCES

Excluded guidelines

Paper	Reason for exclusion
All-Party Parliamentary Group on Obesity. *Prevention is better than a cure*. London: National Obesity Forum; 2003]	Does not meet inclusion/exclusion criteria (only recommendations quoted are from other original sources).
All-Party Parliamentary Group on Obesity. *Obesity and Disease: cholesterol and stroke*. London: National Obesity Forum; 2005	Does not discuss identification.
American Association of Clinical Endocrinologists, American College of Endocrinologists. AACE/ACE position statement on the prevention, diagnosis, and treatment of obesity. *Endocrine Practice* 1998;4(5):297–350	Does not discuss identification.
Anonymous. Clinical guidelines on the identification, evaluation and treatment of overweight and obesity in adults. *Wisconsin Medical Journal* 1998;97(9):20–37	Study design.
Baker S, Barlow S, Cochran W, Fuchs G, Klish W, Krebs N, Strauss R, Tershakovec A, Udall J. Overweight children and adolescents: A clinical report of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *Journal of Pediatric Gastroenterology and Nutrition* 2005;40:533–43	Clinical guidance for the management of overweight and obesity. Although screening for BMI gain in children is recommended, no references given and the generally poor developmental rigour suggest exclusion.
Barlow SE, Deitz WH. Obesity evaluation and treatment: expert committee recommendations. *Pediatrics* 1998;102(3):e29–e40	Discusses identification of overweight and obesity only.
Batch JA, Baur LA. Management and prevention pf obesity and its complications in children and adolescents. *Medical Journal of Australia* 2005;182(3):130–5	Discusses identification of overweight and obesity only.
Berg F, Buechner J, Parham E, et al. Guidelines for childhood obesity prevention programs: promoting healthy weight in children. *Journal of Nutrition Education and Behavior* 2003;35(1):1–4	Does not discuss identification.
Board of Science. *Preventing childhood obesity*. London: British Medical Association; 2005	Discusses identification of overweight and obesity only.
Brigham and Women's Hospital. *Obesity in women. A guide to assessment and management*. Boston, MA: Brigham and Women's Hospital; 2003	Discusses identification of overweight and obesity only.

British Columbia Ministry of Health Guidelines and Protocols Advisory Committee. *Overweight, Obesity and Physical Inactivity*. Victoria: BCMH, 2005	Does not discuss identification.
Canadian Task Force. Periodic health examination, 1994 update: 1. Obesity in childhood. *Canadian Medical Association Journal* 1994;150(6):871–79	Discusses of overweight and obesity only.
Crepaldi G, Belfiore F, Bosello O, et al. Special report: Italian consensus conference – overweight, obesity and health. *International Journal of Obesity* 1991;15:7817–90	Discusses identification of overweight and obesity only.
Daniels SR, Arnett DK, Gidding SS, et al. Overweight in children and adolescents : pathophysiology, consequences, prevention and treatment. *Circulation* 2005;111(15):1999–2012	Does not discuss identification.
Douketis J. and Feldman W. Prevention of obesity in adults. In *Canadian Task Force on the Periodic Health Examination. Canadian Guide to Clinical Preventive Health Care*. Ottawa: Health Canada 1994;574–84	Discusses identification of overweight and obesity only.
Feldman W, Beagan BL. Screening for Childhood Obesity In *The Canadian Guide to Clinical Preventive Health Care Section 2 – Paediatric Preventive Care.* Ottawa: Health Canada; 1994	Discusses identification of overweight or obesity only.
Gibson P, Edmunds L, Halsam DW, et al. *An approach to weight management in children and adolescents (2–18 years) in primary care*. London:the Royal College of Paediatrics and Child Health and National Obesity Forum; 2002	Does not discuss identification.
Himes JH, Dietz WH. Guidelines for overweight in adolescent preventive services: recommendations from an expert committee. *American Journal of Clinical Nutrition* 1994;59:307–16	Discusses identification of overweight and obesity only.
Institute for Clinical Systems Improvement (ICSI). *Preventive services for children and adolescents*. Bloomington (MN): Institute for Clinical Systems Improvement; 2004	Does not meet inclusion/exclusion criteria (does not state obesity specifically re periodic examination).
Institute for Clinical Systems Improvement (ICSI). *Preventive services for adults*. Bloomington (MN): Institute for Clinical Systems Improvement; 2004	Does not meet inclusion/exclusion criteria (Does not state obesity specifically re periodic examination).
Lyznicki JM, Young DC, Riggs JA, et al. Obesity: assessment and management in primary care. *American Family Physician* 2001;63(11):2185–96	Discusses identification of overweight and obesity only.
Magnusson J. Childhood obesity: prevention, treatment and recommendations for health. *Community Practitioner* 2005;78(4):147–49	Does not discuss identification.
Ministry of Health. *Tracking the Obesity Epidemic: New Zealand 1977–2003*. Wellington: Ministry of	Does not discuss identification.

Health, 2004	
National Health and Medical Research Council (NHMRC). *Acting on Australia's weight. A strategic plan for the prevention of overweight and obesity*. Canberra: NHMRC; 1997	Does not meet inclusion/exclusion criteria (strategic plan only).
National Health and Medical Research Council (NHMRC). *Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults*. Canberra: NHMRC, 2003	Does not discuss identification.
National Health and Medical Research Council (NHMRC). Overweight and Obesity in Children and Adolescents A Guide for General Practitioners. Canberra: NHMRC, 2003	Does not discuss identification.
National Health and Medical Research Council (NHMRC). Overweight and Obesity in Adults A Guide for General Practitioners. Canberra: NHMRC, 2003	Does not discuss identification.
National Obesity Forum. *Guidelines on management of adult obesity and overweight in primary care*. National Obesity Forum website; 2005	Does not discuss identification.
Obesity Management Task Force. Management of obesity in adults: project for European primary care. *International Journal of Obesity* 2004;28:S226–31	Discusses identification of overweight and obesity only.
Orzano AJ, Scott JG. Diagnosis and treatment of obesity in adults: an applied evidence-based review. *Journal of the American Board of Family Practice* 2004;17(5):359–69	Discusses identification of overweight and obesity only.
Russell RM, PIMA Health System. *Prevention and reduction of pediatric overweight and obesity Clinical Practice Guidelines*. Tucson: PIMA Health System, 2005	Discusses identification of overweight and obesity only (Arizona Health Care Cost Containment System).
Scottish Intercollegiate Guidelines Network (SIGN). *Management of obesity in children and young people. A national clinical guideline*. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003	Discusses identification of overweight and obesity only.
Scottish Intercollegiate Guidelines Network. *Obesity in Scotland, integrating prevention with weight management*. Edinburgh, Scotland: Scottish Intercollegiate Guidelines Network; 1996	Robin Harbour, Quality and Information Director SIGN, confirmed that the link to the evidence in this guideline is not available and that it is currently under review to be updated or withdrawn (by telephone 09.08.05). SIGN have advised us not to use it.
Speiser PW, Rudolf MCJ, Anhalt H, et al. Consensus statement: childhood obesity. *Journal of Clinical Endocrinology and Metabolism*	Discusses identification of overweight and obesity only.

2005;90(3):1871–87	
University of Texas at Austin, School of Nursing, *Family Nurse Practitioner Program. Evaluation and treatment of childhood obesity*. Austin (Texas): University of Texas at Austin, School of Nursing: 2004	Discusses identification of overweight and obesity only.
US Preventive Services Task Force. Screening and interventions for overweight in children and adolescents: recommendation statement. *Pediatrics* 2005;116(1):205–9	Discusses identification of overweight and obesity only.
Whitlock EP, Williams SB, Gold R, et al. Screening and interventions for childhood overweight: a summary of evidence for the US Preventive Services task Force. *Pediatrics* 2005;116(1):125–44	Discusses identification of overweight and obesity only.

Excluded papers

Paper	**Reason for exclusion**
Agras WS, Hammer LD, McNicholas F. Risk factors for childhood overweight: a prospective study from birth to 9.5 years. *Journal of Pediatrics* 2004;145(1):20–25.	Discussion of risk factors only.
Armstrong J, Reilly JJ, Child Health Information Team. The prevalence of obesity and undernutrition in Scottish children: growth monitoring within the Child Health Surveillance Programme. *Scottish Medical Journal* 2003;48(2):32–37	Discusses identification of overweight and obesity only.
Bak H, Petersen L, Sorensen TIA. Physical activity in relation to development and maintenance of obesity in men with and without juvenile onset obesity. *International Journal of Obesity* 2004;28:99–104	Outcomes not relevant to review (relationship of physical activity to obesity).
Ball K, Crawford D, Ireland P, et al. Patterns and demographic predictors of 5-year weight change in a multi-ethnic cohort of men and women in Australia. *Public Health Nutrition* 2002;6(3):269–80	Identifies critical periods only.
Ball K, Crawford D. Socioeconomic status and weight change in adults: a review. *Social Science and Medicine* 2005;60:1987–2010	Literature review.
Blair SN, Nichaman MZ. The public health problem of increasing prevalence rates of obesity and what should be done about it. *Mayo Clinic Proceedings* 2002;77(2):109–113	No study design (discussion paper).
Blundell JE, Cooling J. Routes to obesity: phenotypes, food choices and activity. British	Does not discuss identification.

Journal of Nutrition 2000;83(Suppl 1):S33–38	
Borra ST, Kelly L, Shirreffs MB, et al. Developing health messages: qualitative studies with children, parents, and teachers help identify communications opportunities for healthful lifestyles and the prevention of obesity. *Journal of the American Dietetic Association* 2003;103(6):721–28	Not relevant to this review.
Boudreaux ED, Wood KB, Mehan D, et al. Congruence of readiness to change, self efficacy, and decisional balance for physical activity and dietary fat reduction. *American Journal of Health Promotion* 2003;17(5):329–336	Outcomes not relevant to review (relations between decisional balance and self-efficacy variables on stage of change).
Brown WJ, Miller YD, Miller R. Sitting time and work patterns as indicators of overweight and obesity in Australian adults. *International Journal of Obesity* 2003;27(11):1340–6	Not relevant to this review.
Buiten C, Metzger B. Childhood obesity and risk of cardiovascular disease: a review of the science. *Pediatric Nursing* 2000;26(1):13–18	No study design (discussion paper).
Bulik CM, Sullivan PF, Kendler KS. Genetic and environmental contributions to obesity and binge eating. *International Journal of Eating Disorders* 2003;33:293–8	Discussion of risk factors only.
Burton WN, Chen CY, Schultz AB, et al. The costs of body mass index levels in an employed population. *Statistical Bulletin – Metropolitan Insurance Companies* 1999;80(3):8–14	Not held at British Library. Unable to trace.
Burton WN, Chen CY, Schultz AB, et al. The economic costs associated with body mass index in a workplace. *Journal of Occupational and Environmental Medicine* 1998;40(9):786–92	Not relevant to this review.
Chomitz VR, Colling J, Kim J, Kramer E, McGowan R. Promoting healthy weight among elementary school children via a health report card approach. *Archives of Pediatric Adolescent Medicine* 2003;157: 765–72	Essentially concerns the identification of overweight children.
Coday M, Klesges LM, Garrison RJ, et al. Health Opportunities with Physical Exercise (HOPE): social contextual interventions to reduce sedentary behavior in urban settings. *Health Education Research* 2002;17(5):637–47	Not relevant to this review.
Cole TJ. Children grow and horses race: is the adiposity rebound a critical period for later obesity? *BMC Pediatrics* 2004;4(1):6–12	Not relevant to this review.
Cook C, Simmons G, Swinburn B, et al. Changing risk factors for non-communicable disease in New Zealand working men – is workplace intervention effective? *New Zealand Medical Journal*	Does not discuss identification.

2001;114(1130):175–78	
Danielzik S, Langnase K, Mast M, et al. Impact of Parental BMI on the manifestation of overweight 5–7 year old children. *European Journal of Nutrition* 2002;41:132–38	Discussion of risk factors only.
Danielzik S, Czerwinski-Mast M, Langnase K, et al. Parental overweight, socioeconomic status and high birth weight are the major determinants of overweight and obesity in 5–7 y-old children: baseline data of the Kiel Obesity Prevention Study (KOPS). *International Journal of Obesity* 2004;28(11):1494–502	Discusses identification of overweight and obesity only.
Dausch JG. The problem of obesity: fundamental concepts of energy metabolism gone awry. *Critical Reviews in Food Science and Nutrition* 1992;31(4):271–98	Literature review/discussion of risk factors only.
de Onis M. The use of anthropometry in the prevention of childhood overweight and obesity. *International Journal of Obesity* 2004;28:S81–5	No study design.
De Pinto C. Childhood obesity. A review of the causes, prevention, and the role of the primary care provider. *Maryland Medicine* 2004;5(3):9–11, 13–5.	Literature review.
Dietz WH, Gortmaker SL. Preventing obesity in children and adolescents. *Annual Review of Public Health* 2001;22:337–53	Literature review.
Dietz W. How to tackle the problem early? The role of education in the prevention of obesity. *International Journal of Obesity* 1999;23(Suppl 4):S7–S9	No study design (framework discussion paper).
DuBose KD, Kirtland KA, Hooker SP, et al. Physical activity trends in South Carolina, 1994–2000. *Southern Medical Association* 2004;97(9):806–10.	Does not discuss identification.
Dwyer T, Blizzard CL. Defining obesity in children by biological endpoint rather than population distribution. *International Journal of Obesity* 1996;20:472–480	Not relevant to this review.
Elgar FJ, Roberts C, Moore L, et al. Sedentary behaviour, physical activity and weight problems in adolescents in Wales. *Public Health* 2005;119:518–24	Does not discuss identification.
Elliott MA, Copperman NM, Jacobson MS. Pediatric obesity prevention and management. *Minerva Pediatrica* 2004;56(3):265–276	Literature review.
Faith MS, Berkowitz RI, Stallings VA, et al. Parental feeding attitudes and styles and child body mass index: prospective analysis of a gene-environment	Study population with diagnosed risk.

interaction. *Pediatrics* 2004;114(4):429–46	
Freedman DS, Kettel Khan L, Serdula MK, et al. The relation of childhood BMI to adult adiposity: The Bogalusa Heart Study. *Pediatrics* 2005;115:22–7.	Discussion of risk factors only.
Freedman DS, Khan LK, Serdula MK, et al. Inter-relationships among childhood BMI, childhood height and adult obesity: the Bogalusa Heart Study. *International Journal of Obesity* 2004;28(1):10–6.	Outcomes not relevant to review (appropriateness of preferential classification of taller children as overweight).
Fulton JE, McGuire MT, Caspersen CJ, et al. Interventions for weight loss and weight gain prevention among youth. *Sports Medicine* 2001;31(3):153–65	Literature review.
Garrow JS. Is it possible to prevent obesity? *Infusionstherapie* 1990;17:28–31	No study design (discussion paper).
Gill TP. Key issues in the prevention of obesity. *British Medical Bulletin* 1997;53(2):359–88	Literature review.
Gill T, King L, Caterson I. Obesity prevention: necessary and possible. A structured approach for effective planning. *Proceedings of the Nutrition Society* 2005;64:255–61	Literature review.
Goran MI, Figueroa R, McGloin A, et al. Obesity in children: recent advances in energy metabolism and body composition. *Obesity Research* 1995;3(3):277–89	Does not discuss identification.
Goran MI. Measurement issues related to studies of childhood obesity: assessment of body composition, body fat distribution, physical activity, and food intake. *Pediatrics* 1998;101:505–18	Not relevant to this review.
Griffiths M, Payne PR, Stunkard AJ, et al. Metabolic rate and physical development in children at risk of obesity. *The Lancet* 1990;336:76–8	Discussion of risk factors only
Haire-Joshu D, Nanney MS. Prevention of overweight and obesity in children: influences on the food environment. *Diabetes Educator* 2002;28(3):415–23	Literature review
Harris HE, Ellison GTH, Clement S. Relative importance of heritable characteristics and lifestyle in the development of maternal obesity. *Journal of Epidemiology and Community Health* 1999;53(2):66–74	Does not discuss identification.
He Q, Karlberg J. Prediction of adult overweight during the pediatric years. *Pediatric Research* 1999;46(6):697–703	Superseded by more recent paper (He Q, 2002).
Heywood A, Firman D, Sanson-Fisher R, et al. Correlates of physician counseling associated with obesity and smoking. *Preventive Medicine*	Outcomes not relevant to review (variables associated with GP identification of overweight and

1996;25:268–76	smoking status and occurrence of counselling for these risk factors).
Hill JO, Wyatt HR, Melanson EL. Genetic and environmental contributions to obesity. *Medical Clinics of North America* 2000;84(2):333–46	Discussion of risk factors only.
Hill JO, Melanson EL, Wyatt HT. Dietary fat intake and regulation of energy balance:I mplications for obesity. *Journal of Nutrition* 2000;130(2S Suppl):S284S–8	Not relevant to this review.
Houng V. Putting prevention into practice: counseling patients about behaviour change, part 1. *Journal of the Oklahoma State Medical Association* 2005;98(4):147–50	No study design (discussion paper).
Irving LM, Neumark-Sztainer D. Integrating the prevention of eating disorders and obesity: feasible or futile? *Preventive Medicine* 2002;34:299–309	Does not discuss identification.
Jacobsen BK, Njolstad I, Thune I, et al. Increase in weight in all birth cohorts in a general population. *Archives of Internal Medicine* 2001;161(3):466–72.	Not relevant to this review.
Jensen GL, Kita K, Fish J, et al. Nutrition risk screening characteristics of rural older persons: relation to functional limitations and health care charges. *American Journal of Clinical Nutrition* 1997;66:819–28	Does not discuss identification.
Jonides LK. Childhood obesity: an update. *Journal of Pediatric Health Care* 1990;4(5):244–51	Literature review.
Karp WB. Childhood and adolescent obesity: a national epidemic. *Journal of the California Dental Association* 1998;26(10):771–3	No study design (discussion paper).
Kealy MM. Preventing obesity: exploring the Surgeon General's outline for action. AWHONN lifelines 2003;7(1):24–7	Literature review.
Kearney JM, de Graaf C, Damkjaer S, et al. Stages of change towards physical activity in a nationally representative sample in the European Union. *Public Health Nutrition* 1999;2(1A):115–24	Not relevant to this review.
Kiernan M, Winkleby MA. Identifying patterns for weight-loss treatment. *Archives of Internal Medicine* 2000;160:2169–76	Discusses identification of overweight and obesity only.
Kral JG. Preventing and treating obesity in girls and young women to curb the epidemic. *Obesity Research* 2004;12(10):1539–46	No study design (discussion paper).
Kumanyika SK. Minisymposium on obesity: overview and some strategic considerations. *Annual Review of Public Health* 2001;22:293–308	Literature review.

Laing P. Childhood obesity: a public health threat. *Paediatric Nursing* 2002;14(10):14–6	No study design (discussion paper).
Lambert EV, Lambert MI, Hudson K, et al. Role of physical activity for health in communities undergoing epidemiological transition. *World Review of Nutrition and Dietetics* 2001;90:110–26	Does not discuss identification.
Mascarenhas MR, Tershakovec AM, Stettler N. Nutrition interventions in childhood for the prevention of chronic diseases in adulthood. *Current Opinion in Pediatrics* 1999;11(6):598–604	Not relevant to review.
McElroy SL, Kotwal R, Malhotra S, et al. Are mood disorders and obesity related? A review for the mental health professional. *Journal of Clinical Psychiatry* 2004;65(5):634–51	Study population with mental disorders in the care of health professionals.
McGarvey E, Keller A, Forrester M, et al. Feasibility and benefits of a parent-focused preschool child obesity intervention. *American Journal of Public Health* 2004;94(9):1490–5	Not relevant to this review.
Mo-suwan L, Tongkumchum P, Puetpaiboon A. Determinants of overweight tracking from childhood to adolescence: a 5 y follow-up study of Hat Yai schoolchildren. *International Journal of Obesity* 2000;24(12):1642–7	Discussion of risk factors only.
Montiero POA, Victoria CG. Rapid growth in infancy and childhood and obesity in later life – a systematic review. *Obesity Reviews* 2005;6:143–54	Discussion of risk factors only.
Muller MJ, Asbeck I, Mast M, et al. Prevention of obesity – More than an intention. Concept and first results of the Kiel Obesity Prevention Study (KOPS). *International Journal of Obesity* 2001;25(Suppl 1):S66–74	Does not discuss identification.
Ness AR. The Avon Longitudinal Study of Parents and Children (ALSPAC) – a resource for the study of the environmental determinants of childhood obesity. *European Journal of Endocrinology* 2004;151:U141–9	Discussion of risk factors only.
Neumark-Sztainer D. School-based programs for preventing eating disturbances. *Journal of School Health* 1996,66(2):64–71	No study design (framework discussion paper).
NSW Centre for Public Health Nutrition. *Best options for promoting healthy weight and preventing weight gain in NSW*. Sydney: NSW Department of Health; 2004	Literature review.
Ong, KKL, Ahmed ML, Emmett PM, et al. Association between postnatal catch-up growth and obesity in childhood: prospective cohort study. *British Medical Journal* 2000;320:967–71	Discussion of risk factors only.

Parsons TJ, Power C, Logan S, et al. Childhood predictors of adult obesity:a systematic review. *International Journal of Obesity* 1999;23(Suppl 8):S1–107	Discussion of risk factors only.
Perusse L, Bouchard C. Role of genetic factors in childhood obesity and in susceptibility to dietary variations. *Annals of Medicine* 1999;31(Suppl 1):19–25	Literature review.
Pietrobelli A, Peroni DG, Faith MS. Pediatric body composition in clinical studies: which methods in which situations? *Acta Diabetologica* 2003;40:S270–3	Literature review.
Pietrobelli A. Outcome measurements in paediatric obesity prevention trials. *International Journal of Obesity* 2004;28:S86–9	Outcomes not relevant to review.
Power C, Lake JK, Cole TJ. Body mass index and height from childhood to adulthood in the 1958 British birth cohort. *American Journal of Clinical Nutrition* 1997;66(5):1094–101	Does not discuss identification.
Power C, Lake JK, Cole TJ. Measurement and long-term health risks of child and adolescent fatness. *International Journal of Obesity* 1997;21(7):507–26.	Does not discuss identification.
Prochaska JO, Norcross JC, Fowler JL, et al. Attendance and outcome in a work site weight control program: processes and stages of change as process and predictor variables. *Addictive Behaviors* 1992;17:35–45	Does not discuss identification.
Reilly JJ, Armstrong J, Dorosty AR, et al. Early risk factors for obesity in childhood: cohort study. *British Medical Journal* 2005;330(7504):1357–63	Discussion of risk factors only.
Reilly JJ. Assessment of body composition in infants and children. *Nutrition* 1998;14(10):821–5	Not relevant to this review.
Resnicow K. School-based obesity prevention: population versus high-risk interventions. *Annals of the New York Academy of Sciences* 1993;699:154–66	Does not discuss identification.
Rocchini AP, Pierpont ME. The child at risk for developing heart disease. *Minnesota Medicine* 1992;75:25–92	Literature review.
Rodriguez G, Moreno LA, Blay MG, et al. Body composition in adolescents: measurements and metabolic aspects. *International Journal of Obesity* 2004;28:S54–8	Discusses identification of overweight and obesity only.
Sardinha LB, Going SB, Teixeira PJ, et al. Receiver operating characteristic analysis of body mass index, triceps skinfold thickness and arm girth for obesity screening in children and adolescents. *American*	Discusses identification of overweight and obesity only.

Journal of Clinical Nutrition 1999;70(6):1090–5	
Schmitz MKH, Jeffery RW. Public health interventions for the prevention and treatment of obesity. *Medical Clinics of North America* 2000;84(2):491–512	Literature review.
Schumann L, Nichols MR, Livingston D. Preventing pedatric obesity: assessment and management in the primary care setting. *Nurse Practitioner* 2002;14(2):55–62	Discusses identification of overweight and obesity only.
Schwartz F. Obesity in adult females:the relationship among personality characteristics, dieting and weight. *AAOHN Journal* 1993;41(10):504–9	Not relevant to this review.
Sherwood NE, Morton N, Jeffery RW, et al. Consumer preferences in format and type of community-based weight control programs. *American Journal of Health Promotion* 1998;13(1):12–8	Does not meet inclusion/exclusion criteria (weight management programme).
Shunk JA, Birch LL. Girls at risk for overweight at age 5 are at risk for dietary restraint, disinhibited overeating, weight concerns, and greater weight gain from 5 to 9 years. *Journal of the American Dietetic Association* 2004;104:1120–6.	Discusses identification of overweight or obesity only.
Skinner JD, Bounds W, Carruth BR, et al. Predictors of children's body mass index: a longitudinal study of diet and growth in children aged 2–8 y. *International Journal of Obesity* 2004;28:476–82	Discussion of risk factors only.
Steinbeck KS. The importance of physical activity in the prevention of overweight and obesity in childhood: a review and an opinion. *Obesity Reviews* 2001;2:117–30	Literature review.
Stice E, Presnell K, Shaw H. Psychological and behavioural risk factors for obesity onset in adolescent girls:a prospective study. *Journal of Consulting and Clinical Psychology* 2005;73(2):195–202	Discussion of risk factors only.
Strauss R. Perspectives on childhood obesity. *Current Gastroenterology Reports* 2002;4(3):244–50	Literature review.
Strock GA, Cottrell ER, Abang AE, et al. Childhood obesity: a simple equation with complex variables. *Journal of Long-Term Effects of Medical Implants* 2005;15(1):15–32	Literature review/does not discuss identification.
Strumpf E. *The obesity epidemic in the United States: causes and extent, risks and solutions*. New York: The Commonwealth Fund; 2004	Does not discuss identification.
Swinburn BA, Caterson I, Seidell JC, et al. Diet, nutrition and the prevention of *excess* weight gain and obesity. *Public Health Nutrition 20*04;7(1A):123–	Literature review.

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Talvi AI, Jarvisalo JO, Knuts LR. A health promotion programme for oil refinery employees: changes of health promotion needs observed at three years. *Occupational Medicine* 1999;49(2):93–101	Does not discuss identification.
Thomas NE, Baker JS, Davies B. Established and recently identified coronary heart disease risk factors in young people: the influence of physical activity and physical fitness. *Sports Medicine* 2003;33(9):633–50	Literature review.
VanItallie TB. Waist circumference: a useful index in clinical care and health promotion. *Nutrition Reviews* 1998;56(10):300–13	Literature review.
Veugelers PJ, Fitzgerald AL. Effectiveness of school programs in preventing childhood obesity: a multilevel comparison. *American Journal of Public Health* 2005;95(3):432–5	Does not discuss identification.
Weinstein Y, Kamerman T, Berry E, et al. Mechanical efficiency of normal-weight prepubertal boys predisposed to obesity. *Medicine and Science in Sports and Exercise* 2004;36(4):567–73	Discussion of risk factors only.
Whitaker RC. Predicting preschooler obesity at birth: the role of maternal obesity in early pregnancy. *Pediatrics* 2004;114(1):29–36	Discussion of risk factors only.
Widga AC, Lewis NM. Defined, in-home, prenatal nutrition intervention for low-income women. *Journal of the American Dietetic Association* 1999;99(9):1058–62.	Not relevant to this review.
Wiecha JL, Casey VA. High prevalence of overweight and short stature among head start children in Massachusetts. *Public Health Reports* 1994;109(6):767–73	Discussion of prevalence only.
Williams CL, Gulli MT, Deckelbaum RJ. Prevention and treatment of childhood obesity. *Current Atherosclerosis Reports* 2001;3:486–97	Literature review.
Wing RR. Changing Diet and exercise behaviours in individuals at risk for weight gain. *Obesity Research* 1995;3(Suppl 2):s277–82	Not held at British Library. Unable to trace.
Wisemantle W, Maynard LM, Guo SS, et al. Childhood weight, stature and body mass index among never overweight, early-onset overweight and late-onset overweight groups. *Pediatrics* 2000;106(1):14–22	Discusses identification of overweight and obesity only.
Yancey AK, Jordan A, Bradford J, et al. Engaging high-risk populations in community-level fitness promotion: ROCK! Richmond. *Health Promotion*	Outcomes not relevant to review (risk of chronic disease).

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Contents

Appendix 4

The determinants of weight gain and weight maintenance (‘energy balance’)

EVIDENCE SUMMARY TABLES

Table number **Page**

CHILDREN

ADULTS

EVIDENCE TABLE 1: MAINTAINING ENERGY BALANCE IN CHILDREN

SUMMARY

1.1 Dietary factors

Of the eighteen cohorts of children, ten longitudinal cohorts examined the association of dietary factors with weight change and one cross-sectional study (McConahy 2004) focused on portion size.

O'Loughlin et al. (2000) conducted a 2-year cohort study in 9–12-year-old children in Canada and reported no strong or consistent pattern of associations in either boys or girls for diet indicators and weight change (results not reported). Bogaert et al. (2003) conducted an analysis of 59 8-year-old Australian children and found no significant correlations between body mass index (BMI) over 12 months for any dietary variable.

Klesges et al. (1995) conducted a 2-year analysis of 3–5-year-old children and their parents in Tennessee and found that higher baseline percentages of energy as fat were associated with greater increases in BMI (0.168 kg/m^2 per 5%) and recent increases (year 2–3) in percentage of energy intake as fat were associated with greater increases in BMI (0.201 kg/m^2 per 5% change). Neither baseline total energy nor change in total energy increased variance in change in body mass.

The Growing Up Today Study (Berkey, 2000, 2003a, 2003b, Berkey 2005; Field, 2003, 2004; Taveras 2005) of 9–14-year-old US children included analyses of several potential determinants. Berkey et al. (2003) conducted an analysis of more than 10,000 children over 1 year and reported that for both boys and girls a larger rise in energy intake predicted larger BMI increase (girls 0.0059 per increase of 100 kcal [420 kJ]/day, boys 0.0082) and annual BMI increases were higher in girls with higher energy intakes (BMI increased by 0.061 kg/m^2 per 100 kcal [420 kJ]/day; $p > 0.02$). Over 2 years, boys with energy intake that increased more from the first to the second year predicted larger increases in BMI. In boys and girls no significant associations were noted for energy adjusted dietary fat or fibre and change in BMI ($p > 0.05$).

Overweight children who never ate breakfast lost BMI over 1-year compared with children who ate breakfast nearly every day (boys –0.66 kg/m^2, girls –0.50 kg/m^2). Normal weight children who never ate breakfast gained weight relative to peers who ate breakfast nearly very day (boys 0.21 kg/m^2, girls 0.08 kg/m^2).

Field (2003) conducted an analysis of more than 15,000 children over 3-years and after controlling for Tanner stage of development, age, height change, activity and inactivity (predictors of BMI), girls showed no relation between intake of fruits, fruit juice or vegetables (alone or combined) and subsequent changes in BMI *z*-score. In boys, intake of fruit and fruit juice was not predictive of changes in BMI. Although vegetables intake was inversely related to changes in BMI *z*-score ($p > 0.05$) after adjusting for energy intake, the magnitude of the effect was diminished and no longer significant.

There was no relation between intake of snack foods and subsequent changes in BMI *z*-score among the boys ($\beta = -0.004$), but snack foods had a weak inverse association ($\beta = -0.007$, $p > 0.05$) with weight change among the girls. However, the results were confounded by dieting status, which had a significant positive independent association with BMI change. After controlling for dieting status and whether the mother was overweight, the association between servings per day of snack foods and subsequent changes in BMI *z*-score were not significant in either gender (Field 2004).

Berkey (2005 GUTS) looked at the association between milk, dietary fat, dietary calcium and weight gain in the Growing Up Today Study (GUTS). Children who reported higher total milk intake experienced larger weight gains; children who drank more 1% and skimmed milk had larger weight gains than those who drank smaller amounts of 1% and skimmed; dietary calcium intake was positively correlated with weight gain; and dietary fat was not. The effects of milk and dietary calcium appeared to be explained by energy intake; however skimmed milk intake in girls remained marginally significant after adjustment for energy intake.

Taveras (2005, GUTS) looked at the association between overweight and frequency of family dinner in the Growing Up Today Study (GUTS). Whilst cross-sectional data showed children were less likely to be overweight if they ate dinner most days with their family, this relationship was not apparent in the longitudinal analyses over 2 years. This data was self-reported.

In the study by Thompson (2004) of girls (median age 9 years at baseline and followed for a median of 6 years), girls who ate quick-service food twice per week or more at baseline had the greatest means increase in BMI *z*-score at follow-up, and this change was significantly different from that seen in girls who ate quick-service food once or twice per week or not at all.

Burke (2005) investigated the relationships between different food categories and BMI at 8 years in 340 Australian children. Parents completed a food frequency questionnaire for their children at 6 years. An inverse relationship was found for 'cereals' and '% energy from total fat' (p = 0.046 and p = 0.025 respectively) and a positive relationship with 'takeaways' (p = 0.025).

Elgar (2005) found that skipping meals and snacking (not further defined) were associated with obesity, but did not predict change in BMI between the ages of 11-12 and 15-16 years in 355 Welsh adolescents.

Moore (2003) investigated the relationships between physical activity level, TV viewing and change in body fat in 106, 3-5-year-olds from the Framingham Children's Study over a period of eight years (from 2-5 years of age). Children with high fat diets (>34% calories from fat) exacerbated body fat gain in children watching TV for more than 3 hours per day. They gained approximately 30mm of body fat (sum of five skinfolds) compared with children who watched least TV (<1.75h per day) and consumed a lower-fat diet (<34% calories from fat).

Phillips (2004) investigated the relationship between energy dense snacks (EDS) and BMI z-scores in 196 non-obese pre-menarcheal girls 8 to 12 years old from the Massachusetts Institute of Technology Growth and Development Study (ethnicities included 75% white, 14% black and 11% other races) for four years after menarche. Categories of EDS foods considered were baked goods, ice cream, chips, sugar-sweetened carbonated drinks and sweets. No relationship was found between BMI z score or % body fat and total EDS food consumption. However, carbonated drinks were the only EDS food significantly related to BMI z-score over the 10-year study period (p-value for trend <0.001), but it was not related to % body fat.

Reilly (2005) examined 25 risk factors for obesity from the inter-uterine period to 7 years in the ALSPAC cohort (UK). Eight factors were associated with risk of obesity. None were dietary, although a 'junk food type dietary pattern' (not defined further) at 3 years was significant at the 10% level.

McConahy (2004) looked at dietary behaviours in 5447 children aged 2-5 years from the Continuing Survey of Food Intakes by Individuals across the US, over a two year period. Based on parental self-report, this cross-sectional study found that body weight, food portion size, number of eating occasions and number of foods accounted for 38% of the variance in 2-3-year-olds and 39% in 4-5-year-olds. Portion size as a single predictor explained 17% of the variance in 2-3-year-olds and 19% in 4-5-year-olds.

1.2 Physical activity

Of the eighteen cohorts of children, eight cohorts examined the association of physical activity (PA) factors with weight change. O'Loughlin et al. (2000) reported 1-year predictors of higher decile of change in BMI included no sports outside school (odds ratio [OR] 1.90; 95% confidence interval [CI] 1.18, 3.06) in girls. Two-year predictors of higher decile of change in BMI included no sports outside school (OR 2.14; 95% CI 0.96, 4.77) and least active (OR 2.18; 95% CI 1.01, 4.71) in boys.

Berkey et al. (2003) reported annual BMI increases were higher in girls with fewer hours of activity (BMI decreased by 0.284 kg/m^2 per hour per day of activity; $p > 0.05$) during the year between baseline and follow up. Boys who marginally, had less PA (–0.0261 kg/m^2 per hour of activity; $p = 0.094$) showed larger annual BMI increases. The number of gym classes per week was not associated ($p > 0.10$) with change in BMI in boys. Boys with higher metabolic equivalent tasks (METs) during the year between the two BMIs had marginally smaller ($p = 0.6$) increases in BMI.

Klesges et al. (1995) reported that higher baseline aerobic activity and increased leisure activity from years 2 to 3 were associated with BMI decreases.

Bogaert et al. (2003) reported no significant correlations between BMI over 12 months for any measures of energy expenditure, including hours of television (TV) viewing or percentage of time spent in low, moderate or high intensity activity. A significant correlation was found between activity and weight change for mothers and girls for percent time in moderate to high activity ($r = 0.44$, $p = 0.03$) and between fathers and children for percentage of time spent in low activity ($r = 0.43$, $p = 0.005$).

Datar et al. (2004) conducted a 1-year follow-up of primary school aged children in the USA and examined association between weight change and PA only. The study found that one additional hour of physical education in the first grade compared with the time allowed for physical education in kindergarten reduced BMI among girls who were overweight or at risk for overweight in kindergarten (*p* > 0.01) but had no significant effect among overweight or at risk for overweight boys (*p* = 0.02) or among boys (*p* = 0.31) or girls (*p* = 0.80) with a normal BMI.

Moore (2003) examined 106 children aged 3-5 years from the Framingham Children's Study with Caltrac motion sensors to assess physical activity levels. Children were categorised as having low, medium or high activity levels (based on average number of counts per hour and then averaged over the eight year study period). Children in the highest tertile for daily physical activity had consistently smaller gains in BMI, triceps and sum of 5 triceps throughout childhood. By 11 years, sum of 5 skinfolds was 95.1mm, 94.5mm and 74.1mm for the low, medium and high tertiles respectively (p-value for trend = 0.045). This relationship was evident for both sexes. Children with the lowest levels of PA and highest levels of TV viewing gained nearly 40 mm of body fat than children with highest levels of PA and least TV by 11 years.

Burke (2005) used parental questionnaires to assess levels of physical activity in 1430 Australian children at 6 years. Playing organised sport at age 6 was not predictive of BMI at age 8, but 'being slightly active' and 'active' at 8 years were (OR 0.44; 95 CI 0.28, 0.70 (p<0.001) and OR 0.23; 95 CI 0.14, 0.38 (p<0.001)) respectively. Duration of physical activity was not reported.

Elgar (2005) assessed the relationship between physical activity and change in BMI in 355 Welsh adolescents who were part of the Health Behaviour of School-aged Children Study. Physical activity questions were from the HBSC questionnaire and hours of sports participation was associated with lower increases in BMI (p<0.05) over the four year period (from 11-12 to 15-16 years). Details about amount of hours of sport were not reported.

1.3 Other behavioural, psychological, social and environmental factors

1.3.1 Sedentary behaviours – television/video viewing

Ten cohorts examined the relationship between television (TV)/video viewing and weight change in children. Kaur (2003) analysed 3-year data from 12–17-year-old Californian adolescents and found that 1% variation in follow-up BMI% was explained by TV watching. Watching >2 hours TV per day was related to higher odds of being overweight at follow-up among adolescents at normal weight at baseline (OR 1.9; 95% CI 1.1, 3.5) and among adolescents overweight at baseline (OR 2.8; 95% CI 1.3, 6.3). For each additional hour of TV watching at baseline the average follow-up BMI% increased by 0.5, controlling for ethnicity and baseline BMI%. Forty-eight percent of new-onset overweight among adolescents not overweight at baseline was attributable to watching >2 hours TV per day.

O'Loughlin (2000) reported there was no strong or consistent pattern of association in either boys or girls for TV viewing. One-year predictors of higher decile of change in BMI included playing video games everyday (OR 2.48; 95% CI 1.04, 5.92) in girls.

Robinson (1993) conducted a 2-year analysis of 12-year-old Californian children and reported that hours of after-school TV viewing did not longitudinally predict change in ***sexual maturity index (SMI)*** -adjusted BMI (univariate Spearman *r* = 0.03, *p* = 0.62; multivariate regression co-efficient estimate = 0.05, *p* = 0.82). Hours of after-school TV viewing did not longitudinally predict change in SMI-adjusted triceps skinfold thickness (univariate Spearman *r* = 0.03, *p* = 0.54; multivariate regression co-efficient estimate = –0.19, *p* = 0.67).

Berkey (2003) reported that annual BMI increases were higher in girls with more hours of TV /video/games (BMI increased by 0.372 kg/m^2 per hour per day; *p* > 0.001) during the year between baseline and follow up. Boys who spent more time with TV/videos/games (0.384 kg/m^2 per hour per da***y***; *p* > 0.0001) showed larger annual BMI increases. Over 2 years, boys with higher means hours of TV/video/games were predicted to have larger increases in BMI.

Bogaert (2003) reported no significant correlations between BMI over 12 months for hours of TV viewing.

Burke (2005) examined the relationship between hours per day spent watching TV and BMI at 8 years with the Western Australian Pregnancy Cohort. Parental questionnaires were completed about their children's television viewing habits at age 6 and hours spent TV viewing at age 6 was predictive of BMI at 8 years; OR 1.53; 95 CI 1.16, 2.02 (p<0.002), ie more TV viewing resulted in higher BMI.

Elgar (2005) assessed the relationship between sedentary behaviour and change in BMI in 355 Welsh adolescents who were part of the Health Behaviour of School-aged Children Study. Sedentary behaviour (watching television or playing computer games) at Time 1 predicted BMI four years later ($p<0.05$), ie more sedentary behaviour resulted in higher BMI.

Moore (2003) used parental questionnaires in conjunction with Caltracs to estimate hours of TV viewing and video games per day in 106, 3-5-year-olds from the Framingham Children's Study. TV viewing was divided into tertiles of hours per day: <1.75h, 1.75 to <3.0h, >3.0h. At 11 years, those who watched 3.0h or more per day had a mean sum of 5 skinfolds of 106.2mm compared with 87.6mm for those watching 1.75 to <3.0h, and 76.5mm for those watching least ($p = 0.007$; p-value for trend = 0.028).

Reilly (2005) found two predictive factors for sedentary behaviours within the ALSPAC cohort. Watching more than 8 hours of television per week at age 3 was associated with risk of obesity (adjusted OR 1.55; 95 CI 1.13, 2.12) and short sleep duration (<10.5 hours) at age 3 was also identified as a risk (OR 1.45; 95 CI 1.10, 1.89).

Viner (2005) UK conducted an analysis of the 1970 British Birth cohort of over 8000 subjects followed up at 5, 10 and 30 years (30 year follow-up self-reported) examining the relationship between television viewing and BMI change. Weekend but not weekday TV viewing in early childhood independently predicted increased adult BMI.

Clearer relationships were found from ages 5 to 10 years than to 30 years. Mean hours of weekend TV and frequent TV watching at 10 were independently associated with higher BMI at 10: Using obesity at 10 as the outcome in logistic regression, each additional hour of TV watched on weekdays at 5 years increased the risk of obesity by 12% (OR 1.12; 95 CI 1.04, 1.21; $p = 0.002$); and each additional hour at weekends increased risk by 10% (OR 1.10; 95 CI 1.03, 1.18; $p = 0.003$).

1.3.2 Socio-economic status

Spiegelaere (1998) examined possible association between socio-economic status (SES) (statuses) and the rate of adiposity rebound in 3–5-year-old Belgium children and found that adiposity rebound before age 5 years was inversely related to body mass at age 3 years and was independent of social status. Parental income and education were not associated with change in BMI *z*-score in the study by Thompson et al. (2004).

Burke (2005) considered predictive factors for BMI at 8 years in 1430 Australian children. Categories of higher and lower incomes were based on total family income (categorised as lower = below $40,000, or higher = above $40,000). BMI was similar at 3 years but at 6 and 8 years, BMI was higher in lower income families ($p = 0.004$). A similar pattern was apparent for maternal education; BMI at 6 years was lower in tertiary educated mothers ($p = 0.001$) compared with mothers not educated beyond secondary schooling or having a technical qualification.

Elgar (2005) found that demographic factors and SES did not predict change in BMI in 355, Welsh adolescents (aged 11-14 years) over four years.

1.3.3 Age

Berkey (2003) examined the association between weight change and age and among boys under 12 years old, those who did more PA in the year between the BMI measurements had smaller annual increases in BMI (–0.0746 ± 0.0212).

1.3.4 Overweight biological parents

Klesges (1995) examined possible association between weight change and having one or two overweight biological parents. Boys with both parents overweight had increases in children's BMI (0.67 kg/m^2) and for girls those with just a father overweight showed BMI gains over 2 years (0.40 kg/m^2). O'Loughlin (2000) reported there were no strong or consistent pattern of associations in either boys or girls for family origin (results not reported). Parental BMI was not associated with change in BMI *z*-score in the study by Thompson et al. (2004).

Reilly (2005) found parental fatness was associated with risk of obesity at 7 years in the ALSPAC cohort. This was apparent if one parent was obese and increased If both parents were obese (OR 10.44; 95 CI 5.11, 21.32).

Burke (2005) looked at maternal weight and BMI in 1430, Australian 8-year-olds followed since 16 weeks gestation. BMI at 8 was predicted by maternal weight and maternal BMI and in a subset of 298 children with paternal data, each obese parent independently increased the risk of obesity at 8 by three times.

1.3.5 Birth weight

Reilly (2005) found four child weight related factors associated with obesity risk at 7 years in the ALSPAC cohort. Increasing birth weight was independently and linearly associated with obesity (p<0.001), as were early BMI or adiposity rebound (by 43 months) (OR 15.0; 95 CI 5.32, 42.3), catch-up growth (OR 2.6; 95 CI 1.09, 6.163) and weight gain in first year (OR 1.06; 95 CI 1.02, 1.10).

Burke (2005) also found that birth weight was positively associated with BMI at 8 (p<0.001) and an increasing likelihood of remaining overweight or obese with age.

1.3.6 Baseline body mass index

O'Loughlin (2000) reported that baseline BMI was the only consistent independent predictor of excess weight gain in all four multivariate models. One-year predictors of higher decile of change in BMI included BMI of 90th percentile or more (OR 2.66; 95% CI 1.80, 1.34) in boys and BMI of 90th percentile or more (OR 2.34; 95% CI 1.46, 3.76), in girls. Two-year predictors included baseline BMI of 90th percentile or more (OR 3.26; 95% CI 1.52, 7.01), and BMI of 90th percentile or more (OR 2.22; 95% CI 1.02, 4.81) in girls. Kaur (2003) reported nearly 50% variation in follow-up BMI% was explained by baseline BMI%.

1.3.7 Ethnicity

Two cohorts examined ethnicity and weight change, with one reporting that only 0.3% variation in follow-up BMI% was explained by ethnicity (Kaur 2003). Sixty-eight percent of the children were White, 5% African American, 20% Hispanic and 8% Asian with no other further details regarding ethnicity and weight change. Ambrosius (1998) performed a 14-year follow-up of children mean age 9–10 years at baseline (range 5–20 years) in Indianapolis. He reported that the rate at which BMI increased in Black children was significantly greater than in the White children ($p > 0.0001$). There were no gender differences in the rate of increase of BMI. No other details regarding ethnicity were reported.

1.3.8 Self-esteem

One cohort study examined the association between self-esteem and weight change in 12–15-year-old children in Minnesota (French 1996). Partial correlations were identified between baseline self-esteem and BMI at 3 years. In females, low physical appearance and low social acceptance self-esteem at baseline were associated with higher BMI 3 years later. In males, baseline self-esteem was unrelated to BMI 3 years later. Analyses examining relationships between baseline self-esteem and overweight status 3 years later showed high close friendship self-esteem in females and high physical appearance self-esteem in males were associated with decreased odds of overweight at 3-year follow-up. (All associations were significant but modest in magnitude.)

1.4 Parental fatness

A systematic review (Parsons et al. 1999) identified eight cohort studies that identified factors in childhood that may influence the development of obesity in adulthood. Offspring of obese parent(s) were consistently seen to be at increased risk of fatness, although few studies have looked at this relationship over longer periods of childhood and into adulthood. Data from one study suggested that this relationship may be stronger between mothers and their offspring than fathers and offspring, and that the mother-offspring relationship strengthens over time. One study found that parental obesity was a more important predictor of offspring obesity earlier in childhood (<6 years), becoming less important with increasing age. Data from another study showed that parental obesity influences tracking of the offspring's own obesity, which is much stronger if both parents are obese.

The relative contributions of genes and inherited lifestyle factors to the parent–child fatness association remains largely unknown.

1.5 Evidence of corroboration in the UK

Three of the 18 cohorts of children were conducted in the UK (Elgar 2005, Reilly 2005, Viner 2005) and the other cohorts were mainly conducted in the USA and generalisable to UK children. *(Evidence of implementation not valid for this review as not intervention studies.)*

EVIDENCE SUMMARY TABLES: DETERMINANTS OF WEIGHT GAIN/CONTROL IN CHILDREN

First author, design, aim	**Population**	**Intervention details, length of follow-up**	**Results**	**Confounders adjusted for/comments**
EVIDENCE OF ASSOCIATION BETWEEN DIETARY, PHYSICAL ACTIVITY AND OTHER FACTORS WITH WEIGHT CHANGE				
Parsons et al. (1999) **Aim:** To identify factors in childhood which may influence the development of obesity in adulthood 1++	Various, from eight cohort studies. **Baseline BMI:** Various.	**Year of baseline survey:** Various. **Duration of follow-up**: At least 1 year. **Outcome variable**: Measure of fatness. **Self-reported or measured weight:** Measured. **Statistical analysis**: Various.	Offspring of obese parent(s) were consistently seen to be at increased risk of fatness, although few studies have looked at this relationship over longer periods of childhood and into adulthood. Data from one study suggested that this relationship may be stronger between mothers and their offspring than fathers and offspring, and that the mother–offspring relationship strengthens over time. One study found that parental obesity was a more important predictor of offspring obesity earlier in childhood (<6 years), becoming less important with increasing age. Data from another study showed that parental obesity influences tracking of the offspring's own obesity, which is much stronger if both parents are obese. The relative contributions of genes and inherited lifestyle factors to the parent–child fatness association remains largely unknown.	**Adjusted for:** Various. **Author's conclusions:** Offspring of obese parent(s) were consistently seen to be at increased risk of fatness, and offspring of obese parents who themselves are fatter in childhood may be at particular risk.
Viner 2005 Prospective cohort, Aim: To examine the effects of duration, timing and type of television at 5 years on BMI in adult life.	1970 British Birth cohort of subjects (n = 16 567) living in Great Britain born 5-11th April, 1970. Cohort was representative of the UK population in childhood. At 30 years, 96.3% were white, 0.6% black, 1.8% South	Year of baseline examination and survey: Participants originally enrolled in the longitudinal growth and development study in 1970. Duration of follow-up: Participants were followed-up at 5, 10, 16, 26 and 29-30 years. Outcome variables:	**Attrition:** 32% **Weight change**: Obesity was found in 4.3% at 10 and 11.4% of the participants at 30 years. **Association of diet with weight change:** None reported. **Association of physical activity with weight change:** Higher frequency of playing sport at 10 years was independently associated with lower BMI z-score at 30: adjusted regression coefficient (95 CI) -0.08 (-0.12, -0.04; p<0.0001). **Association of other factors with weight change:** Higher duration of TV watching on weekdays and weekends were both	Adjusted for: Sex, social class, maternal education, birth weight, and BMI z-score of both parents. Also height at 5 and 10 years. Author's conclusions: Could not conclude that TV viewing in early childhood

	Asian, 0.8% Chinese and 0.6% other ethnic groups. At 5 years, data were obtained for 14,875 and 11,261 were interviewed at 29-30. Complete data on 8158.	Change in BMI z-score, calculated from the revised UK 1990 growth reference. Self-reported or measured: Both self-reported and measured. Height and weight measured by health care professionals at and 10 years. Self-report at 30 years. Statistical analysis: Linear regression and multivariate regression models.	significantly associated with higher BMI z-scores at 10 and 30 years. Mean hours of weekend TV and frequent TV watching at 10 were independently associated with higher BMI at 10: Using obesity at 10 as the outcome in logistic regression, each additional hour of TV watched on weekdays at 5 years increased the risk of obesity by 12% (OR 1.12; 95 CI 1.04, 1.21; p = 0.002); and each additional hour at weekends increased risk by 10% (OR 1.10; 95 CI 1.03, 1.18; p = 0.003). Strong maternal beliefs that TV was harmful to children at 5 years, predicted lower viewing at 10 years (p<0.001). Results at 30 years Mean daily hours of TV viewed at weekends predicted higher BMI z-score at 30 years (coefficient=0.03, 95% CI: 0.01, 0.05, P=.01) when adjusted for TV viewing and activity level at 10 years, sex, socioeconomic status, parental BMIs, and birth weight. Each additional hour of TV watched on weekends at 5 years increased risk of adult obesity (BMI > or =30 kg/m2) by 7% (OR=1.07, 95% CI 1.01, 1.13, P=.02). Weekday viewing, type of program and maternal attitudes to TV at 5 years were not independently associated with adult BMI z-score.	directly attributes to increased BMI.
Reilly 2005 Prospective cohort ALSPAC **Aim: To identify risk factors in early life for obesity in children**	8234 children aged 7 years and a sub-sample of 909 children with data on early growth related risk factors for obesity from the UK (Avon Longitudinal Study of Parents And Children). The original cohort of children was 13,971.	Year of baseline survey: April 1991 to December1992 Outcome variable: BMI. Duration of follow-up: 7+ years. Self-reported or measured weight: Measured. Statistical analysis: Multivariable binary logistic regression models in three stages. X^2 tests used for linear trend for ordered categorical	**Attrition:** 43% **Weight changes:** Increasing birth weight was independently and linearly associated with obesity (p<0.001); early adiposity rebound (by 43 months) (OR 15.0; 95 CI 5.32, 42.3); catch-up growth (OR 2.6; 95 CI 1.09, 6.163) and weight gain in first year (OR 1.06; 95 CI 1.02, 1.10). **Association of diet with weight change:** Food frequency questionnaires at 30 and 38 months, but dietary patterns at 3 years were not associated with risk of obesity at 7 years. Although in the final adjusted model, a 'junk food' diet reached significance at the 10% level. **Association of physical activity with weight changes:** No analysis. **Association of other factors with weight changes:** Watching more than 8 hours of television per week at age 3 was associated with risk of obesity (adjusted odds ratio 1.55; 95 CI 1.13, 2.12). Short sleep	Adjusted for: Maternal education, interuterine and perinatal factors, infant feeding and complementary feeding, family demography and lifestyle in early childhood. Author's conclusions: Early life environment implicated in findings. Interventions

		variables.	duration (<10.5 hours) at age 3 was also identified as a risk (1.45, 1.10 to 1.89). Parental obesity was associated with risk of obesity and when both parents obese (10.44; 5.11, 21.32). Maternal smoking between 28 and 32 weeks gestation was significantly associated with risk of obesity (independent of maternal education) at all intensities of smoking eg >20 (1.80, 1.01, 3.39). There was some evidence of a dose response relationship (X^2 test for linear trend 27.17).	might focus on environmental changes for short periods attempting to modify factors in utero, infancy or early childhood.
Elgar 2005 Prospective cohort Aim: To investigate the effect of sedentary behaviour and physical activity on changes in body mass	355 adolescents from the Health Behaviour of School-aged Children Study in Wales. Mean age at baseline was 12.30 (SD = 6.30).	Year of baseline survey: 1994 Outcome variable: Change in BMI. Duration of follow-up: 4+years. Self-reported or measured weight: Measured. Statistical analysis: Multiple regression was used for BMI predictors.	Attrition: 45.5% Weight changes: There were no significant changes in prevalence of overweight and obesity over the four year period for either sex. Association of diet with weight change: Analyses showed skipping meals and snacking were associated with obesity, but were not predictive of BMI change. Association of physical activity with weight changes: Hours of sports participation was associated with lower increases in BMI ($p<0.05$). Association of other factors with weight changes: Sedentary behaviours at 11 years predicted BMI at 15 years ($p<0.001$), but did not influence change in BMI over four years. Demographic and SES did not predict change in BMI at 15 years, but amount of pocket money earned did ($p<0.05$).	Adjusted for: BMI at 11 years Author's conclusion: Sedentary behaviour and physical activity in early adolescence influenced body mass in late adolescence.
Burke 2005 Prospective cohort **Aim: To examine predictors of BMI at age 8 years**	741 boys and 689 girls followed from 16th week of gestation from the Western Australia Pregnancy Cohort Study. The original	Year of baseline survey: May 1989 to November 1991 Duration of follow-up: 8+ years. Outcome variable: BMI. Self-reported or	Attrition: 33% Weight changes: Table shows percentages of overweight (including obese) using the IOTF definitions. Age (years) — Boys — Girls 1 — 22.1 — 25.1 3 — 13.5 — 14.0 6 — 12.6 — 17.9	Adjusted for: sex and maternal education Authors conclusions: Important to recognise role of adverse health-related

<table>
<tr>
<td rowspan="2"></td>
<td>cohort of children was 2087.</td>
<td rowspan="2">measured weight: Measured.
Statistical analysis: Various, but all used some form of regression analysis.</td>
<td rowspan="2">
<table>
<tr><td>8</td><td>15.4</td><td>19.6</td></tr>
</table>
Of the 310 classified as obese or overweight at 1y, 33% were obese or overweight at 8y. 128 classified as obese or overweight at 3y, 53% were obese or overweight at 8y. 196 obese or overweight at 6y, 79% remained obese or overweight at 8y.
Being obese or overweight at 8 was associated with significant odds ratios at younger ages in the table below, all with p<0.001.
<table>
<tr><th>Age (years)</th><th>OR</th><th>95 CI</th></tr>
<tr><td>1</td><td>3.38</td><td>2.50, 4.55</td></tr>
<tr><td>3</td><td>8.45</td><td>5.96, 12.81</td></tr>
<tr><td>6</td><td>51.13</td><td>33.71, 77.52</td></tr>
</table>
Birth weight was positively associated with BMI at 8 (p<0.001).
Association of diet with weight change:
A subset of 340 children, parents completed a food frequency questionnaire and food categories derived via factor analysis. An inverse relationship was found for ‘cereals’ and ‘% energy from total fat’ (p = 0.046 and p = 0.025 respectively) and a positive relationship with the ‘takeaways’ factor (p = 0.025).
Association of physical activity with weight changes:
Playing organised sport at ages 6 and 8 were not significant. Subjective assessment of activity ‘being slightly active’ and ‘active’ at 8 were negatively associated with BMI at 8 years; OR 0.44; 95 CI 0.28, 0.70 (p<0.001) and OR 0.23; 95 CI 0.14, 0.38 (p<0.001) respectively.
Association of other factors with weight changes:
Obesity at 8 was associated with hours per day spent watching TV at age 6; OR 1.53; 95 CI 1.16, 2.02 (p<0.002).
BMI at 8 was predicted by maternal weight and maternal BMI and in a subset of 298 children with paternal data, each obese parent independently increased the risk of obesity at 8 by three times.
Mother being an ex-smoker or never smoked was negatively associated with BMI at 8 years; OR 0.57; 95 CI 0.38, 0.87 (p = 0.009) and OR 0.35; 95 CI
</td>
<td rowspan="2">behaviours particularly in overweight families. Control of excessive weight gain in children beneficial.
Comments: Duration of PA not reported.</td>
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			0.22, 0.53 (p<0.001) respectively.	
			Children from higher income and lower income groups had similar BMI at 3 years but at 6 and 8 years, BMI was higher in lower income families (p = 0.004). Parental income was categorised as lower = below $40,000, or higher = above $40,000. BMI at 6 years was lower in tertiary educated mothers (p = 0.001). Mother's Educational level was categorised as	
			1 not higher than secondary schooling; 2 technical qualification; 3 tertiary qualification.	
Thompson 2004 **Design:** convenience sample from prospective cohort, 2+ **Aim:** To assess the relationship between eating food purchased away from home (FAH) and longitudinal change in BMI *z*-scores among girls, and to assess the longitudinal tracking of eating FAH from childhood to adolescence.	Healthy girls (*n* = 101) between the ages of 8 and 12 years at baseline and 11 and 19 years at follow-up participated in a longitudinal study of growth and development at the Massachusetts Institute of Technology. At baseline the median age was 9 years. 96% of participants had a baseline BMI *z*-score <85th percentile for age and sex. 4% of participants had a BMI ≥85th percentile.	**Year of baseline examination and survey:** Participants originally enrolled in the longitudinal growth and development study in 1990. **Duration of follow-up:** Time varied for all participants, follow-up records were completed a median of 6 years after baseline records were completed **Outcome variables:** Change in BMI z-score, defined as the number of standard deviation units that a person's BMI is from the mean or reference value. *z*-scores were computed with reference to sex and age-specific mean BMI	**Attrition:** 100% – no dropout. **Dietary patterns:** At baseline, 71% of participants ate FAH. At follow-up, this percent increased to 86% and the median number of total FAH occasions had increased from two to three times per week. There was slight FAH tracking from childhood through adolescence. Modest tracking was observed for those who ate quick service food and restaurant food, while no tracking was observed for those who ate at coffee shops. Few participants ate at coffee shops at baseline, but this number increased by 25% at follow-up. **Weight change:** In analysis of variance adjusted for unbalanced cell size, the weekly frequency of consuming quick service food at baseline was positively associated with change in BMI *z*-score ($F = 3.37$, $p \le 0.05$), and this relationship was strengthened after adjusting for baseline BMI *z*-score ($F = 6.49$, $p \le 0.01$). The frequency of eating at coffee shops and in restaurants at baseline was not associated with changes in BMI *z*-score. Duncan's multiple range test showed that participants who ate quick service food twice per week or more at baseline had the greatest means increase in BMI *z*-score at follow-up, and this change was significantly different from that seen in girls who ate quick-service food once or twice a week or not at all. Girls who were eating quick service food twice a week or more were consuming more energy on average than girls who were eating quick-service food once per week or not at all (73 kJ [304 kcal] and 51 kJ [213	**Adjusted for:** Baseline BMI *z*-score. **Author's conclusions:** Consuming quick service food appeared to predispose this sample of girls to increase their relative BMI. **Comments:** It is possible that the tracking observed in this study was as a consequence of increasing age, availability of spending money and/ or self-determination of teens. Most participants were middle to

	The majority of participants (60%) came from families earning at least US$50,000 per year. Most mothers and fathers had at least college level education (72 and 81%, respectively).	values and distributions using the Centers for Disease Control (CDC) and Prevention Growth Chart data. **Self-reported or measured:** Both self-reported and measured. Height and weight measured by health care professionals. Participants kept 7-day dietary records at two points in time, including the place and time for all foods consumed. Foods were classified as quick-service food, coffee-shop food or restaurant food. **Statistical analysis:** Analysis of variance was used to assess the relationship between change in BMI *z*-score and both the frequency of eating FAH and energy derived from eating FAH. The participants' baseline BMI *z*-score was a significant covariate and was controlled for in both	kcal], respectively), but this relationship was not significant **Association of physical activity with weight change:** At baseline 40% of participants considered themselves to be as active as their peers and 51% considered themselves to be more active than their peers PA was not significantly associated with change in BMI *z*-score, therefore was not included in any of the model. **Association of other factors with weight change:** Parental BMI, income and education were not associated with change in BMI *z*-score and so were not included in the models.	upper class White girls who reported being more physically active than their peers, although PA was not a significant covariate, it is possible that PA data were misclassified.

		models. Kappa coefficient was used to assess FAH tracking from childhood through adolescence.		
Phillips 2004 Prospective cohort Aim: To examine the longitudinal relationship of energy-dense snack (EDS) food intake with relative weight status and percentage body fat.	196 non-obese pre-menarcheal girls 8 to 12 years old from the Massachusetts Institute of Technology Growth and Development Study. Ethnicities included 75% white, 14% black and 11% other races.	Year of baseline survey: 1990 and 1993 Outcome variable: BMI z-score, body fat (%BF). Duration of follow-up: 4 years after menarche Self-reported or measured weight: Measured. Statistical analysis: Linear mixed effects modelling	Attrition: 9% Weight changes: None reported without reference to behaviours. Association of diet with weight change: Categories of EDS foods considered were baked goods, ice cream, chips, sugar-sweetened carbonated drinks and sweets, with data collected at annual follow-up visits. No relationship between BMI z score or %BF and total EDS food consumption was observed. Carbonated drinks were the only EDS food that was significantly related to BMI z score over the 10-year study period (p-value for trend <0.001), but it was not related to %BF.	Adjusted for: PA, parental overweight, ethnicity, and dietary variables. Author's conclusion: In initially non-obese girls, overall EDS food consumption does not seem to influence weight status or fatness change over the adolescent period.
Datar 2004 Prospective cohort 2+ **Aim:** To examine the effect of physical education instruction time on BMI change	9751 Kindergartens in the USA. **Baseline BMI or weight:** Boys overweight: 11.6 % Girls overweight: 9.8%	**Year of baseline survey:** 1998 **Duration of follow-up**: 1 year **Outcome variable**: BMI **Self-reported or measured weight:** Measured	**Attrition:** 49% **Weight changes**: Boys, non-Whites (particularly Hispanic children) whose mothers had an educational level of a high school diploma or less, and children from low-income families were significantly more likely to be overweight in kindergarten as well as first grade. **Association of diet with weight change:** No analysis **Association of physical activity with weight change:**	**Adjusted for**: Not reported. **Author's conclusions**: Increasing time spent on physical education programmes in schools, in the form in which they exist, may

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<td>in elementary school (primary school) from kindergarten to the first grade.</td>
<td></td>
<td>**Statistical analysis**: Multivariate linear regression</td>
<td>One additional hour per week of physical education in the first grade compared with the time allowed for physical education in kindergarten reduces BMI among girls who were overweight or at risk for overweight in kindergarten ($p > 0.01$) but has no significant effect among overweight or at risk for overweight boys ($p = 0.02$) or among boys ($p = 0.31$) or girls ($p = 0.80$) with a normal BMI.</td>
<td>be an effective intervention for combating obesity in the early years, especially among girls.</td>
</tr>
<tr>
<td>Growing Up Today study

Berkey, 2000, 2003a, 2003b; Berkey 2005; Field 2003, 2004; Taveras 2005;

Prospective cohort
2+

Aim:
This study examined the role of PA, inactivity and dietary patterns on annual weight changes among preadolescents and adolescents taking growth and development into account.</td>
<td>6149 girls and 4620 boys, aged between 9 and 14 years, from various parts of the USA (50 states who are offspring of Nurses health Study II).

94.7% were White (not Hispanic), 0.9% were Black (not Hispanic), 1.5% were Hispanic, 1.5% were Asian and 1.4% other (including Native American).

Baseline BMI/weight:
At baseline, 23.2% of the boys and 17.4% of the girls were overweight (>85th percentile BMI), while 7.2% of</td>
<td>**Year of baseline survey:**
1996

Duration of follow-up:
Three 1-year periods.

Outcome variable:
BMI.

Self-reported or measured weight:
Self-reported.

Statistical analysis:
Linear regression.</td>
<td>**Attrition:**
Girls 32%, boys 42%.

Weight changes:
Girls who were 11 years old at baseline and boys who were 12 years old had the largest mean annual increase in BMI.

The table below shows the mean annual change in BMI (kg/m^2) by age at baseline:
<table>
<tr><th>Age (years)</th><th>Boys</th><th>Girls</th></tr>
<tr><td>**9**</td><td>0.48</td><td>0.65</td></tr>
<tr><td>**10**</td><td>0.57</td><td>0.61</td></tr>
<tr><td>**11**</td><td>0.7</td><td>0.6</td></tr>
<tr><td>**12**</td><td>0.61</td><td>0.8</td></tr>
<tr><td>**13**</td><td>0.6</td><td>0.78</td></tr>
<tr><td>**14**</td><td>0.47</td><td>0.64</td></tr>
</table>
Weight changes:
At 3-year follow-up, changes in BMI were slightly greater among boys than among girls (0.7–0.8 units per year among the boys vs. 0.6–0.7 units per year among the girls (8203 girls and 6715 boys aged between 9 and 14 years of age from Boston USA).

Association of diet with weight change:
Annual BMI increases were higher in girls with higher energy intakes (BMI increased by 0.061 kg/m^2 per 100 kcal (4.2 kJ)/day; $p > 0.02$).

For both boys and girls a larger rise in energy intake predicted larger BMI increase (girls 0.0059 per increase of 100 kcal [4.2 kJ]/day, boys 0.0082).</td>
<td>**Adjusted for:**
Race, baseline BMI, annual change in height, menstrual history in girls, Tanner stage and age.

Authors' conclusions:
For both boys and girls, a 1-year increase in BMI was larger in those who reported more time with TV/videos/games during the year between BMI measurements and in those who reported that their energy intakes increased more from one year to the next. Larger annual increases in</td>
</tr>
</table>

	the boys and 8.6% of the girls were very lean (<10th percentile BMI).		In boys and girls no significant associations were noted between consumption of energy adjusted dietary fat or fibre and increase in BMI ($p > 0.05$). Overweight children who never ate breakfast lost BMI over 1 year compared with overweight children who ate breakfast nearly every day (boys –0.66 kg/m^2, girls –0.50 kg/m^2). Normal weight children who never ate breakfast gained weight relative to peers who ate breakfast nearly every day (boys 0.21 kg/m^2, girls 0.08 kg/m^2). Over 3 years, normal weight girls who ate breakfast 1–2 days a week gained more weight (+0.072 kg/m^2) than peers who ate breakfast daily. However, overweight boys and girls who skipped breakfast put on less weight than people who had breakfast every day (boys: no breakfasts –0.425 kg/m^2; 3–4 days –0.139; girls who ate breakfasts 1–2 days a week –0.114 and breakfasts on ***3-4*** days per week –0.177. **Association of diet with weight change:** At 3-year follow-up (8203 girls and 6715 boys aged between 9 and 14 years of age from Boston, MA, USA): after controlling for Tanner stage of development, age, height change, activity and inactivity (predictors of BMI), girls showed no relation between intake of fruits, fruit juice or vegetables (alone or combined) and subsequent changes in BMI *z*-score. In boys, intake of fruit and fruit juice was not predictive of changes in BMI. Although vegetables intake was inversely related to changes in BMI *z*-score ($p > 0.05$). However, after adjusting for energy intake, the magnitude of the effect was diminished and no longer significant (Field 2003). At 3-year follow-up (8203 girls and 6715 boys aged between 9 and 14 years of age from Boston, MA, USA): after controlling for Tanner stage of development, age, height change, activity and inactivity, there was no relation between intake of snack foods and subsequent changes in BMI *z*-score among the boys ($\beta = –0.004$), but snack foods had a weak inverse association ($\beta = –0.007$, $p > 0.05$) with weight change among the girls. However, the results were confounded by dieting status, which had a significant positive independent association with BMI change. After controlling for dieting status and whether the mother was overweight, the association between servings per day of snack foods and subsequent changes in BMI *z*-score were not significant in either gender.	BMI were also seen among girls who reported higher energy intakes and less PA during the year between the two BMI measurements. BMI decreased overweight children who never ate breakfast but normal weight children do not. From Berkey 2005; Drinking large amounts of milk may provide excess energy to some children.

			From Berkey 2005; Children who reported higher total milk intake experienced larger weight gains; children who drank more 1% and skim milk had larger weight gains than those who drank smaller amounts of 1% and skim; dietary calcium intake was positively correlated with weight gain; and dietary fat was not. The effects of milk and dietary calcium appear to be explained by energy intake; however skim milk in girls remained marginally significant after adjustment for energy intake. From Taveras 2005; Frequency of family dinner and overweight was explored in the cohort. Subjects were classified as eating dinner with parents ‘never or some days’, ‘most days’ or ‘every day’. Whilst cross-sectional data showed children were less likely to be overweight if they ate dinner most days with their family, this relationship was not apparent over 2 years. **Association of physical activity with weight change:** Annual BMI increases were higher in girls with fewer hours of activity (BMI decreased by 0.284 kg/m^2/h per day of activity; $p > 0.05$) during the year between base line and follow-up. Boys who had marginally less PA (–0.0261 kg/m^2 per hour of activity; $p = 0.094$) showed larger annual BMI increases. The number of gym classes per week was not associated ($p > 0.10$) with change in BMI in boys. **Association of other factors with weight change:** Annual BMI increases were higher in girls with more hours of TV/video/games (BMI increased by 0.372 kg/m^2 per hour per day; $p > 0.001$) during the year between base line and follow up. Boys who spent more time with TV/videos/games (0.384 kg/m^2 per hour per day; $p > 0.0001$) showed larger annual BMI increases. Over 2 years, boys had higher means hours of TV/video/games, gym class participation that increased more from the first to the second year, and energy intake that increased more from the first to the second year predicted larger increases in BMI. Boys with higher METs (a way of measuring PA intensity) during the year between the two BMIs had marginally smaller ($p = 0.6$) increases in BMI. **Age:**	

			Among boys <12 years old, those who did more PA in the year between the BMI measurements had smaller annual increases in BMI (–0.0746 ± 0.0212).	
FRAMINGHAM CHILDREN'S COHORT Moore 2003 Proctor 2003 Moore 1995 Prospective cohort Aim: To examine the relationship between physical activity and TV viewing on body fat change during childhood	106 3-5-year olds from the Framingham Children's Study. These are from families who were third or fourth generation from the original Framingham Study Cohort.	Year of baseline survey: 1987 Outcome variable: BMI Duration of follow-up: 8+ years. Self-reported or measured weight: Measured. Statistical analysis: Various, but all used some form of regression analysis.	Attrition: 3% Weight changes: None reported without reference to behaviours. Association of diet with weight change: Children with the highest levels of TV viewing and high fat diets (>34% cals from fat) gained more body fat than children watching least TV and a lower-fat diet (<34% fat cals) gained less body fat by 11 years; mean sum of 5 skinfolds 99mm vs 69mm (data presented graphically). Association of physical activity with weight changes: Subjects were examined annually. Caltrac motion sensors were used to asses physical activity levels. Children were categorised as having low, medium or high activity levels based on average number of counts per hour for each period of recording. These were then averaged over the 8 years of the study. Children in the highest tertile for daily PA, had consistently smaller gains in BMI, triceps and sum of 5 triceps throughout childhood. By 11 years, sum of 5 skinfolds was 95.1mm, 94.5mm and 74.1mm for the low, medium and high tertiles respectively (p-value for trend = 0.045). This relationship was evident for both sexes. Children with the lowest levels of PA and highest levels of TV viewing gained nearly 40 mm of body fat than children with highest levels of PA and least TV by 11 years (data presented graphically). Association of other factors with weight changes: Questionnaires in conjunction with the Caltracs were used to estimate hours of TV viewing and video games per day. TV viewing was divided into tertiles of hours per day: <1.75h, 1.75 to <3.0h, >3.0h. At 11 years, those who watched 3.0h or more per day had a mean sum of 5 skinfolds of 106.2mm compared with 87.6mm for those watching 1.75 to <3.0h, and 76.5mm for those watching least (p = 0.007; p-value for trend = 0.028).	Adjusted for: sex, exact age and baseline BMI, total energy intake, % fat calories, mean PA level, parents age and education. Author's conclusion: Children who were in the highest level of activity showed less acquisition of body fat, whilst those watching most TV showed the greatest gains in body fat.
Bogaert 2003 Prospective cohort 2+	59 Australian children, aged between 6 and 9 years (mean age	**Year of baseline survey:** Not reported. **Duration of follow-up**:	**Attrition:** 31% **Weight changes:** No significant differences were found for initial, height, BMI percentile and	**Adjusted for:** Not reported. **Author's conclusions:**

Aim: To identify whether measures of energy intake and expenditure predict excessive weight gain over time in children.	8.6 ± 0.2 years) **Baseline BMI or weight:** Not reported.	12 months. **Outcome variable**: Weight (kg), BMI **Self-reported or measured weight:** Measured. **Statistical analysis**: Unpaired t test, Pearson's product moment correlation and Spearman's rank order correlation.	BMI z-scores over the 12 months. The boys BMI z-score was 0.3 ± 0.1 and the girls score was 0.5 ± 0.3. Percentage body fat was 18.4 ± 1.2 for boys and 25.8 ± 1.1 for girls, and percentage lean body mass was 81.6 ± 1.2 for boys and 74.2 ± 1.1 for girls. Girls had a significantly lower mean lean body mass ($p > 0.0001$) and a significantly greater mean fat mass than boys ($p > 0.0001$) after 12 months. **Association of diet with weight change:** No significant correlations were shown between BMI over 12 months for any dietary variable (% energy as protein, carbohydrate, fat, saturated fatty acids, monosaturated fatty acids and polyunsaturated fatty acids). **Association of physical activity with weight change:** No significant correlations were shown between change in BMI over 12 months and any measures of energy expenditure, including hours of television viewing or percent time spent in low, moderate or high intensity activity. A significant correlation was found both between mothers and daughters in percent time spent in moderate to high activity ($r = 0.44$, $p = 0.03$), and also between fathers and children for percent time spent in low activity ($r = 0.43$, $p = 0.005$), which suggests that parental activity levels can significantly affect their child's activity levels.	The study was unable to identify environmental predictors that indicate propensity to weight gain over time in this cohort of children, but has extended the evidence on lifestyle-influenced predictors that do. An overall lack of vigorous activity and correlations between parental and child activity and inactivity have been identified.
Kaur 2003 Prospective cohort 2+ **Aim:** To assess the effect of TV viewing on subsequent change in BMI percentiles in adolescence.	12–17 year olds, $n = 2223$, 52% male, 68% White, California, contacted by random-digit dialled computer-assisted telephone interviewing method as part of California Tobacco	**Year of baseline survey:** 1993 **Duration of follow-up**: 3 years **Outcome variable**: Change in age-specific and sex-specific BMI percentiles. **Self-reported or measured weight:** Self-report.	**Attrition:** 65.8% of sample had data for both time points. **Weight changes:** BMI at follow-up (mean [SD]): 22.57 (3.57); BMI% at follow-up (mean [SD]): 53.83 (26.92). **Association of diet with weight change:** **Association of physical activity with weight change:** Hours of TV viewed at baseline (mean/SD): 2.85 (1.98); model of TV at baseline and BMI% at follow-up explained 50% variation in follow-up BMI%; squared partial correlation coefficients were 0.495 for baseline BMI%, 0.008 for baseline TV, 0.003 for ethnicity; therefore nearly 50% variation in follow-	Adjusted for ethnicity and baseline BMI%. **Author's conclusions:** TV viewing leads to increase in BMI percentiles and overweight.

California Teen Longitudinal Survey of adolescents 12–17 years	Surveys. **Baseline BMI (kg/m^2), mean (SD):** 21.00 (3.52) BMI% 55.92 (26.78)	**Statistical analysis**: Multiple regression modelling and logistic regression.	up BMI% explained by baseline BMI%, 1% by TV, 0.3% by ethnicity. Watching >2 hours TV was related to higher odds of being overweight at follow-up among adolescents at normal weight at baseline (OR 1.9; 95% CI 1.1, 3.5) and among adolescents overweight at baseline (OR 2.8; 95% CI 1.3, 6.3). 48% new-onset overweight among adolescents not overweight at baseline was attributable to watching >2 hours TV per day. For each additional hour TV at baseline the average follow-up BMI% increased by 0.5, controlling for ethnicity and baseline BMI%.	
Ambrosius 2001 Prospective cohort 2+ **Aim:** To determine the rate of change in adiposity over time, making comparisons between racial and gender groups.	Healthy children aged 5–20 years (mean 9.5–10.5 years at baseline) recruited from schools in Indianapolis, USA. Schools were chosen to represent a range of SES. Total *n* = 773; 229 White and 157 Black boys, 213 White and 174 Black girls. Over the course of the study, 250 children (102 Black and 148 White) moved from the area, 114 (54 Black and 60 White) dropped out of the study, and 129 (36	**Year of baseline survey:** Study began 1985 and measurements ended in 1999. **Duration of follow-up**: 6 monthly visits; range 2 (6 months) to 26 visits (12.5 years). **Outcome variable**: Change in BMI and subscapular and triceps skinfold thicknesses. **Self-reported or measured weight:** Measured. **Statistical analysis**: Analysis of covariance was used to test for race and sex differences among the subjects at baseline, after adjusting for age.	**Attrition:** Approximately 39%. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** **BMI etc changes (units per year):** White (W), Black (B) **BMI (kg/m^2):** W boys (*n* = 229) 0.78; B boys (*n* = 157) 0.97 W girls (*n* = 213) 0.76; B girls (*n* = 174) 0.96 **Subscapular skinfold thickness (mm):** W boys 0.64; B boys 0.74 W girls 0.90; B girls 1.00 **Triceps skinfold thickness (mm):** W boys 0.12; B boys 0.13 W girls 0.70; B girls 0.71 **Waist-to-hip ratio:** W boys –0.0047; B boys 0.0006 W girls –0.0045; B girls 0.0008	Age. **Author's conclusions:** Body fat increases at a faster rate in Black children than in White children. It appears that racial and gender differences in prevalence of obesity originates in childhood.

	Black and 93 white) were lost to follow-up. **Exclusion criteria:** History of renal or cardiac disease, hypertension, diabetes mellitus. **Baseline BMI etc., mean (SD):** White (W) Black (B) **BMI (kg/m^2):** W boys 18.3 (4.7), B boys 20.0 (5.3) W girls 17.8 (3.6), B girls 20.3 (5.8) **Subscapular skinfold thickness (mm):** W boys 8.6 (7.7), B boys 11.0 (8.5) W girls 9.2 (6.2), B girls 13.2 (9.0) **Triceps skinfold thickness (mm):**	A random coefficient model was used for the main analysis.		
			Summary: The rate at which BMI increased in Black children was significantly greater than in the White children ($p > 0.0001$) There were no gender differences in the rate of increase of BMI. Results also presented for other measures of fatness. Supplementary analysis was carried out to examine the rates of change with age and educational attainment.	

	W boys 12.7 (6.8), B boys 13.8 (8.5) W girls 13.9 (5.7), B girls 15.6 (8.1) **Waist-to-hip ratio:** W boys 0.84 (0.07), B boys 0.81 (0.06) W girls 0.76 (0.06), B girls 0.77 (0.07**)**			
O'Loughlin 2000 Prospective cohort 2+ **Aim:** To identify 1- and 2-year predictors of excess weight gain amongst preadolescents.	2318 children at 1 year follow-up aged 9–12 years and 633 children aged 9–11 years with 2 years follow-up in 16 elementary schools located in multiethnic low-income neighbourhoods in Montreal, Canada; high ethnic diversity with 80% parents born outside Canada and 80% fathers unemployed **Baseline BMI:** 18.0–	**Year of baseline survey:** 1993–97 **Duration of follow-up**: 2 years **Outcome variable**: Change in BMI. **Self-reported or measured weight:** Measured. **Statistical analysis**: Multiple logistic regression analyses (dependent variable was whether or not the subject was in the highest age and gender specific decile of change in BMI.	**Attrition:** 57.7% available data at 1 year and 60.2% at 2 years **Weight changes:** Students in top decile of change in BMI increased 2–2.5 BMI units over 1 year compared with 1 BMI unit or less among those at the 50th percentile, over 2 years students in the top decile increased 3–4 units compared with 1–2 BMI units among those at the 50th percentile. **Association of diet with weight change:** **Association of physical activity with weight change:** One year predictors of higher decile of change in BMI included no sports outside school (OR 1.90; 95% CI 1.18, 3.06) in girls. Two-year predictors included no sports outside school (OR 2.14; 95% CI 0.96, 4.77) and least active (OR 2.18; 95% CI 1.01, 4.71) in boys. One year predictors of higher decile of change in BMI included BMI of 90th percentile or more (OR 2.66; 95% CI 1.80, 1.34) in boys and BMI of 90th percentile or more (OR 2.34; 95% CI 1.46, 3.76), and playing video games everyday (OR 2.48; 95% CI 1.04, 5.92) in girls. Two-year predictors included baseline BMI of 90th percentile or more (OR 3.26; 95% CI 1.52, 7.01), and only BMI of 90th percentile or more (OR 2.22; 95% CI 1.02, 4.81) in girls.	Cohort is comparison schools (control schools) in a heart health programme; children lost to follow-up lived in less advantaged families of non-Canadian origin. **Adjusted for:** Age at baseline, grade, year of cohort, school, dependence between observations of same subject (*n* = 549) in 1-year follow-up; **Author's conclusions:**

	20.0 kg/m^2.		**Summary of results:** Baseline BMI was only consistent independent predictor of excess weight gain in all four multivariate models; there were no strong or consistent pattern of associations in either boys or girls for family origin, diet indicators, school sports team or TV viewing	Results suggest need for interventions to promote PA in children.
Spiegelaere 1998 Cohort 2+ **Aim:** To determine whether social inequalities in obese adolescents can be partly explained by differences in the evolution of body mass during the critical period of adiposity rebound.	675 children born 1986–90 attending preventive medical services in Brussels, only Belgium children (immigrant children excluded). **Baseline BMI:** Prevalence of overweight (BMI >95th centile distribution for age and sex) 4.6%.	**Year of baseline survey:** Not reported. **Duration of follow-up**: 3 years (analysed retrospectively). **Outcome variable**: BMI change. **Self-reported or measured weight:** Measured . **Statistical analysis:** χ^2 and Kruskal–Wallis test.	**Attrition:** n/a, convenience sample **Weight changes:** Adiposity rebound (BMI at age 5 years greater than BMI at age 3 years) occurred in 30.4% of the children and did not differ between social groups; 205 of 675 had early adiposity rebound and mean BMI increased by 0.76 (0.82) kg/m^2. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change: Adiposity Rebound** After controlling for BMI at baseline, relationship between social status and presence of an early rebound remained non-significant; In lower socio-economic groups a greater proportion of children had an important increase in BMI between ages 3–5 years (>1.6 kg/m^2, above the 9th decile <0.05) 18.3% lower socio-economic group (active manual workers and not working), 7.1% intermediate social group (active self-employed and technicians) and 7.8% high socio-economic group (upper management and professionals).	**Adjusted for:** Early rebound adjusted for BMI at baseline. **Author's conclusions:** Adiposity rebound before age 5 years was inversely related to body mass at age 3 years and was independent of social status.
French 1996 Prospective cohort 2+ **Aim:** To estimate the change in BMI over 3 years in a cohort of adolescents, dependent on	All students aged 12 to 15 years (UK school years 8 to 10) at baseline in schools in a suburb of Minnesota. Total *n* = 1278 at 3 years; 656	**Year of baseline survey:** Unclear. **Duration of follow-up**: 3 years. **Outcome variable**: BMI. **Self-reported or measured weight:**	**Attrition:** Approximately 16%. **Weight changes:** Not reported separately. *Note:* all associations stated below were significant but modest in magnitude. **Association of diet with weight change:** No analysis.	**Adjusted for**: Fathers occupation, year at school, pubertal status and BMI at baseline. **Author's conclusions:** Self-esteem specific to

baseline self-esteem. Data for this study were collected as part of a longitudinal study on the development of eating disorders.	females and 622 males which represented approximately 84% of children invited to take part in the study. 89% White, 4% other or mixed, 3% Asian American. Approximately 48% fathers and 33% mothers held executive, administrative or professional occupations. **Baseline BMI (kg/m^2), mean (SD):** Males 20.1 (3.7); females 20.5 (3.6) 20.6 % of males and 17.6 % of females were overweight.	Measured. **Self esteem:** The Harter Self-Perception Profile for Adolescents. Pubertal status was assessed. **Statistical analysis**: Prospective relationships between self-esteem at baseline and BMI 3 years later were examined using partial correlations. In addition, a series of logistic regressions were run using overweight status as the independent variable and self-esteem subscales as independent variables.	**Association of physical activity with weight change:** No analysis. **Association of other factors with weight change: self-esteem** Partial correlations between baseline **self-esteem** and BMI 3 years (Table 3 in paper). In females, low physical appearance and low social acceptance self-esteem at baseline were associated with higher BMI 3 years later. In males, baseline self-esteem was unrelated to BMI 3 years later. Analyses examining relationships between baseline self-esteem and overweight status 3 years later showed high close friendship self-esteem in females and high physical appearance self-esteem in males were associated with decreased odds of overweight at 3 year follow-up.	physical appearance is modestly associated with BMI.
Klesges 1995 Prospective cohort 2+ **Aim:** To determine the dietary, PA,	Parents of 146 (110 boys and 93 girls) aged 3–5 years (mean 4.4 years boys, 4.3 years girls) recruited to participate in longitudinal	**Year of baseline survey:** Not reported. **Duration of follow-up**: 3 years (analysed change over 2 years). **Outcome variable**:	**Attrition:** 35 of 203 families at one year and 55 of 203 families at 2 years. **Weight changes:** Adjusted BMI changes over 2 years: Both parents normal weight: boys –0.305, girls –0.230 Father overweight: boys –0.436, girls 0.400 Mother overweight: boys –0.262, girls –0.532 Both parents overweight: boys 0.670, girls –0.230	Participants not told study was to assess predictors of body fat. **Adjusted for:** BMI adjusted for family risk

family history and demographic predictors of relative weight change in a cohort of children.	evaluation of cardiovascular risk development in young children in Memphis, TN, USA. Children had to be natural biological offspring of parents, no physical condition that could effect relative weight, dietary intake or PA. Parents who were married and had no cardiovascular disease and were staying in the area for the following year. Only one child per family. Obese children were over-sampled **Baseline BMI (kg/m^2), mean (SD):** 16.1 (1.4) boys, 16.1 (1.2) girls; 40% overweight (relative weight greater than 75th percentile);	BMI change. **Self-reported or measured weight:** Measured. **Statistical analysis**: Multiple regression analysis (hierarchical and stepwise-selected variables); final regression model resulted in significant equation *F*(13, 119) = 2.71, *p* > 0.0022). BMI, sex, age, family risk and sex by family risk interactions = 9.8% variance. Baseline percentage energy as fat, baseline aerobic activity, change (year 2–3) in percentage energy as fat, change (year 2–3) in leisure activity = 13.1% variance.	BMI increased in girls with fathers overweight and boys with both parents overweight. **Association of diet with weight change:** Higher baseline percentages of energy as fat were associated with greater increases in BMI (0.168 kg/m^2 per 5%) and recent increases (year 2–3) in percentage of intake as fat (0.201 kg/m^2 per 5% change). Neither baseline total energy nor change in total energy increased variance in change in body mass. **Association of physical activity with weight change:** Higher baseline aerobic activity and increased leisure activity from year 2 to 3 were associated with BMI decreases. **Association of other factors with weight change: parental overweight** Boys with both parents overweight had increases in children's BMI (0.67 kg/m^2) and for girls those with just a father overweight showed BMI gains over 2 years (0.40 kg/m^2).	(number parent overweight) baseline BMI, child sex and age and interaction between child sex and family risk. **Author's conclusions:** Modifiable (dietary intake and PA) and non-modifiable factors (age, family history for overweight) were associated with change in BMI in preschool children with largely modifiable factors appearing to be slightly more important.

	45% families had both parents normal weight, 27% father overweight, 17% mother overweight, 11% both parents overweight.			
Robinson 1993 Prospective cohort 2+ **Aim:** To longitudinally examine the relationships between hours of TV viewing and adiposity in female adolescents.	279 adolescent girls, participating in the no-intervention arm of a study about eating disorders. From four schools in California. Mean age 12.37 (SD 0.73) years. 42.7% White, 23.3% Hispanic/Latino. **Baseline BMI (kg/m^2), mean (SD):** 20.33 (3.89)	**Year of baseline survey:** 1989 **Duration of follow-up**: 2 years. **Self-reported or measured weight:** Measured. **Statistical analysis**: All available follow-up data were used to fit subject-specific least-squares regression lines for changes in Sexual Maturity Index (SMI)-adjusted BMI, and SMI-adjusted triceps skinfold thickness (where height and weight were measured, not self-reported). The outcome variable was the slope of these fitted lines. Univariate relations were tested using Spearman	**Attrition:** Unclear. The sample used in the longitudinal analysis was drawn from a total of 536 students who were initially randomised to the no-intervention control group as part of the overall study – suggests attrition of 48%. **Weight changes:** Not reported. **Association of diet with weight change:** No analysis. **Association of physical activity with weight changes:** No analysis. **Association of other factors with weight changes:** Hours of after-school TV viewing did not longitudinally predict change in SMI-adjusted BMI (univariate Spearman $r = 0.03$, $p = 0.62$; multivariate regression co-efficient estimate = 0.05, $p = 0.82$). Hours of after-school TV viewing did not longitudinally predict change in SMI-adjusted triceps skinfold thickness (univariate Spearman $r = 0.03$, $p = 0.54$; multivariate regression co-efficient estimate = –0.19, $p = 0.67$). Reported hours of after-school TV viewing did correlate negatively with PA levels cross-sectionally (Spearman $r = –0.086$, $p = 0.026$) but explained only <1% of the variance. (Regression coefficient estimate = –1.281, $p = 0.043$.)	**Adjusted for:** In multivariate analyses, adjusted for age, race, parent education and parent fatness. TV viewing was measured by asking subjects how much time they spent in 13 different activities after school. While the validity of this method may be questioned, it had good test-retest reliability – over 24 months, r (Spearman) = 0. 37, $p > 0.0001$. **Author's conclusions:**

		correlation. Multivariate relations tested using multivariate logistic regression.		TV viewing was not associated with changes in adiposity, factors such as the content of and responses to viewing, and the family/peer environment may be more important than total viewing hours.
McConahy 2004 Cross-sectional cohort Aim: To evaluate the relationship of dietary behaviours and total energy intake.	5447 children aged 2-5 years who participated in the Continuing Survey of Food Intakes by Individuals.	Year of baseline survey: 1994-1996 Outcome variable: Body weight Duration of follow-up: 2+ years. Self-reported or measured weight: Parental self-report. Statistical analysis: Multiple linear regression.	Attrition: 0% Weight changes: None reported without reference to behaviours. Association of diet with weight change: Portion sizes (mean gramme quantities consumed at an eating occasion) were determined for the top 10 most commonly consumed foods. Z-scores were calculated for quantities consumed by children so data could be entered into the regression analyses. Diet was assessed using two non-consecutive 24h recalls. Body weight, food portion size, number of eating occasions and number of foods accounted for 38% of the variance in 2-3-year-olds and 39% in 4-5-year-olds. Portion size as a single predictor explained 17% of the variance in 2-3-year-olds and 19% in 4-5-year-olds.	Adjusted for: Body weight. Author's conclusion: Feeding recommendations should highlight age appropriate portion sizes and give guidance on frequency of eating and number of foods consumed.

1

EVIDENCE TABLE 2: MAINTAINING ENERGY BALANCE IN ADULTS

2.1 Summary: evidence from reviews

2.1.1 Dietary factors

With regard to the evidence from reviews, Williamson (1996) found that of the eight studies, two of found that total energy intake was positively associated with weight gain (Rissanen et al. 1991; Klesges et al. 1992). In both of these studies a positive association was found only in women. In Klesges et al. (1992) study a higher energy intake by women was directly related to increased weight gain while in men a higher energy intake was associated with decreased weight gain. In Rissanen et al. (1991) total energy intake had a direct association with subsequent weight gain in women only. The significant associations between weight gain and dietary fat intake were also inconsistent. Kant et al. (1995) found that the percentage of total energy intake from fat was positively related to weight gain in men and the association between percentage of energy intake from fat and weight gain was significantly inverse for women. Total fat intake was positively associated with weight gain in women but not men in one study and vice versa in another study.

2.1.2 Physical activity

With regard to the evidence from reviews, Williamson (1996) found three prospective studies that reported results for prospective analyses. Klesges et al. (1992) and Owens et al. (1992) found that women with higher levels of PA gained less weight. Klesges et al. (1992) found that PA was positively associated with weight gain in men whereas another study found no association between weight gain and PA.

Saris (2003) concluded that from13 cohorts reporting PA level (PAL) and weight change, 11 showed an inverse relation between PAL and increase in BMI, body fat, and weight or percent overweight/obese.

2.1.3 Other behavioural, psychological, social and environmental factors

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2.2 Summary: evidence from individual studies

2.2.1 Menopause (all women premenopausal at baseline)
Five cohorts examined weight change in relation to the menopause in women from the USA, UK, Chile and Japan. MacDonald (2003) analysed 1064 White women in the UK who were premenopausal at baseline and followed for 6 years and found that mean weight increased and was influenced more by reduced energy expenditure than increased energy intake.

Nagata (2002) analysed a cohort of Japanese women for 6 years and found that nutrient intakes were not significantly associated with difference in weight change between premenopausal and postmenopausal women. Exercise (METs [hours per week]) was not significantly associated with difference in weight change between premenopausal and postmenopausal women. Higher number of births was significantly associated with weight gain in premenopausal women, and early age at menarche was significantly associated with weight gain in postmenopausal women; hormone replacement therapy (HRT) use, smoking status, alcohol consumption were not significantly associated with difference in weight change between premenopausal and postmenopausal women.

Blumel (2001) analysed 271 Chilean women for 5 years and found that weight gain was similar in those who did or did not use HRT (non users 4.3 ± 4.8; users 3.5 ± 3.7 kg; ex-users, 3.4 ± 5.8 kg).

The Healthy Women's Study followed 500 US women for 3–4 years and found there were no significant differences in weight gain of women who remained pre menopausal and those who had a natural menopause (2.07 vs. 1.35 kg). Women who took HRT and women who stopped smoking during the menopause had significantly greater weight gain.

The Massachusetts Women's Health study followed 400 women for 3 years and found that menopause transition was not consistently associated with increased weight, reduced exercise and increased alcohol consumption were more strongly related to weight gain than menopause transition.

2.2.2 Pregnancy
Seven cohorts examined weight change and pregnancy. Williamson (1994) followed-up 2547 white women aged 25-45 years over 12 years, from the first National Health and Nutrition Examination Survey. The SPAWN study examined long-term weight development after pregnancy of 1423 women from Stockholm Sweden and had a 15-year follow-up. Olsen's (2003) study consisted of 622 healthy adult women who gave birth to live singleton infants from New York State, USA. Rosenberg (2003) followed a cohort of 1200 African American women for 4 years and the CARDIA study followed more than 5000 African American and White women for 4 years. More than 10,000 women were followed for 10 years as part of the NHANES I and NHEFS (Wolfe 1997) to examine the effect of parity on weight and a small study of women who breast-fed examined the effect of having more than one child on subsequent weight over an 18-month period (Sowers 1998).

Results of the studies show that those who gained more weight or ate more during pregnancy were more likely to retain weight gain after pregnancy.

Williamson (1994) examined 2547 white women aged 25-45 years from the first National Health and Nutrition Examination Survey. The risk of becoming overweight was increased by 60-110% in women having live births over the 12-year study period. Over 12 years average weight gain whilst having children was modest in US white women, but for some women the risks of major weight gain and becoming overweight are increased in association with childbearing.

The SPAWN study followed for 15 years 1400 women who had given birth and found women that started to eat more irregularly retained more weight at 1-year postpartum and women that started to exercise less frequently after their pregnancies retained more weight 1-year postpartum. Most important risk factor identified for sustained weight gain/retention 1 year after delivery was weight increase during pregnancy. No difference between women who became overweight and those who remained normal weight regarding total number of children, number of pregnancies before and after index pregnancy, age at index pregnancy, age at delivery of first child. Women who became overweight had lower lactation scores ($p > 0.05$) ; relatively more subjects of the group that became overweight stopped smoking during pregnancy ($p > 0.01$).

Olson (2003) followed 600 mainly White women in New York for 2 years and concluded that women who reported eating much more food in pregnancy were 2.35 times more likely than women who ate a little more to gain excessive weight (women were asked how the amount of food they ate had changed compared with when they were not pregnant, response categories were 'a lot less food', 'a little less food', 'a little more food' and 'a lot more food'). Less PA (OR 1.68; 95% CI 1.1, 2.6) was significantly related to excessive gestational weight gain. Family income of less than 185% of the federal poverty line (OR 2.59; 95% CI 1.6, 4.2) was significantly related to excessive gestational weight gain. Income was not as important an influence on gestational weight gain among women who reported that they increased their food intake (OR 0.33).

Rosenberg 2003 followed 1200 African American women for 4 years and found that women who had a child during follow-up gained more weight than women who remained nulliparous, and those who had a first child gained more than those who had a second or later child. Weight gain associated with childbearing increased with increasing baseline BMI and was appreciable among heavier women.

The ongoing CARDIA study in 5000 African American and White women found primiparous within both race groups gained 2 or 3 kg more weight during the 5-year period than did nulliparous women. Multipara did not differ from nulliparous in adiposity change in either race group. At each level of parity, Black women demonstrated greater adverse changes in adiposity than did White women.

Analysis of parity amongst women in the NHANES I and NHEFS (Wolfe 2004) showed weight gain from baseline to 10 year follow-up averaged 4.4 kg for White women and 5.5 kg for African American women.

Among White women, after adjusting for baseline parity and other socio-demographic variables, the weight gain for non-employed married metropolitan women averaged 4.2 kg for those with no change in parity, compared with 4.7 kg for those with a parity increase of one child and 7.4 kg for those with a parity increase of two or more children. Among African American women, adjusted for the same variables, weight gain for those with no change in parity averaged 4.9 kg, compared with 7.2 kg for those with a parity increase of one or more.

The probability of substantial weight gain (more than 11.4 kg) also rose with parity increase. White women with a parity increase of two or more were also twice as likely to experience substantial weight gain as those with no change in parity. However, the probability increased only slightly for those with a parity increase of just one. Among African American women, those with an increase in parity were about five times as likely to experience substantial weight gain as those with no parity increase.

Sowers (2004) evaluated 45 women who breast-fed and at 18-month follow-up the average weight losses in the postpartum period were 4.7 kg for cases and 4.4 kg for controls, which was not significantly different.

There was no statistically significant difference between the weight retention patterns of all the women. The average weight retention curve for the cases and controls (further parity vs. one parity) had similar shapes, initially they declined and then began to plateau at about 8–10 months postpartum.

Among the cases, post pregnancy weight following the baseline pregnancy was compared with post pregnancy weight following the subsequent pregnancy. On average, cases weighed 1.3 kg more after the subsequent pregnancy than they weighed following the baseline pregnancy.

2.2.3 Marriage

Two cohorts (Kahn 1990; Rauschenbach 1995) assessed weight change and change in marital status. Rauschenbach (1995) found that women who entered marriage had greater weight change than women who remained married, for men there were no statistically significant relationships between marital change and weight change. In the model to predict weight change none of the interactions were significant; in the model to predict weight gain none of the interactions were significant for women but for men the interaction of education with becoming unmarried was significant ($p = 0.024$) and associated with greater weight gain in more educated that become unmarried.

Kahn et al. (1990) evaluated the effect of marriage on weight in data from the NHANES I and NHEFS. The mean 10-year change in BMI was similar for the men who were not consistently married and for the men who were married at both baseline and follow-up (0.90 vs. 0.80, respectively).

The non-consistently married men had a significantly wider distribution of this weight-change variable. Men who became married during the 10-year interval showed a trend towards a greater gain in BMI when compared with men who were consistently married. Those men whose marriage ended appeared to experience a relative loss in BMI.

The incidence of major weight gain was generally greater for the men who were not consistently married. The incidence of major weight loss was also generally greater for the men who were not consistently married. The mid-range weight outcome was generally more common among men who were consistently married.

2.2.4 Smoking

Six cohorts assessed smoking cessation and association with weight change.

Williamson (1991) examined data from the NHANES I study and found those who quit smoking for more than 1 year experienced a greater mean weight gain and were more likely to experience major weight gain than continuing smokers. Significant weight gain occurs in a minority of those who quit. By the end of the study (10 years), however, the mean body weight of those who had quit increased only to that of those who had never smoked.

Burke (2000) followed 1930 Mexican American (MA) and non-Hispanic Whites (NHW) for 9 years and found the estimated risk of becoming overweight or obese attributable to smoking cessation was only 7.4% in MA and 3.1% in NHW. The Israeli CORDIS study followed 3816 male factory workers and showed that smoking cessation is associated with weight gain which is still apparent 6-years post-cessation. Burnette (1998) analysed smoking cessation within the Healthy Women's study of 500 US women and found that smoking cessation in perimenopausal to postmenopausal women is associated with greater weight gain for up to 2 years.

Kawachi (1996) analysed women who gave up smoking in the Nurses Health Study of 121,700 women for 2 years and found that weight gain was minimised if smoking cessation was accompanied with moderate increase in levels of PA.

Swan (1995) analysed men over 16 years from the US Twin Registry and found quitters were more likely to experience weight gain of 2.3 kg or more, and less likely to experience weight loss, than continuing smokers and non-smokers. Amongst quitters, super-gainers were younger, of lower SES, and differed on a number of health habits before quitting.

2.2.5 Occupation- and work-based cohorts

Eleven cohorts assessed associations with weight change amongst adults in various occupations and work settings.

Dietary factors:

Bazanno (2005) followed 17,881 US male physicians aged 40 to 82, free from disease for 13 years. Based on self-reported data, they found those men consuming ≥1 serving per day weighed less than those never or rarely consuming cereals. The trends at 8 and at 13 years were both significant (p-value for trend = 0.001). Men who ate ≥1 serving per day were 22% and 12% less likely to become overweight at 8 and 13 years respectively, compared with men who never/rarely ate cereals; relative risk 0.78; (95 CI 0.67, 0.91) and 0.88; (95 CI 0.76,1.00) respectively.

During the 12-year follow-up in the Nurses Health study (He 2004), participants tended to gain weight with age, but those with the largest increase in fruit and vegetables had a 24% lower risk of becoming obese compared with those who had the largest decrease in intake. Similar results were observed for changes of fruit and vegetables and separately.

Schulze (2004) followed 51,603 young nurses in the USA and reported a higher intake of sugar-sweetened beverages was associated with a greater magnitude of weight gain, attributed to excessive energy from the drinks and large amounts of rapidly absorbable sugars found in the drinks.

The Health Professionals Follow-up Study (Koh Banerjee 2003) followed 16,587 health professionals in the USA for 9 years and concluded that waist gain may be modulated by changes in *trans* fat and fibre consumption, smoking cessation and PA.

Gerace (1996) reported that fire fighters who ate faster at the station than else where gained 9.9 lb (4.49 kg) by follow-up (1991) compared with those who said their pace did not differ by location, who increased 6.8 lb (3.12 kg) by 1991, while those who did not nibble increased by 6.9 lb ($p > 0.05$).

Men who reported consuming a good diet in the Whitehall II study (four of total of four healthy aspects of diet) had OR 0.73 (95% CI 0.64, 0.84) and for women OR 0.83 (95% CI 0.68, 1.02) (Martikainen 1999).

Physical activity: Gerace (1996) reported that fire fighters self-reported PA levels at baseline were not associated with change in weight ($p > 0.05$). Likewise, the amount of energy in PA reported at baseline was not associated with weight change ($p > 0.05$). Subjects who reported engaging in at least one recreational PA three or more times per week gained 7.2 lb (3.26 kg) compared with less active fire fighters who gained 9.5 lb (4.30 kg) ($p > 0.05$).

Men in the Whitehall II study (Martikainen 1999) who reported moderate and vigorous PA were less likely to experience an increase in BMI (age-adjusted OR of having a gain in BMI >3 kg/m^2 compared with having a BMI gain of 0–3 kg/m^2).

UK men who became non-employed were significantly more likely to be inactive compared with men who remained employed (39.4 vs. 36.7%; 95% CI of the difference 0.1, 5.7) (Morris 1992).

In the Nurses Health Study II, vigorous PA was protective against weight gain. Women who engaged in ≥5 hours per week of vigorous activity gained approximately 0.5 kg less than their inactive peers between 1989 and 1995. Total hours of activity per week (including walking) was not associated with weight change. Physical inactivity was associated with weight change. For each 10 hours per week a women spent sitting at home or at work, she gained approximately 0.11 kg more than her less inactive peers.

Other behavioural, psychological, social, environmental factors: In a 3-year study of 119 Japanese factory workers, Yamada (2001) found that statistically, no significant changes were found for either the entire 8-hour shift group or the age subgroups during 1996–99. Authors concluded 12-hour shift might be associated with unhealthy weight gain in some clean room workers.

In the Whitehall II study of 5000 UK civil servants over 5–6 years (Martikainen 1999) it was found that employment grade was strongly related to BMI gain from age 25 years to phase 3 (about 25 years), the lower the grade the larger the gain in BMI, and adjustment for health behaviours (smoking, alcohol, etc.) reduced the grade differences in BMI gain by about 20%.

Nakamura (1998) studied non-management White collar Japanese men and found that working overtime was associated with increases in BMI and waist-circumference over 3 years (only explains 5% variance) although the associations were weak; eating habits of those working overtime may reflect an intervening effect on anthropometric changes.

Gerace (1996) reported that fire fighters aged 20–29 years gained the most weight over 7 years (11.3 lb [5.12 kg]). Subjects who were married or living as married gained 7 lb (3.17 kg) compared with those who were never married, divorced, separated, or widowed who gained 11.7 lb (5.30 kg) ($p > 0.001$). Black non-Hispanics gained 15.7 lb (7.12 kg) compared with White Hispanics who gained 8.9 lb (4.03 kg) and White non-Hispanics who gained 6.7 lb (3.03 kg) ($p > 0.001$). Fire fighters who smoked at baseline and reported being ex-smokers in 1991 gained 13.0 lb (5.89 kg) compared with all other fire fighters who gained 7.7 lb (3.49 kg) ($p > 0.004$). Ex-smokers who had smoked >20 cigarettes per day gained 16.4 lb (7.43 kg) compared with those who smoked up to 19 cigarettes per day who gained 8.3 lb (3.76 kg). Self-reported stress at baseline was not associated with weight change over the 7-year period ($p > 0.05$). However, those who worried over financial security gained 11.2 lb (5.08 kg) versus non-worriers who gained 7.4 lb (3.35 kg) ($p > 0.005$).

In the Whitehall II study poor health control and poor decision latitude at work were related to body mass gain.

Male employees ($n = 1980$) from the Danish National Work Environment Cohort Study were observed for 10 years (Hannerz 2004). Among the background variables, age ($p \leq 0.0001$) and baseline BMI ($p \leq 0$ 0003) were statistically significant, and the estimates indicated that the tendency to gain weight decreases with age and BMI.

Among the psychological variables, that only ones that interacted significantly with baseline BMI were psychological demand ($p = 0.0108$) and job insecurity ($p = 0.0027$). Obese employees with job insecurity gained more weight than obese employees without job insecurity, whereas underweight employees with job insecurity gained less weight than underweight employees without job insecurity.

A UK study evaluated the effect of unemployment/retirement on weight in middle-aged men (Morris 1992). At initial screening, the mean BMI of men who remained employed was similar to that of men who experienced some non-employment later (25.52 vs. 25.40 kg/m^2, respectively). However, men who later became non-employed were more likely to be underweight compared with men who remained employed (3.8 vs. 2.7%; 95% CI of the difference 0.1, 2.2)

Five years later the mean BMI had risen slightly in both men who had experienced some non-employment (25.40 to 25.71 kg/m^2) and in men who had not (25.52 to 25.77 kg/m^2). The percentage of men who were underweight had fallen 2.7 to 2.0% in men who were employed and 3.8 to 2.3% in men who had experienced unemployment, and the percentage of men who were overweight had risen (8.1 to 8.4% in employed men and 7.9 to 9.4% in men who had experienced non-employment).

Men who experienced some non-employment were less likely to remain a stable weight than men who remained continuously employed. 2.9% of men who experienced some non-employment lost more than 10% in weight and 7.5% gained more than 10% in weight compared with 2.1% and 5.0% respectively of continuously employed men (95% CI of the differenced 0.1, 1.8 for weight loss and 0.9, 4.0 for gain).

The Nurse Health Study II (Field 2004) evaluated the effect of weight loss in female nurses on subsequent weight. During a 2-year period from 1989 to 1991, 2590 (5.5%) women lost 5–9.9% of their 1989 weight and 1326 (2.8%) women lost at least 10% of their 1989 weight. The proportion of women who lost >5% of their baseline weight increased with category of BMI from 3% (5–9.9% weight loss) among women with a BMI <22 kg/m^2 to 9% among women with a BMI >30 kg/m^2 in 1989.

Between 1991 and 1995, approximately 50% of the women had regained all of the weight they had lost. Among those women who had lost >10% of their 1989 weight, the percentage who regained all of their large weight loss between 1989 and 1991 decreased across baseline categories of BMI from 71% among the women with a BMI <22 to 54% among the women with a BMI >30 kg/m^2 in 1989.

Less than 10% of the women who had large clinically significant weight loss between 1989 and 1991 were able to successfully maintain their weight loss. Women who lost greater than or equal to 10% of their weight between 1989 and 1991 gained more weight between 1991 and 1995 than their peers who did not lose weight.

2.2.6 General population

Dietary factors:

Data from the UK 1958 Birth Cohort (Parsons, 2005) reported that a decrease in chip consumption and an increase in fried food consumption was associated with weight gain over a 9-year period in men and women; a decrease in fruit and salad consumption was also associated with weight gain in women only.

Data from a number of other smaller studies found similar relationships. Samuel (2003) reported that a smaller fruit and vegetable consumption, and a greater consumption of sweets, was associated with weight gain in American women over 4 years.

An interesting study from Sweden (Heitmann 1995) found that a high-fat diet was associated with 6-year weight gain in women predisposed to obesity (had a least one fat parent), but not amongst those with lean parents.

Data from a large cohort in Australia (Ball 2002) found that restrictive eating practices and women who reported eating takeaway occasionally were 15% less likely to have maintained their weight over 4 years compared with those who rarely or never ate takeaways. In addition, data from the CARDIA study found similar results.

There was no independent association of frequency of eating with prospective weight change over the preceding 8–10 years in the NHEFS cohort (Kant 1995).

In the Danish MONICA study of 3000 Danish adults (who were evaluated for 5 years retrospectively) night eating was not associated with weight changes for either sex. Obesity did not modify the association between preceding weight change and night eating. Six-years prospective analysis found that for men, night eating was not associated with subsequent weight change. Analysis revealed that obese women with night eating experienced a greater average 6-year weight gain. The total average 6-year weight gain for obese night eating women was 5.2 kg, whereas obese non-night eating women experienced only a 0.9 kg average weight gain.

Nooyens (2005) found that over five years, weight gain and increase in waist circumference in 288 Dutch men aged 50-65 years were associated with a decrease in fruit consumption (p = 0.01) and fibre density of the diet (p = 0.01), and with an increase in frequency of eating breakfast (p = 0.03).

Quatrimoni (2002) found that in 737 non-overweight women from the Framingham Offspring/Spouse cohort, the likelihood of becoming overweight at 12 years follow-up was approximately 29%. The relative risk of developing overweight was RR 1.4; (95 CI 0.9, 2.2) in women who ate an ‘Empty Calorie’ diet that was rich in sweets and fats with fewer servings of nutrient-dense fruits, vegetables, and lean food choices, compared with women who ate a lower-fat, nutritionally varied ‘Heart Healthy’ diet.

Schulz (2005) looked at food patterns and subsequent weight gain nearly 25,000 subjects from the German cohort in the EPIC study. Those with a food pattern of a high consumption of whole-grain bread, fruits, fruit juices, grain flakes/cereals, and raw vegetables, and of low consumption of processed meat, butter, high-fat cheese, margarine, and meat were less likely to gain weight. Mean annual weight gain gradually decreased with increasing pattern score (higher score indicates healthier diet) (p-value for trend < 0.0001), i.e., subjects scoring high for the pattern maintained their weight or gained significantly less weight over time compared with subjects with an opposite pattern. However the prediction of annual weight change by the food pattern was significant only in non-obese subjects, ie dietary patterns predicted weight gain in normal weight subjects by not in those already obese.

Physical activity: Data from the UK 1958 Birth Cohort (Parsons 2005) reported that neither a decrease or increase in PA was associated with weight gain over a 9-year period in men and women. Data from a number of other smaller studies also found no relationship.

However, data from a large cohort in Australia (Ball 2002) found that women who reported moderate or high sitting time were 17–20% less likely to have maintained their weight over 4 years. In addition, a large cohort in America (DiPietro 1998) found that higher baseline levels of PA and lower levels of TV viewing were associated with a lower risk of becoming overweight over a 24-year period. Similar associations were found in other studies (Sundquist 1998; Bell 2001; Droyvold 2004). The PRIME study (Wagner 2004) provided interesting results showing that weight gain over 5 years in a large cohort of men was inversely associated with the amount of PA expended in getting to work, and the practice of high intensity recreational activities.

Nooyens (2005) investigated the effects of retirement on lifestyle and weight and waist circumference in 288 Dutch men. Over five years increases in weight and waist circumference were associated with a decrease in several physical activities, such as household activities, bicycling (p = 0.03), and walking (p = 0.02). Increase in body weight and waist circumference was higher among men who retired from active jobs (0.42 kg per year and 0.77 cm per year, respectively) than among men who retired from sedentary jobs (0.08 kg per year and 0.23 cm per year, respectively).

A small study (Larew 2003) found that lower rates of weight gain over 1 year were associated with greater levels of strength and fitness. Similar results were found in the CARDIA study.

Of note, a study from Sweden (Lissner 1997) found that women’s fat intake was a predictor of 6-year weight gain only amongst women who were sedentary.

Kahn et al. (1990) evaluated the effect of income, education and marriage on weight in data from the NHANES I and NHEFS. The incidence of major weight gain was lowest among men who reported high levels of PA or whose baseline BMI was between 24.0 and 27.8 kg/m^2.

Other behavioural, psychological, social and environmental factors
Viner (2005) UK conducted an analysis of the 1970 British Birth cohort of over 8000 subjects followed up at 5, 10 and 30 years (30 year follow-up self-reported) examining the relationship between television viewing and BMI change. Weekend but not weekday TV viewing in early childhood independently predicted increased adult BMI.

Mean daily hours of TV viewed at weekends predicted higher BMI z-score at 30 years (coefficient=0.03, 95% CI: 0.01, 0.05, P=.01) when adjusted for TV viewing and activity level at 10 years, sex, socioeconomic status, parental BMIs, and birth weight. Each additional hour of TV watched on weekends at 5 years increased risk of adult obesity (BMI > or =30 kg/m2) by 7% (OR=1.07, 95% CI 1.01, 1.13, P=.02). Weekday viewing, type of program and maternal attitudes to TV at 5 years were not independently associated with adult BMI z-score.

Kahn et al (1990) evaluated the effect of income, education and marriage on weight in data from the NHANES I and NHEFS. There was a significant increase in the mean BMI change for men with lower education levels compare with those who had gone beyond 12th grade.

The incidence of major weight gain was generally greater for the men who were not consistently married, among these men there was a higher incidence of major weight gain for those who had lower incomes or lower educational levels. The mid-range weight outcome was generally more common among men who had higher family incomes, or had higher educational levels.

A 7-year follow-up of young US adults in the CARDIA cohort (Greenlund 1996) showed that father's body size was positively associated with participant's baseline BMI among Black men, White men and White women. Mother's body size was positively associated with baseline BMI among all race–sex groups, and with change in BMI among White women. Father's education was inversely associated with baseline BMI among Black men and White women, and with change among White women.

Data from the UK 1946 Birth Cohort (Hardy 2000; Langenberg 2003) and data from the large NHANES I study in USA (Kahn & Williamson 1991) found that weight gain was greatest in Black women, in low income families, and in those with less education. These results were supported by most other studies identified in this review.

Women, but not men, gain weight at the start of marriage and lose weight at the end of marriage (Rauschenbach 1995).

Data from a large cohort in Australia (Ball 2002) found that smoking was significantly associated with a decreased likelihood of maintaining weight over 4 years in women. Data from a large cohort in Norway (Droyvold 2004) also found that those who did not drink alcohol were less likely to gain weight over a 9-year period.

A study (Samuel, 2003) found weight gain in US women over 4 years was associated with those more likely to have a high anxiety score, and those who had a lower average Quality of Life score. A small study (Tiggerman 2004) found the neither dietary restraint nor self-esteem alone predicted weight change over 4 years, but those who put on the least amount of weight over time were those low in dietary restraint and high in self-esteem.

2.3 Evidence of corroboration in the UK

Five of cohorts of adults were conducted in the UK, with the majority conducted in the USA and generalisable to UK adults. There were also cohorts in Japan, Chile, China, Australia, Norway, Sweden, Denmark and France.

UK studies were:

- MacDonald (2003) study of weight and menopause conducted in UK.
- Fifty-three year follow-up of UK men and women assessed associations between childhood weight and SES and weight change (Hardy 2000).
- Parsons (2005) followed all births 3–9 March 1958 in England, Scotland and Wales (16,000) and studied at age 33 and at age 42 years and assessed associations between diet and PA factors and weight change.
- Maartikainen (1999) assessed employment grade and weight change in the UK civil servants.
- Morris (1992) study of unemployment and retirement in men from one GP practice in UK followed for 5 years.

Evidence of implementation not valid for this review as not intervention studies.

EVIDENCE TABLES: DETERMINANTS OF WEIGHT GAIN/CONTROL IN ADULTS

First author, design, aim	**Population**	**Intervention details, length of follow-up**	**Results**	**Confounders adjusted for/comments**
REVIEWS OF COHORT STUDIES				
Williamson 1996 (2++) Review of eight cohort studies (1990–95, all at least 12 months follow-up, measuring dietary intake and/or PA) including:				
Colditz 1990 Nurses Health Study	US female nurses in 11 states 31,940 women aged 30–55 years (excluded women diagnosed with coronary heart disease, cancer, diabetes, smokers, on special diets, >15 g alcohol per day, pregnant, at least ten food items blank, total food score implausibly high or low, missing body weight.	**Year of baseline survey:** 1976 **Duration of follow-up:** 8 years **Outcome variable:** Absolute and percent weight change within 2 time periods: 1978–80 and 1980–84. **Self-reported or measured weight:** Self-reported every 2 years from 1976. **Statistical analysis:** • Pearson correlation • Linear regression	**Weight changes:** • From 1976 to 1984: 74% gained weight, 18% lost weight, 8% stayed at same weight. • Mean weight change (kg): 1976–80 +1.9 kg; 1980–84 +1.6 kg • Inverse correlation between weight change in a 2-year period and contiguous 2-year weight change, mean $r = 0.30$. • Weight change correlations involving non-contiguous periods were nearly 0. **Association of diet with weight change:** **Retrospective** (1978–80) weight change regressed on diet in 1980): • Total energy: ß = 0.00025 ($p > 0.0001$). (For every 1000 kcal [4.2 kJ]/day increase, body weight increased 0.25 kg.) • Total fat: ß = 0.0055 ($p > 0.001$). (For every 100 g/day increase, body weight increased 0.55 kg.) **Prospective** (1980–84 weight change regressed on diet in 1980): • Total energy: ß = 0.000021 ($p = 0.67$). • Total fat: ß = 0.0007 ($p = 0.69$). **Association of physical activity with weight change:** Not assessed.	Age, BMI, total energy and prior weight change in 1978–80.
Rissanen 1991	Twelve communities in Finland, 6165 men, 6504 women, aged 25–64 years	**Year of baseline survey:** 1966–72. **Duration of follow-up:**	**Weight change:** • Mean weight change (kg): +0.6 for men, +0.1 for women. • Range: –36 to +42 for men, –40 to +32 for women. • Prevalence of ≥5 kg gain: 18% for men, 15% for women. **Association of diet with weight change:**	Age, BMI, education, marital status, parity, smoking, alcohol, coffee, PA. 'Health

<table>
<tr>
<td></td>
<td>(excluded pregnant women)

Baseline BMI:
<i>not reported</i></td>
<td>5.7 (median).

Outcome variable:
• Absolute weight change.
• Odds of gaining ≥5 kg.

Self-reported or measured weight:
Measured.

Statistical analysis:
• Analysis of covariance
• Logistic regression</td>
<td>OR for gaining ≥5 kg for quintiles of total energy intake (compared with lowest quintile):
<table>
<tr><th>Quintile</th><th></th><th>Men</th><th>Women</th></tr>
<tr><td>Low</td><td>1</td><td>1.0</td><td>1.0</td></tr>
<tr><td></td><td>2</td><td>0.7 (NS)</td><td>1.3(NS)</td></tr>
<tr><td></td><td>3</td><td>0.7 (NS)</td><td>1.2 (NS)</td></tr>
<tr><td></td><td>4</td><td>1.0 (NS)</td><td>1.5 (NS)</td></tr>
<tr><td>High</td><td>5</td><td>0.8 (NS)</td><td>2.0 ($p > 0.05$)</td></tr>
</table>
OR for gaining ≥5 kg for highest vs. lowest quintile (other quintiles not reported).

Women ($p > 0.05$):
<table>
<tr><th>Fat</th><th>Protein</th><th>Carbohydrate</th></tr>
<tr><td>1.7</td><td>2.0</td><td>1.7</td></tr>
</table>
(No association found in men.)</td>
<td>status' (self-report of diabetes, hypertension, or 'other chronic diseases').</td>
</tr>
<tr>
<td>Klesges 1992

Aim:
To determine the relationship between dietary intake, PA and weight change.</td>
<td>Middleclass White adults from Memphis, TN, USA, who participated in a study examining cardiovascular risk factors in adults and their young children; 142 men mean age 34.8 years, 152 women mean age 33.1 years.

Baseline BMI:
27.8 (4.32) kg/m^2 men, 24.83 (4.96) kg/m^2 women.</td>
<td>Year of baseline survey:
Not reported.

Duration of follow-up:
2 years (seen once a year for 3-years to longitudinally predict weight gain over a 2-year period).

Outcome variable:
Weight change (kg).

Self-reported or measured weight:
Measured.

Statistical analysis:
Stepwise regression.</td>
<td>Attrition:
Approx. 30% (123 of 417)

Weight changes:
Mean weight change (kg): 0.265 (4.55) for men, 1.37 (5.89) for women at 2 years.

Association of diet with weight change:
Women:
Total energy, ß = 0.004 ($p = 0.0407$) (for every 1000 kcal [4.2 MJ]/day increase, body weight increased 4 lb [1.8 kg]).
%Energy (fat), ß = 0.527 ($p = 0.0010$) (for every 5% increase in fat, body weight increased 2.6 lb (1.2 kg).
Change in total energy, ß = 0.005 ($p = 0.0289$) (for every 1000 kcals [4.2 MJ]/day increase body weight increased 5 lb [2.3 kg]).
Men:
Total energy, ß = –0.003 ($p = 0.0235$)
Change in fat intake, ß = 0.383 ($p = 0.0216$)
Change in total kcal, ß = –0.002 ($p = 0.1181$)

Association of physical activity with weight change:

Women:</td>
<td>Age, BMI, smoking, alcohol, 'familial risk for obesity', pregnancy.

Stepwise regression may have lead to important confounders being dropped (some results are not intuitive, i.e. increases in energy intake associated with weight gain in men).

Not clear how authors coded work, sports,</td>
</tr>
</table>

			Work ß = –3.54 (p = 0.0939) Sports ß = +3.02 (p = 0.0582) Leisure ß = –6.18 (p = 0.0003) Change in work ß = –5.87 (p = 0.0221) **Men:** Sports ß = +1.86 (p = 0.0920) **Association of other factors with weight change:** cigarette consumption Change in cigarette consumption in women, ß = –0.707 (p = 0.0001). **Summary of results:** Longitudinal regression model explained 32.45 total variability of weight change in women (p > 0.0001) *and* 12% total variability of weight change for men (p = 0.0035). Higher total energy intake at baseline was directly related to subsequent weight gain in women whereas relationship was inverse in men. %Energy from fat at baseline directly related to weight gain only in women. Increased total energy intake was directly related to weight gain in women (increase in 200 kcal (840 kJ)/day for 2 years resulted in 2.206 kg weight gain) and the inverse for men (not significant for men). In men increases in % energy from fat was related to weight gain (5% increases in fat intake over 2 years resulted in weight gain of 0.86 kg). Higher work and leisure activity in women at baseline was associated with lower weight gain and decrease in work activity during follow-up was associated with higher weight gain. In both men and women higher baseline sports activity was associated with increase in subsequent weight gain and higher baseline weight was associated with less weight gain in men and women. Women who became pregnant gained weight and those initially pregnant (5%) lost weight compared with those with no change in pregnancy status. An increase of five cigarettes per day in women resulted in 1.586 kg decrease in weight over 2 years.	leisure. **Author's conclusions:** Different pattern of predictors for weight change for men and women; for women a high dietary energy and fat intake as well as increases in total energy intake were related to higher weight gain and increases in work activity levels were related to decreased weight gain; for men weight gain was predicted by increases in dietary fat intake.

Owens 1992	Women whose names appeared on motor vehicle license data in Allegheny County, Pennsylvania 500 women participated in the study. Age 42–50 years	**Year of baseline survey:** 1983–84 **Duration of follow-up:** 3 years **Outcome variable:** Absolute weight change **Self-reported or measured weight:** Measured **Statistical analysis:** Linear regression	**Weight change:** Mean weight change: +4.9 lb (2.2 kg) **Association of diet with weight change:** Not reported. **Association of physical activity with weight change:** Baseline activity expressed as 'Log kcal/week' • ß = 1.2*9 lb. (*p* > 0.003) (For every log kcal increase in activity there was a decrease in weight gain of –1.29 lb. Change in activity: • ß = –0.00058 lb (*p* > 0.01) (For every 1000 kcal [4.2 MJ]/week increase in activity there was a 0.58 lb [0.26 kg] decrease in weight gain)	Hormone use, smoking status, change in menopausal status during study.

<table>
<tr>
<td>Williamson 1993</td>
<td>National sample of USA aged 25–74 years.

3515 men, mean age 48 years

5810 women, mean age 46 years.</td>
<td>Year of baseline survey:
1971–75

Duration of follow-up:
10 years

Outcome variable:
Weight change (kg)
Weight gain categories (kg: ≤3 to ≤8, >8 to ≤13, >13

Self-reported or measured weight:
Measured.

Statistical analysis:
Linear regression.
Logistic regression.</td>
<td>Weight changes:
Mean weight change (kg) +0.3 for men, +0.7 for women.

Association of diet with weight change:
Not reported.

Association of physical activity with weight change:
Effect on mean weight change (kg):
• No association with baseline activity
• Association with follow-up activity: <i>p</i> > 0.05
<table>
<tr><th>Activity</th><th>Men</th><th>Women</th></tr>
<tr><td>High</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Moderate</td><td>0.9</td><td>1.4</td></tr>
<tr><td>Low</td><td>+1.6</td><td>+1.9</td></tr>
</table>
• Association with change in activity (<i>p</i> > 0.05):
<table>
<tr><th>Activity</th><th>Men</th><th>Women</th></tr>
<tr><td>Stayed high</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Decreased</td><td>+1.4</td><td>+1.9</td></tr>
</table>
Effect on gaining >13 kg (OR):
• No association with baseline activity
• Association with follow-up activity (<i>p</i> > 0.05)
<table>
<tr><th>Activity</th><th>Men</th><th>Women</th></tr>
<tr><td>Stayed high</td><td>1.0</td><td>1.0</td></tr>
<tr><td>Decreased</td><td>2.3</td><td>6.2</td></tr>
</table>
</td>
<td>Age, BMI, race, education, smoking status, alcohol, physician-diagnosed health conditions, parity.</td>
</tr>
<tr>
<td>French 1994</td>
<td>Persons employed in 32 companies in Minnesota (part of a health promotions study)

1639 men participated and</td>
<td>Year of baseline survey:
1988

Duration of follow-up:
2 years

Outcome variable:
Body weight at follow-</td>
<td>Weight change:
Mean weight change: +0.9 lb (0.4 kg) for men, +1.4 lb (0.63 kg) for women.

Association of diet with weight change:
(‘Cross-sectional’ because baseline and follow-up measures included in same model).

Results expressed as increase of one serving per week.

Women:</td>
<td>History of dieting, age, education, occupational, marital status, smoking status, treatment group.</td>
</tr>
</table>

	1913 women. Mean age: 38 years.	up. **Self-reported or measured weight:** Measured. **Statistical analysis:** Linear regression.	French fries: +0.55 lb (0.29 kg) ($p = 0.03$) Sweets: +0.28 lb (0.13 kg) ($p = 0.003$) Diary products: +0.18 lb (0.08 kg) ($p = 0.05$) Meat: +0.35 lb (0.16 kg) ($p = 0.0007$) **Men:** Sweets: +0.19 lb (0.09 kg) ($p = 0.02$) Eggs: +0.52 lb (0.24 kg) ($p = 0.006$)	
Taylor 1994	Persons from four communities in Northern California (part of a health promotion study). 568 men 668 women Age 20–60 years.	**Year of baseline survey:** 1980–82 **Duration of follow-up:** 7 years **Outcome variable:** BMI change per year ('BMI slope' estimated by regression of BMI on time). **Self-reported or measured weight:** Measured **Statistical analysis:** Linear regression.	**Weight change:** Weight change expressed as mean 'BMI slope' • Stratified by sex, age, and smoking status. • Maximum BMI slope: Men: +0.44, 45–54 years olds who quit smoking. Women: +0.46, 45–54 year olds who quit smoking. • Minimum BMI slope: Men 0.00, 55–64 years old, smokers. Women +0.04, 55–64 years old, non-smokers. **Association of diet with weight change:** Authors stated that: 'Dietary habits had inconsistent effects on BMI slope. No dietary results reported. **Association of physical activity with weight change:** ('Cross-sectional' because baseline and follow-up measures included in same model) • Association expressed as difference in BMI slope between sedentary persons who increased their activity and those who didn't. **Women** • Non-smoker –0.06 ($p > 0.05$) • Smoker –0.14 ($p > 0.05$) • Quit smoking –0.09 ($p > 0.05$) **Men** • Non-smoker –0.05 ($p > 0.05$) • Smoker –0.03 (NS) • Quit smoking –0.15 ($p > 0.05$)	Age. All analyses were stratified by smoking status and sex.
Kant 1995 Same as study by Williamson	National sample of US adults aged 25–74 years.	**Year of baseline survey:** 1971–74	**Weight change:** Mean weight change (kg): +2.1 for men, +2.5 for women. **Largest mean weight gain (kg):**	Race, income, smoking status, non-recreational PA, length of

et al., but did not subtract estimated weight of clothing at follow-up survey.	2580 Men 4564 Women Mean age: 45 years	**Duration of follow-up:** 10.6 years (mean) **Outcome variable:** Absolute weight change. **Self-reported or measured weight:** Same as study by Williamson et al., but did not subtract estimated weight of clothing at follow-up survey. **Statistical analysis:** Linear regression	Men +4.8, 25–34 years old, in upper quartile of % energy as fat. Women +6.0, 25–34 years old, in lower quintile of % energy as fat. **Smallest mean weight change (kg):** Men –2.7, 65–74 years old, in lower quintile of % energy as fat. Women –3.8, 65–74 years old, in second quartile of % energy as fat. **Association of diet with weight change:** No association found with total energy. Inconsistent associations found with % energy as fat. **Men** (age >50 years) ß = 0.06 (*p* = 0.10) If % energy as fat increases by 10% then weight increases by 0.6 kg. **Women** (age <50 years) ß = 0.05 (*p* = 0.04) If % energy as fat increases by 10% then weight decreases by 0.5 kg. **Association of physical activity with weight change:** Not reported.	follow-up, total energy, BMI, alcohol, special diet status, parity. Models were also stratified by age and by quartile of total energy, non-recreational PA, BMI, and physician-diagnosed morbidity.

Summary of Williamson's conclusions of review:

Results of associations between dietary and PA variables and weight change were inconsistent.

First author, design, aim	Population	Intervention details, length of follow-up	Results	Confounders adjusted for/comments
Saris 2003 (2++) – review of 13 cohort studies (1990–2001 all at least 4 years, estimating PAL and BMI) including:				
Kahn 1997, 1998 **Aim:** To identify behaviours associated with change in BMI	79,236 White, non-Hispanic healthy adults from 21 selected sites initially recruited for Cancer Prevention	**Year of baseline survey:** 1982 **Duration of follow-up**: 10 years **Outcome variable**:	**Attrition:** Unclear. **Weight changes:** 10-year BMI change for men was 0.6 (1.7) and for women was 1.4 (1.9) kg/m^2. **Association of diet with weight change:**	To obtain original studies and ascertain if reported any other factors associated with weight change.

or with weight gain at the waist. Kahn 1997 included in Saris review and Kahn 1998 identified as individual study but included here as same study	Study II in USA, aged between 50–74 years of age at follow-up; analysis excluded subject who were more than 54 years at baseline, regular diuretic use, cancer history other than non-melanoma skin cancer, diabetes, race/ethnicity other than White non-Hispanic, BMI >32 or <18 kg/m^2, or decrease/increase of greater than 8 kg/m^2 in BMI or 3% over 10 years, or misreported height or weight data. **Baseline BMI:** 25.6 (2.6) kg/m^2 for men, 23.4 (3.0) kg/m^2 for women	Change in BMI. **Self-reported or measured weight:** Self-report **Statistical analysis**: Multivariate linear regression (sex-specific) for change in BMI associated with specific behaviours, multivariate unconditional logistic regression for weight gainers vs. non gainers for weight gain at the waist.	Meat consumption greater than 3 days or servings per week was associated with BMI increase, more strongly for men than women, decrease in BMI for people who consumed greater than 19 days or servings per week of vegetables. **Association of physical activity with weight change:** Jogging/running 1–3 hours per week associated with decrease in BMI (0.2 kg/m^2 for men and 0.5 kg/m^2 for women), for men who performed this activity for ≥4 hours per week there was slightly greater decrease in BMI (0.3 kg/m^2); very few women reported jogging/running for more than 4 hours per week ('impossible to show significant effect'). Aerobics/callisthenics for men at any level was associated with BMI reduction similar to finding for men's jogging/running; for women there was a BMI decrease associated with aerobics/callisthenics performed at least 4 hours per week but not 1–3 hours per week. Tennis/racquetball associated with significant decrease in BMI for women at least 1–3 hours per week but no mean effects on BMI change for lap swimming, bicycling/stationary bike, or dancing. No significant effect on BMI change for heavy housework/vacuuming or heavy home repair/painting, but gardening/mowing/planting was associated with decreases in BMI for men at ≥4 hours per week and for women at ≥1 hours per week (0.1 kg/m^2 both sexes). Walking was highly prevalent activity but no significant effect found on BMI change for persons walking 1–3 hours per week, people who walked ≥4 hours per week experienced small significant decrease in BMI (twice as much for women). Women showed the greatest loss in BMI following PA. In men, those who did gardening or mowing for between 1 and 3 hours per week showed an decrease of –0.03 kg/m^2 while those who did 4 hours showed an decrease of –0.11 kg/m^2 in BMI. Men who walked for between 1 and 3 hours per week showed an increase of +0.01 kg/m^2 and those who did more than 4 hours showed an decrease of –0.8 kg/m^2.	**Adjusted for:** Age, education, BMI at baseline, slope of BMI between 18 years age and baseline, marital status, four regions of the country, estimated total daily energy intake in 1992, smoking, diet, PA and other behavioural characteristics, for women model also adjusted for parity, menopausal status and oestrogen replacement therapy. **Author's conclusions:** Ten-year change in BMI associated positively with meat consumption and smoking cessation and inversely with vegetable consumption, vitamin E

			For women, those who did between 1 and 3 hours of gardening/mowing showed an decrease of –0.09 kg/m^2 and for those who did >4 hours showed an decrease of –0.14 kg/m^2. For those who did between 1 and 3 hours of walking per week showed no change (0.00 kg/m$^{2)}$ and those who did >4 hours showed an decrease of –0.16 kg/m^2 in BMI. **Association of other factors with weight change:** • Vitamin E supplementation ≥100 IU (67 mg α-tocopherol equivalent)/day was associated with BMI decrease of about 0.1 kg/m^2 for men and women; people who continued to smoke experienced modest decrease in BMI (0.2 kg/m^2 for men and 0.3 kg/m^2 for women). The largest mean effect on 10-year BMI was associated with smoking cessation, in comparison with those who did not smoke, quitters experienced an increase of 1.0 kg/m^2. • Men who regularly consumed beer there was a decrease in BMI of 0.1 kg/m^2 but no effect associated with wine or liquor; for women who regularly consumed any form of alcohol experienced a decrease in BMI that was most marked for beer (0.4 kg/m^2) and least marked for wine (0.1 kg/m^2). • Men's likelihood of weight gain at the waist was positively associated with the Household Inequality Index (HII) (*p* = 0.0008), men with a high HII (households above the median receive 81.6 to 82.6% of the income) described weight gain at the waist more often than men from states with a low HII (households above the median receive 77 to 78.5% of the income), OR = 1.12, 95% CI 1.03, 1.22); women's results showed non significant trend in same direction.	supplementation, continued smoking and some vigorous activities. Women's BMI decreased with walking ≥4 hours per week and with regular alcohol intake but these behaviours had smaller effect on men's BMI; also results for waist circumference gain reported in paper. **Conclusion from Saris review:** The main effect of PA had a positive effect of weight gain.
Lee et al. 1993 **Aim:** To investigate body weight and mortality in middle-aged men.	17321 male adults (mean age 46 years) who were Harvard alumni, USA.	**Year of baseline survey:** 1962 **Duration of follow-up:** 12–16 years **Self-reported or measured weight:** BMI	**Association of physical activity with weight change:** No relationship between total or vigorous activity and BMI.	The main effect of PA on weight level of the subjects was non-significant.

<table>
<tr><td></td><td></td><td>Statistical analysis:
Not stated.</td><td></td><td></td></tr>
<tr><td>Rissanen et al. 1991
Aim:
To investigate the determinants of weight gain and overweight in adult Finns.</td><td>6165 males and 6504 female adults from Finland with an average age of 25–64 years.</td><td>Year of baseline survey:
1966
Duration of follow-up:
Median 5.7 years.
Outcome variable:
BMI
Self-reported or measured weight:
Not reported.
Statistical analysis:
Not stated.</td><td>Association of physical activity with weight change:
PA at follow up was inversely associated with weight gain in men and women.
The percentage of men with a BMI >30 kg/m^2 was rare in 14.2% of men, occasional in 11.2% of men and frequent in 6.7% of men. In women 21.4% of women rarely had a BMI >30 kg/m^2, 14.1% occasionally and 8.0% frequently.
The table below shows the estimated PAL of men and women in the study:
<table>
<tr><th></th><th>Men</th><th>Women</th></tr>
<tr><td>Rare</td><td>1.5</td><td>1.4</td></tr>
<tr><td>Occasional</td><td>1.65</td><td>1.55</td></tr>
<tr><td>Frequent</td><td>>1.8</td><td>>1.7</td></tr>
</table></td><td>Statistical adjustments were made for age, education, marital status, parity, smoking, alcohol, coffee, health status.
The main effect of PA had a positive effect of weight gain.</td></tr>
<tr><td>Williamson et al. 1993 (also included in Williamson review)
Aim:
To investigate recreational PA and 10-year weight change in a US national cohort.</td><td>3515 males and 5810 females with a mean age of 47 years from the USA.</td><td>Year of baseline survey:
1971
Duration of follow-up:
10 years
Outcome variable:
BMI
Self-reported or measured weight:
Not reported.
Statistical analysis:
Not clear.</td><td>Association of physical activity with weight change:
Weight change was inversely associated with PA at follow up. Decreased PA was associated with weight gain.
Baseline PA was not associated with weight change.</td><td>Statistical adjustments were made for age, BMI, race, education, smoking status, alcohol, physician-diagnosed health conditions, parity.
The main effect of PA had a positive effect of weight gain.</td></tr>
<tr><td>Heitmann et al. 1997
Finnish Twin Cohort Study</td><td>2110 males and 2490 women (twin pairs) aged between 18 and 39 years</td><td>Year of baseline survey:
1975
Duration of follow-</td><td>Association of physical activity with weight change:
PA at follow up was significantly associated with weight change in group overall. The table below shows the effect of doing differing intensities on BMI:</td><td>Age adjusted for all twins.
The main effect of PA had a</td></tr>
</table>

<table>
<tr>
<td>**Aim:**
To investigate whether the genetic determinants of weight gain modified by LTPA in twins.</td>
<td>from Finland.
Of these, 1571 monozygotic and 3029 dizygotic, same-sex twin pairs.
Baseline BMI, mean (SD):
Men: 23.0 (2.7) kg/m^2
Women: 21.0 (2.6) kg/m^2</td>
<td>**up:**
6 years
Outcome variable:
BMI
Self-reported or measured weight:
Self-reported.
Statistical analysis:
Not clear, various, separate analyses of gene–PA interactions.</td>
<td>
<table>
<tr><th>Intensity</th><th>Men</th><th>Women</th></tr>
<tr><td>**Low PA**</td><td>24</td><td>22</td></tr>
<tr><td>**Moderate PA**</td><td>24</td><td>21.8</td></tr>
<tr><td>**High PA**</td><td>23.6</td><td>21.7</td></tr>
</table>
The table below shows the estimated PAL of men and women in the study:
<table>
<tr><th>Intensity</th><th>Men</th><th>Women</th></tr>
<tr><td>**Low PA**</td><td>1.5</td><td>1.4</td></tr>
<tr><td>**Moderate PA**</td><td>1.65</td><td>1.55</td></tr>
<tr><td>**High PA**</td><td>>1.8</td><td>>1.7</td></tr>
</table>
Simple correlations revealed negative and insignificant associations between PA level and weight gain in men and women.
Other results are presented, but these compare effects by type of twin.
</td>
<td>positive effect of weight gain.
In conclusion, the author’s state that the study shows that genetic factors may modify the effects of PA on weight change, and suggest that a sedentary lifestyle may have an obesity-promoting effect in men with a genetic predisposition.</td>
</tr>
<tr>
<td>Morris et al. 1990
Aim:
To effect of PA/exercise in leisure time and its effect on body weight, coronary attack and death rates.</td>
<td>2250 male adults from the UK aged between 45 and 64 years.</td>
<td>**Year of baseline survey:**
1976
Duration of follow-up:
9.33 years
Outcome variable:
BMI
Self-reported or measured weight:
Not reported.
Statistical analysis:
Not stated.</td>
<td>
Association of physical activity with weight change:
The more frequently subjects exercised the less likely there were to have a larger BMI (kg/m^2). This is shown by the table below:
<table>
<tr><th></th><th>% of subjects BMI > *27*</th></tr>
<tr><td>**None**</td><td>24</td></tr>
<tr><td>**Residual**</td><td>18</td></tr>
<tr><td>**Less frequent**</td><td>14</td></tr>
<tr><td>**Frequent**</td><td>10</td></tr>
</table>
The table below shows the estimated PAL of the subjects in the study:
<table>
<tr><th>Intensity</th><th>Men</th></tr>
<tr><td>**None**</td><td>1.6</td></tr>
<tr><td>**Residual**</td><td>1.78</td></tr>
<tr><td>**Less frequent**</td><td>1.8</td></tr>
</table>
</td>
<td>The main effect of PA had a positive effect of weight gain.</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td><table><tr><td>Frequent</td><td>1.9</td></tr></table></td><td></td></tr>
<tr><td>Guo et al. 1999

Aim:
The study was part of the Fels Longitudinal study, which looked at the effects of aging, body composition and lifestyle.</td><td>102 men and 108 women from the USA with a mean age of 44 years.</td><td>Year of baseline survey:
1976

Duration of follow-up:
9.1 years (mean).

Outcome variable:
Body weight (kg).

Self-reported or measured weight:
Not reported.

Statistical analysis:
Not clear.</td><td>Association of physical activity with weight change:
Low and medium PA was significantly associated with increased body fat in both men and women, as shown in the table below:<table><tr><th>Intensity</th><th>Men (kg)</th><th>Women (kg)</th></tr><tr><td>Low PA</td><td>2.53</td><td>7.5</td></tr><tr><td>Moderate PA</td><td>1.33</td><td>3.52</td></tr></table>The table below shows the estimated PAL of the subjects used in the study:<table><tr><th>Intensity</th><th>Men</th><th>Women</th></tr><tr><td>Low PA</td><td>1.5</td><td>1.4</td></tr><tr><td>Moderate PA</td><td>1.65</td><td>1.55</td></tr><tr><td>High PA</td><td>>1.8</td><td>>1.7</td></tr></table></td><td>Statistical adjustments were made for age, menopausal status and duration of oestrogen use.

The main effect of PA had a positive effect of weight gain.</td></tr>
<tr><td>Sesso et al. 2000

Aim:
The study investigated PA and coronary heart disease in men.</td><td>12,516 men from the USA, with the mean age of 58 years, who were all Harvard Alumni.</td><td>Year of baseline survey:
1977

Duration of follow-up: 16 years.

Outcome variable:
BMI

Self-reported or measured weight:
Not reported.

Statistical analysis:
Not stated.</td><td>Association of physical activity with weight change:
There was no significant difference in BMI's of subjects regardless of total PA done by the subjects per week</td><td>The main effect of PA did not have a significant effect on weight gain.</td></tr>
<tr><td>Haapanen et al 1997

Aim:
The study investigated</td><td>2564 males and 2695 females of working age (19–63 years) from Finland.</td><td>Year of baseline survey:
1980

Duration of follow-up:</td><td>Association of physical activity with weight change:
Those who were involved in more vigorous type exercise two or more times a week had the higher weight increases compare with those who did no regular weekly PA. Those who had no regular weekly PA showed a 1.5 kg increase and 1.9 kg increase for men and women respectively.</td><td>Statistical adjustments were made for age, perceived health smoking and SES.</td></tr>
</table>

the association between LTPA and 10-year body mass change among working aged men and women.		10 years **Outcome variable**: Body weight (kg). **Self-reported or measured weight:** Not reported. **Statistical analysis**: Not clear.	Men who did weekly light intensity PA had a 2.7 kg weight increase while women showed a 3.0 kg increase. Men who took part in vigorous PA once per week plus light PA showed an increase of 3.0 kg while women showed a 2.8 kg increase. Finally, men who took part in vigorous PA two or more times per week showed a 3.2 kg weight increase while women showed a 3.1 kg increase. NB: All activities including unusual jogging, aerobics and tennis significantly inversely related to weight gain	The main effect of PA had a positive effect of weight gain.
Thune et al. 1998 **Aim:** This was part of the Tromso study, which investigated the effect of PA on metabolic risk profiles in men and women	5220 men and 5869 women from the USA, aged between 20 and 49 years.	**Year of baseline survey:** 1982 **Duration of follow-up:** 7 years. **Outcome variable**: BMI **Self-reported or measured weight:** Self-reported. **Statistical analysis**: Not clear.	**Association of physical activity with weight change:** Sustained high or increased PA was associated with less weight gain during follow up period. Men who were sedentary had a BMI of 25.7 kg/m^2, those who did moderate amounts of PA had a BMI of 25.0 kg/m^2, those who did hard levels of PA had a BMI of 24.5 kg/m^2 and those who did very hard had a BMI of 23.9 kg/m^2. Women who were sedentary had a BMI of 23.6 kg/m^2, those who did moderate PA had a BMI of 23.5 kg/m^2 and women who did hard PA had a BMI of 23.1 kg/m^2.	Statistical adjustments were made for age, smoking, coffee, dietary fat and menopausal status. The main effect of PA had a positive effect of weight gain.
Coakley et al 1998 **Aim:** This was part of the Health professionals follow-up study which looked at predictors of weight change in men.	10,272 males from the USA, aged between 44 and 54 years.	**Year of baseline survey:** 1986 **Duration of follow-up:** 4 years **Outcome variable**: Body weight (kg). **Self-reported or measured weight:**	**Association of physical activity with weight change:** Those who did more vigorous leisure-time PA (LPTA) showed the smallest increases in body weight. **Weight change**: 44–54 years old, mean weight at 4 years follow-up: 82.6 kg (increase of 1.4 kg). 55–64 years old, mean weight at 4 years follow-up: 81.4 kg. >65 years old, mean weight at 4 years follow-up: 78.4 kg (decrease of 0.2 kg). Overall mean weights at 4 years follow-up: 81.5 kg (increase of 0.8 kg). **Association of diet with weight change:**	Statistical adjustments were made for age, diet, smoking, baseline values (including PA and TV use), weight, height, blood pressure and cholesterol. **Authors'**

		Self-reported. **Statistical analysis**: Multivariate regression analyses.	Eating between meals was associated with weight gain. Recently being on diet was more strongly associated with weight loss among older men. **Association of physical activity with weight change:** Those who decreased their vigorous LTPA by 1.5 hours a week showed a 1.7 kg weight increase. Those who maintained less than 1.5 hours of vigorous LPTA per week showed a 1.1 kg increase in body weight while those who maintained over 1.5 hours of vigorous LPTA showed an increase of 0.8 kg of body weight. Finally, those who increased their vigorous LPTA to >1.5 hours showed an increase of only 0.2 kg of body weight. Vigorous activity was associated with weight reduction and TV/video viewing with weight gain. The prevalence of obesity among middle-aged men was lowest among those who maintained a relatively high level of vigorous PA, compared with those who were relatively sedentary. **Association of other factors with weight change (please state factors):** Quitting smoking and a history of voluntary weight loss prior to the study period were consistently related to weight increase. Middle-aged men who increased their exercise decreased their TV viewing and stopped eating between meals, lost an average weight of 1.4 kg, compared with a weight gain of 1.4 kg among the overall population.	**conclusions:** increasing vigorous activity, as well as decreasing TV use and changing eating habits, results in weight maintenance or a modest weight loss over 4 years.
Wier et al. 2001 **Aim:** To determine the amount of PA needed for long-term weight control.	341 males, with a mean age of 42.1 years and 155 females with a mean age of 36.1 years who were all employees from the NASA space centre in the USA.	**Year of baseline survey:** 1990 **Duration of follow-up:** 5.5 years for males and 4.9 years for females. **Outcome variable**: Body weight (kg). **Self-reported or measured weight:** Not stated. **Statistical analysis**:	**Association of physical activity with weight change:** Average weight gain progressively limited for both males and females at levels of PA. Men who were inactive showed a 1.7 kg increase in body weight while women showed an 8.8 kg increase. Moderately active men showed a 1.3 kg increase in body mass while women showed a 1.1 kg increase. Active men showed a 0.5 kg increase in weight while women showed a 0.7 kg increase. Very active men showed a 1.3 kg decrease in body weight while women showed a 3.1 kg body weight decrease.	Statistical adjustments were made for age and initial weight as well as time elapsed. The main effect of PA had a positive effect of weight gain.

		not stated		
Ball et al. 2001 **Aim:** This study looked at the associations of PA with body weight and fat in men and women.	1301 male and females aged 18–78 years from Australia.	**Year of baseline survey:** 1990 **Duration of follow-up:** Not stated. **Outcome variable**: % Overweight. **Self-reported or measured weight:** Self-reported. **Statistical analysis**: Not stated.	**Association of physical activity with weight change:** The percentage of males overweight was higher than the percentage of women overweight regardless if they were sedentary, had low levels of PA or high levels of PA. 50% males who were sedentary were overweight while only 35% of sedentary females were overweight. 42% males who were had low levels of LTPA were overweight while 27 % of women who had low levels of LTPA were overweight. 34% of males who had high activity LTPA levels were overweight while only 20% of women who had high levels of LTPA were overweight.	The main effect of PA had a positive effect of weight gain.
Summary of Saris's conclusions of review: 30 min of exercise is insufficient to prevent weight gain for many individuals. Between 45–60 min or 1.7 PAL per day of moderate intensity exercise is required to prevent the transition of being overweight to obese; this is likely to be more for children.				
INDIVIDUAL COHORT STUDIES: MENOPAUSE				
First author, design, aim	**Population**	**Intervention details, length of follow-up**	**Results**	**Confounders adjusted for/comments**
MacDonald 2003 Prospective cohort 2+ **Aim:** To investigate whether energy intake or energy	1064 initially premenopausal White women aged 45–54 (mean 48 years) years selected from a randomly selected osteoporosis screening programme in	**Year of baseline survey:** 1993 **Duration of follow-up**: 6.2 (0.6) years **Outcome variable**: Mean weight change. **Self-reported or measured weight:**	**Attrition:** 85.2% (*n* = 907) women returned for follow-up of which 898 completed questionnaires **Weight changes:** Difference weight (kg): premenopausal (*n* = 51) 3.08 (4.45), perimenopausal (*n* = 117) 3.68 (5.29), postmenopausal (*n* = 328) 3.02 (5.32), past HRT use (*n* = 115) 4.41 (5.19), present HRT use (*n* = 284) 2.99 (4.63). **Association of diet with weight change:** Alterations in dietary intake had small but significant effect (0.6%,	**Author's conclusions:** Mean weight had increased and was influenced more by reduced energy expenditure than increased energy intake, HRT and dietary

expenditure affects 5–7-year weight gain in perimenopausal and early postmenopausal women and whether HRT use or dietary calcium intake are contributory factors.	Aberdeen, Scotland, not on HRT at baseline or suffering from any condition or taking any medication that would interfere with bone metabolism. **Baseline BMI:** 24.6 (4.0) kg/m^2.	Measured. **Statistical analysis**: Multiple regression analysis.	*p* = 0.013). **Association of physical activity with weight change:** Changes in PAL influenced weight change explaining 4.4% (*p* = 0.001) of the variation. **Association of other factors with weight change: calcium intake** Dietary calcium intake had no effect on weight or weight change; including menopausal status and HRT use as variables in the regression did not add significantly to the model.	calcium intake did not influence weight gain.
Nagata 2002 Prospective cohort 2+ **Aim:** To evaluate the effect of menopause on weight change in Japanese women.	828 Japanese premenopausal women aged 40–54 years randomly selected from women participating in Takayama study; excluded menopause by surgery (*n* = 25), or by radiation/medication (*n* = 9) those who did not report weight (*n* = 16) or menopausal status (*n* = 1), reported history of cancer (*n* = 2). **Baseline BMI:** (adjusted for age at baseline)	**Year of baseline survey:** 1992 **Duration of follow-up**: 6 years. **Outcome variable**: Change in weight (kg). **Self-reported or measured weight:** Self-report (intraclass coefficients between self-report and measured weight of women in another sample form Takayama study) was 0.97. **Statistical analysis**: Regression model.	**Attrition:** 81% response rate. **Weight changes:** Weight gain (kg) (adjusted for age and weight at baseline) premenopausal at follow-up: 0.41 (SE 0.18); postmenopausal at follow-up: –0.18 (SE 0.19); years since menopause at follow-up 1–2 years: –0.26 (SE 0.29); ≥3 years: –0.04 (SE 0.25). Weight gain was significantly higher in women who remained premenopausal at follow-up compared with those who had natural menopause; weight change was less in women who were postmenopausal more than 2 years than those in first or second year of menopause but the difference was not significant. **Association of diet with weight change:** Nutrient intakes were not significantly associated with difference in weight change between premenopausal and postmenopausal women. **Association of** physical activity **with weight change:** Exercise (METs × hours per week) was not significantly associated with difference in weight change between premenopausal and postmenopausal women. **Association of other factors with weight change: number of births, age at menarche** Higher number of births was significantly associated with weight gain in	**Adjusted for:** Age and weight at baseline and menopausal status at follow-up. **Author's conclusions:** Reproductive factors rather than sociodemographic factors and behavioural factors appeared top be associated with weight change during the perimenopausal period; onset of menopause may diminish weight gain whereas early menarche and

	premenopausal at follow-up: 22.4 (SE 0.15); postmenopausal at follow-up: 22.2 (SE 0.15); years since menopause at follow-up 1–2 years: 22.4 (SE 0.23); ≥3 years: 22.0 (SE 0.21).		premenopausal women, and early age at menarche was significantly associated with weight gain in postmenopausal women. HRT use, smoking status, alcohol consumption were not significantly associated with difference in weight change between premenopausal and postmenopausal women.	high parity showed relationships with weight gain.
Blumel 2001 [524] Prospective cohort 2+ **Aim:**To evaluate the influence of menopause on weight and the effect of weight gain on coronary risk factors	271 Chilean premenopausal women (not receiving HRT) aged between 40 and 53 (mean 45.3) years. **Baseline BMI or weight:** Mean weight and BMI for 40–44-year-olds: 60.9 ± 10.1 kg and 25.3 ± 3.5 kg/m^2, 45–49-year-olds: 63.7 ± 8.6 kg and 26.3 ± 3.8 kg/m^2, 50–54-year-olds: 65.1 ± 9.7 kg and 27.3 ± 4.4 kg/m^2.	**Year of baseline survey:** 1991–92 **Duration of follow-up**: 5 years **Outcome variable**: Weight (kg), BMI. **Self-reported or measured weight:** Measured. **Statistical analysis**: Kruskall–Wallis test, Bartlet test and the χ^2 test.	**Attrition:** 57% **Weight changes:** Women showed a weight gain of 4.0 ± 4.6 kg ($p > 0.0001$) and an increase in the BMI of 1.7 ± 2.4 kg/m^2 (from 25.9 ± 3.8 to 27.6 ± 4.1 kg/m^2, $p > 0.0001$). The percentage of overweight and obese women increased from 54.2% observed in 1991–92 to 70.9% ($p > 0.0001$). The risk of obesity (BMI >30 kg/m^2) by the end of the study depended on the initial BMI: only 1.6% of women with BMI <25 kg/m^2 at baseline were obese at follow up, whereas 28.6% of those who were overweight at baseline were obese at follow-up and 91.4% of those who were obese at follow-up. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change: HRT use** Weight gain was similar in those who did or did not use HRT (non users, 4.3 ± 4.8 kg; users 3.5 ± 3.7 kg, ex-users, 3.4 ± 5.8 kg).	**Adjusted for:** Not reported. **Author's conclusions:** During the perimenopausal period there is a weight gain that does not seem to depend on the menopause.

<table>
<tr>
<td>Wing 1991

Prospective cohort
2+

Healthy Women Study. (two papers).

Three main aims:
1) To describe the weight changes that occurs in a sample of healthy women at time of menopause;

2) To determine whether change in weight is related to change in CHD risk factors during the menopausal period;

3) To identify specific variables associated with weight gain to help determine which individuals are</td>
<td>485 women aged between 42 and 50 years old and menstruated within the past 3 months, had no surgical menopause, a diastolic blood pressure less than 100 mmHg, and not to be taking lipid-lowering drugs, insulin, thyroid medication, estrogens, antihypertensive drugs or psychotropic drugs.

Baseline BMI/weight:
See results table.

Burnette 1998
541 menopausal women from Pittsburgh who were non smokers, ex-smokers or smokers

Baseline BMI or weight:</td>
<td>Year of baseline survey:
1983–84

Duration of follow up:
3–4 years (depending on when baseline measurements were taken for Wing, 2 years for Burnette).

Outcome variable:
Weight (kg, lb) and BMI.

Self-reported or measured weight:
Measured.

Statistical analysis:
Regression analyses (Wing) chi square (Burnette).</td>
<td>Wing 1991

Attrition:
11%

Weight changes:
Women gained a mean of 2.25 kg during follow-up. The SD for weight gain was 4.19 kg with a range from a 14.85 kg loss to a 32.4 kg gain. 20% of the women gained ≥4.5 kg, while only 3% lost ≥4.5 kg.

The table below shows changes in weight, BMI and skinfold thicknesses in premenopausal, perimenopausal and postmenopausal women:

<table>
<tr><th>Measurement</th><th>Premenopausal</th><th>Perimenopausal</th><th>Postmenopausal</th></tr>
<tr><td>Baseline weight (kg)</td><td>64.8 ± 11.9</td><td>67.2 ± 12.6</td><td>68.8 ± 13.9</td></tr>
<tr><td>Change in weight (kg)</td><td>2.1 ± 4.1</td><td>2.5 ± 3.3</td><td>1.4 ± 4.9</td></tr>
<tr><td>BMI at baseline (kg/m^2)</td><td>24.34 ± 4.17</td><td>24.85 ± 4.62</td><td>26.01 ± 5.33</td></tr>
<tr><td>Change in BMI (kg/m^2)</td><td>1.09 ± 1.63</td><td>1.29 ± 1.28</td><td>0.98 ± 1.95</td></tr>
<tr><td>Triceps skinfold thicknesses at entry (mm)</td><td>24.8 ± 7.3</td><td>25.1 ± 7.1</td><td>26.0 ± 7.7</td></tr>
<tr><td>Change in triceps skinfold thicknesses (mm)</td><td>2.9 ± 8.0</td><td>2.6 ± 7.1</td><td>3.2 ± 8.3</td></tr>
</table>

From the table, it is possible to see there were no significant differences in weight gain of women who remained pre menopausal and those who had a natural menopause (2.07 vs. 1.35 kg)

Association of diet with weight change:
No analysis.

Association of physical activity with weight change:
No analysis.

Association of other factors with weight change:
<i>Hormone therapy:</i> Women who took hormone therapy appeared to be greater than that seen in other groups. These women had significant</td>
<td>Adjusted for:
Not reported.

Author's conclusions:

(Wing):
Weight gain is a common occurrence for women at menopause.

Authors' conclusions: (Burnette)
Smoking cessation in perimenopausal to postmenopausal women is associated with greater weight gain but appears to be modestly associated with certain positive changes in cardiovascular risk factors.</td>
</tr>
</table>

at risk of gaining weight at menopause **Burnette 1998** To investigate the relationship between smoking cessation, subsequent weight gain and cardiovascular disease risk factors from premenopause to postmenopause.	Non-smokers mean weight 147.08 ± 27.72 lb (66.7 ± 12.6 kg); all smokers mean weight 143.67 ± 30.51 lb (66.5 ± 13.8 kg). Smokers who continued through second year post menopause mean weight 143.81 ± 30.46 lb (65.2 ± 13.8 kg). Smokers who reported quitting at years 1 and 2 post menopause mean weight 143.09 ± 31.18 lb (64.9 ± 14.1 kg).		increases in weight ($p > 0.0001$), BMI ($p > 0.0001$), triceps skinfold thickness ($p > 0.0001$) and suprailiac skinfold thickness ($p > 0.05$). *Smoking:* In non-smokers ($n = 339$) the mean weight gain during the 3 years of follow up was 2.12 ± 4.05 kg. Weight gain in women who were premenopausal ($n = 202$) averaged 2.21 kg; in those who were perimenopausal ($n = 67$), weight gain averaged 2.30 kg; in postmenopausal women at follow up ($n = 33$), weight gain averaged 0.63 kg. Women who took hormone therapy ($n = 20$) gained 2.30 kg and those who had never had a hysterectomy ($n = 17$) gained 3.11 kg. Changes over time were significant ($p > 0.0001$), although they did not significantly differ among the various menopausal statuses of women. **Burnette 1998** **Attrition:** 8% **Weight changes:** *First-year post menopause:* significant group effects were found for weight; after-baseline quitters gained significantly more weight ($n = 28$, mean 11.36 lb [5.1 kg]) than non-smokers ($n = 297$, mean 5.32 lb [2.4 kg]) and continuing smokers ($n = 91$, mean 5.45 lb [2.5 kg]). *Second-year post menopause:* after baseline quitters experienced significantly greater weight gain ($n = 26$, mean 14.43 lb [6.5 kg]) than non-smokers ($n = 265$, mean = 7.69 lb [3.5 kg]). **Association of other factors with weight change: smoking** NB: Quitters had significantly greater decrease in alcohol consumption than non-smokers and continuing smokers.	
Crawford 2000 Prospective cohort 2+ Massachusetts Women's Health Study **Aim:**	418 women aged between 50–60 years from MA, USA **Exclusion criteria:** Subjects must have had an intact uterus, at	**Year of baseline survey:** 1986 **Duration of follow-up**: 3 years. **Outcome variable**: Weight (kg) and BMI. **Self-reported or**	**Attrition:** 22.4% **Weight changes**: Mean change in weight between annual consecutive interviews was small, ranging from 0.2 kg to 0.04 kg and was not significantly different from zero at any follow up. The percentage of women with stable weight (annual change of no more than 1 kg) rose from 25.9% at year 1 follow-up and 34.9% at year 3 follow-up. 20.4–25.1% of subjects at an interview were over weight and another 18.2–	**Adjusted for:** Baseline weight. **Author's conclusions:** Menopause transition was not consistently associated with increased weight, exercise

To investigate weight gain linked to the menopause.	least one ovary, and at first contact no more than 11 consecutive months of amenorrhoea. **Baseline BMI or weight:** Mean weight of subjects 72.2 kg, mean BMI 27.6 kg/m^2. 22.6% of subjects overweight (BMI 27.3–32 kg/m^2). 20.2% of subjects obese (BMI >32 kg/m^2).	**measured weight:** ***measured*** **Statistical analysis**: Multivariate linear regression.	21.7% were obese. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** Exercise: change in exercise was significantly related to adjusted log weight (p = 0.04), with higher adjusted log weight among women who ceased exercising. **Association of other factors with weight change (please state factors):** *Smoking:* Adjusted weight was higher among women who stopped smoking compared with continuing smokers (p = 0.04), although smoking change as a whole was not significant (p > 0.05). *Alcohol:* Higher alcohol consumption at a previous contact and a larger increase in ethanol consumption between annual contacts also were marginally significantly related to higher adjusted weight (p = 0.07–0.08).	and alcohol were more strongly related to weight than menopause transition.
INDIVIDUAL COHORT STUDIES: PREGNANCY				
First author, design, aim	**Population**	**Intervention details, length of follow-up**	**Results**	**Confounders adjusted for/comments**
Williamson 1994 Prospective cohort Aim: To examine the effect of childbearing on weight change	2547 white women aged 25-45 years who were initially weighed in the First National Health and Nutrition Examination Survey (NHANES) (n = 3699).	Year of baseline survey: 1971-1975 Duration of follow-up: 10+ years Outcome variable: Measured. Self-reported or measured weight: Measured.	Attrition: 31% Weight changes: Estimated weight gain for women who did not have any live births during the study period (n = 2239) was 3.8 kg. Association of diet with weight change: None reported Association of physical activity with weight change: None reported Association of other factors with weight change: pregnancy	Adjusted for: Duration of follow-up, age, BMI, initial parity, education, and other lifestyle behaviours. Author's conclusions: Generally the risk of weight

		Statistical analysis: Linear and logistic regression	Compared to parous women who did not give birth during the study period, the mean excess weight gain was 1.6 kg (95 Confidence Limits, +/- 2.3 kg) for nulliparous women, and was 1.7 kg (+/- 1.1 kg), 1.7 kg (+/- 2.0 kg), and 2.2 kg (+/- 4.3 kg), for women having one, two and three live births, respectively. Among women who were nulliparous at baseline, those that had their live births during the study period gained similar amounts of weight to that of women who began childbearing before the beginning of the study. The risk of gaining more than 13 kg was increased by 60% for women having one live birth and by 40%for women with two live births. The risk of becoming overweight (BMI >27.3) was increased by 60% and risk of becoming severely overweight (BMI>30) was 110% in women having live births during the study.	gain was modest, but for some women the risks of major weight gain and becoming overweight were increased in association with childbearing.
Wolfe 1997 **Design:** Prospective cohort NHANES 1 (1971–75) and NHEFS (1982–84) **Aim:** To examine how the relationship between parity increase and weight gain is modified by socio-demographic and behavioural factors.	2952 adults (2534 White women and 418 African American women) aged 25–45 years residing in the contiguous 48 US states participated in NHANES 1 and were systematically followed up in the NHEFS. Mean baseline weight for White women = 64.3 kg. Mean baseline weight for African American women = 71.3 kg.	**Year of baseline examination and questionnaire:** 1971–75 **Duration of follow-up:** Approximately 10 years. **Outcome variable:** Parity associated weight gain. **Self-reported or measured weight:** Measured within a personal interview and medical examination. **Statistical analysis:** Multiple linear regression analysis Eight socio-demographic covariates and their interactions with parity	**Attrition:** Not mentioned **Weight changes:** Weight gain from baseline to follow-up averaged 4.4 kg for White women and 5.5 kg for African American women. Among White women, after adjusting for baseline parity and other socio-demographic variables, the weight gain for non-employed married metropolitan women averaged 4.2 kg for those with no change in parity, compare with 4.7 kg for those with a parity increase of one child and 7.4 kg for those with a parity increase of two or more children. Among African American women, adjusted for the same variables, weight gain for those with no change in parity averaged 4.9 kg, compared with 7.2 kg for those with a parity increase of one or more. The probability of substantial weight gain (more than 11.4 kg) also rose with parity increase. White women with a parity increase of two or more were also twice as likely to experience substantial weight gain as those with no change in parity. However the probability increased only slightly for those with a parity increase of just one. Among African American women, those with an increase in parity were about five times as likely to experience substantial weight gain as those with no parity increase.	**Adjusted for:** Baseline height, the square of the subject's age to adjust for the curvilinearity of the relationship between body weight and age, and the number of years between the baseline and follow-up measurements as a control for the duration of opportunity for weight change. **Author's conclusions:** The effects of socio-demographic and behavioural factors on

		change in relation to weight gain were examined, these included; baseline weight, baseline parity, baseline age, employment status at baseline, marital status at baseline, rural versus metropolitan residence, family income at baseline and educational level at baseline. Three behavioural variables and their interactions with parity change in relation to weight gain were examined. These included cigarette smoking, recreational exercise and non-recreational PA.	For Whites, a parity increase of two or more was associated with greater weight gain in women with higher baseline weight compare with those with lower baseline weight, in non-employed compare with employed women and in non-married compare with married women. Smoking also interacted with parity increase in its effect on weight gain in White women, but with mixed results. Among women with a parity increase of two or more, smokers gained less additional weight (when compare with women with no parity increase) than non-smokers, but among women with a parity increase of just one, smokers gained much more additional weight. Among African American women, a parity increase of one or more was associated with greater weight gain in women with lower baseline weight, in those with lower incomes and in non-smokers. Smokers in this group not only gained less than non-smokers, but they also gained far less than smokers with non-parity increase. Among White women, being not employed, unmarried, in a rural residence, with lower educational attainment, having fewer children at baseline and having a higher level of non-recreational PA at baseline, all increased the probability of gaining more than 11.4 kg given an increase in parity of two or more. Younger age increased the probability given an increase in parity of one. Among African Americans, the effect of a parity increase of one or more on the probability of gaining >11.4 kg was similar to a parity increase of two or more among Whites. Those with lower educational attainment and fewer children at baseline were more likely to have a substantial weight gain. Older women were more likely to experience substantial weight gain with an increase in parity then were their younger counterparts.	parity-associated weight gain varied by race and parity change, with the most consistent findings being that unmarried and unemployed White women had greater parity associated weight gain, while both White and African American women who smoked, had higher education, or higher parity had lower parity associated weight gain.
Sowers 1998 **Aim:** To compare the weight changes in lactating women within an 18-month inter-	The 25 cases and 20 controls were recruited from a parent population comprised of 115 women, aged 20–40 years and 0–1 parity, who	**Year of baseline examination and survey:** Not stated. **Duration of follow-up:** Evaluation included six measurements in the postpartum period at	**Attrition:** 100% – no dropouts **Weight change:** The average weight loss in the postpartum period was 4.7 kg for cases and 4.4 kg for controls, which was not significantly different. There was no statistically significant difference between the weight retention patterns of all the women. The average weight retention curve for the cases and controls had similar shapes, initially they declined and then	**Adjusted for:** Energy intake, energy expenditure and weight gain during the subsequent gestational period.

pregnancy interval with women who also breastfed but did not have an immediate subsequent pregnancy.	were enrolled in a previous bone mass and lactation study. Cases were women who breastfed an index infant for 6-months and subsequently became pregnant within 18-months. Controls were women who also breastfed an index infant for 6-months but had no ensuing pregnancy within 18 months. Mean age = 29.3 years. Mean BMI prior to pregnancy = 22.2 (range, 16.9 – 33.8) kg/m^2. Mean weight prior to pregnancy = 59.7 (range, 43– 93) kg.	0.5, 2, 4, 6, 12 and 18 months. The 25 cases did not continue with the scheduled measurement intervals; instead these women were measured for the final time within 14 days of their subsequent delivery. **Outcome variables:** 1) Postpartum weight retention – calculated by subtracting weight prior to the pregnancy of the reference infant from weight at each evaluation point during the postpartum period. 2) Across pregnancy weight difference, which was the difference between the weight of the cases 2 weeks after the birth of the reference infant and 2 weeks following the birth of the subsequent infant. **Self-reported or measured:** Measured. **Statistical analysis:** *t* tests were used to assess the comparability of the	began to plateau at about 8–10 months postpartum. Among the cases, post pregnancy weight following the baseline pregnancy was compared with post pregnancy weight following the subsequent pregnancy. On average, cases weighed 1.3 kg more after the subsequent pregnancy than they weighed following the baseline pregnancy. At their final measurement, controls weight 4.59 kg less than their post-pregnancy baseline. **Association of diet and physical activity with weight change:** Not a great deal mentioned other than, estimates of energy intake and/or PA were not important factors in explaining the weight differential between the baseline postpartum weight and the subsequent postpartum weight. **Association of other factors with weight change:** No other factors were considered.	**Author's conclusions:** Data suggest that there is no evidence that women with an inter-pregnancy interval <18 months have a different weight retention pattern than other women who delay a subsequent conception >24 months. **Comments:** Subtle differences in weight retention patterns between cases and controls would have been difficult to observe because of the sample size. Participants in this study were White, non-smokers with high education levels who may have had a different inter pregnancy interval

		controls with the cases. Paired *t* tests were used to assess the change in weight between the baseline post parturition measure and the subsequent postpartum measure among the cases. Simple linear regression analysis was used to describe any factors that might explain the weight changes between the beginning of the initial or baseline postpartum period and subsequent postpartum measure. The comparison of weight retention patterns for the cases and the controls was evaluated by longitudinal analysis using non-parametric mixed models.		experience than women from more diverse populations.
Linne 2003 Prospective cohort 2+ **Aim:** To examine long-term	1423 Women in Stockholm who delivered children in 1984–85. **Pre-pregnant mean weight:** 59.5 (8.1) kg;	**Year of baseline survey:** 1985 **Duration of follow-up**: 15 years. **Outcome variable**: Change in weight and	**Attrition:** 61% (*n* = 1423) of women eligible (*n* = 2342) completed initial questionnaire and 40% (*n* = 563) participated in 15-year follow-up questionnaire. **Weight changes:** Mean weight increase during pregnancy was 14.1 kg (4.1); 1-year after delivery mean weight increase was 1.5 kg, when corrected for underreporting and general phenomenon of weight increase over time the net mean weight increase induced by pregnancy was 0.5 kg, but range was	Women who participated in the 15-year follow-up had higher income and higher educational attainment than non-responders

weight development after pregnancy. The Stockholm Pregnancy and Women's Nutrition Study – SPAWN Also Ohlin 1994, 1996; Rossner 1995; Linne 2002.	pre-pregnant BMI: 21.5 (2.8) kg/m^2.	BMI. **Self-reported or measured weight:** Self-report and retrospective until after birth then prospective and measured (200 of 563 self-reported weight at 15 years). **Statistical analysis**: *t* test and χ^2 test.	very wide and 1.5% women had retained at least 10 kg. Over 15 years the initially normal weight group increased BMI from 20.7 to 22.3 kg/m^2 and the overweight group (BMI >25 kg/m^2 at 15 years) increased from 23.3 to 28.6 kg/m^2 (t = 0.342, df = 548, p > 0.0001); (women who were overweight at both time points [n = 33] and those who lost weight and regained a BMI in the normal range at 15 years [n = 10] were excluded from analysis). Women who became overweight had a higher pre-pregnant BMI (p > 0.001) and gained more weight during pregnancy (p > 0.001). **Association of diet with weight change:** Women that started to eat more irregularly retained more weight at 1-year postpartum. **Association of physical activity with weight change:** Women that started to exercise less frequently after their pregnancies retained more weight 1-year postpartum. **Association of other factors with weight change: pregnancy** Most important risk factor identified for sustained weight gain/retention 1 year after delivery was weight increase during pregnancy (large variances in weight meant any statistically significant relationships were rather weak at 1-year post delivery so other 1-year results not reported here); No difference between women who became overweight and those who remained normal weight regarding total number of children, number of pregnancies before and after index pregnancy, age at index pregnancy, age at delivery of first child. Features of pregnancy that did not differ between the two groups were total gestational duration, type of delivery, sex and birth weight of child, city of residence, breastfeeding and smoking cessation. Women who became overweight had lower lactation scores (p > 0.05); relatively more subjects of the group that became overweight stopped smoking during pregnancy (p > 0.01).	and national average. No control group of women without children. Impossible to determine if 15-year data represent a linear development over time as not seen since 1-year postpartum. **Author's conclusions:** Pregnancy is a vulnerability factor for some women to become overweight, demographic, behavioural, physical and psychological factors only partly explain the weight gain observed at 15-years follow-up
Olsen 2003 Prospective	622 healthy adult women who gave birth	**Year of baseline survey:** Not reported.	**Attrition:** n/a as analysed completer sample **Weight changes:**	Factors related to excessive gestational

cohort 2+ **Aim:** To evaluate whether potentially modifiable psychological and behavioural factors are related to gestational weight gain and whether the same factors relate to both excessive and insufficient weight gain.	to live singleton infants in a 10-county area of upstate New York, 96% White, rural and socio-economically diverse **Baseline BMI: not stated, mean gestational weight gain: 29.7lb**	**Duration of follow-up**: From early pregnancy until 2 years postpartum. **Outcome variable**: Weight change. **Self-reported or measured weight:** Measured. **Statistical analysis**: Multiple linear and logistic regression with adjustment for timing of measurements and length of gestation.	Mean gestational weight gain = 29.7 (11.7) lb (13.5 [5.3 kg]); high-BMI women were five times more likely than normal BMI women to exceed the top of the range of the Institute of Medicine guidelines. **Association of diet with weight change:** Women who reported eating much more food in pregnancy were 2.35 times more likely than women who ate a little more to gain excessive weight. **Association of physical activity with weight change:** Less PA (OR 1.68; 95% CI 1.1, 2.6) was significantly related to excessive gestational weight gain. **Association of other factors with weight change (please state factors):** Family income of less than 185% of the federal poverty line (OR 2.59; 95% CI 1.6, 4.2) was significantly related to excessive gestational weight gain. Income was not as important an influence on gestational weight gain among women who reported that they increased their food intake (OR 0.33).	weight gain only are reported here. **Adjusted for:** Not clear. **Author's conclusions:** Food intake, PA and smoking accounted for 27% variance in gestational weight gain.
Rosenberg 2003 Prospective cohort 2+ **Aim:** To evaluate the effect of childbearing on weight gain in African American women Participants in Black Women's Health Study.	11,196 African American women parous and nulliparous at baseline who had a singleton birth in 1995 to 1997 and none in 1997 to 1999 or nulliparous from 1995–99 and did not report occurrence of cancer; 9966 remained nulliparous, 598 had first child, 387 primiparous women had	**Year of baseline survey:** 1995 **Duration of follow-up**: 4 years. **Outcome variable**: Weight gain (kg). **Self-reported or measured weight:** Self-report. **Statistical analysis**: Multivariate linear regression (women who remained nulliparous served as comparison group).	**Attrition:** unclear **Weight changes:** BMI increased by 1.6, from 26.5 to 28.1 kg/m^2, equivalent to weight gain 4.4kg BMI 23 kg/m^2 in 1995, BMI change: nulliparous = 1.7, parity 1 = 1.9, parity 2 = 1.8, parity 3+ = 1.8 kg/m^2 BMI 36 kg/m^2 in 1995, BMI change: nulliparous = 1.3, parity 1 = 2.4, parity 2 = 2.1, parity 3+ = 2.1 kg/m^2 **Association of other factors with weight change: parity** Women who had a child during follow-up gained more weight than women who remained nulliparous, and those who had a first child gained more than those who had a second or later child, weight gain associated with childbearing increased with increasing baseline BMI and was appreciable among heavier women	**Adjusted for:** Predicted values of BMI change between 1995 and 1999 for parous and nulliparous women with selected characteristics (25–29 years at baseline, age at menarche 12–13 years, 16 years of education, non-smoker, single, BMI 20–24 kg/m^2 at age

	second child, 245 had third or later child **Baseline BMI: 26.5 kg/m^2**			18, 1–4 hours vigorous activity per week, 1–4 hours TV/videos per day, non-use hormonal contraception, no medication-treated depression. **Author's conclusions: childbearing is an important contributor to weight gain among African-American women.**
CARDIA (Coronary Artery Risk Development in Young Adults) Prospective cohort 2+ **Aim:** To estimate the change in BMI over 10 years in a cohort of young US men and women, and assess differences by a range of	CARDIA is a population based prospective study of 5,115 African American and White men and women in USA aged 18–30 year at baseline. Study population was balanced on: Age (45% 18–24 years) Sex (46% men) Ethnicity (52% African	**Year of baseline survey:** 1985–86 **Duration of follow-up**: Ongoing. **Outcome variable**: Measured. **Statistical analysis**: Various, but all used some form of regression analysis. Women who remained nulliparous (*n* = 925) at 5 years were compared with women who had a single pregnancy and who	**Attrition:** Baseline data were collected on 51% of eligible persons contacted. Overall retention rates were 90% at 2 years, 86% at 5 years, 81% at 7 years, 79% at 10 years, and 74% at 15 years. **Association of other factors with weight change: Pregnancy** **Pregnancy (based on 5-year follow-up of 2788 women at baseline):** Primiparous within both race groups gained 2 or 3 kg more weight during the 5-year period than did nulliparous. Primiparous also had greater increases in waist-to-hip ratio that were independent of weight gain. Multipara did not differ from nulliparous in adiposity change in either race group. **Pregnancy – Black and Minority Ethnic Groups:** At each level of parity, Black women demonstrated greater adverse changes in adiposity than did White women. **Conclusion:** Women experience modest but adverse increases in body weight and fat distribution after a first pregnancy and that these changes are persistent.	All analyses were **adjusted for** covariates: Age Education Smoking status Also adjusted for PA in analysis. Overweight was defined as BMI >25.0 kg/m^2.

variables. Smith 1994 (Pregnancy – based on 5-year follow-up.)	American). No data on income presented in this paper. **Baseline weight (kg) as mean (SD) and overweight (%):** African American women: 69.5 (18.3) kg, 44.7% White women: 63.1 (12.8) kg, 22.1% African American men: 77.5 (15.6) kg, 36.9% White men: 77.1 (12.6) kg, 12.6%.	were at least 12 months postpartum at 5 years.		

1

INDIVIDUAL STUDIES: SMOKING CESSATION				
First author, design, aim	**Population**	**Intervention details, length of follow-up**	**Results**	**Confounders adjusted for/comments**
Williamson (1991) Prospective cohort 2+ **Aim:**	A population sample of US adults who entered NHANES I at ages 25–74 years. Continuing	**Year of baseline survey:** 1971–75 **Duration of follow-up**: About 10 years – follow-up 1982–84.	**Attrition:** Unclear. 9332 of the original 14,407 participants took part in the NHANES 10-year follow-up (attrition of 35%). (But remember that only a sub-sample of this cohort is the subject of this analysis – only continuing smokers and sustained quitters – sample size 2653.) **Mean BMI changes:** Not reported for overall sample.	**Confounders adjusted for:** Age, race, level of education, alcohol use, illnesses related to change in weight, baseline

<table>
<tr>
<td>To evaluate associations between smoking cessation and weight change.</td>
<td>smokers (748 men, 1137 women) and sustained quitters (those who had quit smoking for a year or more – 409 men and 359 women).

Baseline BMI (kg/m^2):
Continuing smokers:
Men: 25.1
Women: 24.0
Sustained quitters:
Men: 25.7
Women: 24.5</td>
<td>**Outcome variable**:
Weight change as a continuous variable and as a categorical variable:
1) Gained 0.0–3.0 kg
2) Gained 3.1–8.0 kg
3) Gained 8.1–13.0 kg
4) Gained 13.1 kg+

Self-reported or measured weight:
Measured.

Statistical analysis:
When BMI change considered as a *continuous* variable: multiple linear regression models.
When BMI change considered as a *categorical* variable: multivariate logistic regression models.</td>
<td>
Association of other factors with weight changes:
1) Mean weight gain attributable to smoking variable (kg) – adjusted for the confounders listed in next column.
<table>
<tr><th></th><th>Continuing smokers</th><th>Sustained quitters</th><th>Difference* (95% CI)</th></tr>
<tr><td>Men</td><td>0.3</td><td>3.1</td><td>**2.8** (2.0, 3.6)</td></tr>
<tr><td>Women</td><td>1.7</td><td>5.5</td><td>**3.8** (2.9, 4.7)</td></tr>
</table>
*Both significantly ($p > 0.05$) greater than 0.0 kg.

2) Smoking and level of weight gain (kg)

a) Percentages (i.e. unadjusted).
<table>
<tr><th></th><th>Continuing smokers</th><th>Sustained quitters</th></tr>
<tr><td>**Men**</td><td></td><td></td></tr>
<tr><td>0.0–3.0 kg</td><td>65.1</td><td>55.8</td></tr>
<tr><td>3.1–8.0 kg</td><td>23.9</td><td>22.0</td></tr>
<tr><td>8.1–13.0 kg</td><td>8.4</td><td>12.5</td></tr>
<tr><td>>13.1 kg</td><td>2.5</td><td>9.8</td></tr>
<tr><td>**Women**</td><td></td><td></td></tr>
<tr><td>0.0–3.0 kg</td><td>62.3</td><td>48.5</td></tr>
<tr><td>3.1–8.0 kg</td><td>23.5</td><td>26.7</td></tr>
<tr><td>8.1–13.0 kg</td><td>9.3</td><td>11.4</td></tr>
<tr><td>>13.1 kg</td><td>4.9</td><td>13.4</td></tr>
</table>
b) Adjusted OR (sustained quitters vs. continuing smokers, all significantly ($p > 0.05$) greater than 1.0).
<table>
<tr><th></th><th colspan="3">Weight gain (kg)</th></tr>
<tr><th></th><th>3.1–8.0</th><th>8.1–13.0</th><th>>13.1</th></tr>
<tr><td>Men</td><td>1.4</td><td>2.6</td><td>8.1</td></tr>
<tr><td>Women</td><td>2.1</td><td>2.5</td><td>5.8</td></tr>
</table>
</td>
<td>weight and PA.

Author's conclusions:
Major weight gain is strongly related to smoking cessation, but occurs in only a minority of those who stop smoking. (The authors note that weight gain is not likely to negate the health benefits of smoking cessation, but may interfere with attempts to quit for cosmetic reasons.)</td>
</tr>
</table>

			Among sustained quitters, factors significantly related to higher odds of major weight gain were: - Being Black (compared with White); - Being underweight at baseline (compared with normal weight, women only – BMI ranges used not stated); - Having smoked >25 cigarettes per day (compared with <15); - *Lower* recreational PA in men; - Higher recreational PA in women; - Being 25–54 years old at baseline (compared with 55–74 years); - Having had one or more live births (compared with none, women). **Summary of results:** Those who have quit smoking for >1 year experienced a greater mean weight gain and were more likely to experience major weight gain than continuing smokers. By the end of the study, however, the mean body weight of those who had quit increased only to that of those who had never smoked.	
Burke 2000 Prospective cohort 2+ **Aim:** To examine the influence of smoking cessation on weight gain in MA.	1930 MA and 1126 NHW aged between 25–64 years of age from low, middle and high-income neighbourhoods in San Antonio, TX, USA. **Baseline BMI or weight:** MA males never smoked (*n* = 457) BMI = 27.8 kg/m^2, quitters (*n* = 102) BMI = 28.5 kg/m^2, continuous smokers (*n* = 178) BMI =	**Year of baseline survey:** 1979 **Duration of follow-up**: 9 years. **Outcome variable**: Weight (kg), BMI. **Self-reported or measured weight:** Measured. **Statistical analysis**: Linear regression.	**Attrition:** MA 42%, NHW 40% **Weight changes:** As a result of smoking cessation, a total of 342 became overweight during follow up (had a BMI <25 kg/m^2 at baseline and a BMI ≥25 and <30 kg/m^2 at follow-up). Of those, 18 (5.3%) were estimated to be attributed to smoking cessation. For MA, 13 of the 196 (6.6%) were estimated to be attributed to smoking cessation. For NHW, 5 of the 146 (3.4%) were estimated to be attributed to smoking cessation ($p > 0.05$). 331 individuals became obese during follow up (BMI <30 kg/m^2 at follow-up); 18 were attributed to smoking cessation. For MA, 12 of 219 (5.5%) were attributed to smoking cessation; for NHW, 6 of the 112 (5.4%) were estimated to be attributed to smoking cessation ($p > 0.05$). A total of 377 individuals became overweight or obese during follow-up (had a BMI <25 kg/m^2 at baseline and BMI ≥25 kg/m^2 at follow-up). Of the 377 21 (5.6%) were attributed to smoking cessation. For MA, 16 of the 216 (7.4%) were estimated to be attributed to smoking cessation, for NHW 5 of the 161 (3.1%) were estimated to be attributed to smoking cessation. This ethnic difference was borderline statistically significant ($p = 0.072$).	**Adjusted for:** Not reported. **Author's conclusions:** There is an ethnic difference in the influence of smoking cessation on weight gain in MA and NHW. Although, in both ethnic groups this effect is quite small and makes only a slight difference and only makes a slight contribution to

	27.5 kg/m^2. MA females never smoked (*n* = 457) BMI = 27.7 kg/m^2, quitters (*n* = 102) BMI = 27.0 kg/m^2, continuous smokers (*n* = 178) BMI = 27.2 kg/m^2 NHW males never smoked (*n* = 457) BMI = 26.8, quitters (*n* = 102) BMI = 25.5 kg/m^2, continuous smokers (*n* = 178) BMI = 26.4 kg/m^2.		**Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** Smoking Overall, the estimated risk of becoming overweight or obese attributable to smoking cessation was only 7.4 % in MA and 3.1% in NHW.	the overall increase in prevalence of obesity in the cohort.
	NHW females never smoked (*n* = 457) BMI = 24.7 kg/m^2, quitters (*n* = 102) BMI = 23.7 kg/m^2, continuous smokers (*n* = 178) BMI = 24.2 kg/m^2.			
The Israeli CORDIS II study	3816 (68.8%) of male employees working in 21 factories in Israel were	**Year of baseline survey:** 1985–87 **Duration of follow-up**: 1988–90. Average	**Attrition:** Difficult to assess. At follow-up in 1988–90 (CORDIS II) only 1338 could be re-examined (many had been made redundant in the interim). Of these, 129 were excluded (missing data), thus *n* = 1209.	Data are presented here only for two groups: QSAE and CS, since

Prospective cohort 2+ **Aim:** To quantify the risk of weight gain after cessation of smoking, the duration of the risk, and the effect of possible moderating variables. **NS**: never smoked **QSBE**: quit smoking before entry to study **QSAE**: quit smoking after entry to study **CS**: current smokers	offered free screening examinations for selected risk factors 1985–87. 68% (*n* = 3816) agreed. These were then subdivided into four groups; NS, QSBE, QSAE, CS. ALL baseline data as mean (SE). QSAE: *n* = 65 CS: *n* = 392 **Age:** QSAE: 40.7 (10.3) years CS: 42.7 (10.9) years **Ethnicity**: (father born in North Africa, Iraq, Iran, Yemen): QSAE: 46.1% CS: 47.4% **Education** (reporting >12 years of education): QSAE: 49.2% CS: 61.0%	follow-up = 2.6 (range 2–4) years. **Outcome variable**: BMI . **Self-reported or measured weight:** Measured. **Statistical analysis**: Multivariate analysis was used to determine the predictive power of a model consisting of all independent variables (smoking status, age, sports activity, education, alcohol consumption, ethnicity, duration of follow-up and BMI at entry) to predict the increase in BMI over the follow-up period.	**Weight changes:** During follow-up, the mean age-adjusted increase in BMI was 0.99 kg/m^2 among QSAE and 0.24 kg/m^2 among CS. QSAE gained weight regardless of age; CS gained less weight with increasing age, and none gained weight after 50 years of age. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** Sports activity was negatively associated with gain in BMI during follow-up. **Association of other factors with weight change:Smoking** No significant interactions were found between **smoking** status and any other variable. Cessation of smoking after entry to study (QSAE) was positively related to an increase in BMI, whereas age, initial BMI, alcohol consumption were negatively associated with gain in BMI during follow-up. Cessation of smoking after entry, age, BMI at entry, and sports activity explained 8.7% of the variance in increase in BMI during follow-up. Further analysis of the QSBE group suggested that the increased rate of weight gain after smoking cessation is transient. However, the weight gained is retained for at least 6 years.	this is most meaningful comparison for this review, i.e. 'what happens when people give up smoking compared with those who do not quit'. **Adjusted for**: All variables included in the model. **Authors' conclusions:** The increased gain of weight gain after smoking cessation is transient. However, the weight gained is retained for at least 6 years.

<table>
<tr>
<td></td>
<td>Exclusion criteria:
None.

Baseline BMI:
QSAE: 25.3 (4.0) kg/m^2
CS: 25.4 (3.8) kg/m^2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wing 1991

Prospective cohort
2+

Healthy Women Study. (two papers).

Three main aims:
1) To describe the weight changes that occurs in a sample of healthy women at time of menopause;

2) To determine whether change in weight is related to change in coronary heart disease risk factors during</td>
<td>Wing 1991
485 women aged between 42 and 50 years old and menstruated within the past 3 months, had no surgical menopause, a diastolic blood pressure less than 100 mmHg, and not to be taking lipid-lowering drugs, insulin, thyroid medication, estrogens, antihypertensive drugs or psychotropic drugs.

Baseline BMI/weight:
See results table.

Burnette 1998</td>
<td>Year of baseline survey:
1983–84

Duration of follow up:
3–4 years (depending on when baseline measurements were taken for Wing, 2 years for Burnette).

Outcome variable:
Weight (kg, lb) and BMI.

Self-reported or measured weight:
Measured.

Statistical analysis:
Regression analyses (Wing) chi square (Burnette).</td>
<td>Wing 1991
Attrition:
11%

Weight changes:
Women gained a mean of 2.25 kg during follow up. The SD for weight gain was 4.19 kg with a range from a 14.85 kg loss to a 32.4 kg gain. 20% of the women gained ≥4.5 kg, while only 3% lost ≥4.5 kg.

The table below shows changes in weight, BMI and skinfold thicknesses in premenopausal, perimenopausal and postmenopausal women:

<table>
<tr><th>Measurement</th><th>Premenopausal</th><th>Perimenopausal</th><th>Postmenopausal</th></tr>
<tr><td>Baseline weight (kg)</td><td>64.8 ± 11.9</td><td>67.2 ± 12.6</td><td>68.8 ± 13.9</td></tr>
<tr><td>Change in weight (kg)</td><td>2.1 ± 4.1</td><td>2.5 ± 3.3</td><td>1.4 ± 4.9</td></tr>
<tr><td>BMI at baseline (kg/m^2)</td><td>24.34 ± 4.17</td><td>24.85 ± 4.62</td><td>26.01 ± 5.33</td></tr>
<tr><td>Change in BMI (kg/m^2)</td><td>1.09 ± 1.63</td><td>1.29 ± 1.28</td><td>0.98 ± 1.95</td></tr>
<tr><td>Triceps skinfold thickness at entry (mm)</td><td>24.8 ± 7.3</td><td>25.1 ± 7.1</td><td>26.0 ± 7.7</td></tr>
<tr><td>Change in triceps skinfold thickness (mm)</td><td>2.9 ± 8.0</td><td>2.6 ± 7.1</td><td>3.2 ± 8.3</td></tr>
</table>

From the table, it is possible to see there were no significant differences in weight gain of women who remained pre menopausal and those who had a natural menopause (2.07 vs. 1.35 kg).

Association of diet with weight change:
No analysis.</td>
<td>Adjusted for:
Not reported.

Author's conclusions (Wing):
Weight gain is a common occurrence for women at menopause.

Author's conclusions: (Burnette)
Smoking cessation in perimenopausal to postmenopausal women is associated with greater weight gain but appears to be modestly associated with certain positive changes in cardiovascular risk factors.</td>
</tr>
</table>

the menopausal period; 3) To identify specific variables associated with weight gain to help determine which individuals are at risk of gaining weight at menopause. **Burnette 1998** **Aim:** To investigate the relationship between smoking cessation, subsequent weight gain and cardiovascular disease risk factors from pre-menopause to post-menopause.	541 menopausal women from Pittsburgh who were non smokers, ex-smokers or smokers. **Baseline BMI or weight:** Non-smokers mean weight 147.08 ± 27.72 lb (66.7 ± 12.6 kg); all smokers mean weight 143.67 ± 30.51 lb (65.1 ± 13.8 kg); smokers who continued through second year post-menopause mean weight 143.81 ± 30.46 lb (65.2 ± 13.8 kg); smokers who reported quitting at years 1 and 2 post-menopause mean weight 143.09 ± 31.18 lb (65.3 ± 14.1 kg).		**Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** *Hormone therapy:* Women who took hormone therapy appeared to be greater than that seen in other groups. These women had significant increases in weight (*p* > 0.0001), BMI (*p* > 0.0001), triceps skinfold thickness (*p* > 0.0001) and suprailiac skinfold thickness (*p* > 0.05). *Smoking:* In non-smokers (*n* = 339) the mean weight gain during the 3 years of follow up was 2.12 ± 4.05 kg. Weight gain in women who were premenopausal (*n* = 202) averaged 2.21 kg; in those who were perimenopausal (*n* = 67), weight gain averaged 2.30 kg; in postmenopausal women at follow-up (*n* = 33), weight gain averaged 0.63 kg. Women who took hormone therapy (*n* = 20) gained 2.30 kg and those who had never had a hysterectomy (*n* = 17) gained 3.11 kg. Changes over time were significant (*p* > 0.0001), although they did not significantly differ among the various menopausal statuses of women. **Burnette 1998** **Attrition:** 8% **Weight changes:** *First year post-menopause:* Significant group effects were found for weight; after-baseline quitters gained significantly more weight (*n* = 28, mean 11.36 lb [5.2 kg]) than non-smokers (*n* = 297, mean 5.32 lb [2.4 kg]) and continuing smokers (*n* = 91, mean 5.45 lb [2.5 kg]). *Second-year post-menopause*: After baseline quitters experienced significantly greater weight gain (*n* = 26, mean 14.43 lb [6.5 kg]) than non-smokers (*n* = 265, mean = 7.69 lb [3.5 kg]). **Association of other factors with weight change: Smoking** NB: Quitters had significantly greater decrease in alcohol consumption than non-smokers and continuing smokers.	
Kawachi 1996	121,700 US women aged	**Year of baseline survey:**	**Attrition:** 15,197 of 24,503 women excluded due to incomplete data leaving 9306	**Adjusted for:** Adjusted

Prospective cohort 2+ **Aim:** To examine whether exercise can modify weight gain after smoking cessation in women. Nurses Health Study (evaluated every 2 years since 1976).	40–75 years (excluded women with history of myocardial infarction, stroke, diabetes, cancer, or who were pregnant or reported extreme levels of exercise). **Baseline BMI: 64-67kg** **Weight**: 64.1–67.3 kg.	1986 **Duration of follow-up**: 2 years. **Outcome variable**: Weight change (kg). **Self-reported or measured weight;** Self-report. **Statistical analysis:** Multiple linear regression to assess impact of PA on post cessation weight gain (excluded 198 women who quit smoking and reduced level of exercise plus 2684 women who continued smoking but change their exercise habits).	analysed; 1474 of 9306 women (15.8%) stopped smoking 1986–88. **Weight changes:** Excess 2.4 kg weight gain associated with smoking cessation. **Association of diet with weight change:** Neither baseline total energy intake nor energy-adjusted fat intake predicted baseline weight or weight change. **Association of physical activity with weight change:** Values are for hypothetical women with same average characteristics as cohort (52 years, 1.6 m high, total daily energy intake 1740 kcals) compared with women who continued smoking without altering their exercise habits (*n* = 5148). No change in PA *n* = 898 smoking 1–24 cigarettes per day in 1986 = 2.3 kg (95% CI 1.9, 2.6) 25 cigarettes per day or more = 4.5 kg (95% CI 3.9, 5.2). Increase by 8–16 METs per week, *n* = 169 smoking 1–24 cigarettes per day in 1986 = 1.8 kg (95% CI 1.0, 2.5) 25 cigarettes per day or more = 3.9 kg (95% CI 2.5, 5.3) Increase by >16 METs per week, *n* = 2091 smoking 24 cigarettes per day in 1986 = 1.3 kg (95% CI 0.7, 1.9) 25 cigarettes per day or more = 2.9 kg (95% CI 1.5, 4.3)	increase in weight from 1986–88 among women who stopped smoking, by level of smoking in 1986 and change in PA between 1986–88 adjusted for age, height, baseline weight, weight change during 2 years before baseline, baseline total energy intake, energy-adjusted baseline fat and alcohol intake, personal history of hypertension of high serum cholesterol. **Author's conclusions:** Weight gain is minimised if smoking cessation is accompanied with moderate increase in levels of PA.
Swan 1995 Prospective cohort 2+	Men from the National Academy of Sciences – National	**Year of baseline survey:** 1967–69 **Duration of follow-up**:	**Attrition:** Non-response rate: 22% at baseline; 34% at follow-up. **1) Effect of smoking category on weight change**	The authors report only unadjusted values, as overall results

<table>
<tr>
<td>Aim:
To determine characteristics of individuals that were predictive of excessive weight gain after smoking cessation.</td>
<td>Research Council Twin Registry, USA – recruited into the armed forces during World War II.

<i>n</i> (total) = 6593
<i>n</i> (quitters subsample) = 2 179

Also included subsample of 146 monozygote twin pairs and 111 dizygote twin pairs.

Mean age 46.3 years at baseline.

Baseline BMI:
Mean 24.7 kg/m^2.</td>
<td>16 years.

Outcome variable:
Mean weight change (kg) and weight loss category.
Weight loss = lost >2.3 kg.
Stable weight = gained or lost 2.3 kg or less.
Weight gain = +2.4 to +11.2 kg.
Excessive weight gain = +11.3 kg or more.

Self-reported or measured weight:
Self-reported.

Statistical analysis:
Analysis of variance unless otherwise stated.

Twin concordance rate defined as <i>C/(C+D)</i> where <i>C</i> is the number of pairs concordant for weight change (i.e. in the same category) and <i>D</i> is the number of discordant pairs. Difference between monozygote and dizygote concordance rate tested by a one-sided <i>z</i> test of the proportions.</td>
<td>a) as a continuous variable (<i>p</i> value not stated)
<table>
<tr><th>Smoking category</th><th><i>n</i></th><th>Mean (SD) weight change (kg)</th></tr>
<tr><td>Quitters</td><td>2179</td><td>+3.5 (6.9)</td></tr>
<tr><td>Continuing smokers</td><td>1569</td><td>+0.9 (6.8)</td></tr>
<tr><td>Continuing non-smokers</td><td>2751</td><td>+1.1 (5.7)</td></tr>
<tr><td>New smokers</td><td>94</td><td>Not reported</td></tr>
</table>
b) as a categorical variable (%) (chi-squared <i>p</i> > 0.001)
<table>
<tr><th>Smoking category</th><th>Weight loss</th><th>Stable weight</th><th>Weight gain</th><th>Excessive weight gain</th></tr>
<tr><td>Quitters</td><td>15</td><td>33</td><td>39</td><td>13</td></tr>
<tr><td>Continuing smokers</td><td>21</td><td>45</td><td>30</td><td>4</td></tr>
<tr><td>Continuing non-smokers</td><td>23</td><td>42</td><td>29</td><td>6</td></tr>
</table>
2) Analysis of quitters: comparison of super-gainers and stable weight group

a) at baseline

Super-gainers:
• Were slightly younger (45.9 vs. 46.5 years);
• Were of lower SES (rank 66.2 vs. 71.2);
• Started smoking at a younger age (17.6 vs. 18.7 years);
• Were heavier smokers (26.6 vs. 23.0 cigarettes per day);
• Were slightly less physically active (rank 3.3 vs. 3.7);
• Drank more coffee (4.3 vs. 3.8 cups per day);
• And ate slightly fewer pastries (1.5 vs. 1.6 per day).
At baseline than those in the stable weight category (<i>p</i> > 0.05).

No significant effects for:
• BMI at age 25 years;
• BMI at baseline;
• alcohol consumption;</td>
<td>did not change with adjustment for age, SES and baseline weight.

Author’s conclusions:
Super-gainers differ in important ways from those who do not gain weight after smoking cessation. These weight changes may be partly influenced by genetic factors.</td>
</tr>
</table>

			• frequency of candy per day; • dieting. **b) at follow-up** Super-gainers were more likely: • to be single (15 vs. 10%) • to report having to diet to keep weight low (53 vs. 28%) at follow-up than those in the stable weight category ($p > 0.05$). No significant effects for retirement status or presence of cardiovascular disease. **c) changes in behaviours from baseline** Super-gainers: • reported a smaller increase in wine consumption (3.3 vs. 6.2 drinks per month) but a larger increase in liquor consumption (15.2 vs. 7.9 drinks per month) • reported a larger increase in candy consumption (0.1 vs. 0.0 pieces per day) from baseline to follow-up than those in the stable weight category ($p > 0.05$). No significant effects for change in beer, coffee or pastry consumption. **3) Twin concordance for weight change amongst quitters** Concordance rates for weight gain were 53% for monozygote twins and 38% for dizygote twins (p for difference <0.05). Concordance rates for weight loss were 46% (monozygote) and 27% (dizygote) (p for difference <0.05). **Summary of results:** • Quitters were more likely to experience weight gain of 2.3 kg or more, and less likely to experience weight loss, than continuing smokers and non-smokers. • Amongst quitters, super-gainers were younger, of SES, and differed on a number of health habits before quitting. At follow-up, super-gainers reported changes in health habits significantly different from those with stable weight.	

			- Pairwise concordance for weight change amongst quitters was significantly higher for monozygotes than for dizygote twins.	

<table>
<tr><th colspan="5">INDIVIDUAL STUDIES: FAMILIES/AGE</th></tr>
<tr><th>First author, design, aim</th><th>Population</th><th>Intervention details, length of follow-up</th><th>Results</th><th>Confounders adjusted for/Comments</th></tr>
<tr>
<td>Tremblay 1998

Prospective cohort
2+

Aim:
To evaluate changes in participation in PA and in fat and alcohol intake with increasing age.</td>
<td>207 adults (103 males, 104 females; mean age 42.3 years (SD 4.9) at baseline) and their offspring (60 males, 62 females; mean age 12.5 (SD 1.9) years at baseline). All participants of Quebec Family Study, Canada.

Baseline BMI:
Not stated. Baseline weights in kg – mean (SD):
Male adults: 74.6 (11.4)
Female adults: 58.0 (8.6)
Male offspring: 43.2 (12.0)
Female offspring: 41.1 (9.8).</td>
<td>Year of baseline survey:
1978–82

Duration of follow-up:
Average 12 years. Follow-up phase was 1989–94.

Outcome variable:
Mean weight changes (kg) and mean changes in sum of skinfold thicknesses (mm).

Self-reported or measured weight:
Not stated. Skinfold thicknesses measured.

Statistical analysis:
Significant change was tested using paired <i>t</i> test. To assess effects of sex, repeated measures ANOVA.</td>
<td>Attrition:
Not stated.

Mean changes (all significant increases, <i>p</i> > 0.01):

<table>
<tr><th></th><th colspan="2">Parents</th><th colspan="2">Offspring</th></tr>
<tr><th></th><th>Males</th><th>Females</th><th>Males</th><th>Females</th></tr>
<tr><td>Weight changes (kg): mean (SD)</td><td>+2.4
(5.9)</td><td>+4.9
(5.8)</td><td>+29.3
(10.9)</td><td>+16.8
(10.7)</td></tr>
<tr><td>Changes in sum of skinfold thicknesses (mm): mean (SD)</td><td>+15.3
(10.9)</td><td>+35.8
(10.7)</td><td>+21.0
(21.5)</td><td>+27.0
(26.9)</td></tr>
</table>

Before and after values of body weight and skinfold thicknesses were significantly and positively correlated in all groups.

Adult women displayed significantly greater mean increases in body weight and sum of skinfold thicknesses than adult men (<i>p</i> > 0.01).

Association of other factors with weight changes:
Male offspring increased their body weight to a greater extent than females (<i>p</i> > 0.01). Sex differences in offsprings' changes in skinfold thicknesses not mentioned so presumably non-significant (large SDs).

Summary of results:
Body weight and skinfold thickness increased over time in all groups and there were some differences in the size of these increases by sex.</td>
<td>No confounders adjusted for.

Author's conclusions:
The authors note that body weight and skinfold thicknesses increased with age in spite of changes in dietary intake and PA which are commonly thought to facilitate the control of fat balance – suggests strong effect of age-related factors on fat balance.</td>
</tr>
</table>

INDIVIDUAL STUDIES: MARITAL STATUS

First author, design, aim	Population	Intervention details, length of follow-up	Results	Confounders adjusted for/comments
Rauschenbach 1995 Prospective cohort 2+ **Aim:** To evaluate the influence of change in marital status on weight change over 1 year. The National Survey of Personal Health Practices and Consequences – telephone survey.	2436 adults within the US, mean age 39, modal income group US$15,000 to $24,000. **Baseline BMI: not reported**	**Year of baseline survey:** 1979–80 **Duration of follow-up**: 1 year. **Outcome variable**: Weight change. **Self-reported or measured weight:** Self-report. **Statistical analysis:** Regression analysis of weight change and regression analysis of weight at follow-up controlling for baseline weight (not reported as similar to initial analysis) three models – weight change, weight gain and weight loss.	**Attrition:** 81% participated at 1-year follow-up (excluded those with inconsistent height data at follow-up). **Weight changes:** Mean weight change in men was 1.38 (9.94) lb (0.6 [4.5 kg] and 1.26 (10.52) lb (0.8 [4.8] kg), 44% of both men and women gained weight. **Association of other factors with weight change: Marital status** Nineteen men became unmarried and 46 became married; 37 women became unmarried and 33 became married. Women who entered marriage had greater weight change than women who remained married, for men there were no statistically significant relationships between marital change and weight change. In the model to predict weight change none of the interactions were significant; in the model to predict weight gain none of the interactions were significant for women but for men the interaction of education with becoming unmarried was significant (*p* = 0.024) and associated with greater weight gain in more educated that become unmarried.	**Adjusted for:** Age, race, education, family income, children, metropolitan residence; and in model to predict weight change also adjusted for interaction of education, family income and age with change in marital status. **Author's conclusions:** Results suggest gender differences in rate of body weight change after marriage.

1

INDIVIDUAL STUDIES: OCCUPATION- AND WORK-BASED COHORTS

First author, design, aim	Population	Intervention details, length of follow-up	Results	Confounders adjusted for/comments
Bazzano 2005 Prospective cohort	17,881 US male physicians aged 40 to 82, and free from cardiovascular disease,	Year of baseline survey: 1982 Duration of follow-up: 8 and 13 years	Attrition: 17% Association of diet with weight change: Dietary data were from the Semi-quantitative Food Frequency Questionnaire (SFFQ) and breakfast cereals were classified as either whole	Adjusted for: Age, baseline BMI, alcohol, PA, smoking, histories of hypertension

Aim: To examine the association between whole and refined grain cereals with risk of overweight and weight gain.	diabetes and cancer. Subjects were from the Physicians Health Study which s a completed randomised control trial of aspirin and β-carotene in the prevention of cardiovascular disease and cancer (n = 21,431).	Outcome variable: BMI Self-reported or measured weight: Self-report. Statistical analysis: Various, but all used some form of regression analysis.	or refined grain. Men consuming ≥1 serving per day weighed less than those never or rarely consuming cereals. The trends at 8 and at 13 years were both significant (p-value for trend = 0.001). Men who ate ≥1 serving per day were 22% and 12% less likely to become overweight at 8 and 13 years respectively, compared with men who never/rarely ate cereals; relative risk 0.78; (95 CI 0.67, 0.91) and 0.88; (95 CI 0.76,1.00) respectively.	and high cholesterol and vitamin use. Author's conclusions: **BMI and weight gain were inversely associated with intake of breakfast cereals independently of other risk factors.**
Field 2001 NHS II **Design:** Prospective cohort. **Aim:** To assess the prevalence of clinically significant weight loss among women and whether this is associated with smaller long term weight gains. Secondary to this, the study	A total of 47,515 women from the Nurses Health Study II.	**Year of baseline examination and questionnaire:** 1989 **Duration of follow-up:** 6 years 1989–95 **Outcome variable:** Weight gain (kg) **Self-reported or measured:** Self-reported weights in 1989, 1991, 1993 and 1995, dietary intake, PA, inactivity, history of weight cycling and smoking. **Statistical analysis:** Focused on two main	**Attrition:** Not mentioned. **Weight changes:** During a 2 year period from 1989 to 1991, 2590 (5.5%) women lost 5–9.9% of their 1989 weight and 1326 (2.8%) women lost at least 10% of their 1989 weight. The proportion of women who lost >5% of their baseline weight increased with category of BMI from 3% (5–9.9% weight loss) among women with a BMI <22 to 9% among women with a BMI >30 kg/m^2 in 1989. Between 1991 and 1995, approximately 50% of the women had regained all of the weight they had lost. Among those women who had lost >10% of their 1989 weight, the percentage who regained all of their large weight loss between 1989 and 1991 decreased across baseline categories of BMI from 71% among the women with a BMI <22 kg/m^2 to 54% among the women with a BMI >30 kg/m^2 in 1989. Less than 10% of the women who had large clinically significant weight loss between 1989 and 1991 were able to successfully maintain their weight loss.	**Adjusted for:** Age, smoking, BMI at age 18, weight gain from age 18 to 1989, dietary intake, hours per week of vigorous activity, inactivity and history of weight cycling. **Author's conclusions:** Although few women can completely maintain weight losses, women should not be discouraged

aimed to assess factors associated with weight change over time.		outcomes, weight change and weight loss maintenance. – Linear regression analysis was used to assess whether women who had clinically significant weight loss between 1989 and 1991 had different weight change patterns to their peers. Logistic regression was used to determine whether other factors measured, or the amount of weight lost between 1989 and 1991, predicted successful weight maintenance from 1991 to 1995.	Regardless of the definition of weight maintenance, baseline category of BMI was inversely associated with successful weight loss maintenance. Women who lost greater than or equal to 10% of their weight between 1989 and 1991 gained more weight between 1991 and 1995 than their peers who did not lose weight. **Weight maintenance:** In further analysis limited to a subset of women who had clinically significant weight loss between 1989 and 1991, results showed that the more weight a women lost between 1989 and 1991, the more likely she was to maintain that loss between 1991 and 1995. Each 10 lb (4.5 kg) weight loss approximately doubled the probability that women would maintain her weight loss. History of weight cycling between the ages of 18 and 30 years reduced this likelihood. Severe weight cyclers were approximately 40% less likely to maintain their weight loss and mild weight cyclers 20% less likely. There was no association between inactivity or intake of total energy from dietary fat; however, hours engaged in vigorous activity was a significant predictor of weight loss maintenance between 1991 and 1995. Each hour of vigorous activity increased the likelihood of maintaining the weight over 4 years by 7%. **Association of diet with weight change:** Dietary intake during the years 1990–91 was modestly associated with subsequent weight change from 1991 to 1995. Energy intake had a modest positive association with weight gain, whereas, alcohol intake was associated with less weight gain **Association of physical activity with weight change:** Vigorous PA was protective against weight gain. Women who engaged in ≥5 hours per week of vigorous activity gained approximately 0.5 kg less than their inactive peers between 1989 and 1995. Total hours of activity per week (including walking) was not associated with weight change.	from attempting to lose weight since it was observed that women who had a clinically significant weight loss gained less weight than their peers over the 6-year period of the study. Data support the importance of PA as an effective means to prevent weight gain. Data also suggest that weight maintenance and weight gain prevention efforts should be targeted at young adults since BMI at age 18, weight gain from age 18 to 1989 and history of weight cycling between the ages of 18 and 30 years were all independently

			Physical inactivity was associated with weight change. For each 10 hours per week a women spent sitting at home or at work, she gained approximately 0.11 kg more than her less inactive peers. **Association of other factors with weight change:** BMI at age 18 years and weight change during early adult life were predictive of weight gain. Each one unit difference in BMI at age 18 years was associated with gaining an additional 0.32 kg between 1989 and 1995. This association was slightly attenuated when a history of weight cycling between the ages of 18 and 30 years was entered into the statistical model.	predictive of adult weight gain.
Hannerz 2004 Prospective cohort **Aim:** To explore whether factors related to the work environment could predict changes in BMI and whether the effects of psychosocial factors was dependent on baseline BMI.	Of the 2603 potential study participants, 1980 male employees from the Danish National Work Environment Cohort Study were observed during analysis. **Baseline BMI (kg/m^2):** <20 *n* = 59 20–24 *n* = 1,111 25–29 *n* = 692 >30 *n* = 118	**Year of baseline examination and questionnaire:** 1990 **Duration of follow-up:** 10 years, 1990–2000. **Outcome variable:** The change in BMI between the calendar years 1995–2000. **Self-reported or measured weight:** Self-reported over during a telephone interview, i.e. 'what is your weight? **Statistical analysis:** The change in BMI, as a function of a series of background variables and a series of occupational variables, were analysed by multiple linear	**Attrition:** Not mentioned. **Weight changes:** Among the background variables, age ($p \leq 0.0001$) and baseline BMI ($p \leq 0$ 0003) were statistically significant, and the estimates indicated that the tendency to gain weight decreases with age and BMI. Job security was the only significant occupational variable ($p = 0.157$). Among the psychological variables, that only ones that interacted significantly with baseline BMI were psychological demand ($p = 0.0108$) and job insecurity ($p = 0.0027$). Obese employees with job insecurity gained more weight than obese employees without job insecurity, whereas underweight employees with job insecurity gained less weight than underweight employees without job insecurity. The background variables explained 4.8% of the variation in BMI changes. The model, which incorporated all main effects, explained 5.8%, whereas the model that also included significant interaction effects between psychological factors and baseline BMI explained 7.3%. **Association of diet with weight change:** No such relationships were included. **Association of physical activity with weight change:** PA at work was included in the analysis yet it wasn't statistically significant for predicting changes in BMI ($p = 0.0674$). **Association of other factors with weight change**:	**Adjusted for:** Not stated. **Author's conclusions:** Age, baseline BMI, job insecurity, and psychological demands predict changes in BMI. Job insecurity and high or low psychological demands increase the likelihood of weight gain among obese employees, whereas they increase the likelihood of weight loss among employees with a low BMI.

		regression. In the first model, all of the selected variables were jointly analysed for main effects. In a second model, significant two-way interactions between baseline BMI and psychosocial variables were included. **Background variables:** Age, cohabitation, smoking status and baseline BMI. **Occupational variables:** Long working hours, irregular working hours, PA at work, cold work environment, hot work environment, decision authority, psychological demands, possibilities to communicate with colleagues, conflicts at work and job insecurity.	No other mentioned.	**Comments:** All measures were self-reported and so when it comes to the work-environment variables it is possible that different individuals might have perceived the same objective exposure differently.
Morris 1992 Prospective cohort study (British Regional heart Study). **Aim:**	**Setting:** One general practice in 24 towns in Britain. 6057 men aged 40–59 years who had been continuously	**Year of baseline examination and questionnaire:** 1978–80. **Duration of follow-up:** 5 years (1983–85).	**Attrition:** 7112 men were screened for participation yet 6057 were eligible for inclusion based upon the fact that they had experienced no unemployment in the previous 5 years. **Weight changes:** At initial screening, the mean BMI of men who remained employed was similar to that of men who experienced some non-employment later (25.52 vs. 25.40 kg/m^2, respectively) However, men who later became non-	**Adjusted for:** Age, social class and town of residence **Author's conclusions:** In this group of British middle-

To assess the effect of unemployment and early retirement on cigarette smoking, alcohol consumption, and body weight in middle aged British men.	employed for five years before the initial screening. The men were placed into employment groups based on their employment experience over the five years after screening. 4412 men had been continuously employed (mean BMI = 25.52 kg/ m^2) and 1645 had experienced some unemployment or retired (mean BMI = 25.40 kg/ m^2).	**Outcome variable:** BMI, number of cigarettes smoked and units of alcohol consumed per week. **Self-reported or measured weight:** Self-reported via a standard questionnaire, which included questions on occupational history, employment status, smoking habits, alcohol intake and usual patterns of PA. **Statistical analysis:** The adjusted proportions were calculated by fitting logistic regression models and by using the marginal prediction method described by Wilcosky and Chambless Changes in weight were analysed by fitting a nominal polytomous regression model on the six separate weight change categories.	employed were more likely to be underweight compared with men who remained employed (3.8 vs. 2.7%; 95% CI of the difference 0.1, 2.2). Five years later the mean BMI had risen slightly in both men who had experienced some non-employment (25.40 to 25.71 kg/m^2) and in men who had not (25.52 to 25.77 kg/m^2). The percentage of men who were underweight had fallen 2.7 to 2.0% in men who were employed and 3.8 to 2.3% in men who had experienced unemployment) and the percentage of men who were overweight had risen (8.1 to 8.4% in employed men and 7.9 to 9.4% in men who had experienced non-employment). Men who experienced some non-employment were less likely to remain a stable weight than men who remained continuously employed. 2.9% of men who experienced some non-employment lost more than 10% in weight and 7.5% gained more than 10% in weight compared with 2.1% and 5.0% respectively of continuously employed men (95% CI of the difference 0.1, 1.8 for weight loss and 0.9, 4.0 for gain). There was a strong association between cigarette smoking and BMI, with an increase in BMI occurring on stopping smoking. Excluding men who stopped smoking from the analysis reduced the percentage of men who gained more than 10% in weight. However, non-employed men were still significantly more likely to gain more than 10% in weight than men who remained continuously employed. **Association of diet with weight change:** No dietary analysis as such took place. **Association of physical activity with weight change:** Men who later became non-employed were significantly more likely to be inactive compared with men who remained employed (39.4 vs. 36.7%; 95% CI of the difference 0.1, 5.7). Only men retired for reasons other than illness were significantly less likely to be inactive than continuously employed men (31.6% were inactive; 95% CI 0.4, 0.8). **Association of other factors with weight change:** *Smoking:* At initial screening, compared with men who remained employed men who later became non employed were more likely to be current smokers (43% vs. 37%, respectively; 95% CI of the difference 3.2, 9.0) and	aged men the only evidence of those who experienced non-employment adopting behaviour detrimental to their future health was the increased propensity to gain a large amount of weight (>10%) This was not detected if only mean weight change was analysed. The high levels of smoking and alcohol consumption observed in non-employed men was due to these men being more likely to be heavy smokers and drinkers before the non-employment occurred. There was a strong association

			to be heavy smokers (15.5% vs. 13.1%; 95% CI 0.4, 4.7) They were also more likely to have smoked at some time (22.1 vs. 26.3% who remained employed never smoked; 95% CI 1.5, 6.7). Five years later the level of smoking had fallen: 26.8% of smokers had stopped smoking and only 44.6% of heavy smokers still smoked heavily. Overall men who had experienced some unemployment were still more likely to be current smokers than men who had remained continuously employed (33.0% vs. 29.3% respectively; 95% CI 1, 6.5), but they were no longer more likely to be heavy smokers (7.5 vs. 8.1%; 95% CI 2.1, 1.0). The main changes occurred in men who stated their non-employment was due to illness, with the percentage of heavy smokers falling from 23.6% to 5.8% for men unemployed through illness and from 16.0% to 3.1% for those retired through ill health. *Alcohol:* At initial screening, men who later became non-employed were more likely to be heavy drinkers (12.1%) compared with men who remained employed (9%; 95% CI of the difference 1.3, 5.1). Overall, the percentage of non-drinkers was similar among men who later became non-employed and those who remained employed (5.4 and 5.6%, respectively; 95% CI 1.25, 1.5). Five years later, the percentage of heavy drinkers had fallen (9.0 to 3.0% for men who were continuously employed and 12.1 to 4.1% of men who were non-continuously employed) and the percentage of non-drinkers had risen (5.6 to 8.4% in the employed group and 5.4 to 10.8% in the unemployed group). Overall, only 10.7% of men reported increasing their alcohol consumption compared with 36.9% who reported reducing their consumption.	between illness, unemployment, and changes in body weight, alcohol consumption, and cigarette smoking. The men who stated that their non-employment was due to illness were much more likely to lose weight and to reduce their levels of smoking and drinking than both non-employed men and men remaining continuously employed. **Comments:** The study did not comment on financial pressure that may have lead to the reductions in alcohol consumption.
He 2004 Prospective cohort	In 1976, 121,700 female registered nurses aged	**Year of baseline survey:** 1984 (In this paper, 1984 was considered	**Attrition:** 61% of those who took part in the study in 1976 were included in this analysis.	**Adjusted for:** Covariates stated in statistical

2+ Nurses Health Study: this paper focuses on fruit and vegetable consumption. **Aim:** To estimate the change in BMI over 12 years in a cohort of female nurses, dependent on change (not baseline) in fruit and vegetable consumption over the same time period.	30–55 years from 11 US states responded to a mailed questionnaire. 12-year follow-up. Questionnaire was mailed every other year. Analysis for this paper *n* = 74,063 female nurses aged 38–63 at baseline in 1984. This represented approx 61 % of those who were included in the study at 1976, but unclear how many nurses were originally invited to take part in 1976. **Exclusion criteria:** Cardiovascular disease, cancer, diabetes, incomplete information on questionnaire	as baseline since the expanded food frequency questionnaire [FFQ] was used that year.) **Duration of follow-up**: 12 years. **Outcome variable**: BMI. **Self-reported or measured weight:** Self-report. **Statistical analysis**: Change in intake of fruits and vegetables was ranked from largest decrease to largest increase during the 12-year follow-up period and quintiles of this variable were used in the analysis. ORs were computed using logistic regression models. Multivariate ORs were estimated by simultaneously adjusting for age, year of follow-up, change in PA, change in smoking status, baseline BMI, change in alcohol consumption and caffeine intake, change in hormone replacement therapy, and changes in energy	**Weight changes**: Not reported separately **Association of diet with weight change:** During the 12-year follow-up, participants tended to gain weight with age, but those with the largest increase in fruits and vegetables had a 24% lower risk of becoming obese compared with those who had the largest decrease in intake. OR 0.76 (95% CI 0.69, 0.86), *p* for trend <0.0001. Similar results were observed for changes of fruits and vegetables separately.	analysis. **Author's conclusions:** Increasing intake of fruits and vegetables may reduce long-term risk of obesity and weight gain among middle-aged women.

	(e.g. no data on body weight) or implausible information (e.g. total daily energy intake (TDEI) <600 or >3500 kcal [<2.51 MJ or >14.6 MJ]) **Baseline BMI, mean (SD):** 24.9 (5) kg/m^2	adjusted intakes of saturated fat, polyunsaturated fat, monounsaturated fat, trans-unsaturated fatty acid, protein, and TDEI. The median values of quintiles of changes in fruit and vegetable intake were used as a continuous variable for the tests for linear trend. To estimate the mean difference of changes in BMI by category of fruits and vegetables, general linear models with least-square means was used.		
Schulze 2004 Prospective cohort 2+ **Aim:** To examine the relationships between sugar-sweetened beverage consumption and weight and its links to type 2 diabetes in a cohort of young and middle-	51,603 female nurses from the USA, aged 24 to 44 years were used as subjects. Women were excluded if they did not complete a dietary questionnaire or if subjects reported dietary intake was implausible with regard to total	**Year of baseline survey:** 1991 **Duration of follow up:** 8 years. **Outcome variable:** Weight (kg) and BMI (kg/m^2). **Self-reported or measured weight:** Self-reported. **Statistical analysis:** Difficult to assess. Means calculated for	**Attrition:** 44 % (116,671 recruited at initiation, 51,603 left for analysis). **Weight changes:** Mean change in BMI was 0.49 kg/m^2 for 1991–95 and 0.05 kg/m^2 between 1995–99). **Association of diet with weight change:** From 1991–95 and 1995–99, women who increased their intake of sugar sweetened soft drinks from low to high had significantly larger increases in weight (4.69 kg during 1991–95 and 4.20 kg during 1995–99) and BMI (1.72 kg/m^2 during 1991–95 and 1.53 kg/m^2 during 1995–99) than women who maintained a low or a high intake or significantly reduced their intake ($p > 0.01$). The lowest weight gain and increase in BMI were observed among the women who reduced intake from high to low (1.34 kg in 1991–95 and 0.15 kg during 1995–99.	**Adjusted for:** Age, alcohol, PA, smoking, BMI, other lifestyle and dietary confounders at baseline **Author's conclusions**: A higher intake of sugar-sweetened beverages is associated with a greater magnitude of weight gain and

aged women.	energy intake (i.e. <500 kcal/d or >3500 kcal/d [<2.09 MJ or >14.64 MJ]); if they had history of diabetes, cancer, cardiovascular disease at baseline or if they had not provided data on PA in 1991.	the mean weight changes in groups. Cox proportional hazards analysis was used.	Those who increased consumption of fruit punch from one drink or less per week in 1991 to 1 drink or more per day in 1995 gained more weight (3.69 kg) compared with women who reduced their intake (2.43 kg, $p > 0.001$). Increased fruit juice consumption was associated with larger weight gain (4.03 kg) compared with decreased fruit juice consumption (2.32 kg, $p > 0.001$). Oppositely, weight gain in participants who increased their diet soft drink consumption from one drink or less per week in 1991 to one drink or more per day in 1995 (1.59 kg) was significantly lower compared with women who decreased their diet soft drink consumption from one drink or more per day in 1991 to 1 drink or less per week in 1995 (4.25 kg, $p > 0.001$). Subjects who increased soft drink consumption between 1991 and 1995 and continued with this high level of intake during 1995–99, on average gained 8.0 kg between 1991 and 1999. Women who reduced their consumption between 1991 and 1995 and maintained a low level of intake on average gained 2.8 kg between 1991 and 1999. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** No analysis.	an increased risk for development of type 2 diabetes. This was attributed to excessive energy from the drinks and large amounts of rapidly absorbable sugars found in the drinks.
Koh-Banerjee 2003 Prospective cohort 2+ The Health Professionals Follow-Up Study. **Aim:** To determine the associations of	16,587 US male health professionals (dentists, veterinarians, pharmacists, optometrists, osteopathic physicians and podiatrists) aged 40–75 years. **Baseline BMI:** 40–49 years (n = 7577) 24.9	**Year of baseline survey:** 1986 **Duration of follow-up:** 9 years (1986–94 for dietary exposures and 1986–96 for all other exposures) **Outcome variable:** Change in waist circumference. **Self-reported or**	**Attrition:** 1751 excluded due to death, 15,833 excluded due to disease, 17,358 excluded due to incomplete data. **Weight changes:** Mean (SD) waist circumference increased by 3.3 (6.2) cm from 1987 to 1996. **Association of diet with weight change:** 2% increment in energy intake from *trans* fats that were isoenergetically substituted for either polyunsaturated fats or carbohydrates was significantly associated with a 0.77 cm waist circumference gain over 9-years ($p > 0.001$ for each comparison). An increase of 12 g total fibre/day was associated with 0.63 cm decrease in waist circumference ($p > 0.001$).	Adjusted for baseline age, baseline waist circumference, baseline BMI, baseline and changes in total energy, baseline and changes in alcohol consumption, baseline and changes in total PA and changes in

changes in diet, PA, alcohol consumption and smoking with 9-year waist gain in US men.	(2.8) kg/m^2. 50–59 years (*n* = 5314) 25.2 (2.8) kg/m^2. 60–75 years (*n* = 3696) 24.9 (2.6) kg/m^2.	**measured weight:** Self-report waist circumference. **Statistical analysis:** Multivariate linear regression.	Change in total fat intake was significantly related to waist gain of 0.27 cm ($p > 0.001$) but was not significant when further adjusted for concurrent change in BMI; alcohol consumption was not significantly related to waist gain. **Association of physical activity with weight change:** Increases of 25 METs hours per week in vigorous PA and at 0.5 hours per week or more in weight training were associated with 0.38 cm and 0.91 cm decreases in waist circumference respectively ($p > 0.001$ for each comparison). Increases of 25 METs hours per week in vigorous PA remained significant ($p > 0.05$) after control for concurrent change in BMI (–0.19 cm); 0.5 hours per week or more in weight training were associated with 0.74 decreases in waist circumference ($p > 0.001$) after controlling for change in BMI; (also significant decreases in waist circumference with 12–24 MET hours per week and ≥25 MET hours per week. Change in walking volume was not significantly related to waist gain, an increase in walking pace of at least 1 mph (0.45 m/s) was related to loss in waist circumference of 0.50 cm ($p = 0.002$) (–0.27 cm, $p = 0.05$) when BMI held constant); a decrease in walking pace of at least 1 mph was related to a gain in waist circumference of 0.60 cm ($p > 0.001$) (0.26, $p = 0.03$ when BMI held constant). **Association of other factors with weight change: Smoking and TV** Smoking cessation and a 20-hours per week increase in TV watching were associated with a 1.98 cm and 0.59 cm waist circumference gain respectively ($p > 0.001$). Those who quit smoking gained waist circumference 1.98 cm ($p > 0.001$) but this was not significant when change in BMI was controlled for.	smoking. To identify lifestyle factors that predicted increase in waist circumference independent of weight gain changes in BMI were adjusted. **Author's conclusions:** Waist gain may be modulated by changes in *trans* fat and fibre consumption, smoking cessation and PA.
Yamada 2001 Prospective cohort 2+ **Aim:** To clarify the health effects	189 Japanese men, aged 21 to 47 years (mean 31.1 years on the 1 April 1996) who worked in a electronic parts producing factory.	**Year of baseline survey:** 1996 **Duration of follow up:** 3 years **Outcome variable:** Weight (kg) and BMI.	**Attrition:** 1.5% **Weight changes:** For the 12-hour shift workers, mean body weight was 66.6 kg in 1996, 66.6 kg in 1997, 67.6 kg in 1998 that shows a weight gain of 1.0 kg between 1997 and 1998. The BMI of workers on 12-hour shifts increased significantly from 22.8 to	**Adjusted for: not stated** **Author's conclusions:** Implementing a 12-hour shift caused unhealthy

of implementing a 12-hour shift in place of a traditional 8-hour shift in a clean room in an electronic parts-producing factory.	All participants had been working 8-hour shifts for >2 years. Seventeen men aged between 27 and 38 years who had been working 8-hour shifts for >2 years, continued working 8-hour shifts. These were used as a reference group. **Baseline BMI/weight:** Mean baseline BMI of subjects: 22.9 kg/m^2. Subgroup of 20-year-olds: 22.1 kg/m^2. Subgroup of 30-year-olds: 23.4 kg/m^2. Subgroup of 40-year-olds: 23.7 kg/m^2.	**Self-reported or measured weight:** Measured. **Statistical analysis:** StatView 5.0 for windows.	23.2 kg/m^2 for all the workers. The 8-hour shift workers showed a large variation in mean body weight, particularly 67.0 kg in 1996, 66.5 kg in 1997, 67.1 kg in 1998 and 66.3 kg in 1999. 20-year-olds showed a weight gain of 0.8 kg between 1997 and 1998; however, there were only four of them. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** *Age:* 12-hour shift workers – weight gain in the year between 1997 and 1998 was 1.2 kg for the 20-year-olds and 0.9 kg for the 30-year-olds. 40-year-olds showed a weight gain of 0.7 kg in the year between 1997 and 1998 but showed a loss of 1.3 kg between 1998 and 1999. This is a 0.2 kg of body weight over the 3 years. A paired *t* test showed a significant increase in the 12-hour shift workers as well as for the 20-year-olds and 30-year-olds between 1997 and 1998 ($p > 0.05$). For 20-year-olds BMI was 22.0 to 22.4 kg/m^2 and 23.4 to 23.7 kg/m^2 for the 30 year olds between 1997 and 1998. The increase for the 40-year-olds was from 23.8 to 24.0 kg/m^2 with a decrease to 23.6 kg/m^2 in 1999. Eight-hour shift workers – 20-year-olds showed a weight gain of 0.8 kg between 1997–98; however, there were only four of them. Thirty-year-olds showed a weight gain of 0.2 kg between 1997 and 1998 but showed a loss of 1.1 kg between 1998 and 1999. Statistically, no significant changes were found for either the entire 8-hour shift group or the age subgroups during 1996–99. The changes in BMI among the subjects were not found to be significant either ($p > 0.05$). Thirty-year-olds showed a weight gain of 0.2 kg between 1997 and 1998 but showed a loss of 1.1 kg between 1998 and 1999. Statistically, no significant changes were found for either the entire 8-hour shift group or the age subgroups during 1996–99. The changes in BMI among the subjects were not found to be significant either ($p > 0.05$).	weight gain among some clean room workers.

Martikainen 1999 Prospective cohort 2+ **Aim:** To describe socio-economic differences in change in BMI from age 25 years, assess possible factors behind these differences, and study whether socio-economic differences in a variety of coronary risk factors can be accounted for by change in BMI.	5507 men and 2466 women who participated in London-based civil servant Whitehall II study who were 35–55 years old in phase 1 (1985–88) and participated in third phase (1991–1993). **Baseline BMI:** 22.60 (22.53–22.67) kg/m^2 for men, 21.97 (21.84–22.10) kg/m^2 for women.	**Year of baseline survey:** 1985–88 **Duration of follow-up:** 5–6 years **Outcome variable**: BMI gain **Self-reported or measured weight:** Measured but self-reported recall at baseline of weight at age 25 years. **Statistical analysis:** Logistic regression, multinomial logistic regression, linear regression.	**Attrition:** 2335/10308 **Weight changes:** BMI change (mean, 95% CI) from 25 years of age to phase 3: all men 2.52 (2.46, 2.59) (7.8 kg), all women 3.74 (3.59, 3.88) (9.3 kg). **Association of diet with weight change:** Age-adjusted OR of having a gain in BMI >3 kg/m^2 compared with having a BMI gain of 0–3 kg/m^2: Men who reported consuming a good diet (three or four of total of four healthy aspects of diet) had OR 0.73 (95% CI 0.64, 0.84) and for women OR 0.83 (95% CI 0.68, 1.02). **Association of physical activity with weight change:** Age-adjusted OR of having a gain in BMI >3 kg/m^2 compared with having a BMI gain of 0–3 kg/m^2: Moderate and vigorous PA were less likely to experience an increase in BMI, OR for men who took part in vigorous activity was 0.61 (95% CI 0.49, 0.76) and 0.67 (95% CI 0.51, 0.89) for women. **Association of other factors with weight change: employment grade, alchol and smoking** With adjustments for age, duration of follow-up, BMI at age 25 years, the change in BMI was 0.37 kg/m^2 more in grade II than in grade I men and 1.19 for women. The largest grade differences in men and women were observed in those with the largest increases in body mass; men in grade III were 2.5 times more likely to have had a gain in BMI of 6 kg/m^2 or more and for women the OR was 2.8. Age-adjusted OR of having a gain in BMI >3 kg/m^2 compared with having a BMI gain of 0–3 kg/m^2: Grade II men had OR of 1.80 of experiencing a BMI gain of >3 kg/m^2 as compared with grade I men, corresponding OR for women was 2.18. Alcohol consumption was negatively related to BMI gain in women (>10 units per week OR 0.63 (95% CI 0.46, 0.86), consumed 1–2 times per week OR 0.71 (95% CI 0.57, 0.89), consumed daily OR 0.64 (95% CI 0.49, 0.83); in men the relationship was much weaker, with regular and heavy drinkers tending to have a larger gain in BMI.	Grade **I** = administrative, grade **II** = professional and executive, grade **III** = clerical and office support (grade **I** is the reference group for analyses) Mean change in BMI adjusted for age, duration of follow-up, BMI at age 25 years; OR of having a gain in BMI of >3 kg/m^2 compared with having a BMI gain of 0–3 kg/m^2 was adjusted for age. **Author's conclusions:** Employment grade was strongly related to BMI gain from age 25 years to phase 3 (about 25 years), the lower the grade the larger the gain in BMI, adjustment for

			Male smokers and ex-smokers were more likely to gain BMI (OR 1.49, 95% CI 1.22, 1.82 and OR 1.40, 95% CI 1.22, 1.61, respectively); whereas women were more likely to experience a decline in BMI (OR 0.79, 95% CI 0.61, 1.03 and OR 0.88, 95% CI 0.69, 1.12). Poor health control and poor decision latitude at work were related to body mass gain. **Summary of results:** In men separate adjustment for PA and diet accounted for approximately 15 to 20% of the grade difference of having a BMI gain >3 kg/m^2, adjustment for other explanatory values did not make a major contribution; in women the grade differences in OR of BMI gain could only be accounted for by including alcohol consumption in the logistic regression analysis, but grade differences could be partly accounted for by PA and alcohol consumption (about 20% each) and the model that accounted for all explanatory variables accounted for about one-third of the grade differences.	health behaviours reduced the grade differences in BMI gain by about 20%.
Nakamura 1998 Cohort 2+ **Aim:** To determine whether working overtime is associated with anthropometric indices and serum lipids, risks for obesity in White-collar workers.	Non-management White-collar (programmers, designers, clerical) male workers in printing and personal computer manufacturing company in Fukushima, Japan **Baseline BMI:** 22.6 (3.3), range 15.7–34.2 kg/m^2	**Year of baseline survey:** 1990 **Duration of follow-up**: 3 years (analysed retrospectively). **Outcome variable**: BMI change. **Self-reported or measured weight:** Measured. **Statistical analysis:** Multiple linear regression (stepwise).	**Attrition:** 1990 data for 230 of 248 workers present in 1993. **Weight changes:** Change in BMI over 3 years: 0.55 (1.12), range –2.87–5.98 kg/m^2 **Association of diet with weight change:** Overtime hours were inter-correlated with dinnertime ($r = 0.436$, $p > 0.0001$). **Association of other factors with weight change: Overtime** Overtime hours correlated significantly with 3 year **change** in BMI ($r = 0.206$, $p > 0.0017$) and waist circumference ($r = 0.218$, $p = 0.0091$) but not with either the most recent anthropometric indices. Working overtime explains less than 5% variability in change in BMI.	Difficult to ascertain which data is cross-sectional and which is longitudinal. Average monthly overtime worked = 45.5 (SD15.6,)range 0–86.1) hours. **Adjusted for:** Not clear. **Author's conclusions:** Working overtime is associated with increases in

				BMI and waist-circumference over 3 years although the associations were weak; eating habits of those working overtime may reflect an intervening effect on anthropometric changes.
Gerace 1996 Prospective cohort 2+ **Aim:** To assess predictors of weight gain that might be used to prevent increases in weight.	438 male paramedics and fire fighters from Dade Country, Florida, USA. Subjects were aged between 20–58 (mean 35.4) years. The subject sample comprised of Black non-Hispanics, White Hispanics and White non-Hispanic. **Baseline BMI/weight:** Mean BMI for those attended in 1984 and 1991: 25.8 kg/m^2.	**Year of baseline survey:** 1984 **Duration of follow-up:** 7 years **Outcome variable:** Weight (lb). **Self-reported or measured weight:** Measured. **Statistical analysis:** Pearson correlation coefficients were calculated for continuous variables. Analysis of variance and covariance programs were run to examine differences in weight change by group.	**Attrition:** Not reported. **Weight changes:** At follow-up mean body weight increased 8.3 lb (3.8 kg) with 65.2% of fire fighters gained 5 lb (2.3 kg) or more, 42.1% gained 10 lb (4.6 kg) or more; 26.1% gained 15 lb (6.8 kg) or more. In 1991 24% were within 4 lb (1.8 kg) of their weight at baseline measurement. 11% of subjects lost ≥5 lb (≥2.3 kg). 41% of the year-to-year changes were actually increases from the previous year, while in the top quartile, 30% of the year-to-year changes were actually decreases in weight. Weight, % of an individual's ideal weight, BMI and triceps skinfold thickness at follow up were inversely related to weight change ($p > 0.01$). Subjects with the smallest anthropometric values in 1984 tended to have the biggest increases in body weight over the 7 years. **Association of diet with weight change:** Fire fighters who ate faster at the station than else where gained 9.9 lb (4.5 kg) by follow up (1991) compared with those who said their pace did not differ by location, who increased 6.8 lb by 1991, while those who did not nibble increased by 6.9 lb (3.1 kg) ($p > 0.05$) **Association of physical activity with weight change:** Self-reported PA levels at baseline were not associated with change in	Outcomes not adjusted. **Author's conclusions:** Prevention programmes will reach fire fighters likely to gain the most weight if aimed at those who are unmarried, younger, Black, recent ex-smokers, fast eaters and experiencing certain stressful life events.

			weight ($p > 0.05$). Likewise, the amount of energy in PA reported at baseline was not associated with weight change ($p > 0.05$). Subjects who reported engaging in at least one recreational PA three or more times per week gained 7.2 lb (3.3 kg) compared with less active fire fighters who gained 9.5 lb (4.3 kg) ($p > 0.05$). **Association of other factors with weight change:** *Demographic variables:* Fire fighters aged 20–29 years, gained the most weight over 7 years (11.3 lb [5.1 kg]). The Pearson correlation coefficient between age and weight change was –0.17 ($p > 0.01$). Subjects who were married or living as married gained 7 lb (3.2 kg) compared with those who were never married, divorced, separated, or widowed who gained 11.7 lb (5.3 kg) ($p > 0.001$). Black non-Hispanics gained 15.7 lb (7.1 kg) compared with White Hispanics who gained 8.9 lb (4.0 kg) and White non-Hispanics who gained 6.7 lb (3.0 kg) ($p > 0.001$). *Behavioural variables:* Fire fighters who smoked at baseline and reported being ex-smokers in 1991 gained 13.0 lb (5.9 kg) compared with all other fire fighters who gained 7.7 lb (3.5 kg) ($p > 0.004$). Ex-smokers who had smoked >20 cigarettes per day gained 16.4 lb (7.4 kg) compared with those who smoked up to 19 cigarettes per day who gained 8.3 lb (3.8 kg). *Psychological variables:* Self-reported stress at baseline was not associated with weight change over the 7-year period ($p > 0.05$). However, those who worried over financial security gained 11.2 lb (5.1 kg) versus non worriers who gained 7.4 lb (3.4 kg) ($p > 0.005$).	

INDIVIDUAL STUDIES: GENERAL POPULATONS				
First author, design, aim	**Population**	**Intervention details, length of follow-up**	**Results**	**Confounders adjusted for/comments**
Nooyens 2005 Prospective cohort Aim: To study changes in	288 healthy men aged 50-65 years who remained employed or retired over follow-up. Men were from the Doetinchem	Year of baseline survey: 1985–86 Duration of follow-up: 5+ years Outcome variable:	Attrition: 0% Association of diet with weight change: Weight gain and increase in waist circumference were associated with a decrease in fruit consumption (p = 0.01) and fibre density of the diet (p = 0.01), and with an increase in frequency of eating breakfast (p = 0.03). Association of physical activity with weight change:	Adjusted for: Age and behaviour changes at baseline. Author's conclusions:

body weight and waist circumference in men.	Cohort Study (rural Netherlands)	Weight change and waist circumference. Self-reported or measured weight: Measured. Statistical analysis: Linear regression.	Weight gain and increase in waist circumference were associated with a decrease in several physical activities, such as household activities, bicycling (p = 0.03), walking and doing odd jobs (p = 0.02). Association of other factors with weight change: Increase in body weight and waist circumference was higher among men who retired from active jobs (0.42 kg per year and 0.77 cm per year, respectively) than among men who retired from sedentary jobs (0.08 kg per year and 0.23 cm per year, respectively).	Retirement was associated with increases in weight and waist circumference among those with former active jobs, but not among those with former sedentary jobs.
Schulz 2005 Prospective cohort Aim: To identify a dietary pattern predictive of subsequent annual weight change by using dietary composition information.	24,958 middle-aged men and women of the European Prospective Investigation into Cancer and Nutrition-(EPIC) Potsdam cohort, Germany. Men were aged between 24-69 and women 19-70 years.	Year of baseline survey: 1994–1998 Duration of follow-up: 4+ years Outcome variable: Weight change. Self-reported or measured weight: Measured and self-report. Statistical analysis: Linear regression.	Association of diet with weight change: Reduced rank regression method was used to derive dietary patterns with 3 response variables presumed to affect weight change: fat density, carbohydrate density, and fibre density. A scoring system was devised with high scores indicating healthier diet. A food pattern of high consumption of whole-grain bread, fruits, fruit juices, grain flakes/cereals, and raw vegetables, and of low consumption of processed meat, butter, high-fat cheese, margarine, and meat to be predictive of subsequent weight change. Subjects with these food patterns were less likely to gain weight. Mean annual weight gain gradually decreased with increasing pattern score (p-value for trend < 0.0001), i.e., subjects scoring high for the pattern maintained their weight or gained significantly less weight over time compared with subjects with an opposite pattern. The prediction of annual weight change by the food pattern was significant only in non-obese subjects; eg normal weight women (p< 0.0001) vs obese women ((p = 0.184).	Adjusted for: Age, total energy intake, PA, smoking, and other dietary behaviour changes. Author's conclusions: Identified a food pattern characterized by high-fibre and low-fat food choices which helped to maintain body weight or at least prevent excess body weight gain.
Quatromoni 2002 Prospective cohort	1828 non-overweight women from the Framingham Offspring/Spouse	Year of baseline survey: Exam 3, year not given Duration of follow-up:	Attrition: 60% 737 having complete data sets Association of diet with weight change: Five dietary patterns were identified among the cohort at baseline via cluster analysis: 'Heart Healthy', 'Light Eating', 'Wine and Moderate Eating',	Adjusted for: Age, total energy intake, PA, cigarette usage, and

Aim: To investigate relationships between dietary patterns and the development of overweight	(FOS) Cohort. Mean age 45 years, with a range of 30-89 years.	12+ years Outcome variable: BMI >25. Self-reported or measured weight: Measured. Statistical analysis: Various, but all used some form of regression analysis.	'High Fat', and 'Empty Calorie'. Over 12 years, the crude risk of becoming overweight was 29% overall, ranging from 22% of women in the 'Wine and Moderate Eating' cluster to 41% of women in the 'Empty Calorie'. Compared with women who ate a lower-fat, nutritionally varied 'Heart Healthy' diet, women who ate an 'Empty Calorie' diet that was rich in sweets and fats with fewer servings of nutrient-dense fruits, vegetables, and lean food choices were at higher risk for developing overweight; RR 1.4; (95 CI 0.9, 2.2). Women who ate an 'Empty Calorie' dietary pattern were also younger and were more likely to smoke.	other dietary behaviour changes. Author's conclusions: Behavioural interventions may be enhanced by targeting differences in eating patterns, dietary quality, and other lifestyle behaviours of distinct subgroups.
Kahn (1990) Prospective cohort **Aim:** To explore the effects of family income, education and changing marital status on change in BMI over 10 years.	1552 White and Black US men were included in this study of 10-year weight change, therefore representing 77% of the Black and White men who initially entered the Health and Nutrition Examination Survey-I (in 1971–75) at ages 25–44 years.	**Year of baseline examination and interview:** 1971–75 **Duration of follow-up:** 10 years. **Outcome variable:** BMI . **Self-reported or measured:** Measured. **Statistical analysis:** Considering BMI change as a	**Attrition:** Not mentioned **Weight changes: Mean 10-year change:** The mean 10-year change in BMI was similar for the men who were not consistently married and for the men who were married at both baseline and follow-up (0.90 vs. 0.80 kg/m^2, respectively). The non-consistently married men had a significantly wider distribution of this weight-change variable. Multivariate models showed a significant increase in the mean BMI change for men with lower education levels compare with those who had gone beyond 12th grade. Men who became married during the 10-year interval showed a trend towards a greater gain in BMI when compared with men who were consistently married. Those men whose marriage ended appeared to experience a relative loss in BMI.	**Author's conclusions:** Study demonstrated that among US men an education to less than college level was a risk factor for increased mean weight gain and that low family income was a risk factor for major weight gain.

		continuous variable, multiple linear regression was used to estimate the effects of each independent variable of interest. Considering BMI change as a categorical variable, logistic regression analysis was used to estimate the OR of either major weight gain (MWG) or major weight loss (MWL) for subgroups defined by the various categories of family income, educational attainment and marital change.	**Incidence of major weight gain/loss:** The incidence of MWG was generally greater for the men who were not consistently married, among these men there was a higher incidence of MWG for those who had lower incomes or lower educational levels The incidence of MWL was also generally greater for the men who were not consistently married The mid-range weight outcome was generally more common among men who were consistently married, had higher family incomes, or had higher educational levels. **Risk factors for major weight change:** Low family income and either becoming married or remaining unmarried during the 10-year follow-up interval were independently associated with an increased risk of MWG. Education to grade 11 or less was only marginally associated with an increased risk of MWG. Neither low family income nor low education had any effect on the risk of MWL. However, ending a marriage or remaining unmarried was associated with an increased risk of MWL. **Association of diet with weight change:** Not measured. **Association of physical activity with weight change:** The incidence of MWG was lowest among men who reported high levels of PA or whose baseline BMI was between 24.0 and 27.8 kg/m^2. **Association of other factors with weight change:** The incidence of MWG was highest among ex-smokers and those reporting low levels of PA. The incidence of major weight loss was highest for men with the highest BMI at baseline or men who continued to smoke. Black race had no consistent effect on MWG or MWL.	Compared with men who were consistently married, men who become married between baseline and follow-up had an increased risk of MWG while men ending a marriage had an increased risk of MWL. Men unmarried at both baseline and follow-up had an increased risk for both MWG and MWL. Findings indicate that US men in greatest need of help in preventing weight gain are those with low family incomes, those with low educational levels and those who are unmarried. **Comments:** Fluctuations in weight that may

				have occurred during the 10-year follow-up were not recorded in this data; therefore, it failed to include everyone who had a major weight change between baseline and follow-up examinations. The definitions of MWG and MWL cannot identify how much of the weight changes were due to changes in the amount of lean or fat tissue. **Adjusted for:** Race (White, non-White), education, smoking status, age and BMI at baseline, length of follow-up, PA, level of morbidity, energy intake, alcohol intake, special diet

				status and parity.
Andersen 2004 (MONICA) **Aim:** To investigate whether night eating per se predicts weight gain, or weight gain predicts night eating. **Design:** Prospective study with initial examination of the cohort in 1982–83 (M-82), re-examination in 1987–88 (M-87) and a third examination in 1993–94 (M-93).	In 1982 to 83 a total of 3608 Danish citizens born in either 1922, 1932, 1942 or 1952 participated. This group invited for re-examination 5 years later in 1987–88, a total of 2987 subjects participated. Finally, in 1993–94 the cohort was invited for a third examination, and 2436 of the initial 3608 individuals participated in all three examinations. In total, 95/1050 (9.1%) women and 76/1061 (7.4%) men reported night eating. Based on data from the 1987–88 examination 14% of male	**Year of baseline examination and questionnaire:** 1982–83 **Duration of follow-up:** 6 years from 1987–88 to 1992–93 **Outcome variable:** 5-year preceding and 6-year subsequent weight change (kg) **Self-reported or measured weight:** Measured. **Statistical analysis:** Association the between night eating and the preceding weight change, multiple logistic regression models were used. To estimate the effect of night eating on subsequent weight change, multiple linear regression analysis was used.	**Attrition:** 67.5% for all three examinations. **Weight changes:** (M-82 to M-87) Night eating was not associated with weight changes for either sex in the crude and adjusted analyses. Obesity in M-82 did not modify the association between preceding weight change and night eating. (M-87 to M-93) For men, night eating was not associated with subsequent weight change. Analysis revealed that obese women with night eating experienced a greater average 6-year weight gain. The total average 6-year weight gain for obese night eating women was 5.2 kg, whereas obese non-night eating women experienced only a 0.9 kg average weight gain. **Association of diet with weight change:** No specific analysis of food types but reference was made to eating patterns, i.e. restraint when eating meals and data were adjusted for this variable. No significant associations with weight change were observed. **Association of physical activity with weight change:** No specific analysis; however, LTPA was recorded on a four point scale ranging from almost completely inactive, some PA, regular PA and regular hard physical training for competition. Data were adjusted for this variable and no significant associations with weight change were observed. **Association of other factors with weight change:** Other factors considered were present smoking habits and education as recorded by the number of years in school. No significant relationships with weight change were noted for either variable.	Adjusted for Age, smoking, years in school, LTPA, restrained eating and baseline BMI. **Author's conclusions:** Findings indicate that when using a simple yes/no question to assess the night eating phenomenon, obesity and night eating have a joint effect on 6-year weight change for women but not for men, suggesting that night eating maybe a significant contributor to further weight gain among already obsess women but not for others. **Comments:**

	and 13% of female night eaters were obese (BMI > 30) and 11% of male and 9% of female non-night eaters were classed as obese.			A simple yes/no question to identify night eaters with no specific time frame may have reduced the sensitivity of the analyses.
Kant (1995) (NHANES I and NHEFS) Prospective cohort **Aim:** To examine the association of frequency of eating occasions with prospective and retrospective weight change.	In total 7147, 2580 men and 4567 women. All respondents were 25–74 years of age at the time of the initial survey. Mean ages of men and women in the analytic cohort were 44.5 and 45.9 years, respectively.	**Year of baseline examination and survey:** 1971–75 **Duration of follow-up:** 8–10 years . **Outcome variable:** Weight change (kg). **Self-reported or measured:** Measured. **Statistical analysis:** The association of weight change with frequency of eating occasions at baseline and at follow-up were examined using sex-specific multivariate regression analyses. All regression analyses were run with and without adjustment for variables that may potentially affect body	**Attrition:** At follow-up in 1982–84, 46 respondents did not answer the two questions regarding the number of meals and number of snacks consumed daily, leaving 7101 respondents in the follow-up eating occasion cohort. Two or fewer eating occasions were reported by only 2% of the cohort at baseline 24-hour recall. At follow-up, from a summary of two questions on snack and meal frequency, nearly 15% of the cohort reported eating frequency of less than two occasions. Nearly 30% of the cohort reported more than six eating occasions at baseline using 24-hour recall relative to only 5% at follow-up based on answers to two questions on meal and snack frequency. In absolute terms, men and women reported a mean frequency of 5.3 and 4.9 eating occasions at baseline, respectively; at follow-up the mean frequency was 3.6 eating occasions for both men and women. No clear relation between frequency of eating and weight change was evident. **Weight change:** At baseline, weight changes and frequency of eating occasions were positively related in unadjusted models for both men and women. For every unit increase in frequency of eating, men and women gained 0.22 and 0.34 kg of body weight, respectively, over the period of the follow-up. After adjustment for age, and other confounders, the relationship was no longer significant. At follow-up, there was no association of weight change with eating frequency in men or women. **Association of diet with weight change:** At baseline, relative to all other categories, the eating occasion category of	**Author's conclusions:** There was no independent association of frequency of food ingestion estimated from 24-hour dietary recall with prospective weight change or frequency of eating estimated from answers to questions on number of meals and snacks consumed daily with weight change over the preceding 8–10 years in the NHEFS cohort. **Comments:** Twenty-four-hour dietary recall may not

		weight.	<2 was associated with the smallest mean weight change in men, but the largest mean weight change in women. In women, mean baseline BMI, triceps skinfold thickness, subscapular skinfold thickness and plasma cholesterol decreased with increasing baseline frequency of eating occasions. In men, the mean baseline BMI and subscapular skinfold decreased with increasing frequency of eating occasions. Trends in triceps skinfold and plasma cholesterol were not consistent. Mean dietary energy and alcohol intake increased with increasing baseline-eating frequency in both men and women. At follow-up, the highest frequency category (>6) was associated with the largest mean weight change and baseline BMI in women but not men. Mean plasma cholesterol measured at baseline was inversely associated with frequency of eating at follow-up in women but not in men. Mean alcohol intake decreased with increasing frequency of eating at follow-up in both men and women. **Association of physical activity with weight change:** Self-reported level of usual PA at baseline or at follow-up were not related with frequency of eating at baseline or follow-up (data not shown). **Association of other factors with weight change:** Whites, respondents with >12 years educations, and >1 poverty income ratio reported higher mean frequency of eating occasions both at baseline and at follow-up. Current smokers, and alcohol drinkers reported a higher frequency of eating occasions at baseline, but lower frequency at follow-up.	represent respondents 'usual' eating patterns. Different measures of dietary intake were used at baseline and follow-up. The extents of changes in frequency of food ingestion were unable to be measured.
Parsons 2005 Prospective cohort 2+ **Aim:**	All births 3–9 March 1958 in England, Scotland and Wales studied at age 33 and at age 42 years.	**Year of baseline survey:** 1991 **Duration of follow-up**: 9 years	**Attrition:** 860 out of 16460 **Weight changes: not stated** **Association of diet with weight change:** Among women the proportion who decreased chip consumption also	Outcomes not adjusted. **Author's conclusions:** Associations between BMI

To investigate whether adults studies in 1991 and 1999 improved their diet and PA level in the direction of recommendations.	**Baseline BMI:** Not reported.	**Outcome variable**: BMI quartile. **Self-reported or measured weight:** Self-report? **Statistical analysis**: Trends in % subjects increasing/decreasing activity, consumption of chips, fried food or fruit and salad, compared with remaining stable across the BMI quartile were assessed.	increased slightly with higher BMI ($p > 0.0001$); among women proportion who increased fried food consumption increased with lower BMI ($p = 0.001$); among women the proportion who decreased fruit and salad consumption increased with higher BMI ($p = 0.03$); among men significant difference between proportion who decreased chip consumption and between proportion who decreased fired food consumption fried food consumption ($p = 0.04$ and 0.01, respectively). **Association of physical activity with weight change:** No significant differences by BMI group among men and women who increased or decreased PA, or who increased chip consumption, or who increased fruit/salad/raw vegetable consumption.	and change in activity or diet were inconsistent.
Larew 2003 Prospective cohort 2+ **Aim:** To determine the relationship of muscle metabolism to exercise performance (results not relevant to this review) and of exercise performance to rate of weight gain	83 Black and White premenopausal women aged 23–47 years (mean age 34 [6.1] years with normal body weight (BMI 21–25 kg/m^2); some had previously been overweight; normal glucose tolerance, not smoked in previous year, not taking medication known to affect metabolism. **Baseline BMI:** 23.6	**Year of baseline survey:** Not reported. **Duration of follow-up**: 1 year. **Outcome variable**: Change in weight. **Self-reported or measured weight:** Measured. **Statistical analysis**: Multiple regression analysis.	**Attrition:** 61 of 83 subjects returned at 1 year. **Weight changes:** Mean rate of weight gain 3.8 (4.7) kg/year/to the power minus 1 (range –5.6kg/year/to the power minus 1 to 12.8 kg/year to the power minus 1). **Association of physical activity with weight change:** Greater muscle metabolic economy ($r = -0.25$, $p = 0.04$); greater quadriceps muscle strength ($r = -0.34$, $p > 0.01$); greater VO_{2max} ($r = -0.22$, $p = 0.04$) and longer treadmill endurance time ($r = -0.21$, $p = 0.04$) were significantly correlated with lower rates of weight gain over 1 year. Muscle metabolic economy, VO_{2max} and quadriceps muscle strength all independently and significantly contributed to the estimate of rate of weight gain model and the model explained 23% of weight gain variability ($r = 0.48$, $p > 0.01$). **Association of other factors with weight change (please state factors):** None.	**Adjusted for:** Not reported. **Author's conclusions:** Greater exercise endurance reduces weight gain.

<table>
<tr>
<td></td>
<td>(1.2) kg/m^2,
n = 83.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sammel 2003

Prospective cohort
2+

Aim:
To evaluate correlates of weight gain in women aged 35–47 years.</td>
<td>336 African American and White American women, urban residents (Philadelphia, PA, USA), participating in the Penn Study of Ovarian Aging.

Age at baseline between 35 and 47 years; mean 41.0 years (SD 3.5 years). Premenopausal at baseline.

Baseline BMI:
29.3 (8.2) kg/m^2.</td>
<td>**Year of baseline survey:**
Not reported.

Duration of follow-up:
4 years (seen six times after baseline measurements – about 8 months apart).

Outcome variable:
A net weight gain of more than or equal to 10 lb (4.5 kg) at the final assessment compared with baseline (dichotomous).

Self-reported or measured weight:
Measured.

Statistical analysis:
Multivariate logistic regression models. The final model was developed using backward selection.</td>
<td>**Attrition:**
23%

Weight changes:
Median weight change was 2.4 lb (1.1 kg). 25% of the women gained 10 lb (4.5 kg) or more.

1. Unadjusted associations (all adjusted only for BMI categories at baseline, except BMI category, which is completely unadjusted).

Association of diet with weight change:
Summary dietary variables (average no. of servings per day, adjusted for):
<table>
<tr><th></th><th colspan="2">Weight gain of >10 lb (4.5 kg)</th><th>*p* value</th></tr>
<tr><th></th><th>Yes</th><th>No</th><th></th></tr>
<tr><td>**Fruit/vegetables**</td><td>**3.4**</td><td>**4.3**</td><td>**0.055**</td></tr>
<tr><td>Breads/cereals</td><td>1.8</td><td>2.0</td><td>0.606</td></tr>
<tr><td>Dairy foods</td><td>2.7</td><td>2.8</td><td>0.898</td></tr>
<tr><td>**Sweets**</td><td>**0.9**</td><td>**1.5**</td><td>**0.015**</td></tr>
<tr><td>Protein</td><td>1.1</td><td>1.7</td><td>0.086</td></tr>
<tr><td>High fat foods</td><td>2.1</td><td>2.2</td><td>0.739</td></tr>
</table>
Association of physical activity with weight changes:
No analysis.

Physical activity variables (average per day):
<table>
<tr><th></th><th colspan="2">Weight gain of >10 lb (4.5 kg)</th><th>*p* value</th></tr>
<tr><th></th><th>Yes</th><th>No</th><th></th></tr>
<tr><td>No. of blocks walked</td><td>10.5</td><td>10.5</td><td>0.698</td></tr>
<tr><td>Hours vigorous activity</td><td>1.1</td><td>1.1</td><td>0.651</td></tr>
<tr><td>No. of flights of stairs climbed</td><td>9.5</td><td>8.9</td><td>0.667</td></tr>
</table>
Association of other factors with weight changes:

Other variables:</td>
<td>**Adjusted for:**
Independent variables – all at baseline.

The lack of association between significant weight gain and dietary and PA variables may reflect the relatively crude methods used to measure them. Diet measured with FFQ. PA variables were also self-reported and depended on recall. Recall bias may have been a factor.

Sample was unrepresentative – high attrition could have created bias; only urban women and two ethnic groups represented.

Author's conclusions:</td>
</tr>
</table>

Significant:
Those with significant weight gain:

- Were more likely to be younger ($p = 0.039$);
- Were more likely to have a high anxiety score ($p = 0.037$);
- Had a lower average Quality of Life score ($p = 0.041$).

Marginally significant:
Those with significant weight gain:

- Were more likely to have a high depression score ($p = 0.053$);
- Had a greater number of pregnancies ($p = 0.086$);
- Were more likely to be on a diet ($p = 0.082$).

Non-significant:

- BMI category; waist-to-hip ratio;
- Perceived stress;
- Current cigarette smoking status; alcohol consumption (average. no of drinks per week);
- Race; education; whether employed outside the home;
- Reproductive hormone values.

2. Final model (with significant results in **bold**):

	OR	**95% CI**	***p* value**
BMI (kg/m^2)			**0.008**
<21	**0.21**	**0.03–0.56**	
21–24	–	–	
25–29	0.90	0.44–1.82	
30+	0.62	0.32–1.23	
Age (years)			**0.054**
35–39	–	–	
40–44	0.80	0.44–1.43	
45–49	**0.39**	**0.18–0.87**	
Race			0.741
White	–	–	
African	1.11	0.61–2.00	
Education			0.632
> High school	–	–	
> High school	1.26	0.48–3.31	
Increasing parity	1.12	0.97–1.29	0.129

The major predictors of weight gain were psychological factors – depressed mood, anxiety and quality of life.

			Depression score **0.024** <16 – – >16 **1.90** **1.09–3.31** **Increased consumption of sweets** **0.74** **0.60–0.91** **0.004** **Summary of results:** • Underweight women were least likely to experience significant weight gain. • A high depression score made significant weight gain twice as likely. • The only significantly predictive dietary variable was *low* consumption of sweet foods. • PA variables were not predictive of significant weight gain.	
Kahn 1991 Two prospective cohort studies from NHANES 2+ **Aim:** To examine the association between race and weight gain in adults, and whether this can be explained by socio-economic confounders. Kahn 1991 2+ Analysed the female sample – the same except defined	A population sample of Black and White US adults who entered NHANES I at ages 25–44 years. 3284 women (84% White); 1552 men (90% White). **Baseline BMI:** Not stated	**Year of baseline survey:** 1971–75 **Duration of follow-up**: About 10 years – follow-up was between 1982 and 1984. They computed an estimated weight change for exactly 10 years for each participant by linear adjustment. **Outcome variable**: Mean BMI change (kg/m^2) as a continuous variables and separately in three categories: Major weight gain: BMI ≥ +5.0 for women, BMI ≥ +4.0 for men Major weight loss: BMI ≥ –2.5 for	**Attrition:** White women: 23%; White men: 21%. Black women: 30%,; Black men: 40%. **Mean BMI changes (kg/m^2):** White women: +1.07 (SD 3.00); White men: +0.81 (SD 2.37). Black women: +1.38 (SD 3.48); Black men +0.98 (SD 2.25). **Effects of variables:** **Association of diet with weight change:** No analysis. **Association of physical activity with weight changes**: No analysis. **Association of other factors with weight changes:** **1) Mean BMI change** a) Unadjusted • Women: The mean BMI change was significantly greater for Black than White women (unadjusted difference = 0.31 BMI points, 95% CI 0.01, 0.63). The variance in weight change was significantly higher in Black women (p > 0.0001). • Men: There was no significant different in mean BMI change (or variance in mean BMI change) in Black vs. White men.	**Confounders adjusted for:** Age, BMI at baseline, smoking, PA, parity, rural vs. urban background, region of the country. **Author's conclusions:** Black race does not increase the risk of weight gain; in women it may be associated with reduced likelihood of weight loss. In addition, unadjusted effects of race may be mainly to do with family incomes, as a

<table>
<tr>
<td>major weight change using change in kg rather than kg/m².

The pattern of results was the same as in Kahn & Williamson 1991, so the results of only the latter are described here.</td>
<td></td>
<td>women, BMI ≥ –2.0 for men)
Mid-range weight change.

Self-reported or measured weight: Measured.

Statistical analysis: When BMI change considered as a <i>continuous</i> variable: multiple linear regression models. When BMI change considered as a <i>categorical</i> variable: logistic regression analyses where weight gain / weight loss were considered in comparison to the mid-range weight change reference group.</td>
<td>b) Adjusted (see next column for confounders). Effects of variables on mean 10-year change in BMI. Significant results (<i>p</i> > 0.05) in bold.
<table>
<tr><th></th><th>Women</th><th>Men</th></tr>
<tr><td>Race</td><td></td><td></td></tr>
<tr><td>White</td><td>–</td><td>–</td></tr>
<tr><td>Black</td><td>+0.6</td><td>+0.2</td></tr>
<tr><td>Family income</td><td></td><td></td></tr>
<tr><td>Favourable</td><td>–</td><td>–</td></tr>
<tr><td>Moderately low</td><td>0.0</td><td>+0.2</td></tr>
<tr><td>Low</td><td>–0.1</td><td>–0.1</td></tr>
<tr><td>Education</td><td></td><td></td></tr>
<tr><td>>12th grade</td><td>–</td><td>–</td></tr>
<tr><td>12th grade</td><td>+0.3</td><td>+0.3</td></tr>
<tr><td><12th grade</td><td>+0.3</td><td>+0.6</td></tr>
<tr><td>Marital change</td><td></td><td></td></tr>
<tr><td>Stayed married</td><td>–</td><td>–</td></tr>
<tr><td>Marriage ended</td><td>–0.4</td><td>–0.3</td></tr>
<tr><td>Became married</td><td>+0.8</td><td>+0.4</td></tr>
<tr><td>Stayed unmarried</td><td>+0.1</td><td>0.0</td></tr>
</table>
2) Major weight change

a) Unadjusted. These are percentages.
<table>
<tr><th></th><th colspan="2">Major weight gain</th><th colspan="2">Major weight loss</th></tr>
<tr><th></th><th>Women</th><th>Men</th><th>Women</th><th>Men</th></tr>
<tr><td>Race</td><td></td><td></td><td></td><td></td></tr>
<tr><td>White</td><td>7.6</td><td>6.9</td><td>6.9</td><td>8.9</td></tr>
<tr><td>Black</td><td>11.1</td><td>7.3</td><td>8.8</td><td>9.3</td></tr>
<tr><td>Family income</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Favourable</td><td>7.1</td><td>5.6</td><td>5.4</td><td>9.2</td></tr>
<tr><td>Moderately low</td><td>10.3</td><td>7.4</td><td>9.3</td><td>7.4</td></tr>
<tr><td>Low</td><td>12.1</td><td>9.7</td><td>11.9</td><td>10.8</td></tr>
<tr><td>Education</td><td></td><td></td><td></td><td></td></tr>
<tr><td>>12th grade</td><td>6.4</td><td>6.1</td><td>5.2</td><td>9.3</td></tr>
<tr><td>12th grade</td><td>8.9</td><td>6.6</td><td>6.9</td><td>8.7</td></tr>
<tr><td><12th grade</td><td>8.5</td><td>9.3</td><td>9.3</td><td>9.0</td></tr>
<tr><td>Marital change</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Stayed married</td><td>7.8</td><td>6.1</td><td>6.5</td><td>8.3</td></tr>
<tr><td>Marriage ended</td><td>7.4</td><td>4.4</td><td>10.1</td><td>11.4</td></tr>
</table>
</td>
<td>greater proportion of Black than White women had low incomes.</td>
</tr>
</table>

Became married	13.6	15.8	3.6	6.3
Stayed unmarried	9.1	11.4	8.3	13.6

b) Adjusted (see next column for confounders).

i) Adjusted OR for **major weight gain**. Significant results ($p > 0.05$) in **bold**.

	Women	**Men**
Race		
White	–	–
Black	1.1	0.8
Family income		
Favourable	-	-
Moderately low	1.4	1.3
Low	**1.7**	**1.8**
Unknown	0.8	1.8
Education		
>12th grade	–	–
12th grade	1.2	1.2
<12th grade	0.9	1.6
Marital change		
Stayed married	–	–
Marriage ended	0.8	0.7
Became married	**1.8**	**3.3**
Stayed unmarried	0.9	**2.1**

ii) Adjusted OR for **major weight loss**. Significant results ($p > 0.05$) in **bold**.

	Women	**Men**
Race		
White	–	–
Black	**0.6**	0.8
Family income		
Favourable	–	–
Moderately low	1.4	0.8
Low	**1.8**	1.1
Unknown	1.6	0.6
Education		
>12th grade	–	–
12th grade	0.9	0.9

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>
<table>
<tr><td><12th grade</td><td>0.7</td><td>0.9</td></tr>
<tr><td>**Marital change**</td><td></td><td></td></tr>
<tr><td>Stayed married</td><td>–</td><td>–</td></tr>
<tr><td>Marriage ended</td><td>1.2</td><td>**1.8**</td></tr>
<tr><td>Became married</td><td>0.6</td><td>1.3</td></tr>
<tr><td>Stayed unmarried</td><td>0.8</td><td>**2.5**</td></tr>
</table>

Summary of results:

Race
• No significant effects by race for men.
• Black women had a greater mean BMI change than White women, even when adjusting for confounding variables (independent effect of race was 0.6 kg/m^2, $p > 0.05$). This is, however, probably due to differences in odds of major weight *loss* (Black vs. White women: adjusted OR 0.6, $p > 0.05$). Although the crude incidence of major weight gain was nearly 50% higher in Black than White women, race did not independently alter odds of major weight gain in women.

Family income
No effect for mean BMI changes but low income was associated with significantly greater odds of major weight gain in both men and women and greater chance of major weight loss only amongst women.

Education
Less education was independently associated with greater mean BMI change in both men and women. No effects by education for major weight change.

Marital variables
Women's but not men's mean BMI change showed effects for marital change (increase with start of marriage, decrease with end of marriage). Women were more likely to experience major weight gain if they became married than if they were consistently married. Men were more likely to experience major weight gain if they became married or if they stayed unmarried than if they were consistently married. Men were more likely to experience major weight loss if they stayed unmarried or if their marriage ended than if they were consistently married.
</td>
<td></td>
</tr>
<tr>
<td>Lissner 1997

Prospective</td>
<td>361 healthy women</td>
<td>**Year of baseline survey:** 1968–69</td>
<td>**Attrition:**
437 of the original baseline sample were randomly selected to attend follow-up interview (for diet history). 373 of these also took part in the</td>
<td>**Confounders controlled for were:**</td>
</tr>
</table>

<table>
<tr>
<td>cohort
2+

Aim:
To test the hypothesis that a high-fat diet has a different predictive value for long-term weight change at varying levels of PA.</td>
<td>participating in **The Population Study of Women** in Gothenburg, Sweden. 38–60 years old at baseline.

Baseline BMI (kg/m^2):
Lower fat consumers: 24.6 (4.1); higher fat consumers: 24.1 (4.1) (no significant difference).</td>
<td>**Duration of follow-up**: 6 years.

Outcome variable: Mean weight change (kg).

Self-reported or measured weight: Measured.

Statistical analysis: Multivariate regression analysis. Where interactions were significant, did stratified analysis - effect of dietary fat on weight change in each separate PA group. Leisure time and occupational PA analysed separately. Computation of activity categories reported elsewhere. Low fat intake defined as <38.5% energy from fat; high as 38.5%+.</td>
<td>follow-up examination (for follow-up weight measurement). Twelve excluded because of cancer, myocardial infarction, stroke or diabetes at baseline. Suggests attrition of 17%.

Weight changes:
Lower fat consumers (*n* = 180): +0.64 (1.8) kg
Higher fat consumers (*n* = 181): +0.79 (1.8) kg

Association of diet with weight change:
No analysis.

Association of physical activity with weight changes:
Leisure time physical activity: In the prediction of weight change, there was a significant interaction (*p* = 0.03) between PA level and dietary fat.

1) Unadjusted analysis. Dietary fat consumption predicted weight gain in the physically inactive women (*p* = 0.03) but not in the two groups reporting higher activity levels.

Weight change in kg, mean (SD):
<table>
<tr><th></th><th colspan="3">LTPA category</th></tr>
<tr><th></th><th>Sedentary</th><th>Somewhat active</th><th>More active</th></tr>
<tr><td>Low-fat group</td><td>**–0.64** (1.09)</td><td>**1.96** (0.39)</td><td>**1.27** (1.07)</td></tr>
<tr><td>High-fat group</td><td>**2.64** (0.96)</td><td>**1.25** (0.40)</td><td>**1.92** (1.01)</td></tr>
<tr><td>Difference</td><td>**+3.28**</td><td>**–0.71**</td><td>**+0.65**</td></tr>
<tr><td>*p* value</td><td>0.03</td><td>0.20</td><td>0.66</td></tr>
</table>
2) Adjusted analysis of weight change (kg). Same pattern of result except that effect of fat intake on weight gain in sedentary group is now only marginally significant (*p* = 0.06).

Adjusted least-squares mean weight change in kg, mean (SD):
<table>
<tr><th></th><th colspan="3">LTPA category</th></tr>
<tr><th></th><th>Sedentary</th><th>Somewhat active</th><th>More active</th></tr>
<tr><td>Low fat group</td><td>**–0.59** (1.07)</td><td>**2.05** (0.39)</td><td>**1.27** (1.08)</td></tr>
<tr><td>High fat group</td><td>**2.24** (0.97)</td><td>**1.17** (0.40)</td><td>**1.93** (1.02)</td></tr>
<tr><td>Difference</td><td>**+2.83**</td><td>**–0.88**</td><td>**–0.06**</td></tr>
<tr><td>*p* value</td><td>0.06</td><td>0.12</td><td>0.67</td></tr>
</table>
</td>
<td>Initial body weight, current smoking status and age.

No adjustment for socio-economic factors.

Author's conclusions:
Sedentary recreational activity *plus* a low-fat diet may have a combined contribution to weight change that is not equivalent to the sum of the separate effects.</td>
</tr>
</table>

			Same pattern of results for overall energy intake. The high-fat association with weight gain in the sedentary group became marginally significant after controlling for overall energy intake and vice versa – i.e. the two dietary measures explained the same variance. *Occupational physical activity:* No interactions, data not shown in paper. **Association of other factors with weight changes:** No analysis. **Summary of results:** Women's fat intake was a predictor of 6-year weight gain *only* amongst women sedentary in leisure time.	
Ball 2002 Prospective cohort 2+ **Aim:** To investigate patterns of weight change, the incidences of major weight gain, overweight and obesity and how weight varied by sex, age, education, and initial body mass.	12,125 men and 17,674 women aged 35–69 years from Melbourne, Australia. **Baseline BMI or weight:** 1.1% of men and 4.1% of women were underweight; 28.2% of men and 41.0% of women were in healthy weight range; 53.2% of men and 35.7% of women were overweight; and 17.5% of men and 19.2% of women were obese.	**Year of baseline survey:** 1994 **Duration of follow-up:** 5 years **Outcome variable:** Weight change **Self-reported or measured weight:** Measured at baseline and self report throughout the rest of the study **Statistical analysis:** Linear regression.	**Attrition:** Not reported. **Weight changes:** Women gained (2.42 kg) significantly more ($p > 0.01$) weight than men (1.58 kg). Within each ethnic group, women gained significantly more weight than men ($p > 0.01$). Mean weight changes were 1.54 kg and 2.35 kg, respectively, for Anglo-Celtic men and women; 1.82 kg and 1.68 kg, respectively for Greek men and women; and 1.64 kg and 2.69 kg, respectively, for Italian/Maltese men and women. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change: Age, education, baseline weight** *Age:* Those in younger age groups gained significantly more weight than older groups, with those aged 35–44 years gaining the most weight within every sex or ethnic group. In all three ethnic groups, younger men were more likely to report larger weight gains ($p > 0.01$ for all groups), with men aged 35–44 years more likely than any other age group to have gained 2–4.99 kg, 5–9.99 kg or 10 kg or more. Younger women ($p > 0.01$ for all ethnic groups) were more likely to	**Adjusted for:** Not reported. **Author's conclusions:** Findings of widespread weight gain and obesity across the entire population sample, particularly among younger women and women who were already overweight, are a cause for alarm.

			experience moderate to large weight gains. *Education:* Education level was not significantly associated with weight gain, except among Anglo-Celtic men, with those who were tertiary educated gaining most weight. Education level was not associated with weight change for Greek (p = 0.23) or Italian/Maltese (p = 0.13) men. Anglo-Celtic men who were primary educated were the most likely to have maintained their weight, and those who were tertiary educated were most likely to report small to moderate gains (2–9.99 kg) (p > 0.05). However, education level was not associated with weight gain among women in any ethnic group. *Baseline weight:* Obese Anglo-Celtic women were likely to gain 10 kg or more than were all other women. Across all three ethnic groups, overweight and obese women also tended to be more likely than other women to report major weight loss (>10 kg).	
Ball 2002 Prospective cohort 2+ **Aim:** To investigate the prevalence and predictors of weight maintenance over time in Young Australian Women. More specifically relationships between weight maintenance and behavioural factors like PA, diet, and	8726 young women, who are residents of Australia, aged 18–23 years at baseline. **Baseline BMI or weight:** 47% of women were categorised as having a healthy weight (BMI 20–25 kg/m^2), 23.3% as overweight or obese (BMI 25–30 kg/m^2) and 11% who had height or weight missing and could not be classified.	**Year of baseline survey:** 1996 **Duration of follow-up**: 4 years. **Outcome variable**: BMI/ weight. **Self-reported or measured weight:** Self-reported. **Statistical analysis**: Logistic regression.	**Attrition:** 0% **Weight changes:** Only 44% of the women reported their BMI at follow up to be within 5% of their baseline BMI; 41% had gained weight and 15% had lost weight. **Association of diet with weight change:** Restrictive eating practices (p > 0.05) and women who reported eating takeaway occasionally were 15% less likely to be weight maintainers than those who rarely or never ate takeaway. **Association of physical activity with weight change:** Women who reported moderate or high sitting time were 17–20% less likely to have maintained their weight **Association of other factors with weight change: Smoking** **Smoking** was significantly associated with decreased likelihood of weight maintenance. Low **alcohol** intake was associated with increased likelihood of maintaining weight. Weight maintainers were more likely to be in managerial or professional occupations; to have never married; to be currently studying and not to be	**Adjusted for:** Not reported. **Author's conclusions:** Early adulthood may be an important time for implementing strategies to promote maintenance of healthy weight.

alcohol consumption.			mothers.	
Bell 2001 Prospective cohort 2+ **Aim:** To describe and analyse 8-year weight change in Chinese adults and to determine the baseline characteristics of those who gained weight in the time period.	2488 Chinese adults aged between 20–45 years from seven provinces of China. **Baseline BMI or weight:** Mean weight of males 58 kg and BMI 21.2 kg/m^2. Mean weight of females 52 kg and BMI 21.7 kg/m^2.	**Year of baseline survey:** 1989 **Duration of follow-up**: 8 years. **Outcome variable**: Weight (kg), BMI. **Self-reported or measured weight:** Measured. **Statistical analysis**: Multiple logistic regression.	**Attrition:** 41% **Weight changes:** Mean BMI increased from 21.5 to 22.4 kg/m^2. From 1989 to 1997 the proportion of underweight men and women dropped by 2.3% and 4.4%, respectively. There was a 9% increase in the proportion of men and women who were overweight. The prevalence of obesity in women increased 7-fold from 0.2 to 1.5% over 8 years. By 1997 14.1% of men and 20.7% of women were overweight or obese compare with 5.0 and 10.5% in 1989. Overweight (BMI > 25 kg/m^2) doubled in females (10.4–20.8%) and almost tripled in males (5.0–14.1%). **Association of diet with weight change:** Energy intake did not affect the risk of weight gain. **Association of physical activity with weight change:** Men who experienced large weight gain (>5 kg) were three more times likely to have engaged in light rather than heavy work related activity, two and a half times more likely to have engaged in moderate rather than heavy PA. For men, having light to moderate activity levels at work (vs. heavy) was predictive of subsequent weight gain. Only PA played a role in weight gain for women. Women who gained >5 kg were 83% and 69% more likely to have done light and moderate rather than heavy PA compared with those who remained stable weight. **Association of other factors with weight change: Height, education, alcohol, smoking** For men, being **tall** at baseline and having a college **education** (vs. primary school education) were predictive of subsequent weight gain. For women having a college education at baseline was predictive of subsequent weight loss. Men who experienced large weight gain (>5 kg) were 55% more likely to have consumed **alcohol**. **Smoking** did not affect the risk of weight gain.	**Adjusted for:** Anthropometric and socio-economic variables were included as control variables. **Author's conclusions:** The prevalence of overweight increased dramatically in this particular cohort. Light work-related PA was the strongest predictor of the weight gain.
DiPietro 1998 Prospective cohort 2+	4599 men and 724 women with an age range of 20–82 years (mean	**Year of baseline survey:** 1970 **Duration of follow-up**:	**Attrition:** Not stated. **Weight changes**: Small weight gain over the follow up (0.61 ± 5.29 kg for men and	**Adjusted for**: Age, height, baseline weight, baseline treadmill time,

Aim: To determine the longitudinal relationship of change in cardiopulmonary fitness to subsequent change in body weight in a cohort of healthy middle-aged adults.	43 ± 9 years) from Dallas, TX, USA (no personal history of heart attack, hypertension, stroke or diabetes and no resting electrocardiogram (ECG) or exercise ECG abnormalities). **Baseline BMI or weight:** Mean weight of men: 81.2 ± 10.7 kg. Mean weight of women: 43.1 ± 8.7 kg.	24 years. **Outcome variable**: Weight (kg). **Self-reported or measured weight:** Measured. **Statistical analysis**: Multivariate linear regression.	1.51 ± 4.67 kg for women; $p > 0.001$), which is consistent with population trends for middle-aged adults. NB: These summary statistics, however, may mask heterogeneous patterns of change, as some participants lost substantial amounts of weight over the follow-up, while others gained weight. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** *Physical activity and television viewing:* Each 1 min improvement in treadmill time, significantly attenuated weight gain in both men ($p > 0.001$) and women ($p > 0.001$), respectively. Each 1 minute improvement in treadmill time, reduced the odds of a >5 kg gain by 14% in men and by 9% in women; and the odds of a >10 kg gain by 21% in both men and women. Higher baseline levels of PA and lower levels of TV/video viewing remained independently related to a lower risk of becoming overweight. The association between the 2-year change in PA or TV/video viewing and the 2-year change in BMI was also examined in the same male cohort. This suggests a small significant correlation between changes in activity or sedentary behaviour and BMI. Each 10 METs per week increase in PA (1 extra hour of running per week) was associated with a 0.03 BMI (0.44 kg) attenuation in weight gain and each 10 hour per week increase in TV/video viewing correlated with an excess weight gain of 0.05 BMI units (0.73 kg) over 2 years. .	smoking status, number of clinic visits and follow up time were all adjusted for. **Author's conclusions:** Improvements in fitness, appear important in attenuating age-related weight gain in healthy middle-aged adults. Thus, an active lifestyle should be promoted early and maintained through adulthood to prevent substantial weight gain and obesity with age.
Droyvold 2004 Prospective cohort 2+ **Aim:** To study the association between PA at baseline and change in BMI	9357 healthy women aged 20–49 years who had a normal body weight (a BMI of 18.5 – 24.9 kg/m^2) at baseline from Nord-Trondelag County, Norway (not >50 years	**Year of baseline survey:** 1984–86 **Duration of follow-up**: 9 years. **Outcome variable**: BMI. **Self-reported or measured weight:**	**Attrition:** Not reported. **Weight changes:** Mean BMI gain was 2.5 (range 5.6 –18.5) kg/m^2. The mean BMI increased in all age cohorts and in all categories of LTPA, smoking, education, baseline BMI, marital status and alcohol consumption. By follow-up 60.3% were in the normal weight category and the proportion of those in the overweight category (BMI of 25.5–29.9 kg/m2) was 36.4%. 3.1% were classified as obese (BMI >30 kg/m2). 1.3% of subjects gained >5 kg during the 11th year of follow-up time and	**Adjusted for:** Age, education and BMI at baseline to investigate association between LTPA and BMI 11 years later. **Author's conclusions:**

during follow up (11 years).	old and no reports of diabetes, stroke, angina, myocardial infarction, or long term illness impairing their function in daily life). **Baseline BMI or weight:** Average BMI of 22.0 kg/m^2.	Measured. **Statistical analysis**: Linear regression.	only 1.4 % lost >5 kg. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** Those with moderate and high levels of leisure PA at baseline gained less weight than those with low levels. However, the observed difference in mean weight change between low and moderate levels of LTPA did not reach statistical significance. Those with high level of activity gained 0.18 kg/m^2 (95% CI 0.05, 0.32) less than those with low level of PA over 11 years. **Association of other factors with weight change: BMI, age, PA, education, alcohol** Characteristics associated with highest BMI gain were high baseline BMI level, younger age, low or moderate LTPA level, low level of education and not drinking alcohol in the last 14 days.	LTPA has a moderate effect on BMI. However, not even a high level of LTPA was sufficient to prevent weight gain and BMI increase in all subgroups of the study population.
Hardy 2000; Langenberg 2003 Prospective cohort 2+ **Aim:** To investigate the effect of childhood weight and childhood socio-economic status on the pattern of change in BMI between 20 – 53 years.	2547 women and 2815 men born in the first week of March in 1946 from **England, Scotland and Wales.** **Baseline BMI/weight:** Number of men overweight (BMI >25 kg/m^2): 134 Number of men obese (BMI >30 kg/m^2): 8 Percentage of men overweight: 11.5% Percentage of men obese:	**Year of baseline survey:** 1946. **Duration of follow-up:** 53 years. **Outcome variable:** BMI. **Self-reported or measured weight:** Ages 7–14, 36, 43 and 53 years measured . Other ages self-reported. **Statistical analysis:** Repeated measures.	**Attrition:** At 43 years 6.8 % had died, 12.1 % had withdrawn from the study, 11.5% were living abroad and 8.8% had temporarily refused to participate or could not be traced. **Weight changes:** In general, the rate of increase in BMI with age was non-linear, with the rate of increase in mean BMI accelerating with increasing age at differing rates for both sexes**.** Mean BMI, which was calculated separately for each measurement, increased with age for both sexes and at every age the mean BMI was lower among women than men. Birth weight was positively associated with adult BMI (0.53 kg/m^2 for every kg increase in birth weight). **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** *Age:* There was a greater percentage of men overweight (>25 kg/m^2) at	**Adjusted for:** Assessment of influence of father's social class at 4 years of age was adjusted for offspring's own social class in young adulthood and middle-age (Langenberg). Final childhood risk factor model was adjusted for adult social class and educational attainment to assess whether the influence of

	0.7% Number of women overweight: 113 Number of women obese: 16 Percentage of women overweight: 10.1% Percentage of women obese: 1.4%		each age but a lower percentage obese (>30 kg/m^2). At all ages those from a manual **social class** had a greater proportion classified as overweight and obese compared with those from non-manual social classes. Of those overweight at 20 years and by 43 years, 80% were overweight. The increase in obesity was also very high in this particular group increasing from 6% at 20 years to 35% at 43 years. For men at age 20 years the estimated mean BMI was 23.33 kg/m^2 while for women it was 21.72 kg/m^2. The estimated mean linear increase in BMI was greater among men at 0.12 kg/m^2 per year than women for whom it was 0.03 kg/m^2. Women had a mean BMI of 0.61 kg/m^2 less than men at 20 years, which is 1 kg/m^2 less at both 26 and 36 years with the difference decreasing again to 0.6 kg/m^2 less at 43 years. *Social class:* Father's social class at 4 years was inversely associated with adult central and total obesity at age 53 years in both men and women. The mean difference of waist-to-hip ratio between fathers professional social class I and unskilled manual social class V was 2.6 (range 0.7–4.6)% for men and 2.5 (range 0.5–4.4)% for women. The effect of fathers social class remained after adjustment for participants own social class in young adulthood and middle age. Both adult social classes were inversely related to obesity among women, but not men. Active men and women were less obese than participants remaining in their fathers' social class and their levels of obesity tended to be between the class they left and the class they joined. At 14 years, mean BMI and faster rate of increase than others and those from a manual social class background had a higher mean BMI and a faster rate of increase than those from a non-manual background.	childhood factors was independent of adult social factors (Hardy). **Authors' conclusions:** Childhood relative weight and childhood social class were shown to have an effect on BMI in adult life and change in BMI from ages 20 to 43 years, even after adjustment for adult SES and education. The effect of social class on adult obesity differed according to the stage in the life course at which social class was measured, and gender. Childhood circumstances had enduring influences on adult obesity.
CARDIA (Coronary Artery Risk	CARDIA is a population based	**Year of baseline survey:** 1985–86	**Attrition:** Baseline data were collected on 51% of eligible persons contacted. Overall retention rates were 90% at 2 years, 86% at 5 years, 81% at 7 years, 79%	All analyses were **adjusted for**:

Development in Young Adults) Prospective cohort 2+ **Aim:** To estimate the change in BMI over 10 years in a cohort of young US men and women, and assess differences by a range of variables. Lewis 2000 Black and minority ethnic group [BMEG]-based on 10-year follow-up data) Pereira 2005 Fast Food – based on 15 year follow-up data. Sternfeld 1998 PA – based on 7-year follow-up data of selected individuals who completed a treadmill test at	prospective study of 5,115 African American and White men and women in the USA aged 18–30 years at baseline. Study population was balanced on: Age (45% 18–24 years) Sex (46% men) Ethnicity (52% African American) **Baseline weight (kg) as mean (SD) and overweight (%):** AAW: 69.5 (18.3) kg, 44.7% WW: 63.1 (12.8) kg, 22.1% AAM: 77.5 (15.6) kg, 36.9% WM: 77.1 (12.6) kg, 12.6%	**Duration of follow-up**: Ongoing. **Outcome variable**: measured height and weight (and % overweight) at baseline and again at 2, 5, 7, 10 and 15 years), and waist-to-hip ratio. Self-reported or measured variables: • Age • Education • Smoking status • CARDIA PA history questionnaire • Physical fitness (treadmill test, only assessed in selected subsample) • CARDIA dietary assessment = a structured interview (was not done at year 2 follow up) and CARDIA diet history. • Parental fatness and education were derived from self and interviewer-administered questions	at 10 years, and 74% at 15 years. **Association of diet with weight change** (based on 15 year follow-up data)**:** Fast foods were quantified based on eating out occasions at restaurants 'such as McDonalds, Burger King, Wendy's. Arby's. Pizza Hut or Kentucky Fried Chicken'. **Fast food intake** was lowest for WW (about 1.3 times per week) compared with the other race-sex groups. Baseline **fast food frequency** was directly associated with changes in weight in both black (p = 0.0050) and white people (p = 0.0013). Change in fast-food frequency over 15 years was directly associated with changes in bodyweight in white individuals (p<0.0001), with a weaker association recorded in black people (p=0.1004). By comparison with average 15-year weight gain in participants with infrequent (less than once a week) fast food restaurant use at baseline and follow up (*n* = 203), those with frequent (more than twice a week) visits to fast food restaurants at baseline and follow up (*n* = 87) gained an extra 4.5 kg weight (p = 0.0054) . **Association of physical activity with weight change:** *Note:* analysis based on a selected subgroup (*n* = 1777) who completed a symptom-limited graded treadmill exercise test at baseline and year 7. Decreased fitness during young adulthood is strongly associated with increased weight (correlations ranged from –0.34 in WM to –0.49 in WW). Decreased PA was moderately associated with increased weight in WM and BW (correlations –0.13 and –0.15, respectively). Analysis by baseline physical fitness and PA was not presented. **Association of other factors with weight change:** *BMEG (based on 10-year follow-up):* Weight gain 0.96 kg/year (95% CI 0.79, 1.13) in AAW; 0.55 kg/year (95% CI 0.41, 0.69) in WW. *Pregnancy (based on 5 year follow-up of 2788 women at baseline):* Primiparous within both race groups gained 2 or 3 kg more weight during the 5-year period than did nulliparous. Primiparous also had greater increases in waist-to-hip ratio that were independent of weight gain.	Age; Education; Smoking status. Also **adjusted for** PA in analysis. AAW: African American Women WW: White Women AAM: African American Men WM: White Men Overweight was defined as BMI >25.0 kg/m^2.

baseline and 7 years. Smith 1994 Pregnancy – based on 5-year follow-up. Greenlund 1996**;** To assess whether parental educational attainment, parental body shape, and offspring's education were associated with BMI and change in BMI over 7 years		**Statistical analysis**: Various, but all used some form of regression analysis. Women who remained nulliparous (*n* = 925) at 5 years were compared with women who had a single pregnancy and who were at least 12 months postpartum at 5 years.	Multipara did not differ from nulliparous in adiposity change in either race group. *Pregnancy – Black and ethnic minority groups:* At each level of parity, Black women demonstrated greater adverse changes in adiposity than did White women. In conclusion: women experience modest but adverse increases in body weight and fat distribution after a first pregnancy and that these changes are persistent. **Association of other factors with weight change:** (education/body size) **Parental education:** With adjustments for major independent variables, significant associations between fathers educational level and participants baseline BMI were observed among Black men and White women. Father's educational level was associated with a 7-year difference in BMI for White women only. Further adjustment for smoking, alcohol consumption, and PA yielded similar results. In analysis adjusted for age only, father's educational level was also associated with baseline BMI among Black women. In similar models in which father's educational level was replaced by mother's education, only the association with a 7-year change in BMI was significant among White women. **Parental body size:** Father's body size was positively associated with BMI among Black men, White men and White women. Trends were similar in analyses adjusted for age only and analyses adjusted for other lifestyle factors. Mother's body size was positively associated with BMI among all four race-sex groups, and with a change in BMI among White women. When adjusted for age only, a positive association with change in BMI among Black men and Black women was also observed. When adjusted for smoking, alcohol consumption and PA level, results were similar.	

			Participant education: Those participants with the highest education had the lowest BMI and change in BMI over 7 years.	
Wagner 2004 Prospective cohort 2+ PRIME Study **Aim:** To examine the influence of PA on change in BMI (and waist) in middle-aged men over a 5-year period, with special regard to moderate-intensity activities.	Data for this study were collected as part of the PRIME Study (arisen out of the MONICA study). Total *n* = 8069. A cohort of 8865 men aged 50–59 years from centres in France and Northern Ireland. Weight data were missing for 796 of these men at 5 years. No data on ethnicity presented in this paper. **Exclusion criteria:** History of coronary heart disease, diagnosis of cancer during follow-up. **Baseline BMI, mean (SD):**	**Year of baseline survey:** 1991–93. **Duration of follow-up**: 5 years. **Outcome variable**: BMI. **Self-reported or measured weight:** Measured at baseline, but self-reported at yearly follow-ups. **Statistical analysis**: Multiple linear regression.	**Attrition:** 90% of those who took part in the study in 1991–93 were included in the analysis at 5 years. **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** Change in BMI was inversely associated with PA expenditure spent in getting to work, and the practice of high-intensity (> 6 METs) recreational activities. Men who regularly spent more than 10 MET hours per week on walking or cycling to work had a mean change in BMI 0.06 kg/m^2 lower than those who expended less than 10 MET hours per week on walking or cycling to work. In the subgroup of men who did not perform high intensity activities, the level of recreational PA expended was *not* associated with weight gain. **Association of other factors with weight change:** No analysis. **Summary:** In middle-aged men, PA of moderate intensity, which are probably easier to promote than more vigorous activities and, in particular, a more current daily activity, walking or cycling to work, may have a more favourable effect on weight gain.	**Adjusted for**: Covariates: Educational level; Smoking status; Alcohol consumption; Centre; Age; Marital status; Pursuit of weight-control diet; SES. *Note*: Lengthy details about how PA was categorised and calculated are in the paper. PA – the MOSPA-Q was used to assess the amount of PA performed during the previous year, according to the category of PA (occupational activity, walking or cycling to and from work, and leisure-time activities)

	26.6 (3.4) kg/m^2			
Heitmann 1995 Prospective cohort 2+ **Aim:** To examine the influence of dietary fat on changes in BMI in adult women at 6 years while taking into account their predisposition to obesity, total daily energy intake, leisure PA, smoking status, and menopausal status. **Ow/Op:** Overweight women (BMI > 25 kg/m^2) with at least one obese parent; *n* = 56. **Ow/Np:** Overweight women (BMI > 25 kg/m^2) with non-obese parents; *n* = 53. **Nw/Op:** Ideal weight women	*n* for this analysis = 308. Data for this study were collected on a subset of 437 women, selected randomly at baseline from a larger population sample of 1462 women aged 38, 40, 50, 54 or 60 years living in Gothenburg, Sweden. At baseline in 1968–69, 418 of these women participated in a diet history interview, a 24-hour dietary recall, and a health examination. Six and 12 years later, in 1974–75 and 1980–81, all participants were invited to follow-up health examinations. The second examination (at 6 years) was attended by 373	**Year of baseline survey:** 1968–69 **Duration of follow-up**: 6 years. **Outcome variable**: BMI (measured height and weight). **Self-reported or measured weight**: Measured **Statistical analysis**: The relation between change in BMI over 6 years and fat intake at baseline within the four groups of women was assessed by regression. In the regression analysis, a number of covariates at baseline were included; age, BMI, total daily energy intake, LTPA, smoking habits. Menopausal changes between baseline and 6 years were included as covariates.	**Attrition:** 70% **Association of diet with weight change:** *Summary:* High dietary fat (>40% total daily energy intake) was significantly associated with a 6-year gain in BMI only among women predisposed to obesity (*p* = 0.003), but not among obese women with lean parents, or lean women with or without obese parents. *Note*: Only six Ow/Op women had fat intakes >40% total daily energy intake. **Association of physical activity with BMI change:** No analysis. **Association of other factors with weight change**: No analysis.	**Adjusted for:** Covariates stated in statistical analysis.

(BMI <25 kg/m^2) with at least one obese parent; *n* = 87. **Nw/Np:** Ideal weight women (BMI <25 kg/m^2) with non-obese parents; *n* = 112.	(89%) of the 418 women, and the third examination (at 12 years) was attended by 324 (78%) of the 418 women. At the12-year follow up, 316 of the 324 women answered questions about the fatness of their mother and father. For this paper, only women who provided baseline data, data on height and weight at 6 years, and answered questions about the fatness of their mother and father at 12 years were included. Of the potential 316 women who could be included in this analysis, eight were excluded (had cancer at baseline).			

	Women already overweight with one or more obese parent(s) were considered to be predisposed to obesity. No data on ethnicity, education or income presented in this paper. **Exclusion criteria:** Pre-existing major chronic diseases at baseline (stroke, myocardial infarction, diabetes, cancer) **Baseline BMI (kg/m^2), mean (SD):** Ow/Op (*n* = 56) 29.6 (4.0) Ow/Np (*n* = 53) 28.0 (2.7) Nw/Op (*n* = 87) 22.4 (1.7) Nw/Np (*n* = 112) 21.9 (1.9)			
Sundquist 1998 Prospective	1972 women and 1871 men (*n* = 3843) aged	**Year of baseline survey:** 1980/81	**Attrition:** 17%	None stated **Author's**

cohort 2+ **Aim:** To assess the influence of ethnicity (country of birth) and SES on BMI.	between 25–74 years, from Sweden. The subjects were all Swedish residents either born in Sweden, Finalnd, Western Europe and Western Europe. **Baseline BMI:** Baseline mean BMI for male subjects: 25–34 years: 23.5 kg/m^2 35–44 years: 24.4 kg/m^2 45–54 years: 25.2 kg/m^2 55–64 years: 25.3 kg/m^2 65–74 years: 25.4 kg/m^2 Baseline mean BMI for female subjects: 25–34 years: 21.7 kg/m^2 35–44 years: 22.7 kg/m^2 45–54 years: 24.1 kg/m^2 55–64 years: 24.9 kg/m^2 65–74 years:	**Duration of follow-up**: 8 years. **Outcome variable**: BMI. **Self-reported or measured weight**: Not stated. **Statistical analysis**: Pearsons correlation coefficient was used to calculate the correlation between BMI in 1980–81 and 1988–89.	**Weight changes:** The mean BMI increased significantly between 1980–81 and 1988–89 in both men and women in all age groups, apart from the age group 65–74 years where BMI decreased. **Association of other factors with weight change:** *Socioeconomic status:* People of a low level of education had the highest BMI. All educational groups increased their BMI over 8 years with the exception of poorly educated men. Less educated individuals increased their mean BMI by 0.25 kg/m^2 less than highly educated people (reference group), based on educational level 1988–89. Men and women who were single in 1980–81 and married in 1988–89 increased their BMI by 0.37 and 0.65 kg/m^2 more than those who were married at both times. Poor health status was related to a decreased BMI among men but not among women. Males who reported good health status in 1980–81 and bad health status at follow up decreased their BMI by 0.28 kg/m^2 less than males who were in good health status at baseline and follow-up. *Ethnicity:* The different ethnic groups had similar changes in BMI changes in BMI from 1980–81 to 1988–89. The BMI of men and women born in Sweden and other western countries and of women born in Finland increased significantly through the 1980s. The BMI of southern European Men increased from 25.5 to 27.0 kg/m^2 during the same period. Southern European men had a higher BMI compared with the reference group; this was the same for southern European women, but no significantly so. Finnish women had an increased BMI on adjusting for the age, smoking, exercise, education, marital status, health status and time. *Smoking:* Male smokers had an increased BMI compared with those who had never smoked. Female smokers had a much lower BMI compared with those who have never smoked. *Physical activity:* Not taking exercise was associated with an increased BMI for men and women.	**conclusions:** SES and ethnicity are two separate independent factors that influence BMI in males and females. Former smokers had a larger increase in BMI than those who have never smoked. Males who quit doing exercise had a larger increase in BMI than regular exercisers.

	25.1 kg/m^2		Males taking exercise in 1980–81 but not at follow up increased their BMI by 0.28 kg/m^2 more than the reference group (people taking exercise at baseline and follow-up). Females who did not take exercise on both occasions decreased their BMI by 0.37 kg/m^2.	
Tiggemann 2004 Prospective cohort 2+ **Aim:** To assess dietary restraint and self-esteem as predictors of weight change over 8 years.	*n* = 77 young adults (19 men, 58 women), mean age 25 years, all undergraduate first-year students at University in Australia. No data on ethnicity, education or income is presented in this paper. **Exclusion criteria:** Pregnancy, medical condition that significantly affected weight **Baseline weight (kg), mean (SD):** Men: 75.2 (6.2) Women: 58.0 (7.0)	**Year of baseline survey:** Not reported. **Duration of follow-up**: 8 years. **Outcome variable**: BMI. **Self-reported or measured weight**: Self-reported. **Statistical analysis**: Hierarchical multiple regression.	**Attrition:** 60% of those who took part in the study at baseline (*n* = 166). **Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** Neither dietary restraint nor self-esteem predicted weight change on its own in men or women, but their interaction did in women. The women who put on the most weight were those low or high in both dietary restraint and self-esteem. The group who put on the least weight were those low in dietary restraint and high in self-esteem.	None stated.
van Lenthe 2000	*n* = 767 young Dutch adults (362 men, 405	**Year of baseline survey:** 1991	**Attrition:** Difficult to assess.	None stated.

Prospective cohort 2+ GLOBE study **Aim:** To assess socio-demographic variables as predictors of weight change over 6 years in a group of young Dutch adults.	women), age 20–49 years at baseline. **Exclusion criteria:** Missing information, serious heart problem, cancer, and diabetes. **Baseline BMI (kg/m^2), mean (SD):** Men: 24.3 (2.9) Women: 23.0 (3.3)	**Duration of follow-up**: 6 years. **Outcome variable**: BMI. **Self-reported or measured weight:** Self-reported. **Statistical analysis:** Multivariate linear regression.	**Association of diet with weight change:** No analysis. **Association of physical activity with weight change:** No analysis. **Association of other factors with weight change:** Despite significant associations between BMI and SES at baseline, no statistically significant associations were found between SES variables and the 6-year change in BMI.	Author's conclusions: SES was not associated with the 6-year change in BMI.

MEDLINE SEARCH STRATEGY

1. weight gain/ph
2. (prevent$ adj3 weight gain).ti,ab
3. or/1–3
4. limit 4 to yr=1990-2005
5. limit 5 to English
6. animal/
7. human/
8. 7 not (7 and 8)
9. 6 not 9

MEDLINE SEARCH STRATEGY FOR UPDATE SEARCH TO 1ST DECEMBER 2005

1. Weight gain.tw
2. Cohort.tw
3. 1 and 2
4. Limit 3 to yr=2005

Line 2 of the original search strategy (see below) was omitted in order to widen the search in an attempt to capture all key cohorts. Lines 5-9 of the original search strategy were unnecessary given the relatively small number of hits for the update.

DATA SOURCES

The following information sources were searched:

AMED
ASSIA
British Nursing Index
CAB Abstracts
CENTRAL (Cochrane Controlled Trials Register)
CINAHL
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
CRD (EED database) http://www.york.ac.uk/inst/crd
DARE
Embase
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC
Food Standards Agency - http://www.food.gov.uk/science/research/
HDA Evidence Base - http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA - http://www.ncchta.org
NICE – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus

The electronic search strategies were developed in Medline and adapted for use with the other information sources.

EXCLUDED REFERENCES

Excluded references not meet all review parameters. The main reason for exclusion was that the study was not a prospective cohort with at least 12 months duration or it was a non-systematic review.

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Appendix 5

Raising awareness of what constitutes a healthy weight range and the need to stay within such a range

EVIDENCE SUMMARY TABLES

EVIDENCE TABLE 1: **RAISING AWARENESS OF WHAT CONSTITUTES A HEALTHY WEIGHT RANGE AND THE NEED TO STAY WITHIN SUCH A RANGE**

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
O'Loughlin et al. 1998	RCT	1	+	Intervention *n* = 94 Control *n* = 94 Data based on completers (intervention = 82, control = 75) **Age:** Intervention group: Female: 67.1% Age: 39.2 years ± 14.5 Control group: Female: 72.0% Age: 37.0 ± 12.6 years **Education attainment (%):** Intervention group:	This RCT investigated the impact of a low intensity, healthy weight intervention in low-income adult volunteers from inner city St Henri, Canada. Pamphlets (18 four-page, two-colour, glossy and pre-punched, two or three per week) were distributed to the	**Intervention:** 8 weeks. **Follow-up:** 10 weeks (2 weeks after end of intervention).	816 people were contacted but 188 (23%) volunteered to receive the pamphlets. Seventy-three participants were recruited from the Awareness and Participation Survey (13.6%); 115 participants were recruited from the 279 households contacted in the supplemental survey (41.2%). Eighty-two of 94 intervention participants (87.2%) and 75 of 94 control participants (79.8%) completed both interviews. The intervention had no effect on body mass index (BMI).	Short follow -up period. Data were self-reported. Use of telephone interviews (minimal face to face contact) possibility of bias related to social desirability. **Generalisability:** Unclear, low-income low-literacy inner city population of

				Less than secondary: 17.1 Completed secondary: 39.0 Completed university: 43.9 Control group: Less than secondary: 17.8 Completed secondary: 38.4 Completed university: 43.8 **Main activity in past 12 months (%):** Intervention group: Work: 54.9 Looking for work: 3.7 Student: 15.9 Retired: 13.4 Homemaker: 7.3 Other: 4.9 Control group: Work: 63.5 Looking for work: 2.7 Student: 17.6 Retired: 5.4 Homemaker: 6.8 Other: 4.1 **Marital status:** Intervention group: Married: 41.5% Single (never married): 37.8% Separated/widowed/Divorced: 20.7***%*** Control group: Married 38.7%	participants' homes for an 8-week period. The pamphlets focussed on increasing awareness of healthy weight ranges, increasing self-acceptance and satisfaction with weight, and improving eating habits, while not putting much emphasis on dieting and weight loss. Pamphlets designed to be highly accessible to persons of low literacy and based on Canadian recommendations 1988 for healthy weight, pamphlets were piloted. Recruited during October 1995 Awareness and Participation		**Awareness:** Intervention participants remembered receiving 13.1 (± 4) of 18 pamphlets, 89.6% had read one or more and 90.4% found the information useful. Participants in the intervention group were 3.7 times more likely than participants in the control group to report they knew how to control their weight. Participants in the intervention group were also less likely to report they were too heavy (odds ratio [OR] 0.3).	French/English-speaking Canadians.

				Single (never married) 48.0% Separated/widowed/Divorced: 13.3% **Income sufficiency (%):** Intervention: Insufficient: 12.2 Sufficient: 22.0 High: 45.1 Missing: 20.7 Control group: Insufficient: 17.3 Sufficient: 22.7 High: 46.7 Missing: 13.3 Volunteers more likely than non-volunteers to be female, younger and obese and less likely to be in pre-contemplation stage of readiness to improve eating habits. Adults were randomly selected from households which were randomly selected from residential telephone subscriber lists for the main survey; additional survey households also randomly selected but individual who answered the phone was asked to identify one adult member who might want to participate in the trial. All participants then 'randomly	telephone survey of adults in St Henri (plus a supplemental sample from telephone subscriber list) one of three annual surveys to monitor community penetration of Coeur en sante St Henri activities (multifactorial community heart health promotion programme in Montreal). **Providers of intervention:** Research staff.			

				allocated' to intervention or control group.				
Wardle et al. 2001; Miles et al. 2001	Before and after study design with one cross-sectional survey by the Office of National Statistics (ONS) and pre-post survey of random sample of respondents.	2	+	ONS survey: Total sample *n* = 1894 Men *n* = 938 Women *n* = 956; All adults but targeted more to overweight and obese adults. Age (years) **Women (%) Men (%)** 16–24 11.2 16.5 25–34 18.1 16.3 35–44 20.3 18.8 45–54 16.8 18.4 55–64 13.5 11.3 65 +0.1 18.7 Ethnicity **Women (%) Men (%)** White 95.1 94.7 Non-White 4.9 5.3 Maritial status % **Women(%) Men (%)** Single 15.9 24.4 Married/ cohabiting 63 66.7 Separated/ divorced/ widowed 21.1 8.9 Occupational social class	The study's primary objective was to evaluate the BBC's national 'Fighting Fat, Fighting Fit' (FFFF) campaign's success in achieving public awareness of the need for obesity prevention and putting over its message of healthy eating and increased physical activity (PA). The campaign aimed to stimulate behaviour change and was based on behaviour change theories such as Social Learning Theory and the Health Belief Model. Main message of campaign was that weight problems are	Campaign was for 7 weeks. General population survey by ONS: 3 months after the campaign finished. (March 1999). Registrants survey (random sample of 6000) where pre-campaign baseline behaviour assessed retrospectively 5 weeks into the 7-week campaign and again 5 months later.	70% (*n* = 1894 interviews) of random sample of ONS survey participated in telephone interview; 0.9% sent for registration pack; 0.2% registered with scheme. **Registrants survey:** 14% of those who requested an information pack returned their registration card, 61% returned the baseline questionnaire, 58% of people who completed baseline questionnaire also completed 5-month follow-up questionnaire (35% of original random sample of 6000). Non-completion rate of activity measure was 12% so results here should be treated with caution. Adults from higher socio-economic groups not only more likely to complete baseline questionnaire but complete follow-up questionnaire (suggesting more active participation in campaign). **Office of National Statistics survey:** 56.6% (*n* = 1072) had heard of the campaign, 29% recalled watching one of the television	Self-reported data. Generalisation of the results is limited due to the 70% response rate for ONS survey and less than 1% registered and of these 6000 surveyed in registrants survey.

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<p>Years of education</p>
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<p>Campaign registrants survey randomly selected sample of 6000 from 33,474. Evaluation participants were more likely to be female (87%), aged between 25–49 years, have an educational qualification, have a degree, be in paid work, have access to car/van and own their own home – suggesting they came from higher socio-economic status (SES) groups. They were less likely to be smokers, less likely to be classified as vigorous exercisers and more likely to be classified as obese compared with the British adult population.</p>
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<td>best tackled with small but permanent changes to diet and exercise rather than short-term dieting to achieve rapid weight loss.
The FFFF was promoted over 7 weeks of campaigning during peak and day-time programming across BBC one and two, BBC radio two and local BBC radio programmes and was additionally supported by the BBC FFFF official website, Ceefax, a book, a video, the <i>Radio Times</i> and telephone lines that provided further information to the general public. People could write or telephone for an information pack</td>
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<td><p>(TV) programmes and about the same number remembered the campaign involved either healthy eating or being more active. Less than 1% registered to participate in the scheme.</p>
<p>Higher levels of awareness, a greater likelihood of watching the programmes and better memory for the messages were found among younger, White, female respondents and those with more years of education. There were no significant regional differences or any differences associated with body weight.</p>
<p>People who remembered having seen one of the TV programmes were significantly more likely to recall the lifestyle message independent of demographic predictors indicating TV programmes were effectively transmitting the message. 87% said they were introduced to campaign through TV, 14% by radio.</p>
<p>The campaign was effective in reaching its target audience (non-manual and skilled manual aged 21–45 years) as a significantly larger proportion had heard of the campaign compared with those</p>
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					for £2 including self-help guide and three registration cards to return over 5 months to chart progress also money-off vouchers for FFFF book and exercise video up to total of £3, other incentives/prizes such as years free supply of fruit and vegetables. The FFFF campaign aimed to target specifically groups with higher prevalence of obesity (those in socio-economic groups 3M and 4). The crossover between those most likely to be obese and BBCs typical audience was considered to be those in		not in target audience (67% vs. 54%, $p > 0.001$). **Registrants survey:** Average post-campaign weight was 2.3 kg lower for full sample (baseline scores carried forward to follow-up for those who did not complete follow-up questionnaire, $n = 3661$) and 4.2 kg for completers ($n = 2122$, $p > 0.001$) with 44% full sample and 78% completers losing weight. Average BMI remained in the obese category. Predictors of change (completers only): men were more likely to report changes in weight, exercise and fried food intake, deprivation level was associated only with decreases in fried food intake, baseline weight predicted weight loss and positive changes in diet with obese reporting greater changes. Predictors of change (all participants): groups with higher levels of deprivation were less likely to report weight loss or exercise increase, obese did not report greater changes in diet and weight loss and changed less in terms of exercise than normal weight groups.	

					social classes 3NM and 3M aged between 21–45 years (skilled non-manual and manual groups). The generic campaign trail was broadcast on TV and radio late in December 1998 and in early January 1999. Principal TV programmes (with different target audiences) were ‘Weight of the Nation’, ‘Fat Free’, ‘Fat Files’ (Horizon trilogy), and ‘Body Spies’. BBC radio had 3-day launch with celebrities, TV chef, health minister and phone-in. FFFF campaign mentioned in 60 magazines, 9 national newspapers and 120 regional		Men, people aged <25 years, low SES and Black and Minority Ethnic Groups (BMEGs) may require specifically targeted campaigns – significantly fewer participants in these groups failed to complete the follow-up (registrants survey).	

					newspapers and articles in national press during 7 weeks about 28 times. **Providers of intervention:** The Health Behaviour Unit, Department Epidemiology and Public Health from University College, London and the BBC Education Department.			
Tudor-Smith et al. 1998	Before and after design but samples are independent (cross-sectional) population surveys with an intervention community and a	2	–	**Geographical area:** Wales, UK and north-east England (reference area). Wales: 1985: *n* = 18538 1990: *n* = 13045 North-east England: 1985: *n* = 1483 1990: *n* = 4534 All participants were aged between 18–64 years No further details	To assess the 5-year effect of an intervention of a community-based demonstration project called 'Heartbeat Wales'. The main aim of Heartbeat Wales was to help prevent cardiovascular disease in adults (aged 18–64 years) by focussing on modifiable behaviour risks	Cross-sectional survey took place before and after the end of the 5-year intervention in intervention and control community.	In Wales, the response rate for the household interview was 88% in 1985 and 79% in 1990 and the self-completion response to questionnaire was 67% and 61 % respectively. In the reference area the household interview response was 84% in 1985 and 77% in 1990 and the self-completion response was 64% and 61 % respectively. Altogether 31,583 questionnaires (18,538 in 1985 and 13,045 in 1990) were returned over the surveys in Wales, with 6017 (1483 and 4534, respectively) returned in the north-east of	Self-reported data. The sample size at the baseline measurement at baseline in the North East was too small to give sufficient statistical power to detect a net intervention effect. There is evidence of increases in funding for heart health promotion in the reference area and

	matched reference area.				such as smoking, diet and exercise. Two population surveys (multistage cluster sampling) were conducted in the summer and autumn of 1985 and 1990 in nine different districts of Wales and a matched reference area in the North East of England. Sample size in 1985 survey was determined to detect a 5% change in smoking prevalence within each of the 10 strata (two-tailed). In 1990 sample size was increased in reference area. Heart health promotion used public education campaigns alongside policy		England. Positive changes (for health) in behavioural outcomes were observed among the population in Wales, including a reduction in reported smoking prevalence and improvements in dietary choice. There was no net intervention effect for the programme over and above observed change in the reference area. **Percentage point changes 1985–90 (95% confidence intervals [CI]) aged 18–64 years:** BMI at least 24 kg/m^2 for women and 25 kg/m^2 for men, Wales 2.5 (1.0, 4.0) kg/m^2, control 1.1 (–2.9, 5.1) kg/m^2. Positive change in all behaviour indicators except for overweight, 14 of 15 behaviour-change indicators significant in Wales and 9 of 15 significant in control (13 positive changes).	diffusion of other health promotion campaigns (contamination).

					and infrastructure change. TV programmes were especially developed by BBC Wales and HTV. such as ‘Don’t Break Your Heart’, ‘Fit for Life’ and the BBC Diet programme, ‘Quit and Win’, a smoking cessation programme, food labelling and nutrition education with a major grocery retailer, ‘Heartbeat Awards’, a restaurant and canteen scheme to increase the availability of healthy food choices and smoke free areas and ‘Make Health Your Business’, which was a worksite health promotion programme.			

					In the north-east of England (reference area), no additional community heart health promotion was planned though considerable activity did take place, in order to influence people health behaviours in the north-east. **Providers of intervention:** Health promotion Wales and Research Staff.			

EVIDENCE TABLE 2: RAISING AWARENESS OF WHAT CONSTITUTES A HEALTHY DIET

First author	**Study design**	**Research type**	**ResEarch quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for dietary outcomes								
O'Loughlin et al. 1998	RCT	1	+	Intervention group *n* = 94 Control group *n* = 94 Data below are based on completers (intervention *n* = 82, control *n* = 75). Intervention group: Female: 67.1% Age: 39.2 ± 14.5 years Control group: Female: 72.0% Age: 37.0 ± 12.6 years See weight outcomes table (Table 1) for more detail .	See weight outcomes table (Table 1) for more detail.	**Intervention:** 8 weeks. **Follow-up:** 10 weeks (2 weeks after end of intervention).	The frequency of consumption of junk food/high-fat food remained stable in control and decreased in the intervention group (*p* = 0.019). Intervention participants reported more improvements in their eating habits than control (*p* = 0.021).	
Departm	CBA	2	+	National evaluation of five-a-day	**Aim:**	One-year	Response rate information not	

ent of Health 2003			/ – * [?]	pilot projects in five areas of the UK. No details provided in the executive summary and none available from project despite two approaches (fiveaday@sh.gsi.gov.uk) by Cardiff.	To assess the feasibility of implementing an area-wide approach to increasing fruit and vegetable consumption by improving access, increasing awareness and consumption. The intervention included action to improve access to fruit and vegetables by retailers, food co-operatives and targeted promotional activities in the community and by primary health care professionals. Interventions provided by community based cross-sectoral teams in each area. **Delivered by:**	intervention with pre- and post-questionnaires.	available. The community initiatives stemmed a fall in fruit and vegetable intake against the national trend. There was a fall in intake in the control group by almost half a portion (although baseline data suggested control group had a higher intake by 1.5 portions compared with intervention sites). Overall the intervention had a positive affect on people with the lowest intakes. Those who ate less than five-a day at baseline increased their intake by one portion over the course of the study. In contrast, those who ate five or more a day at baseline decreased intakes by about one portion per day. **Awareness:** 17% increase in proportion of intervention group who correctly reported that five-a-day was the optimal fruit and vegetable intake compare with 8% in the control group.	

					Higher education researchers. No power calculation.			
Wardle et al. 2001; Miles et al. 2001	Before and after study design with one cross-sectional survey by ONS and pre-post survey of random sample of respondents.	2	+	ONS survey: Total sample $n = 1894$ Men $n = 938$ Women $n = 956$; Age (years) **Women (%) Men (%)** 16–24 11.2 16.5 25–34 18.1 16.3 35–44 20.3 18.8 45–54 16.8 18.4 55–64 13.5 11.3 65 +0.1 18.7 See weight outcomes table (Table 1) for more detail.	The study's primary objective was to evaluate the BBC's national FFFF campaign. See weight outcomes table (Table 1) for more detail.	Campaign was for 7 weeks.	**Registrants survey: values are for full sample, all values in parenthesis are for completers only** Fruit and vegetable intake increased by 0.8 (1.3) portions per day, $p > 0.001$. Percentage eating recommended five portions per day increased by 13% (23%), $p > 0.001$. Number of participants eating fried food less than once per week increased by 16% (28%), $p > 0.001$. Proportion consuming whole milk decreased from 10 to 7% (9 to 4%), $p > 0.001$. Cutting visible fat off meat increased, $p > 0.001$. Snack intake decreased by 3 (5) snacks per week, $p > 0.001$. Number of starch-based meals increased slightly with 4% (6%) changing from eating one or fewer to two or more a day.	

							Number of pats of butter/margarine used decreased by 0.6 (1.3), *p* > 0.001); number of pats of low-fat spread decreased by 0.4 (0.7), *p* > 0.001. **Predictors of change (all participants):** Groups with higher levels of deprivation were less likely to report weight loss or exercise increase, obese did not report greater changes in diet and weight loss and changed less in terms of exercise than normal weight groups.	
Tudor-Smith et al. 1998	Before and after design, but samples are independent (cross-sectional) population surveys with an intervention community and a matched reference	2	–	**Geographical area:** Wales, UK and north-east England (reference area). Wales: 1985: *n* = 18538 1990 *n* = 13045 North-east England: 1985 *n* = 1483 1990 *n* = 4534 All participants were aged between 18–64 years. No further details.	The main objective of the study was to assess the 5-year effect of an intervention of a community-based demonstration project called 'Heartbeat Wales'. See weight outcomes table (Table 1) for more detail.	Cross-sectional survey took place before and after the end of the 5-year intervention in intervention and control community.	Positive changes (for health) in behavioural outcomes were observed among the population in Wales, including a reduction in reported smoking prevalence and improvements in dietary choice. There was no net intervention effect for the programme over and above observed change in the reference area. Percentage point changes 1985–1990 (95% CI) aged 18–64 years: Consume fresh fruit at least 4 days a week: Wales 8.4 (6.7, 10.1), control: 8.6 (3.0, 14.2). Consume green vegetables or	

	area.						salad at least 4 days per week: Wales 7.2 (5.1, 9.3), control 9.4 (2.7, 16.1). Consume fried food cooked in lard or other solid fat at least 2 days per week at home: Wales –18.7 (–16.8, –20.6), control –21.5 (–14.6, –28.4); note that consumption of fried food was significantly lower in Wales than reference area at baseline. Positive change in all behaviour indicators except for overweight, 14 of 15 behaviour change indicators significant in Wales and 9 of 15 significant in control (13 positive changes).	
Van Wechem et al. (1997)	Before and after design but samples are independent (cross-sectional) with an intervention community and a control communi	2	–	*n* = 1000 Control community group *n* = 500 Experimental community group *n* = 500 All participants were from Alkamaar in the Netherlands (intervention) and Gouda in the Netherlands (control). Participants were selected by random sampling from local telephone books. Every subject that was selected were contacted a maximum of five times during weekdays at different times of the day. Household members who	Community-based campaign ‘Fat Watch’ 1992, primary aim was to reduce fat intake by 10% among the general Dutch population. Within framework of nationwide fat watch campaign (1991–1994). This intervention was used as a pilot study, which looked at the	Not clear but telephone questionnaires were used before (February 1992) and after (December 1992) the campaign so approximately 8 months.	In Alkamaar, 56% of all respondents reported to be aware of a campaign about dietary fat in their community. A significant lower proportion of all respondents in the control community (17%), with exposure to the nationwide Fat Watch campaign only, were aware of the campaign about dietary fat in their community ($p > 0.001$). 43% of respondents in Alkamaar aware of national campaign and in control this was significantly lower at 34% ($p > 0.01$). In Alkamaar of those who were	

	ty.			would be the first ones celebrating their birthday were selected to be interviewed.	effectiveness of strategies and activities, with the hope of applying the campaign to other cities. The intervention conveyed a positive message about a low-fat diet (i.e. a healthy diet) and was put over in a motivating and informing way, which highlighted the positive consequences of low-fat diets and the consequences of a high-fat diet. During the campaign a total of eighty-one activities took place and attempted to communicate the messages of 'Fat Watch'. These activities were aimed mainly at intermediaries		aware of local campaign, 80% had noticed mass media written information, campaign activities which required more active participation by target groups were less noticed; mean appreciation rating of 7 (out of 1–10, with 10 positive) to local campaign among those who were aware. In the post-test no significant difference in actual fat consumption was found between Alkamaar and the control community. In the experimental community, a small but significant decrease (3%) in fat consumption was found in Alkamaar ($p > 0.04$) when pre test results were compared with post-test results, in control community there was no decrease in fat consumption pre- to post-test (28.3 to 28.4). A significant difference at post-test between Alkamaar and the control community was found for self rated dietary fat consumption. In Alkamaar 65% of all respondents rated their fat intake as ' fat' or 'relatively fat', whereas this was 56% in the control community ($p > 0.02$) (i.e. after the campaign self-rated fat consumption was significantly	

					and partly at the local population. The project group, who ran the project, organised 24 activities, which were aimed at various intermediary organisations, such as supermarkets, hotel and catering industry, health units, common welfare workers, educational organisations and several media. The majority of the activities were based on transfer of diverse, mostly written, mass mediated information and interpersonal communication. Research staff provided intervention and assisted intermediaries (e.g.		higher in intervention community) Additionally in the post-test, more respondents in Alkamaar (32%) than in the control community than in the control community (24%) reported that they had tried to lower their dietary fat intake in the past 6 months (*p* > 0.01). There was no significant difference (*p* > 0.05) between the experimental and control group community in the proportion of these respondents that referred to the Fat Watch campaign as a reason for their behavioural change. No significant post-test differences were found between the experimental and the control group with respect to attitude, perceived social support and self-efficacy expectations towards a reduction in fat consumption and intention to buy lower-fat food products. In the post-test, more participants in Alkamaar (20%) than in the control group (12%) showed the intention to eat lower fat food products in the following 6-month period (*p* > 0.01). Of those respondents who intended to eat lower-fat food products,	

					supermarkets, educational organisations, media) to organise local intervention activities.		significantly more respondents in Alkamaar (29%) than in the control group (11%) referred to the Fat Watch campaign as a motive for this intention ($p > 0.01$). This difference was not found among respondents who intended to buy lower-fat food products.	

EVIDENCE TABLE 3: RAISING AWARENESS OF THE NEED TO BE PHYSICALLY ACTIVE

First author	Study design	Research type	Research quality	Study population	Research question and design (include power calculation if available)	Length of follow-up	Main results (include effect size(s)/confidence intervals for each outcome if available)	Confounders (potential sources of bias)/comments
Evidence of efficacy (internal validity) for physical activity outcomes								
Cavill & Bauman 2004	Systematic review, eight studies were before and after studies, seven were controlled CBAs, most studies used repeat cross-	2	++	**Inclusion criteria:** 1) Campaign had to have at least one media element with mass reach. 2) Campaign needed to use the media in a purposive and organised manner to influence awareness/knowledge/saliency/attitudes, beliefs/self-efficacy/intention/behaviour. 3) Campaign had to employ at least a pre-post design using population samples to measure changes brought about as a result of the campaign. 4) There has to be clear PA mass media component to the	Review of 15 mass media campaigns with an explicit focus on PA to explore impact.	Twelve campaigns used random probability samples with the other three using some form of quota sample; response rates varied from 45 to 96%. **Length of intervention/follow-up:** Varied from	Campaigns achieved high recall with a median 70% (range 38% to 97%) of target group aware of the campaign. Important to note that baseline awareness can be as high as 15–20% if no campaign or message exists. Levels of awareness are likely to vary according to type of media used and scale of the campaign – number of campaigns is too limited for conclusions on minimum dose of media needed. Increases in knowledge or attitudes to PA were found among half the campaigns that reported	Authors unable to determine reliably the extent to which many of the studies represented true ‘community-wide’ campaigns and as a result it is difficult to separate out the effect of the mass media component in addition to any community activity. Important to measure the dose of the intervention as there

	sectional surveys to assess effects, eight used a cohort and four combined both cross-sectional and cohort.			intervention. Sample sizes ranged from 204 to 7097, with a median sample size of 1800 adults surveyed at baseline.		pre-post surveys only a few weeks apart to follow-up of a cohort after 7 years.	this measure (6 of the 15 studies). Impact on behavioural intention is equivocal. All 15 campaigns measured PA levels. Thirteen of the studies evaluated total population identified as the target group at the start of the campaign and among these only five showed significant increase in PA at the population level. Five studies reported an increase in PA levels and ten reported no significant increases in measures of PA. Four studies reported change in PA in motivated subgroups of volunteers and all four studies showed increases in PA. Campaigns increase awareness of the issue of PA but may not have a population level effect on behaviour.	is a strong relationship between amount of media exposure of a campaign message and the resulting level of awareness – the scale of expenditure, media exposure or outputs from the campaigns was unclear in 10 of 15 campaigns studied. Malmgrem 1986 and Miles 2001 were organised by media providers themselves rather than media space purchased at commercial rates. Difficult to ascertain how much attention was paid to the PA component in the five studies that covered factors other than PA (exposure to PA element likely to be lower in multiple-risk factor media campaigns). Many of the included campaigns were

								single events, others were integrated parts of community-wide cardiovascular education, few were sustained and focused PA initiatives over a number of years. Most campaigns measured distal variables (behaviour), which are least likely to change in the short-term, more measurement need of proximal variables (knowledge, etc.).
RESULTS OF INDIVIDUAL STUDIES INCLUDED IN SYSTEMATIC REVIEW								
Meyer (1980) Part of Stanford Heart Disease Prevention Programme	Quasi-experimental, compared two intervention groups vs. control with baseline and three annual follow-			Adults aged 35–59 years at high risk of cardiovascular disease in three Californian communities (each approx. n = 15,000)	Compared media plus face-to-face (Watsonville) with media only (Watsonville and Gilroy) and control (Tracy). Radio and TV spots; radio and TV programmes; billboards, posters.	3 years.	Watsonville n = 605 (73%); Gilroy n = 542 (82%); Tracy n = 532 (81%); probability samples. No significant increase in metabolic equivalent tasks (METs) score indicator.	

	ups.							
Malmgren & Andersson 1986 'Get fit with *Corren*' (name of newspaper)	Analysis of all registrants reports; follow-up survey of registrants (12 months) and single survey of random sample.			Adult (≥17 years) readers of the *Corrren* newspaper in Linkoping, Sweden.	Newspaper-initiated health information campaign. Fitness tests offered to participants. Analysis of registrant's reports, follow-up survey of registrants (12 months). Single survey of random sample of inhabitants in Linkoping.	Unclear.	All registrants *n* = 2887. 56% sent in one report, 7% sent in all 12. Survey of registrants *n* = 935 (60% response). Random sample of residents in Linkoping *n* = 204 (82% response). 97% inhabitants aware of the campaign (prompted recall), 75% had read about programme. 6% aware of the campaign and follow it fully. Increase in exercise and fitness among those who registered for the campaign and completed fitness test.	
Aaro 1991a	Quasi-experimental, two experimental and one control group, using cohort surveys.			Residents of Oppland County aged 40–54 years. *n* = 1440 per area, (two experimental and one control group).	Cardiovascular disease intervention programme in Oppland County, Norway 1982–84. Described as mass media and community approach, but details not clear. Two experimental and one control group, using cohort surveys.	Unclear.	Response rate 63.1% Average increase of one training session every third week.	
Aaro	Cohort			Adults aged 16–	One-week campaign	Unclear.	Response rate 60%.	

1991b Sogn og Fjordane County campaign 1983	survey			68 years in Sogn og Fjordane County Western Norway. *n* = 1000	combining community action with mass media. Cohort survey.		64.3% had heard about campaign. Increase in proportion having tried a new activity.	
Booth et al. 1992 'Exercise: make it part of your day'	Pre and post repeat random cross-sectional surveys.			Australian residents aged >15 years.	Cinema commercials, radio and newspaper, linked to community activities such as publicity and events, PA days, competition during heart week. Population samples.	Few weeks.	Response rates vary between 45% and 60% of households = 2426 pre and 2474 post. Unprompted campaign recall 46% pre, 77% post ($p > 0.001$). Non-significant increase in proportion believing that exercise helped a lot in the prevention of heart disease. Significant association between stage of change and pre-post surveys ($p > 0.01$). 3.9% increase in proportion reporting any walking for exercise in the previous 2 weeks.	
Osler & Jespersen 1993 Slangerup – a heart healthy town	Quasi experimental design comparing intervention and control			Adults aged 20–65 years in Slangerup, Denmark. Baseline *n* = 1072 (51% response).	Cinema commercials, radio and newspaper linked to community activities. Strong links to activities such as fitness tests, lectures, heart day.	One-year follow-up.	One-year follow-up *n* = 1196 (59% response). 82% aware of the programme compare with 67% in control area ($p > 0.001$). Health beliefs measured but not specific to PA.	

	areas with two repeat cross-sectional surveys.				Random samples of central person register.		20% considered doing more exercise (17% control). 'Advice from social network and mass media' was related to trying to be more active (*p* > 0.001). 9% participated in local projects. No significant difference in exercise participation between intervention and control.	
Owen et al. 1995 'Exercise: take another step'	Pre- and post-repeat random cross-sectional surveys.			Australian residents aged ≥15 years.	TV adverts, radio public service announcements (PSAs), campaign materials, scripts in national soaps, unpaid media, associated community activity. Community and health agency activities, physician education, serial heart week campaign. Built on previous campaign 1991 (Booth 1992).	Few weeks	Response rates vary between 45% and 60% of households, *n* = 2584 pre and 2517 post. Unprompted recall 62.5% pre and 73.5% post (*p* > 0.001). No change in intention to exercise. No significant change in walking or inactivity.	
Blake et al. 1987; Luepker et al.	Quasi experimental with three			Sampled from 4,000,000 persons aged 25–74 years resident in six	High-intensity campaign via the mass media linked to community activity	7 years. Half of the sample	Average total survey response rate = 78.7%. *n* = 6039 at baseline, 67.1%	

1994 Minnesota Heart Health Program	intervention communities and three controls. (i) Repeat cross-sectional surveys. (ii) Cohort surveys. Random samples of 300–500 adults from each of the six communities.			communities in the Upper Midwest, USA. *n* = 6039 at baseline.	and training and education programmes. PA covered in annual 1–3-month concentrated campaigns. Strong community component including health professional education, screening, counselling. Random sample from within cross-sectional sample taken.	followed-up after 2 years, other half after 4 years, and all cohort after 6–7 years.	completed all waves. During one concentrated PA campaign 93% heard of at least one campaign event. Awareness of media not reported for complete programme but 60% of all adults were recruited to the training and education programmes. Single question 'Are you active in your leisure time?' showed small increase in proportion physically active at 2 years but most of this was light PA. The longer Minnesota Leisure Time Physical Activity (MLTPA) questionnaire showed decline in PA.	
Young et al. 1996 Stanford five-city community-wide cardiovascular risk reduction project.	Quasi-experimental residents of two intervention communities compare with two			All residents of Monterey and Salinas Counties, California aged 12–74 years.	Print materials, weekly news column, talks, seminars, workshops, segments in TV news and PSAs. Associated worksite and school programmes. Average of nine messages per person per year.	Unclear	(i) Each random sample approx. *n* = 1800 to 2500 response rates for each wave: 65, 70, 65 and 56% (ii) Cohort *n* = 408 men and 499 women. 39% completed all waves. No evidence of significant impact on knowledge attitudes or self-efficacy. No significant differences were	

	control communities and an additional control community for cardiovascular disease morbidity and mortality data. (i) Repeat cross-sectional surveys. (ii) Cohort surveys.				Strong community-based components including talks, seminars, workshops, walking groups, worksite programmes, competitions.		found for the global estimates of PA for women or men between treatment and controls. Increase in number of 'usual activities' compare with control ($p = 0.014$) for independent and 0.001 for cohort samples).	
Wimbush 1998 HEBS [Health Education Board for Scotland] walking campaig	Before and after design. (i) Awareness: 3 × pre-post tracking survey.	2	+	'Fitline' callers $n = 4036$. Adults of target age (30–55 years) in October 1995: $n = 335$ Adults of target age in February 1996: 370	National campaign in Scotland, to increase the number of individuals, aged between 30–55 years of age, who are not regular exercisers to take up walking. 2 × 1 month bursts of	**Length of intervention:** TV advertising: September and October 1995 and March and April 1996. **Length of follow-up:** June 1995–	(i) Men and women 16–74 $n = 693$ (October 1995), 768 (February 1996) 733 (June 1996). Multistage cluster random probability sample, response rates reported between 62–86%. (ii) Adults $n = 1066$ (June 1995), 1085 (June 1996), response rates not given.	Three stages of developmental and pre-testing research reported. At a population level, the campaign had a notable positive impact on knowledge about walking as a form of exercise but

n 'Walking: take exercise in your stride'	(ii) Impact: 2 × pre-post cross-sectional surveys. (iii) Baseline survey of Fitline callers and follow-up at 10 weeks and 1 year			Adults of target age in June 1996: *n* = 345. All participants were from Scotland. Bias towards lower SES. Female 'Fitline' callers: 59% Male 'Fitline' callers: 41% *n* = 4036 <16 years: 8% 16–29 years: 26% 30–55 years: 46% >55 years: 20% *n* = 3476 **Housing tenure:** Owner occupied: 61% Rented: 29% Other: 10% *n* = 2828 **Social class:** Manual: 40% Non-manual: 60% *n* = 2042	40 second TV advert. Telephone direct response (Fitline) and information pack, little community activity reported. To assess the actual impact of the campaign on those who actively responded to the walking campaign a baseline survey occurred with all those who telephoned 'Fitline' between the 13 September and 25 of October 1995; this accounted for 4036 callers. Two follow-up surveys were carried out with a sub-sample of responders. The baseline had a response rate of between 62–86% and it involved asking questions to participants about their current walking/exercise patterns.	October 1996 (Tracking survey of awareness, October 1995, February 1996 and June 1996; Omnibus survey of knowledge June 1995 and June 1996; Fitline callers survey September/October 1995, January 1996 and September/October 1996).	(iii) Baseline – all Fitline callers, *n* = 4036; 10 weeks *n* = 490, 1 year *n* = 283 (58%). % Agree 'Walking a mile uses up the same energy as running a mile': 20% June 1995, 56% June 1996. % Strongly agree, 'walking is a good form of exercise': 38% June 1995, 57% June 1996. No change for other statements. Intend to walk more: 55% June 1995, 57% June 1996 (not significant). Population change: days spent walking for 30 min: 4.26 June 1995, 4.13 June 1996 (not significant). Fitline callers 0.5 stage increase in average stage of change, overall shift from the contemplation stage of change (Transtheoretical Model) at baseline towards the 'action' stage at the 10-week and 1-year follow-up. In Fitline callers; 48% reported being more physically active, 46% said about the same as before and 7% less physically active at 1 year follow-up. Prompted awareness of HEBS walking campaign – general	had very little impact on walking behaviour. Campaign was efficacious in supporting the exercise behaviour change process among non-regular exercisers in the ' contemplation stage' (of the Transtheoretical Model) through advertising of a free direct response telephone service but response was higher among non-manual, owner-occupier groups and those who were already regular exercisers. Fitline had less appeal to lower SES groups despite higher awareness levels.

					Providers of intervention: Health Education Board for Scotland. Staff from the Centre for Leisure Research at Heriott Watt University, Edinburgh Staff from the Centre for Social Marketing at Strathclyde University, Glasgow		population adults. Awareness of the “Gavin TV advertisement”: October 95 = 70%, February 96 = 54%, June 96 = 69% Awarenes of Local radio features 8%, 13%, 21% Awareness of Fitline October 95 = 5%, February 96 = 16% but only 5% of these respondents used the service. This level of use indicates 0.1% coverage at the beginning of the campaign rising to 1% 4 months later.*n* = 693 in October 1995, 768 in February 1996 and 733 in June 1996 Prompted awareness of HEBs walking campaign – Target group (aged 30–55 years). Prompted awareness of Gavin TV advertisement October 1995 = 67%, February 1996 = 54%, June 1996 = 69% Prompted awareness of Local radio features 8%, 11%, 21% Prompted awareness of Fitline October 1995 = 5%, February 1996 = 16% *n* = 335 in October 95, 370 in February 96 and 345 in June 96.	
Miles et al. 2001; Wardle et	Before and after study	2	+	**Office of National Statistics survey:** Total sample	The study’s primary objective was to evaluate the BBC’s	Campaign was for 7 weeks.	0.9% sent for registration pack; 0.2% registered with scheme.	Self-reported data. Generalisation of the

al. 2001 BBC 'Fighting fat fighting fit' campaign	design with one cross-sectional survey by ONS and pre-post survey of random sample of respondents.			$n = 1894$ Men $n = 938$ Women $n = 956$ All adults but targeted more to overweight and obese adults See weight outcomes table (Table 1) for more detail.	national FFFF campaign. Seven weeks of peak and daytime programming across BBC TV and radio.		Significant increases in brisk walking, moderate activity and vigorous activity, overall 39% (74%) increased their activity levels. Total number of min per week spent in activity increased by 94 (181) min per week, $p > 0.001$. % Classified as sedentary reduced from 34 to 25% (35 to 17%). % Doing irregular moderate exercise decreased from 36% to 29% (36% to 22%). % Regular moderate exercise increased from 29 to 45% (29 to 60%). % Vigorous exercise increased from 3 to 6% (2 to 9%). All $p > 0.001$. **Predictors of change (completers only):** Men were more likely to report changes in weight, exercise and fried food intake, deprivation level was associated only with decreases in fried food intake, baseline weight predicted weight loss and positive changes in diet with obese reporting greater changes. Predictors of change (all	results is limited due to the 70% response rate for ONS survey and less than 1% registered and of these 6000 surveyed in registrants survey Men, people <25 years, lower SES and BMEGs may require specifically targeted campaigns (registrants survey).

							participants): groups with higher levels of deprivation were less likely to report weight loss or exercise increase, obese did not report greater changes in diet and weight loss and changed less in terms of exercise than normal weight groups.	
Hillsdon et al. 2001	Before and after study	2	+	*n* = 6711 Completers *n* = 3189 Non-completers *n* = 3522 All participants were from England, aimed at young women 16–24 years, men 45–55 years, adults ≥50 years. 42.5% of completers were males. 44.7% of non completers were male. 43.6% of the total sample were male. **Social grade %** AB 20.3	Based on concept of social marketing using advertising, public relations and publicity. ACTIVE FOR LIFE campaign was a 3-year health promotion mass-media campaign run in England and commissioned by Department of Health and run by Health Education Authority, aimed to increase knowledge and acceptability of 5 sessions, 30 min each of moderate intensity PA per week (walking, cycling, swimming, dancing, heavy gardening and housework); integrated with professional education and support.	2 years (1995–97).	12,907 addresses were identified and 6711 baseline interviews were conducted (52% response rate). In phase 2 in 1996, 4268 interviews were conducted (64% of baseline) and 3189 in 1997 (48% baseline). 38% of all the participants were aware of the campaign (unprompted and prompted awareness combined), assessed six to eight months after the main period of advertising. 5.5% could recall key images of the TV campaign unprompted with a further 32% recognising still photographs taken from the TV advertisement. Greatest awareness was in those aged 16–24 years (65%) and lowest awareness in those aged 65–74 years (25%). Men were more aware than women as were those with children living at home and those in lower social grades. Participants who were more ready to adopt regular PA and who were already active at a vigorous level were more aware of the campaign than those who were less ready and less active. Those aware of the	Media budget £2 million. Linked to professional education programme. Developmental research and pre-testing. 52% response rate may have lead to an under represented sample. No published reliability and reliability studies exist for the PA questionnaire used in the study. Results of the study may have been confounded by secular trends, e.g. between 1994 and

				C1 30.1 C2 20.8 DE 28.7 Car use 72.1% Non-White 5.4% Home ownership (%) 73 Children (% yes) 30.3 Non-completers were younger; fewer were in social grade AB, owned their own home or car. Fewer had children or perceived that PA would lead to physiological benefits. More were non-White.	Campaign resources, which included posters, leaflets, postcards, two websites and other promotional items were all implemented and developed to promote the main campaign message to specific priority groups. These groups included young women aged between 16–24 years, middle-aged men aged 45–55 years, men and women aged 50 years. All these groups were targeted in three different phases of the campaign. The first phase of the campaign was a 40 second TV advertisement – 'The thirty minute games'. This emphasised the importance of activities such as walking, gardening and cycling for health and that activity		campaign, when asked at year 1 were already more active at baseline than those not aware of the campaign (suggest active people more likely to recall advertising). The proportion of participants' knowledge about moderate PA recommendations increased by 3.0%. (95% CI 1.4, 4.5) between baseline and year 2 and 3.7% (95% CI 2.1, 5.3) between baseline and year 3. No significant difference in knowledge by awareness of the campaign advertising suggesting if campaign did produce these increases in knowledge it was through element other than TV advertisements. (Assessed as knowledgeable if could recall all three elements of a complicated message.) Changes in proportion of participants who knew about recommendations were higher in women, older age group and social grades C2/DE. No significant differences in PA levels at baseline and 1-year follow-up, but at year 2 there were 8.8% fewer people active at a vigorous level and 6.8% more people classified as sedentary. The change in proportion of active people between baseline and year 1 was –0.02% (95% CI 2.0, 1.7) and	1998 the number of sedentary men increased by 5% and the number of women by 6%, while those categorised as physically active remained virtually unchanged.

					should be done for 30 min. It was aired over a 6-week period in the spring of 1996 and it targeted abroad range of people aged 16–74 years. The second phase of the campaign began in 1997 and was aimed specifically at men and women aged >50 years. The TV advertisement was repeated in July 1997 but this phase also included campaigns in tabloid newspapers aimed at middle-aged men. The third and final phase of the campaign took place in 1998 and was aimed at young women aged 16–24 years and used advertisements placed in women's magazines. In addition, two sub-campaigns communicated campaign messages to groups that were		between baseline and year 2 was –9.8% (95% CI –7.9, –11.7). 21% increase in number of people active at recommended levels at year 1, in those not active at baseline, along with 46% of people who ceased being active at this level between baseline and year 1 suggest there was a regression to the mean (demonstrates importance of control group). 1.3% decrease in 'readiness to change' score, participants who were aware of campaign were more ready to take up PA than those not aware ($p > 0.05$).	

					defined as having particular access or communication needs: people from BMEGs and people with disabilities. These were highly targeted by advertising in specialised media or through joint promotions with ethnic minority and disability organisations. A national sample of 3189 adults, aged between 16–74 years was used to assess the impact of the campaign. Multi-stage cluster random probability design used with Postcode Address File for England to get representative sample of adults aged >16 years. Thirty-minute interview conducted in the home, baseline data in September and November 1995 and follow-up data in			

					same months in 1996 and 1997. **Providers of intervention:** The Health Education Authority and the research unit at the London school of Hygiene and Tropical Medicine			
Bauman et al. 2001 Exercise; you only have to take it regularly not seriously.	Quasi-experimental design using: (i) cohort; (ii) independent cross-sectional samples, representative population surveys, before and after the campaign; (iii) control survey in			Adults aged 25–60 years in New South Wales Australia who were ‘motivated but insufficiently active’.	Two × 15 second TV advertisements, print media advertisements and inserts, phone line, campaign materials. Community level support offered including toll-free phone line; local level and regional initiatives and events, physician education. Extensive formative qualitative focus group research.	Unclear.	(i) Cohort, n = 1185 (response rate = 87%), baseline n = 2009 (response rate 83%), follow-up, n = 1700 (response rate 80.6%). (ii) Control baseline n = 3006 (response rate 81.5%), follow-up n = 2253 (response rate 80.3%), random probability samples of population. Unprompted recall increased from 2.1 to 20.9% (p > 0.001), prompted recall increased from 12.9 to 50.7% (p > 0.0001); no change in comparison region (rest of country; prompted recall 14% pre to 16% post). Knowledge of appropriate PA increased significantly in the campaign state (four items used). Intention to be more active showed no change in any group.	Media budget AUD$7,000,000.

	non-campaign states.						26.7% of target group (motivated but insufficiently active) increased their activity to above the recommended thresholds (five times per week for 30 min) ($p > 0.01$).	
Reger et al. 2002 'Wheeling Walks'	CBA Quasi experimental; compared intervention in Wheeling with control town, cohort design using surveys and observational measures (trail use)	2	++	Intervention community *n* = 719. Control community *n* = 753 Intervention group: Female: 67.5% Age (mean): 57.4 years Control group: Female: 68.5% Age (mean): 57.2 years Intervention group: Income >US$30,000: 40.6% College graduates: 29.5% Married: 60.2% Estimated BMI: 28.0 kg/m^2 Control group: Income >US$30,000: 44.6%	The pilot study, which was called 'Wheeling Walks' had two main aims: 1) effect a 10% increase in the proportion that meet the Centers for Disease Control (CDC)/American College of Sports Medicine (ACSM)/Surgeon General standard for regular moderate intensity walking; and 2) effect a 15% forward movement one or more stages in Transtheoretical Model stage of change for regular moderate intensity walking. The intervention took place in the city of Wheeling, West Virginia, USA, and was primarily aimed	Length of intervention: 8 weeks (April 2001 – June 2001). Length of follow-up: post-tests occurred immediately after the end of the 8-week intervention period.	517 of the 719 (72%) of the respondents in the intervention group and 571 of the 753 (76%) in the control group completed the baseline and follow-up survey. Post-test surveys were successfully completed with 69 and 74% of the sedentary adults in the intervention community and 252 in the comparison community. Behaviour observation showed a 23% increase in the number of walkers in the intervention community versus no change in the comparison community (OR 1.31; 95% CI 1.14, 1.50). Thirty-two percent of the baseline sedentary population in the intervention community reported meeting the CDC/ACSM/Surgeon General recommendation for moderate-intensity PA by walking at least 30 min at least five times per week vs. 18.0% in the comparison community (OR 2.12; 95% CI 1.41, 2.24).	Messages were pretested. Poor generalisability because income per capita and educational attainment is lower than in the rest of the USA and heart disease death rates and prevalence of obesity are both 18% higher than the national average in the USA. Short intervention period.

				College graduates: 20.2% Married: 63.5% Estimated BMI: 28.5 kg/m^2	at sedentary and irregularly active adults aged between 50 and 65 years of age. Comparison community was Parkersburg, West Virginia (similar demographics but no overlapping media). The intervention was an 8-week paid media-based community PA campaign using paid advertising, public relations and public health education activities to promote 30 min of moderate intensity walking as a daily activity to people. Applied Theory of Planned Behaviour and social marketing techniques. A Public Relations firm developed two newspaper advertisements, two 30-second TV advertisements and two 60-second radio advertisements.		The intervention community also realised a pre to post increase in positive stage change ($p > 0.001$). **Awareness:** In the intervention community 90% reported hearing about the campaign, 76% saw some or a lot of TV advertisements, 81% saw some or a lot of TV news stories, 32% reported hearing radio advertisements and 5% reported seeing or participating in any of the public health education programmes.	

					Average households exposed to TV campaign 50 times, radio message 70 times and 14 newspaper advertisements were placed in local newspapers over the 8 weeks. Other public relations activities, work-site programmes, website exposure, physicians prescriptions for walking and other public health education programmes were carried out. Telephone survey questionnaire (random digit dialling) at baseline of adults aged 50–65 years and followed up immediately after the 8-week campaign. Telephone survey questionnaire and observation. **Providers of intervention:** Research staff from			

					West Virginia University (college-level research technicians were recruited to observe, count and intercept adult walkers at five predetermined popular walking sites for 2 hours per day for 1 week before and after the intervention). Wheeling-Ohio County Health Department and the local media.			
Renger et al. 2002 Yuma on the move. Tagline 'Think about it. Its your choice to be active'	Before and after design with cross-sectional surveys. Sub-group analysis of 33 who completed pre and post surveys. Separate detailed	2	–	Targeted adults in Yuma, Arizona 1997–99, especially those aged 30–64 years and in pre-contemplation/contemplation stages of change. *n* = 1203 (*n* = 500 for telephone survey, *n* = 703 for written survey). No SES data available, but Yuma county is a rapidly growing area with	The main aim of the study was to develop, implement and evaluate a community-based effort to increase PA. Community members from the Yuma Regional Medical centre and the University of Arizona developed television and worksite media messages, which focussed on the benefits and barriers of PA and on increasing self-	**Telephone interview:** 3 years (1996–1999). **Written survey:** 1 year (1998–99).	Of the 703 respondents to the written survey 84 at baseline and 75 at follow-up were evaluated as respondents who completed survey at both time points were removed and limited to target population – 30–64 years in first two stages of change. Random digit dialling pre-post surveys (*n* = 500 in 1996 and 500 in 1999) response rate not stated. Written surveys to volunteers (created cohort *n* = 33) and cross-sectional samples (*n* = 75) pre *n* = 84 post) of volunteers (convenience sample). 'The media campaign was effective	Formative research with community regarding PA barriers, taskforce developed message a\and used Centers for Disease Control (CDC) resources, other media/poster. Very small sample analysed from written survey. Independent samples at pre- and post-evaluation but a within-participants analysis was done of

	written survey administers at events and health fairs to volunteer completers. Process evaluation of number of campaign posters displayed.			55% of its population <35 years of age and an ethnic distribution that is predominantly Hispanic (48.5%) and White (46.8%).	efficacy. These media messages were developed using and based upon Prochaska's Transtheoretical model and consciousness raising strategy. The task force, which produced the media messages, chose three different methods to deliver the media messages: public service announcements, comic strips and worksite posters. The first comic strip was released in December 1998 in 17 worksite newsletters. The second comic strip was released in October 1999 and was published in five worksite newsletters by 1 December 1999. The first poster was used in January 1999 and 135 posters were displayed at 74 worksites and community buildings.		in changing perceived barriers, perceived benefits and self-efficacy surrounding PA and 'unexpectedly' had a positive effect on changing behaviour (i.e. main purpose was to get people to think about it but some actually changed behaviour).' Mean recall of PA messages on television score increased significantly (only from 30 volunteer responders). Many cited campaign as the message they heard (numbers not further stated). In volunteer samples, knowledge and beliefs assessed, no significant change in ten-item knowledge score, no change in decisional balance score (benefits/barriers to PA). In volunteer samples, increases in self-efficacy reported. The evaluation of the written survey found no significant change in level of activity. Within-subject analysis of 33 participants (took part in baseline and follow-up survey) showed significant change in level of PA from baseline to follow-up *p* > 0.002. Telephone survey showed that 29.8% respondents reported they did not engage in leisure time	33 participants (took part in baseline and follow-up survey) showed significant change in level of PA from baseline to follow-up, *p* > 0.002.

					The second was released in November 1999 with seventy-one posters were on display by 1 December 1999. Posters were put in areas of high traffic as well as other areas where employees may gather. To evaluate the impact of the intervention a telephone interview and a written survey was used. 500 households in Yuma County were contacted by telephone in 1996; the questionnaire consisted of 111 questions, many of which were the same as those used in the Behavioral Risk Factor Surveillance Survey (BRFSS). The telephone interview was repeated in the fall of 1999. The written survey consisted of 11		physical activity (LTPA) in 1997 and in 1999 this was reduced to 25.6%. Corresponding values in Arizona were 33.8% in 1997 and 51.5% in 1999. Analysis of the telephone survey found only one statistically significant change among age categories, with self-reported no LTPA decreasing from 35.6 to 23.1% ($p > 0.05$) amongst women aged 40–64 years.	

					questions was administered to local schools, businesses and at the county fair prior to the media campaign and again administered year later at the same locations.			
INDIVIDUAL STUDIES								
Merom 2005	Before and after study (not controlled)	2	+	Primary school-age children and their parents in New South Wales, Australia.	To describe the reach, participation and support of the New South Wales Walk Safely to School Day (WSTSD). Paid media advertising before the event promoted WSTSD.	One day every year for 4 years	School register: 2001: 496 schools 2002: 717 schools 2003: 708 schools 2004: 751 schools participated in the New South Wales WSTSD (repeat participation over 3 years was low). 53% of all NSW schools registered to participate in one WSTSD and 15% participated for 3 years. Significantly more schools from urban regions participated ($p > 0.05$). School evaluation forms: Only 37% of participating schools returned evaluation – smaller schools had a higher participation rate. 7% schools organised walking related activities, and 28% indicated that promotion of healthy lifestyle was a reason for participating.	Only 37% of participating schools returned evaluation – potential for bias.

							Parent survey: (89% response rate to randomly selected eligible telephone numbers). 53% were aware of WSTSD with main source of information being the school then the media. Relative increase of 31% of children walking attributed to the event. On a population level this equates to an increase prevalence of walking to school of 6.8%. **Author's conclusion:** Stronger interventions required but campaign did result in moderate short-term change.	
O'Loughlin et al. 1998	RCT	1	+	Intervention group *n* = 94 Control group *n* = 94 See weight outcomes table (Table 1) for more detail.	This RCT investigated the impact of a low intensity, healthy weight intervention in low-income adult volunteers from inner city St Henri, Canada.	**Intervention:** 8 weeks. **Follow-up:** 10 weeks (2 weeks after end of intervention).	Intervention participants were 2.7 times more likely than control to change from reporting no exercise at baseline to exercising once or more a week at follow-up.	Short follow-up period. Data were self-reported. Use of telephone interviews (minimal face to face contact) possibility of bias related to social desirability Generalisability unclear, low-income low-literacy inner city

								population of French/English-speaking Canadians.
Huhman et al. 2005	Before and after study (not controlled)	2	+	**Geographical area:** USA *n*= 3120 parent–child dyads All participants were aged between 9 – 13 years of age. Participants were of either Black, Hispanic/Latino, Asian or Native American. No further details.	The intervention aim was to determine the effects of a mass media campaign on PA levels among multi-ethnic children aged 9 to 13 years of age from the USA. Primary aim was to achieve high levels of awareness among the target audience. The VERB campaign combined paid advertisements with school and community promotions and internet activities to encourage children 9–13 years to be physically active every day. Launched in 2002 by CDC, VERB used child-focused commercial marketing methods to advertise being physically active as cool, fun and a	1 year. For the baseline survey, persons in 60.5% of sampled households completed the screening interview. Among eligible adult respondents, 3084 (87.0%) completed the parent interview; 3120 eligible child respondents (81.3%) completed the child interview. As determined with standard American Association of Public Opinion Research response rate formulas, the overall baseline	The overall campaign produced high levels of awareness. 26% of the participants had no recall of the VERB campaign, 7% had recall but no understanding, 50% had aided recall with understanding and 17% of the participants had unaided recall with understanding. Therefore, the overall awareness (all three categories that had recall) achieved by the VERB campaign was 74% among the nation's 9- to 13-year-old youths. Ninety percent of children who were aware of VERB also demonstrated understanding of the messages. Overall awareness for White children and Hispanic/Latino children was 78% and 70%, respectively, significantly higher than that for Black children at 63% ($p > 0.05$). A significant positive relationship was detected between the level of awareness of VERB and weekly median sessions of free-time PA among the total population of 9- to 13-year-old youths ($p <0 .05$), meaning that, as VERB awareness increased, levels of PA increased. Within subgroups, this relationship between increasing levels of awareness and more free-time	Self-report. Reverse causation is a possibility – physically active children becoming more aware of the campaign. Overall awareness for White children and Hispanic/Latino children was 78% and 70%, respectively, significantly higher than that for Black children at 63% ($p > 0.05$).

					chance to have good time with friends. Paid advertising ran nationally from June 2002 to June 2003 targeting youths 9–13 years. A baseline survey was conducted between April and June 2002, before the campaign started, (random digit dialling method). Same cohort of parent–child dyads followed-up after 1 year. **Providers of intervention:** Research staff, advertising agencies, the National Centre for Chronic Disease Prevention and Health promotion and Centres for Disease Control and Prevention in Atlanta.	response rate was 43% (the product of the completion rates for the screening, parent, and child interviews). At the follow-up assessment in 2003, data were collected from 2732 of the same dyads (87.6%).	sessions of PA was also observed at the *p* > 0.05 level for 9- to 10-year-old children, White children, children whose parents had less than a high school education, children from households with incomes of US$25,000 or less, and incomes between $50,000 and $75,000, children living in urban areas of high density, children from rural areas, children who reported engaging in less than three free-time PA sessions at baseline and children who reported engaging in at least three free-time sessions at baseline. The average 9–10-year-old engaged in 34% more free-time PA sessions per week than did 9–10 years olds who were unaware of the campaign. When free-time PA sessions of all US children were compared with those of the children who were unaware of the campaign no overall effect on free-time PA sessions was detected at the population level. However, within subgroups, significant overall effects were observed for 9–10 year old children, girls, children with parental education of less than high school, children from households with income US$25,001 to $50,000, children living in urban areas of high density, and children who were low	

							active at baseline (*p* > 0.05). At the total population level no relationship was found between awareness of VERB and organized activity (*p* > 0.05). Within the subgroup classified as low active at baseline, 39.1% of children were engaged in an organised PA, compared with 31.9% of the comparison group, a significant difference of 7.2 percentage points (*p* > 0.05). The other subgroup effect for organised activity was for children with parents with a college degree or higher education level.	
Tudor-Smith et al. 1998	Before and after design but samples are independent (cross-sectional) population surveys with an intervention community and a matched reference area.	2	–	**Geographical area:** Wales, UK and north-east England (reference area). Wales: 1985: *n* = 18538 1990 *n* = 13045 North-east England: 1985 *n* = 1483 1990 *n* = 4534 All participants were aged between 18–64 years No further details.	To assess the 5-year effect of an intervention of a community-based demonstration project called 'Heartbeat Wales'. See weight outcomes table (Table 1) for more detail.	Cross-sectional survey took place before and after the end of the 5-year intervention in intervention and control community. See weight outcomes table (Table 1) for more detail.	Engage in moderate or strenuous activity at least two times per week for over 20 min each time: Wales 2.1 (95% CI 0.8–3.4), control 3.2 (95% CI –0.7–7.1) percentage point changes.	The sample size at the baseline measurement at baseline in the North East was too small to give sufficient statistical power to detect a net intervention effect. There is evidence of increases in funding for heart health promotion in the reference area and diffusion of other health promotion campaigns (contamination).

EVIDENCE TABLE 4: CORROBORATIVE EVIDENCE (WEIGHT, DIET AND ACTIVITY)

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Hillsdon et al. 2001	Before and after study.	2	+	English adults (NB: non-completers were younger; fewer were in social grade AB, owned their own home or car. Fewer had children or perceived that PA would lead to physiological benefits. More were non-White. Compare with non-completers).	See above.	See above.	See above.	See above.
Tudor Smith 1998	Before and after study.	2	–	Wales	See above.	See above.	See above.	See above.
Miles 2001; Wardle 2001	Before and after study.	2	+	British adults (NB: evaluation participants were more likely to be from higher SES, less likely to be smokers, less likely to be classified as vigorous exercisers and more likely to be classified as obese compare with British population).	See above.	See above.	See above.	See above.
Wimbush 1998	Before and after study.	2	–	Scotland	See above.	See above.	See above.	See above.

Jeffery 2005	Survey of Earlybird cohort.	N/A		UK parents and their children.	Explored parent's awareness of overweight in themselves and their children.	N/A	19% of children, 52% of mothers and 72% of fathers were overweight (including obese). Among overweight parents, 40% of mothers and 45% of fathers judged their own weight 'about right' and 27% of mothers and 61% of fathers were unconcerned about their weight. Only one-quarter of parents recognised overweight in their child. Parents were less likely to identify overweight in sons than in daughters. More mothers than fathers correctly assessed their child's weight. Maternal weight status did not affect mothers awareness of children's weight but only 74% overweight fathers compared with 85% normal weight fathers were correct. 86% of parents who were unaware their child was overweight were also unconcerned. Prevalence of overweight in parents did not differ by SES, neither was there a difference in correct perception of child's weight between SES groups.	
Hastings et al. 2003	Systematic review	N/A		Literature search 1970–2003. Studies used for this particular research	Does food promotion influence children's nutritional knowledge? Five studies were RCTs	No details provided.	The eight studies provide modest evidence of an effect on children's nutritional knowledge. Four studies found that exposure to food promotion had a significant impact	Four of the studies did not take a baseline measure of knowledge and therefore it is very

				question covered an age range of 3–16 years and all but one of the studies was conducted with North American samples in the 1970s and 1980s.	and three were cross-sectional surveys. The control condition in one of the experiments (Ross et al, 1980, 1981) comprised exposure to non-food adverts; in the other four studies the control condition involved no exposure to any adverts. The food promoted in the adverts of the experimental studies were adverts for cereals and soft drinks (Ross et al. 1980, 1981), branded sugar snacks and breakfast cereals (Goldberg et al. 1978a, 1978b), sugared foods (Goldberg et al. 1978a,1978b; Galst 1980) measured whether the effect of a pro-nutritional television programme' was modified by being shown alongside advertisements.		on or was associated with differences in nutritional knowledge. Three studies found that exposure to food promotion had no impact on or was not associated with changes in children's perceptions of the healthiness of different foods or what constitutes a healthy diet.	difficult to ascertain whether experimental and control groups differed in nutritional knowledge before the experiment.
Hastings et al. 2003	Systematic review	N/A		Literature search 1970–2003. Participants were all	Does food promotion influence children's food preference?	No details provided.	Fourteen studies provide reasonably strong evidence of food promotion on children's preferences.	One study (Ritchey & Olson 1983) did not describe the TV viewing measure

				North American and ranged in age from 2 to 18 years. The majority of the studies were conducted in the 1980s.	Fourteen studies were used, with 13 of them being experiments and one being a cross-sectional study (Ritchey & Olson 1983). Twelve of the studies used a similar study design, which involved exposing one or more experimental groups to one or more food promotion stimuli, and 11 of them compared children's subsequent food preferences or attitudes to those of a control group exposed to a different or no stimuli. The food promotion stimuli in the experimental studies were all advertisements for various products (branded sugared snacks, breakfast cereals, non-specific 'sugared foods', salty snacks, sweets, soft drinks, ice cream and 'pronutrition foods'. Six studies measured if different modifications to the experimental stimuli		Of the four higher scoring studies, three found that promotion had significant effects on children's product and brand preferences. Three of these studies (Goldberg et al. 1978a, 1978b; Stoneman & Brody, 1981; Kaufman & Sandman 1983) found that children were more likely to choose high fat, salt or sugar foods than alternative 'healthy' products after viewing food advertisements. Of the five medium scoring experimental studies, three found that food promotion had effects on children's products and brand preferences (Gorn & Goldberg 1980a; Heslop & Ryans 1980; Borzekowski & Robinson 2001). Borzeowski & Robinson (2001) found that children were more likely to choose the advertised brand than a non-advertised brand of the same product type after exposure to food advertisements. Gorn & Goldberg (1980a) found that food promotion had an effect on children's brand and to a lesser extent product preferences. Of the two lower scoring experimental studies, Clarke (1984) found no significant effects ($p > 0.05$) while Norton et al. (2000) found that television advertising was reported to be a significant influence only on degree of liking for three products	used so it was not possible for the author to judge what level of potential exposure was measured. There were inconsistencies in parental and child reporting of child food preferences within the study, and the authors themselves suggested that the preferences measure used was possibly not sensitive enough to detect difference between children. All the studies used for answering the research question were graded for quality. Four studies were high scoring in terms of quality, five experimental studies were medium scoring and two of the studies were lower scoring.

					weakened or strengthened children's effect on food preferences. Five of the studies asked children to pick between products in different categories (lower fat, sugar or salt vs. higher fat, sugar or salt). Five studies also asked children to choose between different brands of the same product, one or more of which had been advertised on the experimental tape and one or more of which had not. Two of the studies (Gorn & Goldberg, 1980; Gorn & Florsheim 1985) measured product preferences but between alternatives that were necessarily designated healthier and less healthy.		which are generally not excessively advertised on television: chicken, apples, beans and low-fat milk. Two studies did not report results.	
Hastings et al 2003	Systematic review	N/A		Literature search 1970–2003. The participants in the studies were 475 9–12-year-old English speaking	Does food promotion influence children's food purchasing and purchase related behaviour?	No data provided.	All seven studies reviewed found that exposure to food promotion had an influence on, or was significantly associated with the specific purchase related behaviour measured in each study. The findings were reported according to the type of behaviour	The two cross-sectional studies would have been stronger had they used multiple regression analysis to examine the

				and French speaking children in Montreal (Goldberg 1990), 36 3–5-year-old children in Georgia and their mothers (Stoneman & Brody 1982), 775 4th–7th grade children in Michigan (Atkin 1975b), 66 mothers of children aged 3–8 years in Californian public ‘preschools’ and elementary schools (Taras et al. 1989), 41 3–11-year-old children (mean age range 4–7 years) in New York and their mothers (Galst & White 1976), 100 children aged 3–13 years in Michigan (Reeves & Atkin 1979) and vending machine users in 12 secondary schools and 12 workplaces in Minnesota (French et al. 2001). The samples achieved a reasonably			measured in each study. **Sales:** Sales of low-fat snacks increased significantly and proportionately with increasing price reductions and promotional labels and signage also had a small, independent effect on low fat-snack sales. Promotion (labelling and signage) was significantly and independently associated with increased low-fat snack sales ($p > 0.04$). Overall sales volume was unrelated to promotion, but was related to price reduction. **Observed purchase influence behaviour:** No significant difference was found between experimental group and control group children in numbers of hours of television reportedly viewed per week, and the two groups of children did not differ in the amount of attention they paid to the experimental tape, which increased the likelihood of the observed differences in behaviour being attributable to the experimental tape. A study by Galst & White (1976) who focused on children’s supermarket behaviour after being exposed to food advertising found the more effort a child exerted to keep the overall videotape playing and the more effort they exerted to watch advertisements the more ‘purchase influence attempts’	relationship between food promotion and other factors on purchase related behaviour.

				representative range of income levels.			they made per minute in the supermarket. **Household purchase:** A study by Goldberg (1990) which examined the degree to which children are affected by television advertising found that children who had the highest level of US TV viewing reported more household purchase of children’s cereals (mean 2.67) than children with a low level of US TV viewing (mean 1.62). There was also a significant effect for income ($p > 0.01$), with low-income children reporting more household purchase of children’s cereals (mean 2.42) than upper-middle income children (mean 2.03). No significant effects were found for language nor were any significant interactions found, although the interaction of level of US TV viewing by income approached significance ($p > 0.007$). **Reported purchase influence behaviour:** A study by Atkin (1975b) who measured exposure using a ‘cereal advertising exposure index’ found that children who reported watching more Saturday morning television more often asked for cereals. More than twice as many ‘heavy viewers’ of Saturday morning television as ‘light viewers’ reported making cereal purchase	

							requests ‘a lot’ of the time. A study by Taras et al. (1989), which investigated the relationship between children’s television viewing and their food purchase requests, found significant correlations were found between hours of TV viewing and the number of food items which mothers perceived had been requested because of television’s influence (*p* = 0.006) and the number of food items subsequently purchased (*p* = 0.01). Snacking while watching television was also significantly positively correlated with number of food items requested and purchased and with energy intake.	
Hastings et al. 2003	Systematic review	N/A		Literature search 1970–2003. Participants in all the 11 studies were all North American and the age range was 2–11 years. Some involved relatively small sample sizes (e.g. Cantor 1981, *n* = 37), while other studies involved samples of several hundred, such as Atkin (1975b) *n* = 775 and Bolton (1983) *n* = 262.	Does food promotion influence children’s food consumption behaviour? Eleven studies investigated the effects of exposure to food promotion on children’s food consumption behaviour (defined as encompassing three types of behaviour: one - off consumption, short-term consumption and self-reported regular patterns of consumption behaviour.	No details provided.	Two experimental studies (Gorn & Goldberg 1980b, 1982) found that exposure to food promotion had an effect on children’s consumption. It reduced likelihood of selecting fruit or orange juice, compare with a sweet for a daily snack. Three cross-sectional studies (Atkin 1975b; Bolton 1983; Ritchey & Olson 1983) found small but significant associations between exposure to television food advertising and frequency of snacking or consumption of foods (*p* > 0.05). Two studies (Jeffrey et al. 1982; Dawson et al. 1988) found variations in consumption behaviour, according to exposure to food promotion, but the results were not statistically significant	

				Several studies involved using participants who were mainly middle class (Galst 1980; Gorn & Goldberg 1980a; Bolton 1983; Dawson et al. 1988).	Eight of the studies were RCTs and three were cross-sectional studies.		($p > 0.05$) and no effect could be concluded. Four studies produced results, which were inconclusive. Galst (1980) appeared to indicate that exposure to food promotion had a positive effect on consumption behaviour (i.e. it reduced children's selection of sugared snacks), whereas Peterson et al. (1984) found that exposure to food promotion had no effect on children's consumption behaviour, but it was not possible in wither study to disentangle the effects of food promotion from other experimental stimuli examined at the same time. Cantor (1981) and Gorn & Goldberg (1980a) reported that exposure to food promotion had an effect on consumption behaviour but that under certain conditions it did not. Cantor (1981) reported the effect was to increase consumption of sweet foods while in Gorn & Goldberg (1980a) the effect was to reduce consumption of ice-cream. Overall, the studies used provide evidence of an effect of food promotion on consumption behaviour. Effects were sometimes inconsistent and were not found in all the studies, but were found in sufficient studies to suggest that food promotion influence children's food consumption.	

Hastings et al 2003	Systematic review	N/A		Literature search 1970–2003. The age range of the participants was 2–20 years. Five of the studies were North American and one was Australian. Dietz & Gortmaker (1985) had a very large sample of nearly 11,500 and Wong et al. (1992), Gracey et al. (1996) and Bolton (1983) also had large sample sizes of 1081, 391 and 262 respectively. Bolton's (1983) sample was predominantly White and of higher SES, whereas in Coon et al. (2001), the sample was non-randomly selected and of above average educational level; the other samples appeared to reflect a range of SES groups.	Does food promotion influence children's diet and health-related variables? Six cross-sectional studies were used to investigate the research question, four of which investigated the relationship between television and children's diet. The other studies examined health related variables and one examining the relationship between TV viewing and obesity.	No details provided.	There were small but significant ($p > 0.05$) associations between TV viewing and diet, television and obesity and television viewing and cholesterol. In five of the studies, the possible effect of food advertising on this relationship could not be distinguished from the general effect of the TV viewing. One study by Bolton (1983) which attempted to measure the specific contribution of food advertising found that the greater a child's food advertising exposure, the more frequent a child's snacking and the lower his or her nutrient efficiency.	Coon et al. (2001) and Gracey et al. (1996) studies had a number of limitations. Gracey et al. (1996) study used a long questionnaire administered under school staff supervision, but with only a one-item question on TV viewing. The validity of this could well be questionable compare with other diary recall types of question. Also the generalisability of the findings to all Australian children maybe questioned. In the Coon et al. (2001) study the way TV viewing was measured was poor and the sample appears to have been unrepresentative of the general population in the study's geographical area.
Hastings et al.	Systematic review	N/A		School children.	If food promotion is shown to have an effect	No details provided.	Seven cross-sectional studies and one experimental study (French 2001).	

2003					on children’s food knowledge preferences and behaviour what is the extent of this influence relative to other factors?		There is evidence from studies of various methodological quality that food promotion or TV viewing significantly influences children’s food behaviour and diet independently of other factors known to influence children’s food behaviour and diet. However there is little evidence to show whether the influence of food promotion on children’s food behaviour and diet is greater or lesser than that of other factors. One study found that 25–50% price changes appeared to have a stronger influence than promotional signage on low-fat snack sales from vending machines in secondary school. However, promotion significantly increased low-fat snack sales independently of pricing strategies (French 2001). Another study showed that food advertising exposure had a small but significant and independent impact on diet but explained less of the variance in snacking frequency than parents snacking frequency (Bolton 1983).	
Conclusion: Food promotion can have and is having an effect on children, particularly in the areas of food preferences, purchase behaviour and consumption. Most studies uncover an effect that will be harmful however there is evidence that promotion can have a beneficial effect. Food promotion has the potential to influence children in a positive way. There is evidence that food promotion has an effect on children’s nutritional knowledge. The evidence presented supports the ideal that food promotion may have little influence on children’s general perceptions of what constitutes a healthy diet, but that it can have an effect on more specific types of nutrition. There is good evidence that food promotion has an effect on children’s food preferences. In particular there is strong evidence that food promotion influences children’s food purchase-related								

behaviour. In the majority of studies the effect was in the direction of increasing purchase requests for foods high in fat, sugar or salt.

There were also significant effects between TV viewing and diet, and between TV viewing and health related variables; food promotion or TV viewing significantly influences children's food behaviour and diet independently of other factors known to influence children's food behaviour and diet. Although there is minimal evidence demonstrating the influence of, food promotion on children's food behaviour and diet is greater or lesser than that of other factors.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/ comments**
Family Food Survey 2003 Prepared by the www.raisingkids.co.uk (Dr P Spungin).	Survey	N/A		Parents and within the UK (all areas). The survey was open to parents with children under the age of 18 years living in the UK. *n* = 1521 parents 29.7% of respondents were one-child families. 44.0% were two-child families. 16.3% were three-child families 10% were four-child families.	A large-scale survey was undertaken on the 'raisingkids.co.uk' website to investigate the influence of food advertising alongside numerous other factors, including knowledge of nutrition and parenting values. The survey and paper covered three main topics: • food knowledge; • food purchasing; • attitudes to advertising to children.	N/a	85% of survey respondents were correct in thinking that children should only be given semi skimmed milk when they are >2 years of age. 56% of respondents knew that beef was the best source of iron from a particular selection of foods. Only 13% of respondents knew that that an 8-year-old boy should consume 1750 kcal (7.3 MJ)/day. When asked about the main source of information about their children's diet and	

				Amongst the sample, in total the families had 2547 children (1718 boys and 1829 girls).			nutrition, 43% said that their main source was from books and magazines and 15% relied on family and friends. Out of 1521 parents, only 13 (0.9%) said their main source of information was the Food Standards Agency. **Food purchasing:** 98% of respondents deemed nutritional value ‘important’ or ‘very important’. Parents may not have flawless food knowledge, but is still a big issue when selecting food. ‘What children prefer’ and ‘value for money’ were next in the rankings with 91% and 86% of people surveyed rating them ‘important’ or ‘very important’ respectively. Regionally and socio-economically, there was very little difference in opinions, although ‘price’ is rated less important by the higher earners.	

							63% stated that advertising was the biggest influence if a child asks for a new product. Other influences included' linked to a TV programme' and 'on the box promotion' receiving 37% and 36% respectively. The peer group is also a significant influence, with 50% of mothers saying 'They've seen it at school or friends have said it's good'. 14% of mothers let their children try a product after being asked to buy the product that a child has seen advertised. The survey reports that most parents make a decision depending on the food values of the product or the price. **Attitudes to advertising to children:** Of the people surveyed only 190 (12.9%) stated that they would like	

							advertising for children to be banned. 45% of respondents agreed with the statement 'I accept advertising is a commercial reality'. Although parents have certain reservations about advertising and the effects it has on children, they accept it. Parents recognise that in educating children to realistic expectations, with by far the largest response (96%) being 'It's up to parents to explain they can't have everything they see advertised'.	
Goode 1996	Survey and in-depth interviews	N/A		420 adults living in Leicester and Leicestershire, 58% female, 53% employed full-time, 95% White.	Examined how respondents made dietary choices.	N/A	High levels of awareness of healthy eating initiatives (72% aware of dietary recommendations aimed at improving the health of the nation), of nutritional knowledge, and of accuracy when asked to apply such knowledge. Despite knowledge there were those who failed to make dietary changes.	

							64% reported having made dietary changes due to increased awareness of healthy eating messages.	
Maddock 1999	Interview-administered survey and group discussions.	N/A		311 people representative of UK in terms of age, socio-economic class, employment status and region.	To investigate the nations current degree of interest in healthy eating and to find out whether people are taking note of guidelines.		High level of awareness of need to reduce sugar/salt and fat intake, some confusion regarding types of fat and their health effects and very few knew recommended intake is five portions of fruit and vegetables per day. No statistically significant difference in involvement in healthy eating according to demographic variables; within the groups respondents indicated that excessive information on healthy eating could have the opposite effect to the one intended.	
McCullough 2004	Questionnaire as part of a case study.	N/A		171 primary school children and 124 parents in one primary school in Manchester UK compares with	To compare awareness towards nutrition education between primary schools in UK and Korea and nutritional knowledge.	N/A	Children and parents are aware of importance of limiting fat, sodium and sugar intakes and requiring non-starch polysaccharide. In the case of some foods they	Data not extracted for Korean children and their parents.

				school in Korea (10–11 years old).			did not have satisfactory knowledge of which foods were high in salt, fat, sugar and non-starch polysaccharide. British **children** had less knowledge of salt levels in cornflakes, ketchup and chips and did not realise that chocolate and cake are high-fat foods. Children identified parents as main source of nutritional information. Children perceived health/nutrition as most important factor in choosing food followed by taste and parental influence (however their preferences suggested taste is most important). 16% British children selected fruit as their favourite snack yet 33% said they would buy fruit if they had an extra £2 for food. British children preferred to learn about nutrition through cookery classes then information packs then computer packages.	

							British **parents** said taste was most important factor for choosing food then health/nutrition, appearance and price. Least important factor was TV and friends. British parents said main source of information on nutrition was from doctor/health professional. 32% British parents said extra £10 per week available for food would be spent on fruit.	

Evidence for implementation – will it work in the UK?

First author	Study design	Research type	Research quality	Study population	Research question and design	Length of follow-up	Main results	Confounders/comments
Hillsdon et al. 2001	Before and after study.	2	+	See above.	See above.	See above.	**Providers of intervention:** Commissioned by Department of Health and run by Health Education Authority.	See above.
Miles 2001; Wardle 2001	Before and after study.	2	+	See above.	See above.	See above.	**Providers of intervention:** The Health Behaviour Unit, Department Epidemiology and Public Health from University College, London and the BBC Education department. Omnibus National Survey used to evaluate.	See above.
Wimbush et al. 1998	Before and after	2	+	See above.	See above.	See above.	**Providers of intervention:** Health Education board for Scotland.	See above.

	study.						Staff from the Centre for Leisure Research at Heriott Watt University, Edinburgh Staff from the Centre for Social Marketing at Strathclyde University, Glasgow.	
Tudor-Smith et al. 1998	Before and after study.	2	–	See above.	See above.	See above.	**Providers of intervention:** Health Promotion Wales and research staff.	See above.

SEARCH STRATEGIES

1. *obesity/pc
2. *weight gain/
3. *weight loss/
4. *body image/
5. *body mass index/
6. *skinfold thickness/
7. waist: hip ratio.tw.
8. overweight.ti.
9. weight control.ti,ab.
10. obes$.ti,ab.
11. weight maintenance.ti,ab.
12. (weight gain or weight loss).ti,ab.
13. exp mass media/ or telecommunications/ or advertising/ or marketing/
14. *internet/
15. (increas$ adj3 awareness).ti,ab.
16. (rais$ adj3 awareness).ti,ab.
17. (assess$ adj3 awareness).ti,ab.
18. (promot$ adj3 awareness).ti,ab.
19. (public adj1 awareness).ti,ab.
20. *awareness/
21. *health promotion/
22. *health education/
23. broadcast media/
24. (television adj campaign).ti,ab.
25. (radio adj campaign).ti,ab.
26. (publicity adj campaign).ti,ab.
27. (health adj campaigns).ti,ab.
28. *health behavior/
29. or/1-12
30. or/13-28
31. 29 and 30
32. limit 31 to (humans and yr="1990 - 2005")

The following seven website addresses were searched using the keywords “obesity”, “raising awareness”, “advertising”, “media” and “marketing”:

Clinical Evidence - http://www.clinicalevidence.org
EPPI-Centre - http://eppi.ioe.ac.uk/
Food Standards Agency - http://www.food.gov.uk/science/research/
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
NCCHTA - http://www.ncchta.org
NICE – www.nice.org.uk

Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamiltonwent.on.ca/CSCARB/EPHPP/ephpp.htm and SIGN – http://www.sign.ac.uk, were also searched for relevant data.

DATA SOURCES

The following information sources were searched:

ABI/INFORM
ASSIA
British Nursing Index
CENTRAL (Cochrane Controlled Trials Register)
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
CRD (EED database) http://www.york.ac.uk/inst/crd
DARE
Embase
Emerald
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC
Food Standards Agency - http://www.food.gov.uk/science/research/
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA - http://www.ncchta.org
NICE – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts

The electronic search strategies were developed in Medline and adapted for use with the other information sources. The Cochrane database was double checked for relevant RCTs – as the agreed review parameters. Bibliographies of included studies were searched, as were key reports and systematic reviews within these topic areas.

EXCLUDED REFERENCES

Paper	Reason for exclusion
A leaner fitter future. Options for Action 2003. Association for the Study of Obesity, MRC Human Nutrition Research, London School of Hygiene and Tropical Medicine.	Multi-sector perspective on overweight in children to stimulate engagement and action within UK – all relevant references collected.
Abbott R. Food and nutrition information: a study of sources, uses, and understanding. *British Food Journal* 1997;99(2):43–9	Self-selecting survey of Boots plc employees in UK re nutritional understanding and awareness – excluded from corroborative evidence as self-selecting employees of Boots plc, may not be generalisable to general British population.
Ashwell M. The media and slimming. *Proceedings of the Nutrition Society* 1991; 50(2):479–92.	Review of how media uses scientific information on obesity.
Bessell TL, McDonald S, Silagy CA, Anderson JN, Hiller JE, Sansom LN. Do Internet interventions for consumers cause more harm than good? A systematic review. *Health Expectations* 2002;5(1):28–37.	Systematic review of Internet vs. non-internet interventions, not aimed at raising awareness.
Bogue J. Determinants of consumers dietary behaviour for health-enhancing foods. *British Food Journal* 2005;107(1):4–16.	Dublin, consumer questionnaire to determine awareness of health benefits of health enhancing foods and dietary behaviour – excluded from corroborative evidence as based in Ireland, may not be generalisable to English mainland.
Booth M, Bauman A, Oldenburg B, Owen *N*, Magnus P. Effects of a national mass-media Campaign on physical activity participation. *Health Promotion International* 1992;7:241–7.	One-month mass media campaign to promote awareness of health benefits of PA in Australia. Not controlled, before and after using independent representative sampling.
Borra ST, Kelly L, Shirreffs MB, Neville K, Geiger CJ. Developing health messages: qualitative studies with children, parents, and teachers help identify communications opportunities for healthful lifestyles and the prevention of obesity. *Journal of the American Dietetic Association* 2003;103(6):721–8.	US-based consumer research to inform future education campaigns to help prevent obesity.
Brown JD, Witherspoon EM. The mass media and American adolescents' health. *Journal of Adolescent Health* 2002; 31(6 Suppl):153–70.	Review of mass media on US adolescents health; obesity only mentioned in context of TV as sedentary behaviour and media images of thinness linked to eating disorders, nothing regarding raising awareness of healthy weight/diet/exercise.

Bull FC, Holt CL, Kreuter MW, Clark EM, Scharff D. Understanding the effects of printed health education materials: Which features lead to which outcomes? *Journal of Health Communication* 2001;6:265–79.	1 month RCT of three different types of printed health education materials in obese Australian adults. Mainly attitudes, beliefs, awareness, some self-report of trying suggestions in booklets.
Caroli M, Argentieri L, Cardone M, Masi A. Role of television in childhood obesity prevention. *International Journal of Obesity and Related Metabolic Disorders* 2004; 28(Suppl 3):S104–8.	Non-systematic review of negative consequences of TV food advertising on food choice and consumption in children.
Cheung L. Do media influence childhood obesity? *Annals of the New York Academy of Sciences* 1993;699:104–6.	Short review of media influence.
Eagle L, Bulmer S, De Bruin A, Kitchen P. Exploring the link between obesity and advertising in New Zealand. *Journal of Marketing Communication* 2004;10:49–67.	Non-systematic review of negative influences of food advertising on children.
Finlay S-J, Faulkner G.Physical activity promotion through the mass media: Inception, production, transmission and consumption. *Preventive Medicine* 2005;40:121–30.	Systematic review of PA promotion through the mass media, includes UK studies. Reviewers excluded this review in preference for systematic review by Cavill et al. 2004. All UK studies included in both reviews. Finlay updates a previous review but substantive focus is on analysis from critical media studies perspective.
Goodman RM, Wheeler FC, Lee PR. Evaluation of the heart to heart project - lessons from a community-based chronic disease prevention project. *American Journal of Health Promotion* 1995;9:443–55.	Mass media plus community intervention – Heart to Heart project – non-UK. To reduce cardiovascular risk factors, pre–post design using matched comparison areas, 5 years.
Goran. Interactive multimedia for promoting PA (IMPACT) in children. *Obesity Research* 2005;13:762–71.	Evaluates efficacy of use of multimedia in schools to promote PA, 8-week CBA.
Halford JC, Gillespie J, Brown V, Pontin EE, Dovey T, Jason CG. Effect of television advertisements for foods on food consumption in children. *Appetite* 2004;42:221–5.	Two-week CBA assessing food consumption in children in Liverpool immediately after exposure to food adverts, obese children appeared to have heightened alertness to food cues.
Harvey-Berino J, Pintauro S, Buzzell P, Gold EC. Effect of internet support on the long-term maintenance of weight loss. *Obesity Research*	RCT with internet support for weight maintenance in one of three arms following

2004;12(2):320–29.	weight loss treatment.
Holmes LaWTM. HeartWell – healthy alliances in action. *Nutrition and Food Science* 1996;(6):25-28.	HeartWell community-based project in Scunthorpe, UK, various projects but media/public health was only one element in community-based projects, no outcomes reported. Excluded from corroborative evidence as no usable outcomes.
Hopper D, Barker ME. Dietary advice, nutritional knowledge and attitudes towards nutrition in primary health care. *Journal of Human Nutrition and Dietetics* 1995; 8:279–86.	Study of dietary advice given by members of Sheffield PHCT and their nutritional knowledge and attitudes towards nutrition – excluded from corroborative evidence as focuses on nutritional advice given by general practitioners (GPs) and practice nurses (more relevant to primary care).
Jansson S. Food and Health: experience from Sweden. *Health Education Journal* 1993;52:253–5.	Review of interviews with Swedish adults on food and health.
Jason LA, Greiner BJ, Naylor K, Johnson SP, Van Egeren L. A large-scale, short-term, media-based weight loss program. *American Journal of Health Promotion* 1991;5:432–7.	Media recruitment obese US adults to RCT with 3-month follow-up to assess media diet and exercise programme vs. media plus self-help group.
Jason LA. Tobacco, drug, and HIV preventive media interventions. *American Journal of Community Psychology* 1998; 26(2):151–87. Ref ID: 1111	Non-systematic review of media interventions.
Jordan Lin C-T, Lee J-Y, Yen ST. Do dietary intakes affect search for nutrient information on food labels? *Social Science and Medicine* 2004;59:1955–67.	Not an intervention; uses survey data to explore dietary intake and self-reported search for food label information in US adults.
Kline SE, Kline MA. Countering children's sedentary lifestyles: An evaluative study of a media-risk education approach. *Childhood* 2005;12(2):239–58.	Not an intervention; non-systematic review of media and sedentary lifestyles.
Kreuter MW. Understanding how people process health information: A comparison of tailored and nontailored weight-loss materials. *Health Psychology* 1999;18(5):487–94.	One-month RCT of tailored vs. non-tailored health education materials for weight loss in obese adult US women – same study as Kreuter 2000.
Kreuter MW. Are tailored health education materials always more effective than non-tailored materials? *Health Education Research* 2000;15(3):305–15.	One-month RCT of tailored vs. non-tailored health education materials for weight loss in obese adult US women.
Lambert N. Dibsdall LA, Frewer LJ. Poor diet	Review that compares anti-smoking

and smoking: the big killers: comparing health education in two hazard domains. *British Food Journal* 2002;104(1): 63–75.	campaign with UK five-a-day campaign, gives useful refs for five-a-day campaign but exclude this particular review – relevant references obtained.
Matson-Koffman. A site-specific literature review of policy and environmental interventions that promote PA and nutrition for cardiovascular health: what works? *American Journal of Health Promotion* 2005;19:167–93.	Review of environmental and policy interventions to increase PA and improve nutrition; included in Broader Community Review (Cardiff).
Meyers AW, Graves TJ, Whelan JP, Barclay DR. An evaluation of a television-delivered behavioral weight loss program: are the ratings acceptable? *Journal of Consulting and Clinical Psychology* 1996;64(1):172–78.	Evaluates efficacy of television delivery of weight loss in obese adults; RCT with 15 month follow-up, obese at baseline.
Miles J, Petrie C, Steel M. Slimming on the Internet. *Journal of the Royal Society of Medicine* 2000; 93(5):254–7.	Assess website content of weight loss diets compare with clinical guidelines.
Molnar AE, Molnar MA. School commercialism hurts all children, ethnic minority group children most of all. *Journal of Negro Education* 2004;72(4):371–8.	Review of school commercialism in USA.
Norman SA, Greenberg R, Marconi K, Novelli W, Felix M, Schechter C et al. A process evaluation of a two-year community cardiovascular risk reduction program: what was done and who knew about it? *Health Education Research* 1990;5(1):87–97.	To increase awareness of cardiovascular disease risk reduction (i.e. smoking and hypertension as well as weight), cross-sectional survey one-year apart, only measures awareness, US study.
Palmer S, Graham G, Elliott E. Effects of a web-based health program on fifth grade children's physical activity. Knowledge, attitudes and behavior. *American Journal of Health Education* 2005;36:86–93.	US crossover study of internet HealthyHeart4Kids in school to increase PA knowledge and behaviours. Only 8–9 weeks duration and doubts over validity of study design.
Philipp R. Public awareness of healthy life-style factors and sources of advice. *Health Education Journal* 1988;47:26–8.	Survey of public awareness of healthy life-style factors – published 1988.
Reid D. How effective is health education via mass communications? *Health Education Journal* 1996;55:332–44. Ref ID: 2514	Non-systematic review of mass media and health education
Rodgers AB**,** Kessler LG, Portnoy B et al. 'Eat for Health': a supermarket intervention for nutrition and cancer risk reduction. *American Journal of Public Health* 1994;84:72–6.	Twenty US supermarkets were matched paired with another 20 supermarkets, campaign for healthy eating ran for 2 years

	with three cross-sectional surveys.
Roefs A, Jansen AE, Roefs MA. The effect of information about fat content on food consumption in overweight/obese and lean people. *Appetite* 2004;43:319-322.	Two taster sessions to assess effect of labelling on food consumption in lean and obese adults in Netherlands.
Sanders TA, Woolfe R, Rantzen E. Controlled evaluation of slimming diets: use of television for recruitment. *Lancet* 1990; 336(8720):918–20.	UK – 6-week RCT of seven commercial slimming diets and placebo, BBC programme 'That's Life' helped carry out trial and presented on TV in 1987.
Seiders K & Petty RD. Obesity and the role of food marketing: A policy analysis of issues and remedies. *Journal of Public Policy Marketing* 2004;23:153–69.	US-based non-systematic review of food marketing.
Singh BM, Prescott JJ, Guy R, Walford S, Murphy M, Wise PH. Effect of advertising on awareness of symptoms of diabetes among the general public: the British Diabetic Association Study.*British Medical Journal* 1994; 308(6929):632–6.	Raising awareness through advertising of diabetes symptoms. Pre–post test, not controlled. Baseline, after 10 weeks advertising, then 10 weeks after advertising withdrawn. UK-based but only on awareness of diabetic symptoms.
Soweid Rema A Afifi. Changes in health-related attitude and self-reported behavior of undergraduate students at the American University of Beirut following a health awareness course. *Educuation and Health* 2003;16:265–78. Ref ID: 1892	Health awareness course within a University. Pre–post design, not controlled. One semester. Move in stages of change for fruit and vegetable intake and exercise for 16 students. American University of Beirut, Lebanon.
Strasburger VCE, Victor C, V. Children and TV advertising: Nowhere to run, nowhere to hide. *Journal of Development and Behavioral Pediatrics* 2001;22(3):185-187.	Commentary on relationship between food advertising, unhealthy eating practice and obesity in children.
Taylor CB, Fortmann SP, Flora J, Kayman S, Barrett DC, Jatulis D et al. Effect of long-term community health education on body mass index. The Stanford Five-City Project. *American Journal of Epidemiology* 1991; 134(3):235–49.	Mass media plus community intervention (non-UK) – Stanford Five City. To reduce cardiovascular risk factors Cohort and cross-sectional data with treatment and control cities 6-year.
Variyam JN, Callahan R. Diet-health knowledge, awareness of federal nutrition information programs, and obesity. *FASEB Journal* 2004;18:A846.	Uses survey data to assess link between awareness of federal nutrition information programs and overweight in US adults, abstract only.
Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The effectiveness of web-based vs. non-web-based interventions: A	Systematic review of web-based vs. non web-based interventions for behaviour change – order two references which may

meta-analysis of behavioral change outcomes. *Journal of Medical Internet Research* 2004;6(4):e40.	be relevant – this review is excluded as other included studies not relevant.
Woodward DR, Cumming FT, Ball PJ, Williams HM, Hornsby H, Boom JA. Does television affect teenagers' food choices? *Journal of Human Nutrition and Dietetics* 1997;10:229–35.	Cross-sectional survey in Australia of children TV and food choice.
Zaccari V. Walking to school in inner Sydney. *Health Promotion Journal of Australia* 2003;14:137–40.	Pre–post not controlled. Project in Australian schools to increase awareness of benefits of walking to school but only 4 weeks.

Contents

Appendix 6

The effectiveness of interventions, including family interventions, to prevent weight gain or maintain a healthy weight in children aged 2–5 years

EVIDENCE SUMMARY TABLES

1. INTERVENTIONS TO PREVENT WEIGHT GAIN, OR IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT (DIET AND ACTIVITY), IN CHILDREN AGED 2–5 YEARS

SUMMARY

Evidence of efficacy for weight management/reduction

Of the five included studies (four randomised controlled trials [RCTs] and one controlled non-randomised trials [CCT]) that have published outcome data, three RCTs found some evidence that the intervention prevented unhealthy weight gain leading to obesity, compared with controls. Ethnic minority children from Head Start programmes in Chicago that received a 14-week diet and physical activity (PA) intervention (Hip-Hop to Health Jr) had significantly smaller increases in body mass index (BMI) compared with control children at 1-year follow-up (0.06 vs. 0.59 kg/m^2; difference –0.53 kg/m^2 (95% confidence interval [CI] –0.91, –0.14), $p = 0.01$; and at 2-year follow-up, 0.54 vs. 1.08 kg/m2; difference –0.54 kg/m^2 (95% CI –0.98, –0.10), $p = 0.02$, with adjustment for baseline age and BMI.

Girls (but not boys) that received the intervention in the STRIP study gained slightly less weight between the ages of 2 and 3 years compared with controls. The already overweight children that received the intervention in the study conducted in China gained much less weight over time compared with controls – but this study was very intensive, costly, and demanded a substantial amount of effort from the parents of the 2–5-year-olds.

There were two studies that reported that interventions were not effective in preventing unhealthy weight gain (Dennison 2004; Healthy Start 2004). For example, Dennison (2004), who investigated if seven educational sessions would encourage reduction in television (TV) viewing, found that although the intervention produced a significant reduction in TV viewing it did not significantly alter anthropometric measurements of the subjects, i.e. did not improve weight loss.

Evidence of efficacy for diet/physical activity outcomes

Eight of the nine completed studies (five RCTs and three CCTs) reported improved diet and/or PA outcomes compared with the controls. These included interventions as part of the Healthy Start (USA), STRIP and the MAGIC (pilot) studies. The MAGIC pilot study, which focussed on a programme of structured PA, reported that there was a significant improvement in PA (based on accelerometry output) of children. Mean fat intake at age 5 years was significantly lower in the intervention group of the STRIP study. The Hip-Hop to Health Jr. study demonstrated only one significant difference between intervention and control children regarding diet/activity outcomes and this was a difference in percent of energy from saturated fat at 1-year follow-up (11.6 vs. 12.8%, $p = 0.002$). Improved outcomes from primary studies included He et al. (2004), McGarvey et al. (2004) and Koblinksky (1992). McGarvey et al. (2004) reported that attending educational sessions significantly improved the frequency of engaging active play with their child and increased frequency of offering the child water. Koblinksky (1992) reported that a parent education programme focusing on nutrition-related behaviour in Maryland, USA, resulted in the intervention group consuming significantly more fruits, vitamin C rich fruits, green vegetables, breads, rice/pasta and orange vegetables than the control group. The only study that reported no effectiveness was an intervention (Horodynski, 2004; controlled before and after [CBA]) that focused solely on nutrition education – a change in knowledge and attitudes was insufficient to change behaviour.

Evidence of corroboration in the UK

Many of the interventions cited within the included studies could be implemented in the UK. It seems reasonable to assume that such interventions could be implemented within the existing programmes and services, e.g. Healthy Start (UK), Sure Start, Child Centres and other existing services (e.g. Healthy Living Centres), and also into nursery and day care provision.

EVIDENCE TABLE 1: INTERVENTIONS TO PREVENT WEIGHT GAIN IN CHILDREN 2 TO 5 YEARS AND THEIR FAMILIES/CARERS

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
Evidence of efficacy (internal validity) for weight maintenance/reduction					
Dennison 2004 Cluster RCT 1+	Sixteen preschool and day care centres in rural upstate New York enrolling children between 3 and 5 years of age. Intervention group *n* = 93, mean age 3.9 years, 47% male, 93% white. Control group *n* = 83, mean age 4.0 years, 53% male, 100% white. The parents were well educated with half having a college degree or higher.	To evaluate an intervention to reduce TV viewing.	**Intervention group:** Seven educational sessions (over 10 weeks) that included a party to celebrate not watching TV for a week Information sent home for parents, children encouraged to read rather than watch TV. **Control group:** Safety and injury prevention programme. This was part of larger 'Brocodile the Crocodile' health promotion programme, which lasted for 39 weeks (no published papers identified on further search).	Sixteen centres entered and completed TV intervention element, 3 of 93 children in intervention group lost to follow-up and 10 of 83 in control group. **Difference in mean changes:** Mean change in intervention group – mean change in control group (95% CI): BMI (kg/m^2) per year: –0.36 (–1.22, 0.50), *p* = 0.38 Standardised BMI/year: –0.19 (–0.83, 0.46), *p* = 0.54 Triceps skinfold thickness (mm/year): –0.41 (–3.52, 2.70), *p* = 0.78 Weight (kg): –0.73 (–1.84, 0.39), *p* = 0.18 Although intervention produced significant reduction in TV viewing it did not significantly alter anthropometric measurements.	Parent-reported child's TV viewing. Only published study on TV viewing intervention in preschool children identified. Generalisability limited as conducted in small centres in rural community with relatively small sample size lasting only 10 weeks.
He 2004 Individual RCT 1+	Two kindergartens of 'average living standard' in Qingdao, China, children aged 4 to 6 years. Intervention group, *n* = 24, 17 male, weight 27.2 (4.1) kg, BMI 19.6 (1.4) kg/m^2.	To explore an effective intervention programme to control obesity in preschool children, to reduce obesity and related diseases at school age.	A 1-year family-based educational programme with joint participation of parents, childcare workers and head of the kindergarten, aimed at changing improper attitude and behaviour of weight control, provided in various forms, such as parent meetings, training of the childcare workers and lessons on children's health. Behaviour	No reported loss to follow-up. Mean change in weight (kg, 95% CI), intervention vs. control: +1.3 (–2.5–+5.2) vs. +5.4 (+3.0–+9.0) kg. Mean change in BMI (95% CI), intervention vs. control; –1.4 (–0.6 to +2.2) vs. +1.5 (–0.3 to +3.8) kg/m^2.	Mean age not reported. All children in intervention and control are obese at baseline – but meets inclusion criteria otherwise.

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	Control $n = 19$, 15 male, weight 27.5 kg (4.0), BMI 19.3 (2.8) kg/m^2.		correction and dietary adjustment (reducing speed of eating, intake of snacks, sugary drinks and fast food), right amount of exercise (active role play and more outdoor activity) emphasised in educational activities and the daily life of the children. No further details reported regarding 'non-intervention control' group. Measurements were taken before and immediately after 1-year intervention.	Author concluded the programme was safe and effective, alleviated obesity levels without restricting normal height growth.	No details of randomisation process. Two groups of obese children were randomised and one group of normal weight children were not randomised but included in study for comparison (data not extracted for normal weight non-randomised group). Reviewers assumed CI for intervention change in BMI was –0.6 to –2.2. Author not contactable by email.
HEALTHY START (USA) 2004 Williams 1998a, 1998b, 2004; Bollella 1999a, 1999b; Spark 1998; D'Agostino 1999 CCT (quasi-randomised cluster trial) 2++	Nine Head Start preschools in upstate New York that served minority children (2 to 5 years old) from families with annual incomes below national poverty line (less than US\$15,000 for family of four). Mean age (months) A = 48.3 (6.9), B = 47.9 (6.4), C = 49.3 (6.1) Boys (%) A = 51.4, B = 51.3,	To evaluate the impact of a multi-component cardiovascular health intervention 'Healthy Start' to promote heart healthy behaviours and decrease cardiovascular disease risk factors.	Modification of preschool food service to reduce saturated fat content 30% or less total energy from fat and 10% or less total saturated fatty acid intake. **Group A:** Food service and supplementary nutrition education (skills based, lessons on healthy eating) – in school and family based. **Group B:** Food service only (education component focused on safety and accident prevention) – in school and	787 enrolled, 88–93% children in all three groups followed up for anthropometric testing. Since no significant difference found between food service and food service plus nutrition education group on outcomes, these groups were combined for analysis. Neither intervention had a significant effect on gain in weight-to-height ratio). The impact of the intervention varied by ethnicity ($p = 0.04$) but not	Quasi-randomised, six centres able to modify food service were randomly assigned by centre, three centres unable to modify food service served as controls. Many baseline differences between groups, the most significant/relevant of which are: differences in

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	C = 50.4 African-Caribbean (%); A = 54.2, B = 44.9, C = 39.8 Hispanic (%); A = 14.2, B = 1.9, C = 57.4 White (%); A = 31.6, B = 53.2, C = 2.8		family based. **Group C:** Control (no food modification and education component focused on safety and accident prevention) – in school and family based – this group was not randomised. Parent meetings on health themes held 2–3 times year for all groups. Three-year intervention, baseline measures in fall 1995 and measures planned semi-annually. Only reports outcomes at follow-up between 4.8 to 6.6 months post-baseline. Study ongoing.	gender ($p > 0.05$). There was a significant difference in weight to height ratio for white participants but not African American or Hispanic. Mean difference (95% CI) change in weight-to-height ratio from baseline to follow-up between groups A + B vs. C: African American = 0.004 (–0.007, 0.014) White = 0.034 (0.023, 0.045), Hispanic = –0.006 (–0.020, 0.009).	ethnicity (only 2.8% white in control vs. 31.6 and 53.2% in other two groups). Time to follow-up significantly different between groups: A = 5.8 (0.6) months B = 6.6 (0.5) months C = 4.8 (1.0) months from baseline to follow-up.
Hip-Hop Fitzgibbon et al. 2002; Stolley et al. 2003 Cluster RCT 1+	3–5-year-old African American and Latino minority children in 24 Head Start sites in Chicago. **Mean age (months):** Intervention: 48.6 months(7.6) Control: 50.8 months(6.4) % Female: Intervention: 49.7% Control: 50.5% % Black: Intervention: 99% Control: 80.7%	Weight change in low-income ethnic minority children. Didn't recruit or retain enough children for original power calculations, power recalculated to detect a difference of 0.35 standard deviations.	Reduction in fat, increase in fibre, increase in PA and inclusion of family are main elements of intervention. Theoretical base is combination of social learning theory and transtheoretical model of stages of change. Children had 45 min, three times per week for 14 weeks, hands-on learning about go and grow foods ('foods that will help you go and grow') vs. slow foods ('will make you slow'), using puppets of characters from each of the food groups.	Fourteen-week active intervention plus 2 years follow-up. Intervention $n = 179$ Control $n = 183$ Intervention children had significantly smaller increases in BMI compared with control children at 1-year follow-up (0.06 vs. 0.59 kg/m^2; difference –0.53 kg/m^2 (95% CI –0.91, –0.14), $p = 0.01$; and at 2-year follow-up, 0.54 vs. 1.08 kg/m^2; difference –0.54 kg/m^2 (95% CI –0.98, –0.10), $p = 0.02$, with adjustment for baseline age and BMI.	Trial was piloted for 3 weeks where elements were changed. Curriculum materials translated and taught in both English and Spanish. Twelve of the sites were randomly assigned to receive the intensive intervention and 12 were assigned to the general health intervention.

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	Baseline BMI: Intervention: 16.5 (1.5) kg/m^2 Control: 16.7 (2.0) kg/m^2 Intervention *n* = 197 Control, *n* = 212		Parents had weekly newsletter, homework (compensated US$5 if completed), and twice weekly 30-minute low impact aerobic classes at children's Head Start sites. Control had 20-min class once per week for 14 weeks spent on general health activity. Parents had weekly newsletter.		Assessors not blinded at baseline but blinded at follow-up.
STRIP Lagstrom 1997; Niinikoski 1997; Rask-Nissila 2000; Talvia 2004 RCT 1+	Babies from well-infant clinics, Turku (Finland), randomised at 7 months of age. Clinics visited regularly by over 98% of Finnish families so sample probably represented range of socio-economic classes (but no details reported).	To evaluate euenergetic, low-saturated fat, low-cholesterol diet to reduce children's exposure to high serum cholesterol values.	Families received individualised counselling at 1–3 month intervals from child aged 7 months to 2 years then twice per year to age 7 years, letters sent home to children between visit to increase interest in food and nutrition. When child aged 7 years separate counselling sessions given to child and parents. Counselling based on constructivist theory of learning. Optimal diet = energy without any restriction, protein 10–15% energy; carbohydrates 50–60% energy; up to 2 years fat 30–35% energy and after 2 years fat 30% energy (unsaturated to saturated fat ratio 2:1). Encouraged to use vegetables, fruit, berries, whole-grain products. Up to 2 years recommended daily supplement of Vitamin A and D_2,	1062 randomised (56.5% eligible age cohort) at age 7 months. 289 of 540 assessed at child age 10 years in intervention group and 268 of 522 in control. Dropout nearly 50%. Infants in both groups were breastfed for mean of 5 (SD 4) months. Relative mean weight gain (SD) (kg) at 2 years in boys: 1.3 (7.6) *n* = 235 vs. 0.7 (7.3) *n* = 221 Relative mean weight gain (SD) at 3 years in boys 1.5 (7.1) *n* = 225 vs. 0.5 (7.3), *n* = 215, *p* = 0.86 Relative mean weight gain (SD) (kg) at 2 years in girls 2.2 (8.6) *n* = 212 vs. 0.9 (9.3), *n* = 219 Relative mean weight gain (SD) (kg) at 3 years in girls 0.8 (8.4) *n* = 200 vs. –0.1 (9.8), *n* = 202 *p* = 0.17 Low fat intake in very young	Important long-term evidence to address restricting dietary intake in the very young. Nordic Nutrition Recommendations propose fat should comprise 30–35% of energy intake and daily energy intake should average 1300 kcal (5.4 MJ) in 1–3-year-olds; previous study in Finnish children with 3-day food records showed mean daily energy intake in 1–2-year-olds was 1167 kcal (4.9 MJ) of which 33% came from fat and 16% came from protein.

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
			breast or formula milk encouraged until at least 12 months (control 1.9% fat cow's milk after 12 months, intervention group advised to replace missing fat milk with vegetable oil). Control families seen twice per year until aged 7 years then once yearly, did not receive any detailed counselling on risk factors of atherosclerosis. Follow-up from age 8 months to 10 years.	children did not adversely affect vitamin and mineral intake and normal physical and neurological growth and lessened age-associated increases in serum cholesterol.	
Evidence of efficacy (internal validity) for diet/physical activity outcomes					
Worsley 2004 Systematic review – five studies: four of which were RCT s and one CCT 1+	Hammond et al. 1998 Kindergarten study in Canada. Mean age: 5 years. Intervention group *n* = 67; 57% male 43% female; control group *n* = 56, 45% male 55% female.	To evaluate whether familiarity with 16 various foods and willingness to eat them would be affected by a nutrition education programme.	The intervention groups were introduced to eight of the test foods. The early childhood nutrition education programme reinforced recent childhood acquisitions of gross and fine motor controls, cognitive skills, language abilities and social competencies at the same time as associating healthy eating habits with social fun and learning. **Intervention:** 7–12 months (throughout school year). **Follow-up:** 7 months.	Education programme had no direct impact on children's willingness to eat specific foods. More parents of the intervention group ($p < 0.001$) than control group children reported their child had stated exposure to a food at school when requesting it at home. Children in the study consistently stated that they were willing to eat a greater number of foods than their parents perceived.	Consumption of food was not measured directly. Instead, stated willingness to eat the foods was assessed using food models. Designation of foods into either food category (introduced or non-introduced) was restricted by the foods available as food models and by the design of the study that included equal representation of the four food groups in each food category.

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
					Active involvement in a situation of interest to preschoolers will more likely result in accurate memory later on.
	Lagstrom et al. (1997). Finnish study (part of STRIP). Intervention group *n* = 540; control group *n* = 522.	To examine whether counselling to parents would reduce a child's intake of saturated fat and cholesterol as well as ensuring adequate energy intake.	The intervention included a nutrition education programme, which included individualised dietary counselling focused on the amount and type of fat in the children's diet. Part of STRIP – see above for intervention details **Follow-up:** 38 months from beginning of intervention (when child aged 8 months).	Children's intake of fat (saturated and polyunsaturated) and cholesterol were significantly improved/lowered with intervention compared with control ($p < 0.01$). After the age of 13 months, the cholesterol intake of the children in the control group exceeded that of the children in the intervention group by 20 mg ($p < 0.01$). The intervention group consumed 3% less (of their energy intake) saturated ($p < 0.01$) and 1% more (of the energy intake) more polyunsaturated fats ($p < 0.01$) than the control group at 13 months and older.	Families knew which group they belonged to (intervention or control).

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	Sangster et al. (1999). Long Day Care Centres (LDCCs) in South Sydney Australia Intervention group *n* = 40 day care centres; Control group *n* = 20 day care centres. Of the 40 intervention centres 23 centres were privately run and 17 centres were community or council based- reflecting the mix of community/council and private centres in the area.	To evaluate the Good Food for Children (GFFC), which was a multi-strategic intervention aimed at improving the nutritional adequacy of food provided in childcare centres.	Assessment of centres' menus with feedback, advice on development of policies and development of workshops for childcare staff. The time between pre and post-test data collections was 14 months.	Generally, the GFFC intervention improved LDCC menus and consequently the nutritional quality of food available to children attending these centres. At post-test 97% of intervention centres had a planned cycle menu for at least 1 week as opposed to 87% in pre-test. There was a 45% increase in the number of centres with adequate served of dairy food on their menu ($p < 0.05$), a 21% increase in the number of centres with adequate servings of bread and cereal ($p < 0.05$) and a 36% increase in the number of centres that diluted fruit juice before serving ($p < 0.05$). Control centres showed no significant improvements.	—

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	Heino et al. (2000). Finnish study (part of STRIP). Intervention group *n* = 100; Control group *n* = 100. All children were aged between 3 and 5 years.	To examine sodium intake and dietary sodium sources of preschool-age children.	The intervention included a nutrition education programme, which included individualised dietary counselling focused on the amount and type of fat in the children's diet. Salt reduction in the children's diet was not included in the counselling before children were aged 5 years. Part of STRIP – see above for intervention details **Intervention:** 24 months **Follow-up:** 24 months	Nutrition counselling had minimal influence on children's sodium intake. Children's mean daily sodium (NaCl) consumption (intervention and control combined) was 1600 ± 527 mg (4.0 ± 1.3 g), 1900 ± 504 mg (4.8 ± 1.3 g) and 2200 ± 531 mg (5.5 ± 1.3 g) at the ages of 13 months and 3 and 5 years of age respectively. Intervention children consumed as much or slightly more sodium than the control children at all ages studied. Half the sodium consumption was derived from added salt in the commercially prepared or homemade foods.	The assessment of children's sodium intake is unreliable. It has been suggested that 3-day food records may underestimate sodium intake by as much as 11%.
	Dixon et al. (2000) Children (*n* = 303) aged 4–10 years with elevated LDL-cholesterol, recruited from paediatric practices in suburbs north of Philadelphia, USA. Intervention group *n* = 148; Control group *n* = 155. Majority were white children from middle	To evaluate the impact of nutrition education promoting lower dietary fat on the overall diet quality in children.	The intervention children were either assigned to the parent–child autotutorial (PCAT) programme, a 1-week home based self-instruction nutrition education programme, or nutrition counselling from a registered dietitian. **Intervention:** 10 weeks **Follow-up:** 3 months	Nutrition education that promoted lower dietary fat improved children's overall diet quality. However, numerous dietary behaviours important for long-term health remained unchanged. Children who received PCAT or counselling significantly improved their overall diet quality (–0.6 and –0.4 change in diet quality index (DQI) scores) compared with at risk control children. Children who received either nutrition education were more likely to meet the recommendations for three components of the DQI (total fat,	Results may not be generalisable to all children.

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	to upper income households.			saturated fat, sodium), but did not improve their intakes of three components of the DQI (vegetables and fruits, complex carbohydrates, calcium) at 3 months.	
Overall conclusions from Worsley 2004 Two out of the five studies published were effective. The authors concluded that the few studies highlight the lack of evaluation in this area, but do suggest that intervention *may* be worthwhile. Although there is little evidence, this age is a key time to establish good nutritional habits especially when involved with parents.					
Dennison 2004 Cluster RCT 1+	As above.	As above.	As above.	Difference in mean change from baseline between intervention and control (95% CI): TV/video-viewing hours per week: –4.7 (–8.4, –1.0). Alternate activities as a result of reduced TV viewing were not stated/measured. No significant changes or differences between intervention and control groups in the frequency of snacking whilst watching TV or the number of days family ate dinner together or watched TV during dinner (actual data not reported).	As above.
He 2004 Individual RCT 1+	As above.	As above.	As above.	'Through intervention, improper behaviours toward obesity out of misunderstanding were changed remarkably, which is beneficial to weight control of obese children. At home their overeating, consumption of double breakfast, eating speed and food intake ($p < 0.01$) but not amount of exercise. At kindergarten eating speed, dietary intake and	

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
				amount of PA ($p < 0.01$). With the guidance of parents and childcare workers in the intervention, obese children's behaviours at home and at kindergarten were changed toward the direction beneficial to weight control.'	
HEALTHY START 2004 Williams 1998a, 1998b, 2004; Spark 1998; Bollella 1999a, 1999b; D'Agostino 1999 CCT (quasi-randomised) 2++	As above.	As above.	As above.	No actual measurements of children's nutritional intake was taken but cholesterol levels were assessed. Results showed change in total cholesterol from baseline to follow-up by intervention ($p < 0.05$). A nutrition quiz was also administered. Adjusted overall means were higher in A than B (0.606 vs. 0.589) but difference on complete test was not significant.	As above. Cholesterol is included here as a proxy measure of nutrient intake.
Hip-Hop Fitzgibbon et al. 2002; Stolley et al. 2003 Cluster RCT 1+	As above.	As above.	As above.	Demonstrated only one significant difference between intervention and control children regarding diet/activity outcomes and this was a difference in percent of calories from saturated fat at 1-year follow-up (11.6% vs. 12.8%, $p = 0.002$).	As above.
Horodynski 2004 (NEAT) CBA 2–	Low-income, rural families with toddlers/pre school children.	Whether an intervention programme focussing on nutrition education	Early Head Start programme called NEAT linked child development and positive parenting practices with food and nutrition education through empowerment, to promote healthy	Attrition rate = 0% No significant differences found between the control and intervention group on dietary intake.	Parents self-selected intervention or control group (selection bias), toddlers age 1–3 years (average not

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	n = 38 families. Four rural counties in Midwestern USA. Annual income varied between US$17,484 to $32,189 (all below poverty level) and unemployment varied between 5 and 9%. Mean age of adults = 30 (range 16–76) years.	versus a non-treatment control group would improve the nutritional habits of pre school children and their families.	mealtime environment, good communication, children's self-regulated feeding behaviour. Three × 90-minute lessons in each of four Early Head Start sites in groups of four to five mainly mothers. **Intervention:** 3 weeks **Follow-up:** 6 months This pilot study is guiding an ongoing 3-year study. US$5 cash incentive to complete questionnaire at baseline and US$10 at 6-month post-test.	Authors conclude that knowledge alone is insufficient to change eating habits.	reported).
Koblinsky 1992 CCT 2+	Six New York city and five Maryland Head Start centres. Intervention *n* = 89 Control group *n* = 82 Mothers; 80% were aged between 21–39 years. All mothers had income below poverty level for 1987 (US$11 519 for a family of four).	The effects of a parent education programme on the nutrition related behaviour of Head Start parents and the dietary intake of their preschool children.	Treatment group mothers received 13 weekly newsletters and four nutrition workshops (informal presentation, hands on, small group discussion and food demonstrations on nutrition, feeding, meal planning and food shopping). Thirteen-week intervention with follow-up 1 to 2 months later.	80% of mothers who completed pre-programme assessment also completed post-programme assessment. In Maryland children in the intervention group consumed significantly more ($p < 0.01$) fruits, vitamin C rich fruits, green vegetables and breads and also significantly more ($p < 0.05$) rice/pasta and orange vegetables than the control group. No significant differences in food consumption were found between	Parents self-report. Preschool children but mean age not reported. Groups were not balanced at baseline: there were significantly more Hispanic mothers in New York treatment group (76%) compared with New York control group (59%).

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
	85% Maryland mothers were white or black; two-thirds of New York mothers were Hispanic.			New York treatment and control group children. Significantly more treatment group mothers in both states reported reducing sugar in child's diet compared with control.	

First author, study design, research type, quality	Study population	Research aim/question	Intervention details and length of follow-up	Results	Confounders/comments
McGarvey 2004 (Special supplemental nutrition programme for WIC) CBA 2+	Two WIC (Women, Infants and Children) clinics in Northern Virginia, USA. Low-income mothers of 2–4–year-old children. Intervention *n* = 185 parents; Control *n* = 151 parents. **Baseline for completers:** Mean age in intervention group = 3.06 (1.93) years; in control = 3.15 (0.9) years. % Male in intervention group = 46% and in control = 49% BMI (kg/m^2) in intervention = 17.2 (1.93), control = 17.38 (1.688).	To assess the benefits of a programme to promote parental behaviours and prevent obesity in preschool children.	Intervention (modified educational content of sessions) vs. normal educational classes provided by the WIC. Intervention group participants attended educational sessions once every 2 months and had an individual session with a WIC nutritionist every 6 months. Follow-up 1 year.	65% intervention group completed 12 months (*n* = 121) and 43% control group completed (*n* = 65). Pre-test and post-test differences by site were significant for 'frequency of engaging in active play with child' ($p < 0.01$) and frequency of offering the child water' ($p < 0.01$). Intervention demonstrated significant improvement in offering child water and frequency of engaging in active play with child.	Outcomes were Parental self-report which is susceptible to bias. Differential rates of follow-up between intervention and control sites. Groups were not balanced at baseline: Spanish-speaking participants had significantly lower baseline scores for frequency of watching TV whilst eating and frequency of offering child water through the day compared with English-speaking participants.
Reilly et al.	3–4-year-old children	Whether a	Structured PA delivered three times	Children in the intervention group	

First author, study design, research type, quality	**Study population**	**Research aim/question**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
(2003) MAGIC (Pilot Study) RCT Grade pending – to be confirmed on publication of full study	who attend nursery schools in Glasgow. Intervention group *n* = 30; Control group *n* = 30.	programme of structured PA would increase activity levels and improve basic motor skills.	per week (total of 90 min) supplemented with home based health education for 12 weeks.	showed a significant improvement ($p < 0.01$) in both total activity and motor skills development. There was a 40% increase in accelerometry output, as an index of total PA, on days when the intervention was delivered and an increase of 29% on days on which it was not (no further details).	

STRIP Lagstrom 1997; Niinikoski 1997; Rask-Nissila 2000; Talvia 2004 RCT 1+	As above.	As above.	As above.	Daily energy intake was lower in the intervention than the control group but this difference did not reach significance. Daily energy intake (kJ) boys + girls at 2 years (intervention vs. control): 4714 (829) *n* = 424 vs. 4802 (863), *n* = 436, *p* = 0.13. Daily energy intake (kJ) boys + girls at 3 years (intervention vs. control): 5070 (905) *n* = 392 vs. 5191 (980), *n* = 398, *p* = 0.07 % Daily Energy intake (calories) from total fat significantly lower in intervention than control group girls: mean difference total fat (95% CI): –2.5 (–3.1, –1.8), *p* < 0.01. % Daily energy intake (calories) from total fat, intervention vs. control girls (mean, SD): Age 4 years: 29.8 (4.3) vs. 32.2 (4.6) Age 7 years: 30.4 (4.3) vs. 31.8 (4.7) Age 10 years: 29.5 (4.5) vs. 32.1 (4.6) Total daily energy intake was lower in the intervention group girls than the control group girls but this did not reach significance. Mean difference total energy (calories, 95% CI) –134 (–275,to 6), *p* = 0.06. Total daily energy intake (calories) intervention vs. control girls (mean, SD): Age 4 years: Total energy 1253 (217) *n* = 173 vs. 1286 (227) *n* = 187 Age 5 years: Total energy 1343 (231) *n* = 126 vs. 1406 (229) *n* = 133, *p* = 0.027 Age 7 years: Total energy 1492 (240) *n* = 144 vs. 1515 (237) *n* = 151 Age 10 years: Total energy 1669 (320) *n* = 110 vs. 1638 (291) *n* = 116	

STRIP Lagstrom 1997; Niinikoski 1997; Rask-Nissial 2000; Talvia 2004 RCT 1+	As above.	As above.	As above.	% Daily energy intake (calories) from total fat significantly lower in intervention than control group boys: mean difference total fat (95% CI): –1.9 (–2.4, –1.3), $p < 0.001$. % Daily energy intake (calories) from total fat, intervention vs. control boys: Age 4 years: 30.6 (4.9) vs. 32.2 (4.5) Age 7 years: 30.7 (4.6) vs. 31.6 (4.5) Age 10 years: 30.5 (4.7) vs. 32.2 (5.6) Total daily energy intake (calories) was lower in the intervention group boys than the control group boys. Mean difference total energy (calories, 95% CI) –231 (–376 to –86), $p = 0.002$. Total daily energy intake (calories) intervention vs. control boys (mean, SD): Age 4 years: Total energy 1348 (216) $n = 198$ vs. 1404 (252) $n = 194$ Age 5 years: Total energy 1461 (248) $n = 139$ vs. 1484 (239) $n = 141$), $p = 0.41$ Age 7 years: Total energy 1629 (238) $n = 164$ vs. 1662 (274) $n = 165$ Age 10 years: Total energy 1796 (306) $n = 118$ vs. 1890 (349) $n = 137$ At age 5 years mean fat intake in intervention grou*p* was 30.6% of energy intake vs. 33.4% of energy intake in the control grou*p* ($p < 0.001$). At age 5 years mean saturated fat intake in intervention grou*p* was 11.7% total energy intake vs. 14.5% total energy intake in control ($p <0.001$).	
Evidence of corroboration (external validity)					
Evidence of salience from studies conducted in the UK					

First author	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Reilly et al. 2003 MAGIC (Pilot	As above.	As above.	As above.	As above.	As above.

Study) RCT Grade pending – to be confirmed on publication of full study					
Lowe et al. 2004 Food Dudes CBA 2++	Twenty-six children attending day nursery and a centre for child development aged 2–4 years took part in the study (school aged children also took part in the study, but data was analysed for 2–4-year-olds separately in a subgroup analysis).	To assess whether watching a series of six videos featuring heroic peers (the 'Food Dudes') who enjoy eating fruit and vegetables.	**Fruit consumption:** 15 months **Vegetable consumption:** 9 months	At snack-time, fruit consumption had almost doubled to 79%, and vegetable consumption had risen from 34 to 87%. At lunchtime, fruit consumption has risen from 17 to 76%, and vegetable consumption had risen from 20 to 89%.	To contact authors for further details of intervention used.
Department of Health (Sure Start) 2004 National Evaluation 2++	Sure Start represents a unique approach to early intervention for children 0–4 years, and their families, and communities. Rather than providing a specific service, the Sure Start initiative represents an effort to change existing services.	In terms of Sure Start: Do existing services change? Are delivered services improved? Do children and families and communities benefit?	Various and ongoing.	In terms of the National Evaluation, no weight, diet or PA outcomes have been reported as yet.	No results on weight, diet or PA outcomes, but the National Evaluation did assess implementation, impact, local context analysis and cost-effectiveness.
Department of Health (Reid & Adamson) 1997 Systematic review 2++	Various, but specific section in review reported on 2–5 year olds. (Some evidence considered was UK-based.)	Various. The main objectives of the review were to identify any cultural, behavioural or societal opportunities and barriers to good nutritional health which might inform policy by	Various.	1) There is evidence that children's food choices can be influenced by changing the food messages shown on television and the potential for change should make children's television an important forum for future interventions.	

		pointing to new ways of formulating or delivering interventions aimed at improving eating behaviour and improve the nutritional status in women of childbearing age, pregnant women, infants <1-year-old and children aged 1–5 years.		2) Young children do not always understand food messages in the way that they are meant, e.g. the meaning of the term ‘fat’. 3) Mothers who supervise the food intake more closely may be providing an opportunity for the child to develop good nutritional behaviour.	
Evidence for implementation – Will it work in the UK?					
Dennison 2004 1+	As above.	As above.	As above.	**Providers of intervention:** One early childhood teacher and one music teacher.	As above.
He 2004 1+	As above.	As above.	As above.	Qingdao women and children’s medical and healthcare centre staff.	As above.
Healthy Start 2++	As above.	As above.	As above.	**Providers of intervention:** Healthy Start instructors train the teachers and include meeting with Healthy Start nutrition educators who also conduct the parent meetings three to four times per year. School cooks and food service workers receive nutrition education training and one full-day workshop once per year and monthly on-site visits from registered dietitians on the Healthy Start Staff. Healthy Start Education Team perform direct observation of class and meal times, administer the knowledge quiz with a laptop and administer partial dietary recall by phone using direct entry computer interview. Physiological measurement taken	As above.

				by physicians, nurses, and technicians and reviewed by a paediatrician.	
Hip-Hop to Health Jr. 1+	As above.	As above.	As above.	**Providers of intervention:** The Hip Hop study is conducted within the Healthy Start programme, and use Healthy Start nutritionists and staff.	As above.
STRIP 1+	As above.	As above.	As above.	**Providers of intervention:** Nutritionist gave counselling, when children went to school, school personnel asked to help with food recording.	As above.
Worsley 2004 1+ (Systematic review)	As above.	As above.	As above.	Various.	As above.
Horodynski 2004 2–	As above.	As above.	As above.	**Providers of intervention:** Nutrition educators from Michigan State University and Early Head Start centre staff.	As above.
Koblinsky 1992 2+	As above.	As above.	As above.	**Providers of intervention:** Head Start centre staff, nutritionists and research staff.	As above.
McGarvey 2004 2+	As above.	As above.	As above.	**Providers of intervention:** WIC staff (including nutritionists) from the Virginia Department of Health and Virginia University school of medicine staff.	As above.
Reilly 2003 Grade pending – to be confirmed on publication of full study	As above.	As above.	As above.	**Providers of intervention:** Nursery staff. Evaluation of the study highlighted that the intervention was easily implemented into nurseries, enjoyed by both staff and pupils, good attendance.	As above.

2. FAMILY-BASED INTERVENTIONS TO PREVENT UNHEALTHY WEIGHT GAIN IN CHILDREN AGED 5–16 YEARS

SUMMARY

Evidence of efficacy for weight management/reduction
Evidence was identified from one systematic review that included eight relevant interventions (all RCTs in children who were at least 15% above ideal body weight (IBW) at baseline, with weight outcomes at 1 year or more, with four of these eight interventions published pre 1990) plus one RCT of two school-based interventions (Hopper 1996). Six of the studies included in the systematic review assessed different amounts and types of behaviour change therapy taught to both parent and child and all studies included in the review aimed to produce weight loss rather than prevent weight gain. Only two studies assessed behaviour change therapy given to the child alone compared with behaviour change therapy provided to both parent and child together. One of these two studies (in adolescents) showed that treating the mother and child separately appeared to be significantly more effective than treating them together, or treating the child alone. In the other study (10–11-year-old children) there was no significant difference in effect on weight outcomes between treating the parent and child together or separately.

The two school-based studies reported in the RCT (Hopper 1996) showed no significant differences between groups in post-intervention weight or skinfold thicknesses at 6 and 8 weeks follow-up. In younger children (5–12 years), five of the seven interventions reported no significant difference in weight outcomes at follow-up ranging from 1 to 5 years. One three-armed family-based RCT achieved a significant effect at 10-year follow-up. At 10-year follow-up the proportion overweight in the parent/child target group was 11.7% lower than in the child target group and 20.6% lower than in the non-specific target group. Authors also concluded that no significant differences in percent overweight changes were shown for children with one vs. two obese parents at 10-years follow-up. Another study (by the same primary author) concluded that although no significant treatment effect was observed, children with obese parents regained weight faster. One family-based intervention showed that mastery and contingency reinforcement of mastery significantly improved weight loss in obese children up to 1 year but these effects were not maintained at 2 years. There was no evidence to assess variation in effect with age or gender of children. Authors of the systematic review conclude that the studies suggest that parental involvement is associated with weight loss in children and the use of a greater range of behaviour change techniques improves weight outcomes for both parents and children. Although five of the studies showed no significant effect of intervention on weight outcomes only one of the studies did not use any parental involvement in the control group.

Evidence of efficacy for diet/physical activity outcomes
In two school-based RCTs (both reported in Hopper 1996) both treatment groups in ‘Study 1’ scored significantly higher than the control grou*p* on exercise knowledge and obtained a lower proportion of their energy from fat. In ‘Study 2’, the treatment group scored higher than the control group on post intervention fitness and nutrition knowledge as well as consuming more servings of fruit and vegetables. Within the treatment grou*p* a measure of the degree of family involvement significantly correlated with reduction in intake of fat and cholesterol.

Evidence of corroboration in the UK
No studies conducted in the UK were identified. Family based interventions are relatively labour-intensive for both providers and participants. Treating small groups of families at the same time, and using a distant component, can facilitate implementation. Generalisability from the systematic review is limited as two authors conducted five of the studies and the majority were conducted in North America.

Cost-effectiveness data
No evidence.

EVIDENCE TABLE 2: FAMILY-BASED INTERVENTIONS TO PREVENT UNHEALTHY WEIGHT GAIN IN CHILDREN AGED 5–16 YEARS

First author, Study design, Research type, research quality	**Study population**	**Research aim/question**	**Intervention details and length of follow-up**	**Main results** (include effect size(s)/CIs for each outcome if available)	**Confounders** (potential sources of bias)**/ comments**
Evidence of efficacy for weight maintenance/reduction					
McLean 2003 Systematic review 1 ++ Sixteen studies included, seven in school-age children and one in adolescents – only these results are relevant to this review and reported. Of the 8 relevant studies only 3 were published since 1990 plus a 10-year follow-*up* of a study begun in 1979 (Epstein 1990).	Age range 6–13 years (seven studies) and 12–16 years (one study) at baseline; 70% female All children/adolescents overweight by at least 20% IBW at baseline (seven studies) and at least 15% IBW (one study). Studies sizes were small (mean *n* = 52), majority conducted in North America and concerned with weight loss; approximately 15% loss to follow-up.	To evaluate the nature and effectiveness of family-based interventions targeting food intake and/or PA, in terms of weight control, weight maintenance or weight loss. (In comparison to another type of family based intervention or non-family based component.) The aim of seven of the eight interventions considered here was weight loss, and the other's aim was weight control (Israel 1985).	Only RCTs published in English language, with at least 1-year follow-up and incorporating and family-based component were included. All eight interventions included PA plus diet. One study compared an active intervention to a waiting list control only (Israel 1985) and seven compared active interventions. The study in adolescents (Brownell 1983) and one other study (Kirschenbaum 1984) assessed behaviour change therapy given to child alone compared with behaviour change therapy provided to both parent and child together. Six studies assessed different amounts and types of behaviour change therapy taught to both parent and child. Duration of intervention ranged from 9 weeks (Kirschenbaum 1984, Israel 1985) to 2 years (Flodmark 1993) and follow-up from 1 year to 10 years (Epstein	Five of the seven interventions in school-age children found no significant difference between intervention and control at follow-up, ranging from 1 to 5 years. One three-armed family-based RCT achieved a significant effect at 10-year follow-up. At 10-year follow-up the proportion overweight in the parent/child target group was 11.7% lower than in the child target group and 20.6% lower than in the non-specific target group. One family-based intervention showed that mastery and contingency reinforcement of mastery significantly improved weight loss in obese children up to 1 year but these effects were not maintained at 2 years (Epstein 1994). Authors conclude that greater weight loss for parents and children tended to be associated with: the use of a greater range of behaviour change techniques; parent training in behaviour change techniques; and targeting parent and child together. In the study of adolescents (Brownell 1983), focusing the intervention on the mother and child separately was more effective than treating them together and treating the child alone (adolescents lost significantly more weight when treated alone).	No studies of children under age 6 years, no studies found from 1994–2000, no studies found assessing prevention of weight gain, three studies were by the same author and conducted at the same institution, another two studies were conducted by the same author and at the same institution (therefore limiting generalisability). Weight outcomes were heterogeneous

			1990). Majority studies included face-to-face sessions. Four studies included monetary deposits.	No evidence to assess variation in effect with age or gender of children.	within and between studies. The authors conclude that ‘parental involvement is associated with weight loss in children’ even though five of the seven interventions in school-age children found no significant differences in weight outcomes between intervention and control. However, in only one of these studies was the family-based intervention being compared with an intervention that did not involve parents at all, and, as the authors note, the subtlety of differences between

					interventions may have reduced power to detect differences in outcomes between treatment groups.
Flodmark 1993 (included in McLean 2003 systematic review) RCT with non-randomised untreated control group.	Children aged 10–11 years of age screened for obesity at school and then referred to University Hospital, Sweden if obese (BMI of at least 23 kg/m^2). Conventional treatment *n* = 19 (nine girls, ten boys); baseline BMI 25.5 (SE 0.53) kg/m^2. Family therapy *n* = 25 (14 girls, 11 boys); baseline BMI 24.7 (SE 0.36) kg/m^2. Untreated (non-randomised) control group *n* = 50.	To evaluate the effect of family therapy on childhood obesity.	Conventional treatment consisted of dietary counselling by dietitian (ten families saw dietitian once, nine families satisfied with only seeing paediatrician) and regular visits to paediatrician with interest in weight problems (seen twice during initial 6 months then every 6 months, total five visits), 1500–1700 kcal (6.28–7.11 MJ)/day, 30% from fat and encouraged to exercise. Family therapy group received same as above plus six sessions with paediatrician and psychologist spread over 1 year, family therapy focussed on family structure and how to create change through constructing solutions (de Shazer model). Control group received no treatment. Mean duration treatment 14–18 months with follow-up after another year (when children were 14 years).	At end of treatment family therapy group had significantly smaller increase in BMI compared with conventional group when expressed in percent of initial value: 0.66 vs. 2.31%, *p* = 0.042, and reduction in subscapular skinfold thickness: –16.8 vs. 6.8%, *p* = 0.034. At follow-up 1 year after end of treatment there was no significant difference between family therapy and conventional treatment groups for BMI but was significant differences between groups for skinfold thickness. Mean BMI (kg/m^2) (SE) family vs. conventional: End of treatment: 25.0 (0.53) *n* = 22 vs. 26.1 (0.72) *n* = 19, *p* = 0.22. 1 year follow-up: 25.8 (0.73) *n* = 20 vs. 27.1 (0.88) *n* = 19, *p* = 0.15 (non-random control 27.9 [0.61] *n* = 48). Median % change (range) skinfold thickness, family vs. conventional, *n* = 15 in each group. 1 year follow-up: Triceps: –7.2 (55) vs. 8.1 (133), *p* = 0.027 Subscapular: –13.2 (113) vs. 19.6 (167), *p* = 0.005 Suprailiac: –15.1 (113) vs. 30.1 (178), *p* = 0.002 ‘Gender and puberty status did not contribute to variation of BMI.’ Four of 19 children dropped out of conventional	Authors conclude family therapy seems to be effective in preventing progression to severe obesity during adolescence if treatment starts at 10–11 years. Intention to treat (ITT) – school nurses obtained measurements in children who dropped out.

	Baseline BMI 25.1 (SE 0.35) kg/m^2. Twenty children had one obese parent and 13 had two; 17 children had no siblings and 11 had at least one sibling – no significant differences between groups.			treatment. Nine of 24 children (one pilot case excluded from analysis) dropped out of family therapy group.	
Epstein 1981, 1987, 1987, 1990 (included in McLean 2003 systematic review) RCT	Seventy-six families with obese 6–12–year-olds with at least one obese parent, selected from population who applied to enter study (obese defined as >20% IBW). Socio-economic status (SES) of parents equal to medium-sized business owners, minor professionals and technical workers; 53 of 55 families	To test the hypothesis that treatments that target and reinforce habit change and weight loss in obese parents and children together will be superior over 10 years to treatments that focus on child habit and weight change independent of parent success or to a control treatment that targets and reinforces the family members for attendance only.	All three groups received similar diet, exercise and behaviour management training and differed only in the reinforcement for behaviour change and weight loss. Traffic-light diet limiting sweets and sugared beverages, 1200–1500 kcal (5.02–6.27 MJ)/day limit, daily minimum of two servings high protein foods, two servings dairy foods, four servings grains, four servings fruit and vegetables; instructed to begin an exercise programme (Cooper aerobic point system); parent + child and child target groups received self-monitoring and social reinforcement training, money deposited was returned only if parent and child lost weight in parent + child target group and if child only lost weight in child	Change in % overweight at 5 years in parent + child vs. child vs. non-specific groups (SD or SE not reported): –12.7% (*n* = 24) vs. 4.3% (*n* = 21) vs. 8.2% (*n* = 16). Change in % overweight at 10 years in parent + child vs. child vs. non-specific groups: –7.0% (*n* = 20) vs. 4.7% (*n* = 16) vs. 13.6% (*n* = 19). 'No significant differences in percent overweight changes were shown for children with one vs. two obese parents.' Change in weight gain at 10 years in parent + child vs. child vs. non-specific groups: 34.0 kg (*n* = 20) vs. 43.1 kg (*n* = 16) vs. 46.6 kg (*n* = 19); children in child and non-specific groups were significantly heavier than children in parent + child group ($p < 0.05$). No significant difference in percent overweight in *parents* at 10 years in parent + child vs. child vs. non-specific groups: 9.1% (13.9) vs. 4.6% (10.1) vs. 10.6% (13.4).	First long-term study to show that behavioural family-based treatment began between ages 6 to 12 years can have persistent and positive effect on weight through into young adulthood; the importance of targeting and reinforcing only the child vs. the child + parent or only the child vs. non-specific

	were white. Child and parent target group mean age 9.4 (1.8) years, male/female 14/6, weight 47.2 (12.7) kg. Child target mean age 10.4 (1.2) years, male/female 9/7, weight 54.9 (12.6) kg. Non-specific control mean age 9.9 (2.3) years, male/female 13/6, weight 53.2 (13.7) kg.		target group; non-specific target group had money returned on attendance regardless of weight lost and received education on diet through standard lecture-style format. All groups received eight × weekly meetings then six additional meetings in next 6 months, then at 21, 60 and 120-month follow-up meetings.	Effect of study also assessed on non-treated parents and siblings (Epstein 1987) – overweight non-participating siblings of children in the parent + child target group had significantly greater percent overweight change at 5 years than overweight siblings in the child alone target and non-specific target groups (–7.0 [14.6] vs. 4.1% [10.4]). No significant group differences were observed for obese non-participating parents or non-obese non-participating siblings or parents (based on participating parent report).	target cannot be inferred. Study also showed that weight regulation had no effect on height. Outcome results differ in abstract compared with text of study paper (Epstein 1990).
Brownell 1983; (included in McLean 2003 systematic review) RCT	12–16 years, 79% female, at least 20% above IBW, attended with mothers, *n* = 42 in total.	To evaluate any difference in effectiveness between treating adolescents alone, separately from mothers and together with mothers on weight.	Mother and child seen together vs. mother and child seen separately vs. child alone; aim of all three interventions were change in target behaviour of child, mother gave active support in mother and child seen together and mother and child seen separately groups; mother gave passive support in child alone group. Intervention included target setting, monitoring, contingencies, increasing skills, prompts/triggers/cues, social	At 1-year follow-up change in weight, mother-child separately vs. mother-child together vs. child alone: –7.7 (14.2) vs. 2.9 (7.3) vs. 3.2 (5.9) kg. *n* = 42 in total. At 1-year follow-up change in % overweight, mother–child separately vs. mother–child together vs. child alone: –20.5% (22.5) vs. –5.5% (12.1) vs. –6.0% (13.2). *n* = 42 in total. ‘Adolescents targeted separately from their mothers lost significantly more weight than when	

			support, information regarding behaviour and outcome. 16-week intervention with follow-up at 1 year.	targeted with their mothers.'	
Epstein 1986, 1987 (included in McLean 2003 systematic review) RCT	Forty-one families with 8–12-year-old children between 20–80% over IBW (24 children had at least one obese parent)	To investigate the role of parent weight (obese/non-obese) and parent control vs. child self-control on eight loss in obese preadolescent children >3 years old.	Parent control group and child self-control group, US$85 deposit returned on attendance; children and overweight parents given 1200 kcal (5.01 MJ) diet and lifestyle exercise programme, non-obese parents given weight maintenance diet and same exercise programme; children in both groups earned points backed up by privilege and activity reinforcers that were sued to regulate child eating and exercise habits; initially determination of when goals were met were made by therapist this then changed to parents (parent control group) or children (child self-control group). Eight × weekly meetings and ten × monthly meetings in which parent and child seen separately over 1-year period, 3-year data available for 38 families, 5-year follow-up for 33 families.	Parent or child self-control had no significant effect on weight change: change in % overweight, parent control vs. child self-control: 6 months: –17.4 vs. –14.7% (*n* = 38 families in total) 1 year: –12.4 vs. –11.7% (*n* = 38 families in total) 3 years: –5.7 vs. 0.1% (*n* = 38 families in total) 5 years: –3.6 vs. 3.3% (*n* = 33 families in total) Change in % overweight between children of non-obese parents vs. children of obese parents: 6 months: –17.2 vs. –14.3% (*n* = 38 families in total) 1 year: –16.3 vs. –7.7%, $p < 0.01$ (*n* = 38 families in total) 3 years: –5.6 vs. –0.9% (*n* = 38 families in total) 5 years: 10.7% lower in children of non-obese parents vs. children of obese parents ($p = 0.044$, *n* = 33 families in total). Children with non-obese parents were more compliant for energy limit and had better eating behaviour. 'No significant treatment effect was observed but children with obese parents regained weight faster and so parent weight may influence long-term outcome of child weight.'	Authors evaluated effect of parent weight on weight outcomes but parent weight was crossed with treatment condition. Change in percentage overweight between children with obese/non-obese parents differs in two papers but pattern is same (one paper adjusted results for difference in baseline initial percent overweight between parent weight groups).
Epstein 1994 (included in McLean 2003 systematic review)	Forty-four families with obese (20–80% above IBW) 8–12-year-old	To evaluate the effects of mastery criteria and contingent reinforcement for	All subjects had same information regarding self-monitoring, diet (traffic light diet with energy intake goals ranging from 900–1800 kcal (3.77–7.53 MJ) on level 1 to 900–	Changes in % overweight experimental group (*n* = 17 children) vs. control (*n* = 22 children): 6 months: –30.1 vs. –20.0%, $p < 0.05$ 1 year: –26.5 vs. –16.7%, $p < 0.05$ 2 years: –15.4 vs. –10.6%, $p = 0.29$	

RCT	children, mean age 10.2 (1.1) years, 59.6 (22.0)% over 50th percentile for BMI, 74% female; 82% parents were mothers, 54% participating parents were obese and 30.1 (20.9)% participating parents were over 50th percentile for BMI, majority middle class SES status.	family-based behavioural treatment of childhood obesity.	1200 kcal (3.77–5.02 MJ) by level 4 and individually adjusted energy intake control on level 5 based on maintenance requirements) and exercise (lifestyle exercise programme) and both treatments included behaviour management (focussing on praise and stimulus control, also included quizzes, contracting and lottery tickets) and parenting education. In experimental group families progressed through treatment at own rate based on mastery of information and skills and were reinforced on individual basis; control group were 'yoked' to progress in treatment group and did not have to demonstrate mastery of behaviour change skills. Twenty-six × weekly meetings and 6 monthly meetings up to 2 years.	Mastery and contingency reinforcement of mastery can significantly improve weight loss in obese children up to 1 year but these effects were not maintained at 2 years.	
Israel 1985 (included in McLean 2003 systematic review) RCT	Thirty-three families, children aged between 8–12 years and at least 20% over IBW; mean age 11 years and 4 months. Behavioural weight reduction only group, *n* = 12 (nine girls,	To evaluate the effect of explicit and additional training in general child management skills in the context of a behavioural treatment programme for overweight children.	Behavioural weight reduction only group and behavioural weight reduction plus parent training group received identical treatment consisting of stimulus control cues, exercise, food intake and rewards; responsibility for monitoring was divided between parent and child, also included homework. Behavioural weight reduction plus parent training group also received 2-hour-long sessions of instruction in behavioural child	Changes in weight at 1-year behavioural weight reduction plus parent training vs. behavioural weight reduction only: 5.2 (*n* = 11) vs. 4.8 kg (*n* = 9). Change in % overweight at 1 year behavioural weight reduction plus parent training vs. behavioural weight reduction only: –10.2 (*n* = 11) % vs. –1.3% (*n* = 9). No significant difference between two active treatment groups.	

	three boys, range 9–12 years). Behavioural weight reduction plus parent training group, *n* = 12 (eight girls, four boys, range 8–13 years). Wait list control group, *n* = 9 (six girls, three boys, range 9–12 years).		management skills prior to start of programme, understanding was tested in three quizzes and concepts were referred to in treatment programme. Nine × 90 min sessions then brief problem-solving discussions at 1, 2, 4, 6, 9 and 12 months including telephone calls.		
Israel 1994 (included in McLean 2003 systematic review) RCT	Thirty-four children aged 8–13 years and at least 20% over IBW; mean age 10 years 11 months (SD 1 year 2 months).	To evaluate the effect of enhanced self-regulation in the treatment of childhood obesity.	Both treatment groups consisted of stimulus control cues, exercise, food intake and rewards; instruction in general child management principles, families monitored children's food intake and parents rewarded appropriate behaviours. Enhanced child involvement group placed less emphasis on parental control and children trained in self-goal setting, formulating and implementing behaviour change, self-evaluation, self-reward and training for high-risk situations, parents also rewarded children for engaging in self-management skills. Groups of five to seven families, eight × weekly 90-min parent and child sessions held separately followed by 9 × biweekly sessions	26/34 families completed 26 weeks, 20/34 families completed 1- and 3-year follow-up (no difference between groups). Change in % overweight standard treatment vs. enhanced child involvement: 1 year: –0.7 (*n* = 11) vs. –5.8% (*n* = 9) 3 years: 6.4 (*n* = 11) vs. –4.8% (*n* = 9) No significant difference between treatment groups.	

			for 26 weeks, follow-up at 1-year and 3-years post-treatment.		
Kirschenbaum 1984 (included in McLean 2003 systematic review) RCT	Forty parent–child dyads where child aged 9–13 years and at least 20% above IBW and parent at least 10% above IBW. Parent + child group *n* = 16 (mean age 10.4, *n* = 13). Child only group, *n* = 15 (mean age 11.2, *n* = 9). Non-randomised control group, *n* = 9.	To evaluate the effects of parental involvement and family environment on weight loss on obese preadolescents.	Both treatment groups received cognitive-behavioural treatment including self-monitoring, increasing exercise, nutrition education, stimulus control, meal and exercise planning, self-reward, decelerated eating, coping techniques. Parent + child group attended all sessions together. Child only group children only attended sessions and had to bring in parent's homework and emphasis on child becoming the expert. Waiting list control dyads attended assessments only. Nine × weekly sessions plus 3-month and 1-year follow-up sessions; US $30 fee plus $50 deposit refunded contingent on attendances.	Change in % overweight at 1 year, parent + child vs. child only: –7.6% (*n* = 13) vs. –6.2% (*n* = 9). Change in weight at 1 year, parent + child vs. child only: –3.2 kg (*n* = 13) vs. –2.8 kg (*n* = 9). Children in both active treatment groups lost and sustained weight loss over 1 year with no significant difference in effect between the two groups.	Significant difference in treatment dropout between two active interventions groups (voluntary dropout 33% in child only group*p* vs. % in parent +child group, *p* < 0.03, with three of five cases stating parent dissatisfaction at being assigned child only group).
Hopper 1996 RCT (cluster, by class) 1+	**Study 1:** 132 school children, mean age 11.6 (SD 0.7) years plus a participating parent for 42 of the 45 children in the school-and-home treatment condition.	**Study 1:** To assess the effectiveness of including a family participation component in a 6-week school-based programme to develop children's heart-healthy exercise and nutrition habits.	**Study 1:** School-and-home and school-only groups received nutrition education two × half-hour in school sessions per week for 6 weeks; emphasising different meals and targets for behaviour change, focus on reducing saturated fat and heart-healthy foods. Three × 40 min in-school sessions per week for 6-weeks	**Studies 1 and 2:** No significant differences between groups in post-intervention weight or skinfold thickness.	Lack of follow-up is a major weakness of the study. Family was defined as at least one adult and one child sharing usual household activities.

	Study 2: ninety-seven school children, mean age 8.9 (SD 1.18) years, plus a participating parent of each child in the treatment condition.	(School-and-home treatment condition *n* = 45 vs. school-only treatment condition *n* = 43 vs. control condition *n* = 44.) **Study 2:** To assess the effectiveness of a 10-week school-based fitness and nutrition programme with parent involvement. (School-based treatment with parent participation treatment condition *n* = 48 vs. control condition *n* = 49.) Outcomes in the same classes as above.	instruction in physical fitness particularly aerobic exercise. In addition the school-and-home group received weekly homework packs and received points for completing nutrition and exercise activities. Control group received no additional instruction in nutrition and exercise from school curriculum. Length of intervention was 6 weeks. **Study 2:** School-and-home and school-only groups received nutrition education two × half-hour in school sessions per week for 10 weeks; emphasising different meals and targets for behaviour change, focus on reducing saturated fat and heart-healthy foods. In addition the school-and-home group received weekly homework packs and received points for completing nutrition and exercise activities. Four × 30 min in-school sessions per week for 10 weeks instruction in physical fitness particularly aerobic exercise. Control group received no additional instruction in nutrition		

			and exercise from school curriculum. Length of intervention was 10 weeks.		
Evidence of efficacy (internal validity) for diet/physical activity outcomes					
McLean 2003	As above.	As above.	As above.	Not reported	As above.
Hopper 1996	As above.	As above.	As above.	**Study 1:** The school-and-home group scored significantly higher than the control group on post-intervention nutrition knowledge and sit-and-reach flexibility. There was no significant difference between the school-only and control groups. Both treatment groups scored significantly higher than the control group on exercise knowledge and both obtained a smaller proportion of their energy from fat. There were no significant between-group differences in any other measures of dietary intake (grams of protein, carbohydrates or fat, and % energy from protein or carbohydrates) or other performance measures (number of sit-ups in a minute, time to run one mile). **Study 2:** The treatment group scored higher than the control group on post-intervention measures of fitness/nutrition knowledge, and consumption of servings of fruit and vegetables. There were no significant between-group differences in any other post-intervention scores, i.e. any other measures of dietary intake and time to run a mile. Within the treatment group, a measure of the degree of family involvement significantly correlated with reduction in intake of fat and cholesterol but no other change scores.	As above.
Evidence of corroboration (external validity)					

Evidence of salience – Is it appropriate for the UK?					
First author, study design, research type and quality	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/ comments**
McLean 2003 Systematic review 1++	As above.	As above.	As above.	**Country:** Children: Six interventions in USA, one in Sweden. Adolescents: one intervention in USA. Should be generalisable to the UK.	Sample sizes were small, so intervention may have been unable to detect an effect if one existed.
Hopper 1996 RCT 1+	As above.	As above.	As above.	**Country:** USA, so probably generalisable to the UK.	Sample sizes were small, so intervention may have been unable to detect an effect if one existed.
Evidence for implementation – Will it work in the UK?					
First author, study design, research type and quality	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/ comments**
McLean 2003 Systematic review 1++	As above.	As above.	As above.	The family-based interventions were relatively labour-intensive for both providers of the interventions and participants. Families were treated in small groups or individually (though providers of the interventions were mostly not stated in the systematic review), and most interventions had a distant learning component (in the form of assignments and educational materials).	The median dropout rate during the interventions was 18 (range 11–33)%, but not reported for three of the interventions).
Hopper 1996	As above.	As above.	As above.	**Study 1:** The school component involved: (1) physical	

RCT 1+				fitness education: three 40-minute, in-school sessions per week for 6 weeks; (2) nutrition education: two 30 min, in-school sessions per week for 6 weeks. The home component involved weekly packets (containing information and activities) for children to take home and read with their families, with information, and a scorecard to complete. Families were also given reinforcers (stickers, t-shirt, certificates, etc.). Teachers and staff from the State Department of Health and Physical Education delivered the intervention. **Study 2:** The school component was similar to Study 1 except 10 weeks in duration. Home component: as above. Delivery as above.	

SEARCH STRATEGIES

1. exp OBESITY/
2. exp Weight Gain/
3. exp Weight Loss/
4. obes$.ti,ab.
5. (weight gain or weight loss).ti,ab.
6. (overweight or over weight or overeat$ or over eat$).ti,ab.
7. weight change$.ti,ab.
8. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
9. body mass.ti,ab.
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. exp Behavior Therapy/
12. exp Social Support/
13. exp Family Therapy/
14. exp Psychotherapy, Group/
15. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
16. (group therapy or family therapy or cognitive therapy).ti,ab.
17. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.
18. counsel?ing.ti,ab.
19. social support.ti,ab.
20. (peer adj2 support).ti,ab.
21. (children adj3 parent$ adj therapy).ti,ab.
22. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23. exp OBESITY/dh [Diet Therapy]
24. exp Diet, Fat-Restricted/
25. exp Diet, Reducing/
26. exp Diet Therapy/
27. exp FASTING/
28. diet$.ti,ab.
29. (low calorie or calorie control$ or healthy eating).ti,ab.
30. (fasting or modified fast$).ti,ab.
31. exp Dietary Fats/
32. (fruit or vegetable$).ti,ab.
33. (high fat$ or low fat$ or fatty food$).ti,ab.
34. formula diet$.ti,ab.
35. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36. exp EXERCISE/
37. exp Exercise Therapy/
38. □uantita$.ti,ab.
39. (fitness adj (class$ or regime$ or program$)).ti,ab.
40. (aerobics or physical therapy or physical training or physical education or physical activity or physical inactivity).ti,ab.
41. dance therapy.ti,ab.
42. sedentary behavio?r.ti,ab.
43. 36 or 37 or 38 or 39 or 40 or 41 or 42
44. exp Complementary Therapies/
45. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
46. (hypnotism or hypnosis or hypnotherapy).ti,ab.
47. (acupuncture or homeopathy or homoeopathy).ti,ab.
48. (□uantit medicine or □uanti medicine or herbal medicine or ayurvedic).ti,ab.
49. 44 or 45 or 46 or 47 or 48
50. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
51. (weightwatcher$ or weight watcher$).ti,ab.
52. (correspondence adj (course$ or program$)).ti,ab.
53. (fat camp$ or diet$ camp$).ti,ab.
54. 50 or 51 or 52 or 53
55. exp Health Promotion/
56. exp Health Education/
57. (health promotion or health education).ti,ab.

58. (media intervention$ or community intervention$).ti,ab.
59. health promoting school$.ti,ab.
60. ((school or community) adj2 program$).ti,ab.
61. (family intervention$ or parent$ intervention).ti,ab.
62. (parent$ adj2 (behavio?r or involve$ or control$ or attitude$ or educat$)).ti,ab.
63. 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62
64. exp Health Policy/
65. exp Nutrition Policy/
66. (health polic$ or school polic$ or food polic$ or nutrition polic$).ti,ab.
67. 64 or 65 or 66
68. exp OBESITY/pc [Prevention & Control]
69. exp Primary Prevention/
70. (primary prevention or secondary prevention).ti,ab.
71. (preventive measure$ or preventative measure$).ti,ab.
72. (preventive care or preventative care).ti,ab.
73. (obesity adj2 (prevent$ or treat$)).ti,ab.
74. 68 or 69 or 70 or 71 or 72 or 73
75. exp Controlled Clinical Trials/
76. exp Random Allocation/
77. exp Double-Blind Method/
78. exp Single-Blind Method/
79. exp PLACEBOS/
80. exp *Research Design/
81. exp Intervention studies/
82. exp Evaluation studies/
83. exp Cost Benefit Analysis/
84. (time adj series).tw.
85. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
86. exact{CONTROLLED-CLINICAL-TRIAL}.pt.
87. placebo$.ti,ab.
88. (matched communities or matched schools or matched populations).ti,ab.
89. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
90. (comparison group$ or control group$).ti,ab.
91. matched pairs.ti,ab.
92. (outcome study or outcome studies).ti,ab.
93. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
94. (nonrandomi?ed or non randomi?ed or pseudo randomi?sed).ti,ab.
95. randomi?ed.hw.
96. (cohort or survey: or qualitative).ti,ab.
97. 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96
98. exp Meta-Analysis/
99. meta-analys$.ti,ab.
100. metaanalys$.ab,ti.
101. meta analys$.ab,ti.
102. Cochrane.ab,sh,ti.
103. (review$ or overview$).ti.
104. review$.pt.
105. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
106. pooled analys$.ab,ti.
107. ((data adj2 pool$) and studies).mp. [mp=title, original title, abstract, name of substance, mesh subject heading]
108. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
109. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
110. ((review$ or overview$) adj10 (systematic$ or methodologic$ or uantitative$ or research$ or literature$ or studies or trial$ or effective$)).ab.
111. 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110
112. (retrospective$ adj2 review$).ab,sh,ti.
113. (case$ adj2 review$).ab,sh,ti.
114. (record$ adj2 review$).ab,sh,ti.
115. (patient$ adj2 review$).ab,sh,ti.
116. (patient$ adj2 chart$).ab,sh,ti.
117. (peer adj2 review$).ab,sh,ti.

118. (chart$ adj2 review$).ab,sh,ti.
119. (case$ adj2 report$).ab,sh,ti.
120. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
121. 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120
122. 121 not (121 and 111)
123. 111 not 122
124. 22 or 35 or 43 or 49 or 54 or 63 or 67 or 74
125. 10 and 124 and 97
126. 10 and 124 and 123
127. 125 or 126
128. animal/
129. human/
130. 128 not (128 and 129)
131. 127 not 130
132. limit 131 to yr=1990–2004
133. exp CHILD/
134. exp ADOLESCENT/
135. exp INFANT/
136. (child$ or adolescent$ or infant$).af.
137. (teenage$ or young people or young person or young adult$).af.
138. (schoolchildren or school children).af.
139. (pediatr$ or paediatr$).af.
140. (boys or girls or youth or youths).af.
141. 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140
142. 132 and 141

DATA SOURCES

The following information sources were searched:

AMED
ASSIA
British Nursing Index
CAB Abstracts
CENTRAL (Cochrane Controlled Trials Register)
CINAHL
Clinical Evidence – http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
CRD (EED database) http://www.york.ac.uk/inst/crd
DARE
Embase
EPPI-Centre – http://eppi.ioe.ac.uk/
ERIC
Food Standards Agency – http://www.food.gov.uk/science/research/
HAD Evidence Base – http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales – http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) – http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA – http://www.ncchta.org
NICE – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) -
http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus

The electronic search strategies (Appendix 1) were developed in Medline and adapted for use with the other information sources.

EXCLUDED REFERENCES

Excluded individual studies	**Reason for exclusion**
Anderson JV, Bybee DI, Brown RM, McLean DF, Garcia EM, Breer ML, Schillo B. 5 A Day fruit and vegetable intervention improves consumption in a low income population. *Journal of the American Dietetic Association* 2001;101(2):195-202.	Only parental outcomes reported.
Anliker JA, Laus MJ, Samonds KW, Beal VA. Parental messages and the nutrition awareness of preschool children. *Journal of Nutrition Education* 1990:22(1):24–9.	Not an intervention study.
Division of Health Examination Statistics: National Centre for Chronic Disease prevention and Health promotion Nutrition Status of Children Participating in the Special Supplemental Nutrition Program for Women, Infants, and Children – United States, 1988–1991. *Morbidity and Mortality Weekly Reports* 1996;45(3).	No outcome data reported.
Bauer C, Rosemeier A A Handicap for Life – Overweight and obesity in pre-school children in Karlsruhe. Gesundheitwesen 2004;66:246-250.	Foreign language.
Baughcum AE, Chamberlin L A, Deeks CM, Powers SW, Whitaker RC. Maternal Perceptions of Overweight Preschool Children. ProQuest Nursing Journal. *Paediatrics* 2000;106(6):1380.	No control and cross-sectional study.
Bautista-Castano I, Doreste J, Serra-Majem L. Effectiveness of interventions in the prevention of childhood obesity. *European Journal of Epidemiology* 2004;19,617–22.	Studies are school-aged/based.
Benton D. Role of parents in the determination of the food preferences of children and the development of obesity. *International Journal of Obesity* 2004;28:858–69.	Not an intervention study.
Birmingham B, Armstrong-Shultz J, Edlefsen M. Evaluation of a Five-A-Day Recipe Booklet for Enhancing the Use of Fruits and Vegetables in Low-Income Households. *Journal of Community Health* 2004;29(1):45-62.	Not an intervention study.
Borzekowski DLG, Robinson TN. The 30-second effect: An experiment revealing the impact of television commercials on food preferences of preschoolers. *Journal of the American Dietetic Association* 2001;101(1):42-46.	Due to short duration.
Burdette HL, Whitaker RC. Neighbourhood playgrounds, fast food restaurants, and crime: relationships to overweight in low-income preschool children. *Preventive Medicine* 2004;38:57–63.	Not an intervention study.
Byrd-Bredbenner C, Marecic MFL, Bernstein J. Development of a Nutrition Education Curriculum for Head Start Children. *Journal of Nutrition Education* 1993;25(3):134-139.	No outcome data reported.
Caballero B, Clay T, Davis SM, Ethelbah B, Rock BH, Lohman JN, Story M, Stone EJ, Stephenson L, Stevens J. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *American Journal of Clinical Nutrition* 2003;78:1030–8.	In school children.
Chomitz VR, Collins J, Kim J, Kramer E, McGowan R. Promoting Healthy Weight among elementary school children via a health report card approach. *Archives of Paediatrics and Adolescent Medicine* 2003;157(8): 765-772.	Children were of school age (primary).
Cody R, Lee C. Development and evaluation of a pilot program to promote exercise among mothers of preschool children. *International Journal of Behavioural Medicine* 1999;6(1):13–29.	Not an intervention study and no direct relevance to implementation in the UK settings.
Cooke LJ, Wardle J, Gibson EL, Sapochnik M, Sheiham A, Lawson M. Demographic, Familial and trait predictors of fruit and vegetable consumption by pre-school children. *Public Health Nutrition* 2003;7(2):295–302.	Not an intervention study.
Crawford PB, Gosliner W, Strode P, Samuels SE. Walking the talk: fit WIC wellness programs improve self-efficacy in pediatric obesity prevention counseling. *American Journal of Public Health* 2004;94(9):1489.	Not clear if intervention study.
Davies PSW. Diet composition and body mass index in pre-school children. *European Journal of Clinical Nutrition* 1997;51:443–8.	Not an intervention study.
Davis K, Christoffel KK. Obesity in pre-school and school-age children.	Paper is on treatment of

Treatment early and often may be best. *Archives of Pediatric and Adolescence Medicine* 1994;148:1257.	obese children, not prevention.
Dennison BA, Rockwell HL, Baker SL. Excess fruit juice consumption by pre-school aged children is associated with short stature and obesity. *Pediatrics* 1997;99(1):15-22.	Not an intervention study.
Dennison BA, Erb TA, Jenkins PL. Television viewing and television in bedroom associated with overweight risk among low-income pre-school children. *Pediatrics* 2002;109(6):1028.	Not an intervention study. No control and cross-sectional survey.
Dorosty AR, Emmett PM, Cowin IS, Reilly JJ, ALSPAC Study Team. Factors associated with early adiposity rebound. *Pediatrics* 2002;105(5): 1115.	Not an intervention study. No control and longitudinal cohort study.
Epstein LH, Valoski A, McCurley J. Effect of weight loss by obese children on long-term growth. *American Journal of Diseases in Childhood* 1993;47:1076.	Not an intervention study. No corroborative evidence.
Epstein LH, Coleman KJ, Myers MD (1996). Exercise in treating obesity in children and adolescents. *Medicine and Science in Sports and Exercise* 1996;28(4);428–45.	Age of children (6–15 years) and treatment of obesity.
Fahrenwald NL, Sharma J. Development and expert evaluation of 'Moms on the Move', a physical activity intervention for WIC mothers. *Public Health Nursing* 2002;19(6):423–39.	Not an intervention study. Does not provide corroborative/economic evidence of direct relevance.
Ford RM, Evans D, McDougall JP. Progressing in Tandem: A Sure Start initiative for enhancing the role of parents in children's early education. *Education and Child Psychology* 2003;20(4):80-95.	Not an intervention study.
Goran MI, Reynolds KD, Lindquist CH. Role of physical activity in the prevention of obesity in children. *International Journal of Obesity* 1999;23 (Suppl 3):S18–33.	Not an intervention study .
Harrell JS, Gansky SA, McMurray RG, Bangdiwala SI, Frauman AC, Bradley CB. School-based interventions improve heat health in children with multiple cardiovascular disease risk factors. *Pediatrics* 1998;102(2):371.	Study in school children.
He Q, Ding ZY, Fong DYT, Karlberg J. Risk factors of obesity in preschool children in China: a population-based case–control study. *International Journal of Obesity* 2000;24:1528–36.	Nationwide case study in China – not an intervention study
Hendy HM, Raudenbush B. Effectiveness of teacher modelling to encourage food acceptance in preschool children. *Appetite* 2000;34:61–76.	Not an intervention study.
Hindin TJ, Contento IS, Gussow JD. A media literacy nutrition education curriculum for head start parents about the effects of television advertising on their children's food requests. *Journal of the American Dietetic Association* 2004;104(2):192-198.	No outcome data available.
Horne PJ, Tapper K, Lowe CF, Hardman CA, Jackson MC, Woolner J. Increasing children's fruit and vegetable consumption: a peer-modelling and rewards-based intervention. *European Journal of Clinical Nutrition* 2004;58:1649–60.	Study on 5–7-year-olds.
Jackson DM, Reilly JJ, Kelly LA, Montgomery C, Grant S, Paton JY. Objectively measured physical activity in a representative sample of 3 to 4 year old children. *Obesity Research* 2003;11(3):420.	Not an intervention study.
Jackson DM, Grant S, Paton JY, Reilly JJ. Correlates of physical activity in Scottish pre-school children prior to the adiposity rebound. *Obesity Research 2000*;8 (Suppl.1): 018.	Not an intervention study. Abstract only.
James J, Brown J, Douglas M, Cox J, Stocker S. Improving the diet of under fives in a deprived inner city practice. *Health Trends* 1992:24(4):160-164.	Not an intervention study, also not controlled.
Jin, J., Wang, Y., Pei, Y., Lu, H., Le, L. Analysis of the physical fitness status of pre-school children aged 3-6 years in Beijing. Sports science (Beijing) 1998;18(4):46-48.	Needs translating/not english language
Klesges RC, Stein RJ, Eck LH, Isbell TR, Klesges LM. Parental influence on food selection in young children and its relationships to childhood obesity. *American Journal of Clinical Nutrition* 1991;53:859–64.	Not an intervention as such – intervention in mothers influence on eating. Also study done 1991.

Kranz S, Siega-Ritz AM, Herring AH. Changes in diet quality of American preschoolers between 1977 and 1998. *American Journal of Public Health* 2004;94(9):1525.	Not an intervention study.
Lagstrom H, Niinikoski H, Lapinleimu H, Viikari J, Ronnemaa T, Simell O. Modifying coronary heart disease risk factors in children: is it ever too early to start? *Journal of the American Medical Association* 1998;279(16):1261–12.	No outcome data available
Lawatsch DE. A comparison of two teaching strategies on nutrition knowledge, attitudes and food behaviour of pre-school children. *Society for Nutrition Education* 1990;22:117–23.	Due to short duration.
Leonard CP, D'Augelli AR, Smickiklas-Wright H. Effects of a weight-control promotion programme on parents responses to family eating situations. *Journal of the American Dietetic Association Research* 1984;84(4):424–27.	Does not provide corroborative/economic evidence of direct relevance.
Levine B. Childhood obesity associated with the excessive consumption of soft drinks and fruit juices. *Clinical Nutrition* 1997;13(1):69–73.	Not an intervention study.
Lomperis AMT. Teaching mothers to read: evidence from Colombia on the key role of maternal education in preschool child nutritional health. *Journal of Developing Areas* 1991;26:25–52.	Not an intervention study.
Luo J, Hu FB. Time trends of obesity in pre-school children in China from 1989 to 1997. *International Journal of Obesity* 2002;26:553–8.	Cross Sectional and Longitudinal analysis.
Manios Y, Katatos A, Mamalakis G. The effects of a health education intervention initiated at first grade over a 3 year period: physical activity and fitness indices. *Health Education Research* 1998;13(4):593–606.	Not preschool children.
McConahy KL, Smicklas-Wright H, Mitchell DC, Picciano MF. Portion size of common foods predicts energy intake among preschool-aged children. *Journal of the American Dietetic Association* 2004;104:975–9.	Not an intervention study.
Montgomery C, Reilly JJ, Jackson DM, Kelly LA, Slater C, Paton JY, Grant S. Relation between physical activity and energy expenditure in a representative sample of young children. *American Journal of Clinical Nutrition* 2004;80:591–6.	Not an intervention study.
Mo-Suwan L, Pongprapai S, Junjana C, Putetpaiboon A. Effects of a controlled trial of a school-based exercise program on the obesity indexes of preschool children. *American Journal of Clinical Nutrition* 1998;68:1006–11.	Not preschool children.
Myers S, Vargas Z . Parental perceptions of the preschool obese child. *Pediatric Nursing* 2000;26(1):23.	This is a cross-sectional survey of what parents think about their child's weight and food intake.
Newby PK, Peterson KE, Berkey CS, Leppert J, Willett WC, Colditz GA. Dietary composition and weight change among low-income preschool children. *Archives of Pediatrics and Adolescent Medicine* 2003;157(8):759.	Not an intervention study.
Pate RR, Pfeiffer KA, Trost SG, Ziegler P, Dowda M. Physical activity among children attending preschools. *Pediatrics* 2004;114(5):1258-1263.	Not an intervention study. Short duration.
Perry CL, Bishop DB, Taylor GL, Davis M, Story M, Gray C et al. A Randomized school trial of environmental strategies to encourage fruit and vegetable consumption among children. *Health Education and Behaviour* 2004;31(1):65–76 .	Study does not provide corroborative/economic evidence of direct relevance.
Pienaar AE, Badenhorst, P. Physical activity levels and play preferences of pre-school children: recommendations for appropriate activities. *Journal of Human Movement Studies* 2001;41105–23.	Not an intervention study. Not control or comparison study. Duration.
Proctor MH, Moore LL, Gao D, Cupples LA, Bradlee ML, Hood MY, Ellison RC. Television viewing and change in body fat from preschool to early adolescence: The Framingham Children's Study. *International Journal of Obesity* 2003;27:827–33.	Not a controlled study.
Ray R, Lim LH, Ling SL. Obesity in preschool children: an intervention programme in primary health care in Singapore. Annals Academy of Medicine Singapore 1994;23: 335-341.	Not an intervention study.
Robinson TA. Reducing children's television viewing to prevent obesity. *Journal of the American Medical Association* 1999;282(16):1561.	Doesn't provide corroborative/economic

	evidence of direct relevance to implementation in UK settings.
Rogers IS, Emmett PM, ALSPAC Study Team. Fat content of the diet among preschool children in Southwest Britain: ii relationship with growth, blood lipids, and iron status. *Pediatrics* 2001;108(3)URL: http://www.pediatrics.org/cgi/content/full/108/3/e49.	Not an intervention study.
Sahota P, Rudolf MCJ, Dixey R, Hill AJ, Barth JH, Cade J. Randomised controlled trial of primary school based intervention to reduce risk factors for obesity. *British Medical Journal* 2001;323(3):1–5.	Not preschool children.
Singleton JC, Achterberg CL, Shannon BM. Role of Food and nutrition in the health perceptions of young children. *Journal of the American Dietetic Association* 1992;92(1):67-90.	Four-week study and follow-up only.
Stephen C, Brown S. The impact of government intervention in pre-school provision. *Early Child Development and Care* 1999;153:1–17.	No real outcome data on what, PA or food.
Sugimori H, Yoshida K, Izuno T, Miyakawa M, Suka M, Sekine M, Yamagami T, Kagamimori S. Analysis of factors that influence body mass index from ages 3 to 6 years: A study based on the Toyama cohort study. *Pediatrics International* 2004;46:302–10.	Not an intervention study.
Taylor LJ, Gallagher M, McCullough FSW. The role of parental influence and additional factors in the determination of food choices for pre-school children. *International Journal of Consumer Studies* 2004;28:337–46.	Not an intervention study.
Trost SG, Sirard JR, Dowda M, Pfeiffer KA, Pate RR. Physical activity in overweight and non-overweight preschool children. *International Journal of Obesity* 2003;27: 834–839.	Not an intervention study.
Wardle J, Cooke LJ, Gibson L, Sapochnik M, Sheiham A, Lawson M. Increasing children's acceptance of vegetables; a randomized trial of parent-led exposure. *Appetite* 2003;40:155–62.	Two-week study only.
Warren JM, Henry CJK, Lightowler HJ, Bradshaw SM, Perwaiz S. Evaluation of a pilot school programme aimed at the prevention of obesity in children. *Health Promotion International* 2003;18(4):287–96.	In school children.
Whitaker RC, Sherman SN, Chamberlin LA, Powers SW. Altering the perceptions of WIC health professionals about childhood obesity using video with facilitated group discussion. *Journal of the American Dietetic Association* 2004;104(3):379–86.	No control. No follow-up
Williams CL, Bollella MC, Barbara CDN, Strobino BA, Spark A, Nicklas TA, Tolosi lb, Pittman BP. Healthy Start: Outcome of an intervention to promote a heart healthy diet in preschool children. *Journal of the American College of Nutrition* 2002;21(1):62–71.	No outcome data available
Yoshinaga M, Sameshima K, Miyata K, Hashiguchi J, Imamura M. Prevention of mildly overweight children from development of more overweight condition. *Preventive Medicine* 2004;38:172–4.	Not preschool children.

Excluded systematic reviews	**Reason for exclusion**
Campbell K, Waters E, O'Meara S, Summerbell C. Interventions for preventing obesity in childhood. A systematic review. *Obesity Reviews* 2001;2:149–57.	Study not relevant to pre-school children apart from Mo-Suwan (1998).
Clar C. Reduction of obesity by lifestyle management in children and adolescents. A review of systematic reviews. University of Aberdeen 2005, unpublished.	Unpublished – excluded because it is a review of reviews.
Haddock CK, Shadish WR, Klesges RC, Stein RJ. Treatments for childhood and adolescent obesity. Annals of Behavioral Medicine 1994, 16(3), 235-44.	Not relevant.
Jago R, Baranowski T. Non-curricular approaches for increasing physical activity in youth: a review. *Prevention Medicine* 2004;39:157–63.	No studies used in the review were of preschool age.
Kahn EB, Ramsey LT, Brownson RC, Heath GW, Howze EH, Powell KE et al. & the Task Force on Community Preventive Services. The Effectiveness of Interventions to Increase Physical Activity. *American Journal of Preventive Medicine* 2002;22(4s):73–107.	No outcomes or details of interventions available. The paper offers generalised physical activity guidelines to increase PA and fitness.
Lanigan JA, Bishop JA, Kimber AC, Morgan J. Systematic review concerning the age of introduction of complementary foods to the healthy full-term infant. *European Journal of Clinical Nutrition* 2001; 55:309–20.	Most of the children studies are under 2 years of age.
O'Meara S, Glenny AM, Sheldon T, Melville A, Wilson C. Systematic Review of the effectiveness of interventions used in the management of obesity. *Journal of Human Nutrition and Dietetics* 1998;11:203–6.	Generalised to the whole population and not pre school children.
Reilly JJ. Obesity prevention in childhood and adolescence: a review of systematic reviews. In: Cameron N, Norgan NG, Ellison G, eds. Childhood obesity: strategies for prevention. Boca Raton: CRC Press (in press).	No specific information on preschool studies.
Reilly JJ, McDowell ZC. Physical activity interventions in the prevention and treatment of paediatric obesity: systematic review and critical appraisal. *Proceedings of the Nutrition Society* 2002;62:611–9.	The section on 'Ongoing research' highlights the MAGIC study and results of the MAGIC pilot study.
Riddoch C, Puid-Ribera A, Cooper A. Effectiveness of Physical activity promotion schemes in primary care: a systematic review. London; Health Education Authority 1998.	Is more generalised and not specific to preschool children.
Stone EJ, McKenzie TL, Welk GJ, Booth ML. Effects of physical activity interventions in youth. Review and synthesis. *American Journal of Preventive Medicine* 1998;15(4):298–302.	Has some relevance to preschool children.
Swadener SS. Nutrition education for preschool children. Journal of Nutrition Education, 1995; 27: 291-297.	Relevant studies but written in 1994.
Tedstone AE, Aviles M, Shetty PS, Daniels LA. Effectiveness of interventions to promote healthy eating in preschool children aged 1 to 5 years: *A Review*. Health promotion effectiveness reviews 10. London: Health Education Authority, 1998.	A lot of relevant studies but not as up to date as Worsley 2004

Appendix 7

School-based interventions to prevent obesity

EVIDENCE SUMMARY TABLES

EVIDENCE TABLE 1: SCHOOL-BASED INTERVENTIONS TO MAINTAIN A HEALTHY WEIGHT/PREVENT OVERWEIGHT OR OBESITY

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
DIET ONLY STUDIES								
James 2004	RCT Cluster, by class	1	++	**Setting:** Schools in Christchurch, Dorset, UK. **Participants**: Twenty-nine classes in six junior schools in children aged 7–11 years. 320 females, 324 males, mean age 8.7 (range 7–10.9) years. *n* (randomised to intervention) 325 (15 classes). *n* (randomised to control) 319 (14 classes). Baseline mean BMI (SD): Intervention: 17.4 (0.6) kg/m^2	**Aim:** To reduce consumption of carbonated drinks. One investigator delivered programme to all classes and teachers assisted. One-hour session each class each term (four sessions) encouraging children not to drink carbonated drinks but to switch to water or fruit juice diluted 1:3 with water. Study had 90% power.	12-month intervention.	Assessed at 12 months: Intervention *n* = 295 Control *n* = 279 10.9% not assessed Change in body mass index (BMI) over 12 months not significantly different between intervention and control 0.7 (0.2) vs. 0.8 (0.3) kg/m^2. Percentage of overweight and obese children increased in the control group by 7.5% at 12-months compared with a decrease in the intervention group of 0.2% (mean difference 7.7%, 95% confidence interval [CI] 2.2, 13.1).	

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				Control: 17.6 (0.7) kg/m^2				
PHYSICAL EDUCATION ONLY STUDIES								
Flores 1995	RCT Cluster, by class	1	+	**Setting:** Four physical education (PE) classes at one school in Palo Alto, CA, USA. **Participants**: 10–13-year-olds, boys and girls, mean age 12.6 years. 54% female. *n* (intervention baseline) = 43; *n* (control baseline) = 38. **Baseline BMI:** Intervention girls: 22.9 (SD 6.1) kg/m^2 Control girls: 22.9 (SD 4.4) kg/m^2 African American (44%) and Hispanic	**Aim:** To evaluate an aerobic dance programme to help maintain or decrease weight. **Intervention:** Culturally sensitive health education curriculum twice a week plus dance orientated aerobic physical education class three times a week (50 min each) for 12 weeks. **Control:** Usual PA (playground activities) Delivered by teachers and trained personnel from the research team.	12 weeks.	*n* (intervention follow-up) = 26 girls, number of boys not reported *n* (control follow-up) = 23 girls, number of boys not reported. Statistically significant reductions in BMI (kg/m^2) between intervention and control girls at 12-weeks: Intervention girls: 22.1 (SD 6.0) Control girls 22.5 (SD 4.4) This represents a change of –0.8 kg/m^2 in the intervention grou*p* and +0.3 kg/m^2 in the control grou*p* ($p<0.05$). No statistically significant change between intervention and control boys re BMI (BMI –0.2 kg/m^2 intervention boys vs. –0.6 kg/m^2 control boys).	Only results for girls were presented in the paper. Programme piloted. Attendance at intervention was mandatory as it took place in usual PE class. Rewards given (juice, stickers, t-shirts) for participation.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				(43%)	Power not stated.			
Jamner 2004	CCT Cluster by school	2	+	**Setting:** Two public high schools in Orange County, CA, USA **Participants:** 58 female adolescents, 25 intervention and 22 control. Mean age = 14.94 (SD 0.79) years. Mean baseline BMI percentile = 67.28 for intervention completers) mean baseline BMI percentile = 60.47 for control completers. 53% non-Hispanic white, 29% Hispanic, 8% Asian and 3% 'other'.	**Aim:** To evaluate the effect of a school-based intervention designed to increase PA among sedentary adolescent females. **Intervention**: Special PE class. The class met five days per week for 60 min each day (approximately 40 min of activity time). Types of activity included aerobic dance, basketball, swimming and tae bo. One day per week of class time was devoted to a lecture or discussion focusing on the health benefits of physical activity (PA) and strategies for	4 months	At follow-up, data were available for 25 intervention participants and 22 control participants. The intervention had no significant effect on BMI percentile, 67.28 at baseline and 66.74 at 4 months; % body fat 32.64 at baseline and 31.85 at 4 months.	Study participants overall reported more moderate and less light activity at baseline, as these measures were obtained during summer vacation, whereas follow-u*p* assessments were conducted during the school year which may have confounded results.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					becoming more physically active. Not stated who delivered intervention. Power not stated – small study.			
Mo-suwan 1998	RCT Cluster, by class	1	+	**Setting**: Two kindergartens in privately owned schools Southern Thailand (Hat Yai municipality, Songkla province). **Participants**: Second year kindergarten pupils, boys and girls, aged 4.5 (SD 0.4) years. *n* (intervention baseline) = 158; *n* (control baseline) = 152. **Baseline BMI (kg/m^2):** Intervention: 16.25	To evaluate the effect of a school-based aerobic exercise programme on obesity indexes of preschool children. 15-min walk before morning class, 20-min aerobic dance session after afternoon nap, three times per week for 29.6 weeks. Delivered by teachers and Aerobic session led by trained personnel. Power not stated.	30 weeks	*n* (intervention follow-up) = 147 *n* (control follow-up) = 145. Both intervention and control groups experienced reduction in BMI (kg/m^2) and not significantly different between groups at 30-weeks: Intervention: 15.76 (2.46) Control: 15.94 (2.26) Not significant No significant difference between groups in skinfold thickness at 30-weeks. Intervention girls had significantly lower mean BMI at 30-weeks than intervention boys ($p < 0.01$). Intervention girls had lower likelihood of having an increased	Statistically accounted for the potential unit of analysis errors. Both schools had 1 hour physical education per week and one school had swim class for 1-hour per week (adjustments made for these children). Triceps skinfold thickness (TSF) also available. Appears to be informed by an environmental change model.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				(2.35) Control: 16.36 (2.22)			BMI slope than the control girls (Odds ratio [OR] 0.32; 95% CI 0.18, 0.56).	
Pangrazi 2003	CCT Control schools were not randomly selected	2	+	**Setting:** Thirty-five schools in Arizona, USA **Participants**: Fourth grade, mean age for boys and girls was 9.8 years (SD 0.6). PLAY + PE: *n* = 183 PE only *n* = 175 PLAY only *n* = 150 No treatment control *n* = 91	**Aim:** To evaluate the effects of the PLAY intervention Promotes 30–60 min moderate to vigorous PA daily, 15-min activity break each day to teach variety of physical activities, promotes attitudes and behaviours to sustain active habits for life; includes self-monitoring and self-awareness. Teachers received training from county health co-ordinators. PLAY is not intended to replace comprehensive PE programme but act as important supplement.	12 weeks	However, no significant differences between groups were found for BMI.	Previously adopted in Arizona elementary schools and 24,000 children have received the intervention. No treatment control not randomly assigned.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					The intervention comprised three stages: Step 1: promote play behaviour (first week) teachers and students participated, more walking, less standing, sitting, children were informed about the importance of PA and identified appropriate adult role models. Step 2: teacher-directed activities (3 weeks) games and activities that were enjoyable and could be played outside school. Step 3: encourage self-directed activity (8 weeks) with students aiming to achieve 30 min of			

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					activity per day independently of teacher outside school. Treatment and PE schools, children received log sheets similar to the PLAY ones but were asked to record their after school activities (active and sedentary). Teachers trained by county co-ordinators, with programme implemented across Arizona with more than 24,000 children receiving PLAY. Power not stated.			
Pate 2005	RCT Cluster by school	1	+	**Setting**: Twenty-four high schools in 14 South Carolina counties, USA. **Participants**: 2744 girls, 48.7% African American	**Aim:** To evaluate school-based PA intervention among high school girls. **Intervention:** LEAP, based on social ecological	Start of 9th grade through until Spring? Approx. 6 months?	Intervention: 863 Control: 741 Completers only Slightly higher % African American girls lost to follow-up. % Girls classified as overweight or at risk for overweight (at least	

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				and 46.7% white, mean age 13.6 years, mean BMI 23.1 kg/m^2.	model drawn mainly from social cognitive theory; LEAP project staff supported the LEAP teams within the schools which included a LEAP champion; girl friendly PA of moderate to vigorous PA for 50% or more of PE class time (aerobics, dance, walking, self-defence, martial arts, weight training plus competitive sport and traditional PE). Environmental change included role modelling by school staff, family and community-based activities. School personnel headed by a champion implemented programme with training from		85th percentile BMI 34% both groups) or overweight (at least 95th percentile BMI 17% both groups) did not differ between intervention and control.	

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					research staff. Power not stated.			
Robinson 1999	RCT Cluster, by school	1	++	**Setting**: Two public elementary schools in San Jose**,** CA, USA. **Participants**: Third and fourth grade students, mean age 8.9 years, boys and girls. *n* (intervention baseline) = 95; *n* (control baseline) = 103. BMI (kg/m^2) at baseline: Intervention: 18.38 (3.67) Control: 18.10 (3.77)	**Aim:** To evaluate a school-based intervention to reduce TV, videotape and video game use on adiposity. Designed to have 80% power to detect an effect size of 0.20 or greater. Based on Bandura's social cognitive theory; 18 × lessons of 30 to 50 min, included self-monitoring of TV, videotape and video game use, then 10-day turn-off, then 7-hour budget, children taught to become selective viewers and advocators of reducing media use.	6 months	*n* (intervention follow-up) = 92; *n* (control follow-up) = 100. Three children lost to follow-up in each group. Compared with controls, children in the intervention group had statistically significant relative decreases in BMI –0.45 kg/m^2 with 95% CI –0.73, –0.17, *p* = 0.002; TSF –1.47 mm with 95% CI –2.41, –0.54, *p* = 0.002; and waist-to-hip ratio –0.02 with 95% CI –0.03, –0.01, *p* <0.001.	Each household received electronic television time manager (control power to TV and VCR). Schools were matched. Assessors blinded.

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					Parental involvement. Programme built into standard curriculum and taught by classroom teachers trained by research staff. Study 80% power to detect effect size at least 0.20.			
Sallis 1993, 1997	RCT Cluster, by school	1	+	**Setting**: Seven suburban elementary schools in Southern California, USA. **Participants**: Elementary school children, mean age 9.25 years. Seven schools involved, six schools randomly assigned to the three experimental conditions and one further school added to the	To evaluate a school-based intervention involving physical education and self-management (delivered either by specialists or teachers) on weight and adiposity, Three × 30-min classes per week including warm-up, fitness activities such as walk/run/jog/aerobic dance and sports	2 years	Total 549 children assessed at follow-up (305 boys and 244 girls); 26% attrition. Boys (after intervention) *n* control = 101, *n* specialist-led = 91, *n* teacher-led = 113. Girls (after intervention) *n* control = 97, *n* specialist-led = 60, *n* teacher-led = 87. Specialist PA promotion programme did not produce significant reductions in children's BMI or adiposity. No differences observed between teacher-led and specialist-led programme.	Interim results only (2 year data from 3-year study). Actual data for BMI and skinfold thicknesses is only presented in graphical form.

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				control group. 85% non-Hispanic white. *n* total (intervention and control at baseline) = 745.	skills such as soccer/basketball/softball; plus weekly 30-min self-management training, also incentives and parental involvement through newsletters and signature on weekly goal sheets. Two intervention groups receiving same programme but provided by either certified PE specialist or teachers trained for total 38 hours in-house over 2 years with substitute teachers provided and provided with detailed daily lesson plans to implement programme. Power not stated.		All boys in all three groups increased their BMI over 2 years. Control girls had significantly lower BMI than girls in either teacher-led or specialist-led intervention group ($p < 0.01$). Changes in skinfold thicknesses not significant between groups in girls or boys.	
Schofield 2005	CCT	2	+	**Setting:** Three high schools	To pilot efficacy of using pedometer as	12 weeks	Pedometer: *n* = 23 Minutes: *n* = 21	

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	Cluster by school			in central Queensland, Australia. **Participants**: Low active girls (defined from previous study as those girls who took least amount of recorded steps). Mean age 15.8 years. **BMI:** Pedometer intervention: 22.3 (SD 4.1) kg/m^2 Minutes intervention: 23.7 (SD 6.6) kg/m^2 Control 24.5 (SD 5.5) kg/m^2 Pedometer intervention: *n* = 27 Minutes intervention: *n* = 28 Control: *n* = 30	basis of time efficient yet effective non-curriculum school-based programme Intervention; group meetings once a week for 6 weeks for 30 min each in groups of eight either before or after school or in lunch break. Intervention groups received log book to record min in PA or amount of step counts; actual activity intervention was 12 weeks with weeks 7–12 maintenance phase (no group meetings). **Pedometer intervention:** 1000–2000 step increase daily each week until reached 10,000 steps per day.		Control: *n* = 24 No significant difference between groups for BMI or from baseline to follow-up.	

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					Minutes intervention: Increase by 10–15 min daily each week until reached daily average of 30–60 min/day. Power not stated.			
Stephens 1998	CCT Cluster, by school	2	+	**Setting:** Two urban elementary public schools in Cleveland, OH, USA. **Participants:** 56% boys, 8.4 years, 98% African American in intervention group; 43% boys, 8.4 years, 78% African American in control. 'Predominantly from low income families' – no other details reported.	To evaluate a school-based supplementary programme of PA on weight in addition to usual PE (45 min once per week). Control children received usual PE (45 min once per week). Delivered by medical student volunteers who received a 2-day orientation session. Power not stated.	15 weeks	Control group gained significantly more weight (*p* <0.001). Weight (kg) intervention vs. control at 15 weeks = 25.8 vs. 27.0. Significant decrease in skinfold thickness intervention vs. control, *p* < 0.01. Baseline: 25 vs. 26 mm 15 weeks: 23.5 vs. 28.5 mm	Significantly more black children in intervention compared with control group (*p* < 0.01).

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				n (intervention – baseline and follow-up) = 45; *n* (control – baseline and follow-up) = 44. Weight in kg at baseline intervention vs. control = 25.4 vs. 26.1.				
Trudeau 2000, 2001	Unclear, controlled, CCT	2	–	**Setting**: Primary schools in Trois-Rivieres, Quebec, Canada. **Participants**: Primary school boys and girls aged 6 years at baseline, all children French descent. Intervention: *n* = 272 Control: *n* = 275	To evaluate whether a programme of PA and fitness in school children over 6 years would result in enhanced cardiovascular fitness in adulthood. The Trois-Riveries Growth and Development study was a 6-year intervention involving 1 hour per day (5 hours per week) of physical education to increase aerobic and muscular capacity, in	Twenty-two-years follow-up of 6-year intervention study	Random selected sample (22% of original group) contacted by telephone for follow-up: Intervention: *n* = 68 Control: *n* = 65 Mean age 33–34 years No significant difference between intervention and control with respect to BMI, body fat, skinfold thickness, waist-to-hip ratio (Trudeau 2000). Baseline values not reported. Comparisons of tracking suggested intervention and control developed similar gains in BMI and skinfold thicknesses over 22-year interval (Trudeau 2001).	Small sample followed-up, with control women significantly older and intervention and control women earning significantly less income per annum despite similar education levels (14 years of schooling). Author contacted regarding BMI status of intervention and control groups during original study.

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					comparison to a control group that received single 40-min PE per week. Delivered by research team for follow-up. Professional physical educators provided original intervention. Power not stated, subgroup analysis unlikely to be powered.		Change in BMI (kg/m^2) over 22 years intervention vs. control: 5.7 (0.4) females (*n* = 57), 8.6 (0.4) males (*n* = 56) vs. 5.8 (0.3) females (*n* = 38), 8.0 (0.2) males (*n* = 40). BMI was not significantly different between intervention and control groups at age 10, 11, 12 and 34 years. Skinfold thickness change also available (not significant between groups).	
DIET AND PHYSICAL EDUCATION STUDIES TO PREVENT OBESITY								
Caballero 2003	RCT Cluster, by school	1	+	**Setting**: Forty-one elementary schools in seven American Indian communities in Arizona, New Mexico, South Dakota, USA. **Participants**: Mean age 7.6 ± 0.6 years. Sex not reported.	**Aim:** To evaluate a school-based multi-component intervention to reduce percentage body fat in American-Indian children. **Intervention:** Four components: 1) Change in dietary	3 years	*n* (intervention at follow-up) = 727 *n* (control at follow-up) = 682 17% attrition. Completer analyses only. No significant difference in weight, BMI, % body fat or skinfold thickness between intervention and control groups. BMI in the intervention group at baseline was 19.0, at follow-up 22.0. In the control group BMI was 19.1 kg/m^2 at baseline and	Intervention piloted. Compared with Centers for Disease Control (CDC) reference values, distribution of BMI in study children was shifter towards higher values.

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				American Indian school children. Six schools randomly assigned to the three experimental conditions and one further school added to the control group. *n* (intervention) = 879 *n* (control) = 825	intake (Pathways guidelines for food-service personnel and regular visit by Pathways nutritionist to support and monitor school lunches). 2) Increase in PA (3 × 30-minute moderate to vigorous PA based on SPARK programme (see Sallis 1993) per week during term-time, exercise break during classroom time and guided play during recess). 3) A classroom curriculum focused on healthy eating and lifestyle (12 weeks per year, 8 weeks in 5th grade, twice weekly 45-min classroom lessons integrating social learning theory with		22.2 kg/m^2 at follow-up. Mean difference in BMI = –0.2 (95% CI –0.50, 0.15) kg/m^2. % Body fat increased by approximately 7% in both groups at 3 years.	

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					American Indian traditions and indigenous learning modes such as story telling). 4) A family-involvement programme (family fun nights, workshops, events at school and fun packs linked to classroom curriculum). Almost the entire intervention was delivered by school personnel, teachers and food service staff; the Pathways staff focused on research measurements and training and support of school staff. Teachers, food service staff and PE teachers trained annually by SPARK or PATHWAYS instructors and			

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					supported within schools. Power not stated.			
Donnelly 1996	CCT By school	2	+	**Setting:** Elementary schools in rural Nebraska, USA. **Participants:** Age 9.2 years. Boys and girls (no values given). 94% White, 42–44% received free and reduced school lunches. Mean BMI (kg/m^2): Intervention: 18.3 (SD 3.9) Control: 18.5 (SD 3.4) Intervention *n* = 102; Control *n* = 236	**Aim:** To evaluate a school-based PA and nutrition programme to attenuate obesity and promote fitness. Components included a nutrition intervention (changes to school lunches using Lunchpower! which is a reduced energy, fat and sodium lunch, and nutrition education in curriculum) and PA intervention of 30–40 min per day 3 days per week of aerobic activities. Utilised school curriculum and existing staff resources.	2-years	Completer analysis only for BMI (kg/m^2) at 2 years Intervention Baseline: 17.9 (SD 3.8) *n* = 44 2-years: 18.9 (SD 4.3) *n* = 44 Control Baseline: 18.1 (SD 2.6) *n* = 64 2-years: 19.3 (SD 3.2) *n* = 64 Significant increase in both groups from baseline to follow-up but no significant difference between groups. Authors suggest children compensate in energy intake and PA outside school.	Small rewards for volunteers.

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					Research nutrition staff consisted of PhD student in nutrition, registered dietitian, and several graduate students. PA research staff comprised an exercise physiologist and graduate students. Power not stated.			
Gortmaker 1999; Austin 2005	RCT By school	1	+	**Setting**: Ten secondary schools in Boston, USA. **Participants**: Girls and boys, grades 6 and 7, mean age 11.7 (SD 0.7) years for both intervention and control. 48% female BMI (kg/m^2): Baseline 20.6 (SD 4.5)	**Aim:** To evaluate impact of school-based health behaviour intervention known as PLANET HEALTH on obesity amongst boys and girls in grades 6 to 8. Implemented programme via existing school staff and curricula. Underpinned by behavioural change and social cognitive	Two school years.	Intervention *n* = 641, control *n* = 654, 17% loss to follow-up. At 2 years: prevalence of obesity among girls in the intervention schools was reduced compared with controls, controlling for baseline obesity (OR 0.47; 95% CI 0.24, 0.93; *p* = 0.03). Among boys obesity declined among both control and intervention students however, after controlling for co-variates, there was no significant difference in outcome (OR 0.85; 95% CI 0.52, 1.39, *p* = 0.48).	Obesity definition based on BMI and TSF measure greater than or equal to 85th percentile of age and sex-specific reference data statistically accounted for the potential unit of analysis errors. Blinded outcome assessment was reported. Also reported on the issue of the promotion of unintended side

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				Intervention, 20.7 (SD 4.0) Control (based on completers only) Higher % African American girls in control schools (17 vs. 10%) and Hispanic boys in control schools (18 vs. 12%). Intervention *n* = 1560 on total at baseline	theory. Promotion of PA, modification of dietary intake (decreasing consumption of high-fat foods, increasing fruit and vegetable consumption) and reduction of sedentary behaviours (with a strong emphasis on reducing television viewing). 32 classroom lessons of 45-min each over 2 school years. Utilised school curriculum and existing staff resources. Only 33 incident cases of obesity 'limited the statistical power of the study to detect differences'.		There was greater remission of obesity among intervention girls vs. control girls (OR 2.16; 95% CI 1.07, 4.35, $p = 0.04$). Intervention reduced television hours among both girls (–0.58 hours; 95% CI –0.85 to –0.31, $p = 0.001$) and boys (–0.4 hours, 95% CI –0.56, –0.24; $p < 0.001$). Author concludes that reductions in TV viewing predicted obesity change and mediated the intervention effect (in girls but not boys). Among girls, each hour of reduction in television viewing predicted reduced obesity prevalence (OR 0.85; 95% CI 0.75, 0.97; $p = 0.02$). Measures of extreme dieting behavior remained unchanged (and low) throughout the intervention and were not different between intervention and control schools. Analysis of girls only using self-report, showed a reduced risk of using self-induced vomiting,	effects (extreme dieting behaviours). Schools experienced with interdisciplinary curricula found it easier to implement Planet Health material.

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							laxatives or diet pills to control weight within the previous 30 days.	
Graf 2005	CCT Cluster by school	2	+	**Setting:** Seven primary schools in Cologne, Germany. Three schools were chosen to participate in a prospective programme of intervention, the step TWO programme, for prevention of obesity. Four schools served as controls. **Participants:** In total, 830 boys and 848 girls took part. Mean age = 8.2 ± 1.3 years; mean BMI = 17.1 ± 2.9 kg/m^2. Of all children 7.3% were obese, 10.4%	**Aim:** To present the baseline and final data from the step TWO programme. The step TWO programme, which is designed for overweight and obese children, consisted of health education and PA delivered by a team of nutritionists, gymnasts, psychologists and medical doctors. Power not stated.	8–9 months	Forty controls and 145 in the intervention group The increase in BMI tended to be lower in those undergoing intervention mean difference in BMI for the intervention and control groups were 0.27kg/m^2 and 0.66 kg/m^2 respectively (p = 0.069) After intervention, the increase in waist circumference with time was lower than the controls (3.11cm and 4.56cm respectively)	Intervention group had higher BMI, waist circumference and blood pressure at baseline than control. Body weight showed high correlations with the result of bioelectric analyses (r = 0.770, $p \le 0.001$) and waist circumference (r = 0.857, $p \le 0.001$), and low correlation with the waist-to-hip ratio (r = 0.180, p = 0.001) adjusted for gender and age. BMI showed high correlation with the results of bioelectric analyses (r = 0.839, $p \le 0.001$) and waist circumference (r = 0.861, $p \le 0.001$), and low correlation with the waist-to-hip ratio

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				were overweight, 75.7% were normal weight and 6.6% were underweight.				(*r* = 0.251, *p* = 0.001) adjusted for gender and age.
Kain 2004	CCT By school	2	+	**Setting**: Five primary schools in Santiago, Curico, Casablanca, Chile. **Participants**: 53.5% boys and 46.5% girls in intervention group, 52% boys and 48% girls in control. Mean age 10.6 (SD 2.6) years in both groups. Low SES (approximately 35% received school lunch programme). Intervention *n* = 2375 Control *n* = 1202 **BMI (kg/m^2):** Intervention 19.6 (SD 3.8) *n* = 2141	**Aim:** To evaluate a school-based nutrition education and PA intervention on adiposity and physical fitness. Post hoc power 0.8, alpha 0.05. Intervention children received 8–11 hours dietary education in 6th grade and 5–6 hours for 7th and 8th grade over 6 months; 90 min per week of PA (sport) by school PE/classroom teacher or research PE for 6 months; active recess once a day for the last 3 months; healthy kiosks; parental involvement (two	6 months	Intervention: 2141 Control: 945 12.7% attrition BMI significantly higher in control boys only at 6 months compared with intervention boys (intervention boys BMI maintained whilst control boys BMI increased). **Boys** BMI (kg/m^2) at baseline intervention vs. control: 19.5 (SD 3.7) vs. 18.9 (SD 3.3). BMI (kg/m^2) at 6-month follow-up intervention vs. control: 19.5 (SD 3.5) vs. 19.2 (SD 3.1). $p < 0.001$ TSF decreased insignificantly over time in both intervention and control boys. Waist circumference declined in intervention boys by mean 0.9 cm whilst in control boys it increased by mean 0.9	Study design allowed for bias in intervention schools for increased prevalence of obesity compared with control schools (significantly more obese in intervention schools). Include element of smoking cessation advice. **Process evaluation:** Healthy kiosks were not implemented despite meeting with vending owners. PE implemented because incorporated into the curriculum.

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				Control: 19.2 (SD 3.6) *n* = 945	meetings) and special activities including prize for eating the most healthy snacks. Delivered by research team when half of the teachers initially unwilling to provide nutrition education, research PE teacher when no regular PE teacher available. Teachers were directly involved and received 1-hour training per day from nutritionist and 2 hours per week from PE teacher for 4 months. All teachers received 2-day onsite training. Post hoc power of 0.8, alpha 0.05.		cm, $p < 0.0001$. **Girls** BMI (kg/m^2) at baseline intervention vs. control: 19.7 (SD 3.9) vs. 19.4 (SD 3.8). BMI (kg/m^2) at 6-month follow-up intervention vs. control: 20.0 (SD 3.8) vs. 19.6 (SD 3.8). Not significant. Slight non-significant increase in TSF and waist circumference in both intervention and control girls.	
Neumark	CCT	2	+	**Setting:**	To evaluate an	7-months total,	*n* (intervention) = 89	Girls knew were

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-Sztainer 2003	Cluster, by school			Six secondary Schools in twin cities area, school districts Minnesota, USA. **Participants:** 201 females. Mean age 14.9 (SD 0.9) years in intervention, 15.8 (SD 1.1) years in control. **BMI (kg/m^2) at baseline:** Intervention vs. control: 27.6 (SD 7.2) vs. 25.9 (SD 5.8). **Inclusion criteria:** Girls with BMI at or above 75th percentile *n* (intervention) = 89 *n* (control) = 112	obesity prevention programme that aimed to increase enjoyment and self-efficacy In high-school based girls. Girls-only PE programme with physically inactive girls who would be unlikely to attend after school clubs. Replaced existing low-aerobic physical education classes with dance classes (high-aerobic PA). Underpinned by social cognitive theory. The intervention addressed personal and behavioural factors in addition to PA four times per week, nutrition and social support session every other week for total of 16 weeks. Aided by community guest	16-week intervention plus 8-week maintenance plus follow-up 1-month later	*n* (control) = 112 **BMI (kg/m^2) at 8-month follow-up:** 26.97 vs. 26.98, *p* = 0.95.	enrolling into intervention or control (schools randomised before girls registered). Parents expressed strong enthusiasm for programme, and all thought it should be continued. They reported their daughters eating more healthily, doing more PA and were more accepting of their bodies. Parents made other suggestions such as being most willing to read relevant literature and buy healthier snacks, but were least willing to attend classes with daughters. The girls liked the food tastings, nutrition sessions, guest instructors, and the array of PA options. They thought the girls only aspect was very important component for the intervention's

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					instructors once a week, who led different activities such as kick-boxing, self-defence and water aerobics, community field trips with free passes to return and community links encouraged. Girls were advised to avoid dieting and increase fruit and vegetables and decrease fats and sugar intake, healthy food choices and taste-testing sessions. A maintenance component for 8 weeks included healthy informal lunch meetings and topic discussion. Postcards were mailed home every 2–3 weeks during first 16 weeks to enhance parental support.			success. In the three intervention schools, the Principals found ways of sustaining New Moves, and offered girls guest instructors and have now integrated nutrition and social support in to PE classes.

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					Delivered by research team, PE teachers and school counsellors. Power not stated.			
Sahota 2001	RCT Cluster, by school	1	+	**Setting:** Ten primary schools in Leeds, UK. **Participants:** 7–11-year-olds, boys and girls, mean age 8 years. *n* (intervention) = 314 *n* (control) = 322	Assessed the impact of a primary school-based intervention, which included teacher training, modification of school meals, the development of school action plans targeting the curriculum, physical education, tuck shops, and playground activities. Sahota used a population approach underpinned by the Health-Promoting Schools philosophy and the intervention involved the whole school community including parents, teachers and catering	1 year	*n* (intervention) = 292 *n* (control follow-up) = 303 (at 1-year follow-up for weight) At 1 year, there was no difference in change in BMI between the children in the two groups (BMI SD score, weighted mean difference 0 (95% CI –0.1, 0.1), nor was there any difference in dieting behaviour.	Statistically accounted for the potential unit of analysis errors 89% of the actions points were implemented in the ten schools and changes were made to the food provision. Both parents and teachers were supportive of the dietary education and promotion of PA. Parental questionnaires (64% returned) detailed suggestions for improvements such as promotion of healthier break-time snacks with enforcement by school, material on healthy eating for children and fun PA ideas. Of the 20 teachers invited, 19

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					staff. 80% power to detect difference in means of a normally distributed outcome measure of at least 1.8 standard deviations at 5% significance level.			attended and were satisfied training, resources and materials offered. Children had higher scores for knowledge, attitudes and were positive about the intervention in focus groups. APPLES intervention was successful in producing changes at the school level, in terms of changing the ethos of the schools and the attitudes of the children, but had little effect on children's behaviour other than a modest increase in the consumption of vegetables.
Sallis 2003	RCT Cluster, schools randomised by district	1	+	**Setting:** Twenty-four public middle schools (grades 6 to 8) in San Diego County, California. **Participants:**	**Aim:** To evaluate the effects of environmental, policy and social marketing interventions on PA and fat intake of middle school	Two school years	Number assessed in each group at follow-up not reported There was a significant reduction in BMI among intervention boys, compared with control boys, but there was no effect for girls.	All 24 schools received an incentive to participate (US$1000 for PE equipment), and intervention schools received an additional US$500 for kitchen equipment and

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				Mean enrolment across 24 schools was 1109 (SD 356) students per school, of whom 49% were female, 44.5%, were non-white, 39.5% received free or reduced school meals and 36.4% were bussed to school. Mean age and mean baseline BMI not reported.	students. The primary aims of the intervention were: 1) Increase the total energy expenditure from PA by the student population at school. 2) Decrease the grams of total saturated dietary fat purchased or brought to school by students. One intervention component was designed to increase PA in PE classes through changing lesson context, lesson structure, and teacher behaviour. Another intervention component was intended to increase PA on campus during leisure periods throughout the school day.		Boys BMI (kg/m^2) at baseline for the intervention and control groups, 20.12 (0.98) and 19.68 (0.63), respectively. BMI for the controls and the boys in the intervention group after 2 years 20.04 (0.85) and 19.84 (0.61). Girls BMI (kg/m^2) at baseline for the intervention and control groups, 19.76 (0.77) and 19.52 (0.89), respectively. BMI for the girls in the intervention group and the controls after 2 years 19.88 (1.16) and 19.73 (1.16), respectively. Gender-specific analyses revealed the time by condition interaction was significant for boys (F = 12.16, p = 0.00) with a large effect size of d = 1.10. The intervention was not significant for girls (F = 0.73, p = 0.396), and the effect size was small.	US$2000 for PA programmes or equipment.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					Interventions with school food service staff and managers were undertaken to provide more low-fat choices at these sources. Delivered by research staff,, teachers, school food service staff and managers. Power not stated.			
Story 2003 GEMS-Minnesota	RCT	1	+	**Setting:** Lunchtime clubs in schools in low income areas, Minnesota, USA **Participants:** 8–10 year-old African American girls, at least 25th percentile for age and gender BMI, with a parent willing to be involved.	**Aim**: To assess feasibility of obesity prevention programme in African American girls **Intervention:** Lunchtime clubs in school designed to improve nutrition, PA and self-esteem through a range of activities. The intervention which was conducted twice	12 weeks	Intervention, *n* = 26 Control, *n* = 28 ITT analysis No significant difference between groups for BMI, waist circumference.	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to detect a significant intervention effect. Fully powered studies of two of the GEMS pilots are currently underway.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				Mean age (years): Intervention: 9.3 (SD 0.9) Control: 9.4 (SD 0.9) Sex: girls only Intervention *n* = 26 Control *n* = 28	per week, focused on increasing healthy eating and PA. Intervention meetings, designed in a 'club meeting' format, were held twice per week for 1 hour after school at each of the schools used in the study. The intervention was based on Social Cognitive Theory (SCT) (Bandura) and targeted key points from three domains: 1) environmental factors such as peer support; 2) personal factors such as knowledge and values; 3) behavioural factors such as goal setting and social reinforcement. **Control:** The control group served as an 'active			

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					placebo', non nutrition/PA condition and focused on promoting positive self esteem and cultural enrichment. Participants attended monthly Saturday morning meetings (three meetings over 12 weeks). This included arts and crafts; self-esteem activities, creating memory books and a workshop on African percussion instruments. Providers of the intervention included University Staff, Trained African American GEMS staff and school staff. Study not powered (pilot).			
Warren 2003	RCT	1	+	**Setting:** Three primary	Be Smart was a school and family-	20-week intervention	Nutrition intervention at follow-up *n* = 42.	Considered the sustainability of their

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
	Individual			schools in Oxford, UK. **Participants:** Children aged 5 – 7 years (children in Year 1 and Year 2). Sex not reported. **Mean BMI (kg/m^2) at baseline:** Nutrition intervention = 16.1 (2.7) PA intervention = 16.0 (2.0) Combined nutrition and PA intervention = 15.8 (2.0) Control = 15.5 (1.6) Nutrition intervention *n* = 56 PA intervention *n* = 54 Combined nutrition and PA intervention *n* = 54	based intervention to prevent obesity in children aged 5–7 years. There were four conditions: a nutrition group, a PA group, a combined nutrition and PA group and a control. The intervention ran for 20 weeks over four school terms (approx. 14 months). Underpinned by SCT and took place in lunchtime clubs where an interactive and age-appropriate nutrition and/or PA curriculum was delivered by the research team, with both involving parents. Power not stated.	over 14 months.	PA intervention at follow-up *n* = 42. Combined nutrition and PA intervention *n* = 42. Control *n* = 46. Dropout *n* = 46 for weight. Only those who completed were included in analysis (not ITT). No significant changes in the rates of overweight and obesity were seen as a result of the three different approaches. At the final assessment, the incidence of overweight and obesity was similar to the initial stage, with subject numbers too small for statistical analyses.	intervention and concluded that it would be too expensive and unsustainable as it was delivered by non-school personnel. Children enjoyed the practical tasks, quizzes and tastings. 83% of parents thought their child had benefited from the programme and all teachers thought that components should be integrated into the Personal, Social and Health Education (PSHE) curriculum. This study may have been subject to ceiling effects as the study population was relatively well educated as 39% of parents had obtained either a degree or a post-graduate qualification.

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				Control *n* = 54				
DIET AND PHYSICAL ACTIVITY INTERVENTIONS TO IMPROVE CARDIOVASCULAR HEALTH OR PREVENT DIABETES								
Trevino 2004, 2005	Cluster RCT	1	+	**Eligibility criteria:** Not clearly described. **Participants:** Fourth-grade students. **Setting:** Elementary schools located in low income inner city neighbourhoods of the San Antonio Independent School District, TX, USA Intervention (five schools) *n* = 200 Control (four schools) *n* = 187 **Age (mean):** Intervention 9.8 years Control 9.7 years	To evaluate the effect of the Bienestar Health Program (programme designed to reduce risk factors associated with the onset of type 2 diabetes) on physical fitness in low-income Mexican American children**.** The intervention was the Bienestar Health Program based on SCT in which personal factors, social factors and behaviour are inter-related and have dynamic influences on each other. The Bienestar program was designed to influence each determinant to	Eight-months follow-up. No further follow-up after 8-month intervention.	**Lost to follow-up:** All fourth grade students were invited to participate. 88% returned parental consent forms. Complete data was collected from 387 students (78%). Of 189 students in control group at baseline, complete data collected from 187. All 200 students in the intervention group at baseline returned complete data. **Weight:** Not reported **% Body fat:** Did not differ between groups; adjusted difference intervention (*n* = 619) vs. control (*n* = 602) +0.18 (95% CI, –1.75–2.11), *p* = 0.56 **Dietary fat intake**: Did not differ between groups (*p* = 0.52). **Physical activity:** Outcome reported is physical	Parents and students who participated in the programme received coupons denoted in dollar amounts as an incentive and reinforcement which could be exchanged for merchandise. These papers may be reporting interim results **Author's conclusion:** It is possible to improve the physical fitness of low-income Mexican American preadolescent children through a comprehensive school-based programme.

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				97% of students were Mexican American, more than 95% were in US Department of Agriculture food assistance programs, 53% female, an average of 3.5 people occupied each household, mean household incomes US$10,337 in the intervention group and US$11,691 in the control schools. **Baseline BMI (kg/m^2):** No difference in baseline BMI between intervention and control groups. Control boys 19.18 (SD 4.14) Intervention boys 19.23 (SD 4.78) Control girls 19.90 (SD 5.42) Intervention girls	decrease dietary fat and increase dietary fibre consumption and to promote participation in moderate to vigorous physical activities. Programme activities were bilingual and included a parent education and involvement programme, a classroom health and physical education curriculum, a student after school health club and a school cafeteria programme. Power not stated.		fitness measured using a modified Harvard step test. Change in physical fitness score (PFS) between pre-intervention and post- intervention was significantly different between intervention and control groups after adjusting for age and pre-intervention BMI, $F(1,381) = 8.69$, $p < 0.003$. Mean change in PFS: Control boys –0.52 (SD 1.08) Control girls 0.13 (SD 1.08) Intervention boys 3.37 (SD 1.08) Intervention girls 2.52 (SD 1.01)	

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				18.92 (SD 4.87)				
Luepker 1996 (CATCH)	RCT Cluster, by school	1	+	**Setting:** Ninety-six public state schools in 12 school districts in California, Louisiana, Minnesota and Texas. **Participants:** Mean age 8.76 years 2461 of 5106 were girls. Total cohort = 5106 at baseline. Ethnically diverse (white, African American and Hispanic).	To evaluate a school-based intervention including a home programme for the primary prevention of cardiovascular disease. Intervention schools further randomised into two groups both involving modifications to school food service (30% fat), enhanced PE (moderate to vigorous activity for 40% class time) and classroom health curricula, and 28 of the 56 intervention schools also had family education (activity packs and family fun nights) Control schools received usual care. Sample size calculation carried	3 years	Total *n* = 4109 at 3 years (21% dropout for serum cholesterol measurement at 3 years). BMI did not differ significantly between groups at 3 years.	Also addressed smoking (may confound). African American students and students in California were more likely to have dropped out. Intensity but not duration of PE lessons changed in intervention group compared with control.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
					out. PE specialists and teachers had 1 to 1.5 days of training each school year; training also for cooks and teachers. Sample size determined.			
Manios 1998, 1999, 2002	CCT By school	2	+	**Setting:** Schools in Iraklio and Rethimno (intervention) and Chania (control) Crete, Greece. **Participants**: First-grade primary school children aged 5.5 to 6.5 years; 509 boys and 453 girls. Random sample of 602 intervention pupils from 24 schools and 444 control pupils selected to test	To evaluate a school-based intervention involving a health and nutrition element and a physical fitness and activity element, on chronic disease risk factors Nutrition component comprised 13–17 hours classroom materials conducted by class teacher each year; 4–6 hours classroom material on theory of physical education and 2 × 45 min PE per week by PE teachers.	6 years	Total 831 available at 6 years, 787 assessed (those who did not change schools and completed) **At 3 years:** Change in BMI (kg/m^2) +0.7 (1.5) vs. +1.7 (1.4) intervention vs. control, $p < 0.0005$. **At 6 years:** BMI change intervention vs. control: +3.68 (SE 0.16) $n = 356$ vs. +4.28 (SE 0.16) $n = 285$, $p < 0.05$. **At 6 years:** Bicep skinfold thickness (mm) change intervention vs. control: +2.97 (SE 0.24) $n = 356$ vs. +4.47 (SE 0.24) $n = 285$,	'Know your body program' also included dental health, drug abuse and accident prevention. Results adjusted for baseline values, sex, BMI, change in height and parental education where appropriate.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				effectiveness of programme.	Delivered by school teachers and PE teachers. Power not stated.		$p < 0.001$. **At 6 years:** Tricep skinfold thickness (mm) change intervention vs. control: +6.46 (SE 0.38) $n = 356$ vs. +7.90 (SE 0.39) $n = 285$, $p < 0.05$.	
Vandongen 1995	RCT Cluster, by school	1	+	**Setting**: Thirty schools in Western Australia. **Participants:** Age range 10–12 years. **BMI (kg/m^2) at baseline:** Fitness group: 18.2 (17.7–18.7) boys, 18.2 (17.7–18.7) girls. Fitness and school nutrition group: 18.1 (17.5–18.8) boys, 17.9 (17.4–18.5) girls School nutrition	To evaluate programme of fitness and nutrition alone and combined and school and home-based nutrition programmes to improve cardiovascular health. **Nutrition programme:** Increase consumption of fruit, vegetables, whole grain bread, and cereals relative to other foods and decrease consumption of fatty, sugary and salty foods, 33% energy	Nine months	971 of 1147 assessed at 9 months for blood pressure, anthropometric and fitness tests. No significant difference between groups for subscapular skinfold thickness (mm), % body fat or BMI (kg/m^2) respectively at 1 year: Fitness group: 18.2 (17.6, 18.8) boys, 18.4 (17.9, 19.0) girls Fitness and school nutrition group: 18.6 (17.9, 19.3) boys, 18.7 (18.0, 19.3) girls School nutrition group: 18.5 (17.9, 19.0) boys, 18.0 (17.5, 18.5) girls	All follow-up measures adjusted for baseline values.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				group: 18.0 (17.5–18.5) boys, 17.5 (17.0–17.9) girls School and home nutrition group: 18.2 (17.4–19.0) boys, 17.5 (16.8–18.2) girls Home nutrition group: 17.7 (17.2–18.1) boys, 18.2 (16.9,18.9) girls Control group: 18.1 (17.5–18.6) boys, 17.6 (16.9–18.3) girls **Number of subjects:** Fitness group: *n* = 81 boys and 77 girls Fitness and school nutrition group: *n* = 81 boys and 81	intake as fat, 12% as sugar, 25 g fibre/day **School-based:** Ten × 1-hour lessons. **Home-based:** Homework exercise sheets. **Fitness:** Six × 30 min classroom sessions and 15 min every school day of activity to increase heart rate to 150–170 beats per min. Delivered by teachers and PE teachers who received in-service training sessions. Power calculations based on alpha level 0.05 and beta level of 0.8 to detect difference of five laps of Leger run with a standard deviation of		School and home nutrition group: 18.4 (17.6, 19.2) boys, 17.8 (17.1, 19.4) girls Home nutrition group: 17.8 (17.2, 18.3) boys, 18.7 (18.0, 18.9) girls Control group: 18.2 (17.6, 18.8) boys, 18.2 (17.4, 18.9) girls Triceps skinfold thickness decreased significantly in fitness + school nutrition group compared with controls.	

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				girls School nutrition group: *n* = 91 boys and 108 girls School and home nutrition group: *n* = 58 boys and 68 girls Home nutrition group: *n* = 97 boys and 84 girls Control group: *n* = 78 boys and 67 girls.	14.			
Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
James 2004	RCT Cluster by class	1	++	Schools in Christchurch, Dorset, UK.	See above.	See above.	See above.	

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Sahota 2001	RCT Cluster, by classroom	1	+	School in Leeds, UK.	See above.	See above.	See above.	
Warren 2003	RCT Individual	1	+	Schools in Oxford, UK.	See above.	See above.	See above.	

Evidence for implementation – Will it work in the UK?

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
James 2004	RCT Cluster by class	1	++	See above. – Dorset, UK.	See above.	See above.	One of the authors delivered the intervention.	Average class size was 22 (SD 5).
Stice 2005	RCT Individual	1	+	**Setting**: High schools and one University in Austin, USA. **Participants:** Girls aged 14–19 with body image concerns (relied on self-selection). Intervention: *n* = 94 Control: *n* = 94 Baseline BMI (kg/m^2):	**Aim**: To evaluate an obesity prevention programme and specifically to evaluate the effects of a weight maintenance diet on bulimic symptoms in adolescent girls Intervention: 3 weekly 1-hour sessions in groups of six to ten participants, including health benefits of a balanced diet, thin	12 months	Intervention: n = 91 Control: n = 89 4% dropout BMI (kg/m^2): Intervention: 23.00 Control: 23.89 Not significant Logistic regression that controlled for initial body mass indicated risk for onset of obesity in non-obese at baseline, at any point in 12 months was significantly lower in intervention (1.2%) than control (11.4%).	Although non-UK, included as corroborative evidence regarding ‘potential harms’. Girls blinded to study hypothesis and assessors blinded. US$100 for completing assessments Mean body dissatisfaction score 3.5 (vs. 3.0 from community

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
				Intervention: 22.82 (SD 4.16) Control: 23.79 (SD 5.44) 57% White, 22% of mothers and 26% fathers had advanced degree.	ideal contrasted with healthy ideal, not asked to count calories or reduce energy intake to certain level, behaviour modification goals and review and individualised plan. **Control:** Assessment only parallel sessions.		Significantly greater increases in 'healthy eating' (fruit and vegetables and low fat) from baseline to 12 months, $p < 0.001$, and significant increases in exercise intensity from baseline to 6-months only compared with control. Significantly greater decreases in bulimic symptoms compared with control at 12 months, $p = 0.004$).	sample of adolescent girls).
Sahota 2001	RCT Cluster, by classroom	1	+	See above.	See above.	See above.	Delivered by teachers but the project team provided training for teachers and the project manager also provided input and support.	
Warren 2003	RCT Individual	1	+	See above.	See above.	See above.	The project team delivered the intervention.	

EVIDENCE TABLE 2: SCHOOL-BASED INTERVENTIONS TO IMPROVE BEHAVIOURS ASSOCIATED WITH MAINTENANCE OF A HEALTHY WEIGHT (DIET AND PHYSICAL ACTIVITY)

Evidence of efficacy (internal validity) for diet outcomes								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
DIET ONLY STUDIES								
French 2004	Review, five controlled studies and one CBA	2	+	Review methods not reported as this was a paper from a workshop. School-based, four studies targeted 4th and 5th grade students and one targeted secondary schools (Nicklas 1998) – all US based	Review of five multi-component school-based intervention studies to promote food and vegetable consumption. One CBA to examine effect of price reduction and promotional signage on sales of lower fat vending machine snacks in 12 secondary schools. Power of individual studies not reported.	All five controlled studies were 2–3 years in duration; the CBA was 1 year All five studies included classroom curriculum focusing on increasing students knowledge, developing behavioural skills, increasing motivation to choose fruit and vegetables	Three studies reported significant increases in fruit and vegetable servings per day among students in intervention vs. control schools (Baranowski 2000; Foerster 1998; Reynolds 2000). Across the five studies increases in fruit intake ranged from 0.2 to 0.6 servings per day and vegetable intake from 0 to an increase of 0.3 servings per day; total changes in fruit and vegetable intake across five studies ranged from 0 to 0.6 servings per day. Four studies reported fruit and vegetables intakes separately and effects were most often attributable to fruit intake; only one study reported significant increases in vegetable intake (Reynolds 2000); two studies reported significant	Most of these studies were funded as part of National Cancer Institute's five-a-day research programme.

						Three studies included food service component to increase fruit and vegetable availability by training food service staff to include more fruit and vegetables in meals and promote fruit and vegetables. At least two of the studies included a parent–home component usually consisting of newsletters to increase home consumption of fruit and vegetables. Two studies included a community component involving	increases in fruit intake (Reynolds 2000, Perry 1998). The one study in secondary schools (Nicklas 1998) did not observe significant effects on fruit and vegetable intake. Cannot assess which independent elements of the interventions affected behaviour change. **CBA:** Price reductions of 10, 25 and 50% on low-fat snacks were associated with significant increases in low-fat snack sales; percentages of low-fat snack sales increased by 9, 39 and 93%, respectively. Promotional signage was independently but weakly associated with increases in low-fat snack sales. Average profits per machine were not affected by the vending interventions.	

						community groups in developing and implementing activities to promote fruit and vegetable intake such as grocery taste tests or cookery demonstrations (Foerster 1998; Baranowski 2000). **CBA:** Low-fat snacks were added to 55 vending machines in a convenience sample of 12 secondary schools. Four pricing levels (equal price, 10% reduction, 25% reduction, 50% reduction) and three promotional conditions (none, low-fat label, low-fat label plus		

						promotional sign) were crossed in a Latin square design. Sales of low-fat vending snacks were measured continuously for the 12-month intervention.		
Woolfe 2005	Review	2	+	Overview of five school-based dietary interventions funded by the Food Standards Agency. Primary and secondary schools throughout UK.	To evaluate feasibility and effectiveness of dietary change interventions in UK school-based settings.	Short-term to 14 months	Overview of five school-based dietary interventions funded by the Food Standards Agency. All five studies focused on different approaches and topics but all have potential to be incorporated into the type of health promoting school approach, which systematic reviews (Lister–Sharp) have indicated is the most effective way of changing behaviour.	Non-systematic review. Supersedes Lister–Sharp systematic reviews of health promoting schools as relatively few included studies were UK-based. In terms of engaging schools: importance of listing support of school gate keepers (secretaries), a hindrance to engaging schools is selection to control, if schools are asked to 'buy-into' future initiatives this may lead to increased commitment compared with a

								research scenario; commitment of schools effects success of the project (tuck shops).
Warren 2003 within review by Woolfe 2005	RCT Individual	1	+	**Setting:** Three primary schools in Oxford, UK. **Participants**: Children aged 5 – 7 years (children in Year 1 and Year 2). Sex not reported.	Be Smart was a school and family-based intervention to prevent obesity in children aged 5–7 years. (See above.)	Twenty-week intervention over 14 months.	Nutrition intervention at follow-up $n = 42$ PA intervention at follow-up $n = 42$. Combined nutrition and PA intervention $n = 42$. Control $n = 46$. Dropout $n = 46$ for weight Only those who completed were included in analysis (not ITT). Significant increase in vegetable consumption ($p < 0.05$) and fruit ($p < 0.01$) in all groups; in males there was a significant increase in fresh fruit consumption $p < 0.01$ regardless of group assignment. Significant increase in fruit consumption in control ($p < 0.05$) and nutrition groups ($p < 0.05$). No significant difference between groups in sweet or crisps consumption. Strong association between parents and children's diets both before and after intervention for crisps, vegetables, salads, and fruit other than fresh ($p < 0.001$). Parental food frequency	See above.

							questionnaires showed little change as they reported low fat and medium to high fibre intakes initially.	
Moore 2001 within review by Woolfe 2005	RCT	1	+	Forty-three primary schools in South Wales and south-west England. 1902 pupils in years 5 and 6 (aged 9–11 years). At baseline, differences were detected in fruit and snack consumption between schools, which were statistically significantly associated with schools' policy on snacks brought into school.	To evaluate fruit tuck shops to increase fruit and vegetable consumption **Intervention:** Each school set up a fruit tuck shop in the autumn term, 1999. Tuck shops sold fruit at 15p per item, and were operated by the schools with no additional funding, and with limited support from the research team. Fruit was supplied to schools by wholesale greengrocers, fruit retailers, or by teachers buying fruit from supermarkets. **Control:** The other 20 schools agreed not to set up a fruit tuck shop in the academic year 1999/2000.	12 months	All 23 intervention schools successfully set up fruit tuck shops, and many schools were very positive about them. In particular, schools identified numerous positive spin-offs from the tuck shops, including benefits for the curriculum, social benefits, community links and litter reduction. In all schools, fruit sales were high in the first few weeks of operation, but then declined at varying rates over the intervention year. At 12 months there was no significant difference between intervention and control for fruit intakes. It is estimated that 70,000 fruits were sold in the 23 intervention schools over the year, but this equates to only 0.06 fruits per pupil per day. Four schools had ceased to operate their tuck shops by the end of the intervention year.	Authors concluded that fruit tuck shops on their own would not have a substantial impact on the fruit intake of pupils. However, they are likely to be a valuable component of any comprehensive plan to increase children's fruit consumption. Within schools, a comprehensive school policy on snacks brought to school supplemented by a school fruit tuck sho*p* (and, in England, by National School Fruit Scheme fruit provided to younger infants) may achieve a more substantial impact.
Livingstone 2002	Controlled study	?	?	Twenty-seven secondary schools	To evaluate interactive CD-ROM	Unclear, 4–5 weeks?	Preliminary evaluation in ten schools with 305 pupils divided equally	Questionnaires not validated.

within review by Woolfe 2005				in UK participated in one or more of the five phases of the study; representative of urban and rural environments and different social and ethnic backgrounds and academic abilities.	to promote nutrition education in 12-year old children. CD 'Dish it up!' was a virtual school day in life of a 12-year old and involved self-monitoring, analysis and food intake and goal setting; positive and entertaining activities aimed at promoting autonomy, decision-making skills and self-esteem with regard to healthy eating; based on social learning theory.		between intervention and control. Significant positive shifts in reported frequency of consumption of fruit, pasta, yoghurt, breakfast cereals (more than usual) and sweets (less than usual) but no other indications of changed eating behaviour. Children particularly liked the intervention.	Authors concluded that interactive multimedia tools have potential to be a sustainable and valuable resource.
Barker 2002 within review by Woolfe 2005	Controlled study	?	?	UK primary schools, main pilot carried out in school in Derbyshire, children aged 4–10 years old.	To test the effectiveness of a 9-month art/play therapy intervention on fruit and vegetable intake. Art/play therapist responsible for management of intervention that was built into the curriculum; aimed to change attitudes to healthy eating	Nine-month intervention, post-intervention delayed due to management reasons for 9 months.	Intervention increased amount of vegetables and salad and fruit juice consumed with an increase in the variety eaten; those children who ate no fruit at baseline appeared to respond more positively. No gender or age differences.	Small-scale pilot.

					through emotion and creativity rather than having a knowledge focus.			
Anderson 2002 within review by Woolfe 2005	CCT	?	?	Two primary schools with 2 matched control schools in Dundee, Scotland 'Five a day the Bash Street Way'. 128 children from year 2 (6–7 years) and year 6 (10–11 years).	To evaluate whole school approach with multiple strategies to increase fruit and vegetable intake. Included food preparation and food testing, increased provision of fruit and vegetables in tuck shops (had to complete with non-healthy foods) and school lunches, point of purchase marketing, teacher information sessions and parent newsletters.	Nine months (October to June of school year).	Fruit consumption increased significantly by average 0.5 portions per child per day in intervention schools compared with control ($p < 0.05$).	Relatively labour and time intensive intervention.
Bere 2005	CCT	2	+	**Setting:** Secondary schools from two Norwegian countries, Hedmark and Telemark. **Participants:** A total of 795, 7th graders (11 or 12 years old at	**Aim:** To investigate the effect of the Norwegian School Fruit Programme on the intake of fruit and vegetables and on the consumption of 'unhealthy' snacks both at standard conditions and when	8/9 months September, 2001 – May/June 2002	Free fruit $n = 222$ Paid fruit $n = 157$ Opted not to participate $n = 416$ The free fruit group reported a significantly higher intake of fruit and vegetables at school than pupils in the two other groups. No actual servings data ($p = 0.001$ for both comparisons).	Schools taking part in the programme at standard conditions and the control group were self-selected, that is, it was the schools that decided whether to take part in the programme or not.

				baseline) participated at both baseline and at follow-up. Free fruit *n* = 222 (nine schools) Paid fruit *n* = 157 (nine schools) Opted not to participate, *n* = 416 (20 schools) % Female and baseline BMI not reported.	provided for free. No more intervention details provided. Power not stated.		Furthermore, the pupils in the Paid fruit group reported a significantly higher intake than did pupils in the no fruit group. No actual servings data, $p = 0.003$. The free fruit group reported a significantly higher fruit and vegetable all day intake than both the paid fruit and the no fruit groups. No actual servings data, $p = 0.03$ and $p = 0.003$, respectively No significant differences were seen between the paid fruit group and the no fruit group regarding fruit and vegetable all day intake. The free fruit group reported a significantly lower intake of soda/candy/chips than the no fruit group. A significant positive effect of the Fruit Subscription Programme was seen for fruit and vegetables at school (with stronger effect for pupils with low baseline habitual fruit and vegetable intake), for fruits and vegetables all day, and for soda/candy/chips (for pupils with low baseline habitual fruit and vegetable intake only).	72% of children and 64% of the parents in the free fruit group rated the programme as 'very good' The pupils without two valid 24-hour recalls (baseline and follow-up *n* = 97) differed from the pupils with valid 24-hour recalls in that they were less physically active (mean values were 3.0 vs. 3.4 times per week, respectively) and a higher proportion of their parents participating in this study had education from college or university (52 vs. 40%).

Horne 2004	CBA	2	–	**Setting:** Two inner-city London schools, UK **Participants:** Children aged 5–11 years. **Intervention school:** Brixton, 364 pupils, 67% free meal entitlement, 85% ethnic minorities. **Control school:** Stockwell, 385 pupils, 46% free meal entitlement, 80% ethnic minorities.	To evaluate 'Food dudes' programme to increase consumption of fruit and vegetables. All children in all schools were presented with fruit and vegetables at lunchtime and 5–7 years received fruit at snack time. Intervention school also watched 'Food Dudes' video over 16 days featuring heroic peers and children received small rewards for eating those food themselves; two home packs also sent to parents to encourage fruit and vegetable consumption at home. Power not stated.	16-days and 4-month follow-up	At 4-month follow up there was a decline in intervention schools from immediate post-intervention but intervention school still consuming substantially more fruit and vegetables compared with baseline. **Baseline mean consumption:** Intervention 5–7 years: 20% fruit, 35% vegetables 7–11 years: 47% fruit, 51% vegetables Control 5–7 years: fruit 11%, 16% vegetables 7–11 years: 20% fruit, 36% vegetables **Four-month mean consumption:** Intervention 5–7 years: 56% fruit, 53% vegetables 7–11 years: 65% fruit, 63% vegetables Control 5–7 years: fruit 9%, 10% vegetables 7–11 years: 9% fruit, 23% vegetables In intervention school the largest increases were found in children who consumed least at baseline In control schools the largest	Was this the study that the 5-a-day data was based on (used as corroborative evidence for another review). Significant differences in fruit consumption at baseline.

							declines were seen in those who consumed most at baseline.	
James 2004	RCT Cluster, by class	1	++	**Setting:** Schools in Christchurch, Dorset, UK **Participants:** Twenty-nine classes in six junior schools in children aged 7–11 years. 320 females, 324 males, mean age 8.7 (range 7–10.9) years. *n* (randomised to intervention) 325 (15 classes) *n* (randomised to control) 319 (14 classes). Baseline mean BMI (kg/m^2) (SD): Intervention: 17.4 (0.6) Control: 17.6 (0.7)	**Aim:** To reduce consumption of carbonated drinks. One investigator delivered programme to all classes and teachers assisted. One-hour session each class each term (four sessions) encouraging children not to drink carbonated drinks but to switch to water or fruit juice diluted 1:3 with water. Study 90% power.	12-month intervention.	Assessed at 12 months: Intervention *n* = 295 Control *n* = 279 10.9% not assessed Both control and intervention groups significantly increased consumption of water (intervention from 3.1 [1.1] glasses over 3 days at baseline to 4.3 [2.0] glasses at 12-months; control from 2.9 [0.3] glasses over 3 days to 5.1 [2.0] at 12 months).	
Loughridge & Barratt 2005	CCT	2	+	**Setting:** Three secondary schools in disadvantaged	**Aim:** To measure the effect of health promotion and the	3 months	The average volume of water drunk by students in the W+P school was greater (p = 0.05) than that drunk in the W and C schools.	Data presented are poor. The children enjoyed

				areas of North Tyneside. **Participants:** All children within the three schools were exposed to the study. Water (W) + active health promotion (P) *n* = 903 W *n* = 1190 Control (C) *n* = 872	free provision of cooled filtered water in school cafeterias, at both morning break and lunch time, on the consumption of water (free cooled filtered water, free jug and cup water, and bottled water on sale) and soft drinks during the school day. **Intervention**: Over a 3-month period one school was given cooled filtered water and active health promotion (W+P) – note that the active health promotion intervention took place over the first month only, one school had water only (W). The control school (C) received neither W or P. Power not stated.		Note: assume this is all sources of water drunk, but unclear from paper. The volume of soft drinks purchased at school by students before and during the intervention remained static in all three schools. Note: all assessments relate to consumption or purchase of drinks at school, not over the whole day.	the cooled filtered water and this is a relatively cheap and sustainable intervention to provide.
Lytle 2004 TEENS study	RCT By school	1	+	**Setting:** Middle schools in Twin cities, Minnesota, USA.	To evaluate school-based intervention to increase fruit and vegetable intake and lower fat food	2 years	Intervention *n* = 1425, control *n* = 1431. No significant difference between groups for total fruit and vegetable	Race and parents education significantly different between groups at baseline and so this

				Participants: 16 schools, *n* = 3, 878 (96% of those eligible). 51% male in intervention and in control; 70.1% white in intervention, 75.7% white in control; 22.2% of intervention and 17.3% control received free school lunch across groups; both parents having high school education all less 14.5% intervention, 10.8% control.	80% power to detect differences of 1.1 servings of fruit and vegetables and 1.9% difference in energy from total fat intake between treatment groups. Included random selection for 24-hour recall and student survey of all students. Ten nutrition education lessons in 7th and 8th grade, based on social cognitive theory. Family component with newsletters, behaviour coupons and prizes School-wide component included school food modification with school nutritional advisory councils made up of school administrators, school staff, parents, students, and TEENS staff.		intake, mean difference –0.492 (95% CI –1.032, 0.049). Or energy from fat, mean difference +0.635 (95% CI –0.866, 2.137). These difference not significant when analysed by high or low dose exposure to intervention. Students in intervention had slightly higher scores for food choice indicative of making lower fat choices (non-validated measure).	was adjusted for in analysis. Significant positive interim results not maintained at 2-year follow-up.

					Due to potential variability in dose of intervention that each school received – secondary data analysis performed by dose of intervention received by students. Regular classroom teachers and food service staff implemented the intervention. Power not stated.			
Perry 2004	RCT Cluster by school	1	+	**Setting:** Twenty-six elementary schools, from one large school district in the Twin Cities metropolitan area of Minnesota. **Participants:** 1,668 total students (49% female), 1st and 3rd grade. Mean age and Baseline BMI not reported.	**Aim:** To determine if a cafeteria-based intervention would increase the fruit and vegetable consumption of elementary school children. **Intervention activities included:** Increasing the availability, attractiveness and encouragement of fruit and vegetables. Special events were	24 months	At follow-up 1,168 (70%) students were observed (numbers in each group not reported). The number of fruits and vegetables on the snack cart was associated with increased fruit and vegetable consumption from baseline to follow-up (although there were no intervention vs. control differences). Significant impact on children's total fruit and vegetable intake (when potatoes were excluded). The impact however, comes from increases in fruit consumption (0.17 vs. 0.14 servings, respectively), as there were no significant differences between conditions for juices and	Intervention dose was limited to the kinds and amounts of fruits and vegetables served, the attitudes and behaviours of the food service staff, and to the specific activities that could be physically done in the lunch-room environment.

					held, such as sampling sessions and challenge weeks. Food service staff delivered the intervention. Power not stated.		vegetables. **Lunch observations:** Verbal encouragement by food service staff in the lunch line was significantly associated with consumption of fruits and vegetables (no potatoes, no juice), fruits and vegetables (no potatoes), fruit (no juice), and increased consumption in fruits and vegetables (no potatoes, no juice) from baseline to follow-up.	
Wells & Nelson 2005	CCT	2	+	**Setting:** Seventeen primary schools on the outskirts of London in south-east England. **Participants**: All children within the 17 schools that were 4–6 years of age (age over which the intervention occurs), and also 7–8 years (to assess the impact of having had the intervention when aged 4–6 years old). Response rate was 51%. Children included in	**Aim**: To measure the short-term and long-term effect of the National School Fruit Scheme (NSFS) on daily fruit consumption. **Intervention:** Eight schools in the NSFS and nine not in the NSFS. Study and control schools were selected in areas of similar deprivation. Power not stated	2 years	Daily fruit consumption was assessed using a questionnaire that was given to each pupil to take home for their parents to complete and return. Median total fruit consumption (excluding fruit juice) in infants receiving free fruit was 117 g/d compared with 67 g/d in infants not receiving free fruit ($p < 0.001$). Median total fruit consumption in juniors who had received free fruit at school as infants was similar to that consumed by those who had not received free fruit (83 vs. 86 g/d).	

				the study were ‘selected’ samples from each year group. Unclear how samples were selected. Total *n* = 1492. Unclear how many in each group.				
PHYSICAL ACTIVITY INTERVENTION								
Robinson 1999	RCT Cluster, by school	1	++	**Setting:** Two public elementary schools in San Jose**,** CA, USA. **Participants:** 3rd and 4th grade students, mean age 8.9 years, boys and girls. *n* (intervention baseline) = 95; *n* (control baseline) = 103. **BMI (kg/m^2) at baseline:** Intervention: 18.38 (3.67) Control: 18.10 (3.77)	To evaluate a school-based intervention to reduce TV, videotape and video game use on adiposity. Designed to have 80% power to detect an effect size of 0.20 or greater/ Based on Bandura’s social cognitive theory; 18 × lessons of 30 to 50 min, included self-monitoring of television (TV), video and video-game use, then 10-day turn-off, then 7-hour budget, children taught to become selective	6 months	*n* (intervention follow-up) = 92 *n* (control follow-up) = 100 Three children lost to follow-up in each group. Daily servings of high-fat foods: (adjusted for baseline value, age and sex) adjusted change: –0.82 (95% CI –1.87, +0.23), not significant.	Each household received electronic television time manager (control power to TV and video). Schools were matched.

					viewers and advocators of reducing media use. Parental involvement. Programme built into standard curriculum and taught by classroom teachers trained by research staff. 80% power to detect effect size of at least 0.20.			
DIET AND PHYSICAL EDUCATION STUDIES TO PREVENT OBESITY								
Caballero 2003	RCT Cluster, by school	1	+	**Setting**: Forty-one elementary schools in seven American Indian communities in Arizona, New Mexico, South Dakota, USA. See above.	**Aim:** To evaluate a school-based multi-component intervention to reduce percentage body fat in American Indian children. Power not stated. See above.	3 years	*n* (intervention at follow-up) = 727 *n* (control at follow-up) = 682 17% attrition Completer analyses only. **24-hour recall:** Total daily energy intake significantly lower in intervention compared with control (1892 kcal [7.92 MJ]/day vs. 2157 kcal [9.02 MJ]/day) and % energy from total fat was significantly lower in intervention vs. control (31.1 vs. 33.56%). Actual school-lunch observation confirmed lower fat intake in intervention group but no difference in energy intake between the two groups.	Intervention piloted. Compared with CDC reference values, distribution of BMI in study children was shifter towards higher values. Included family component. School food modification.

Donnelly 1996	CCT By school	2	+	**Setting:** Elementary schools in rural Nebraska, USA. **Participants:** Age 9.2 years. Boys and girls (no values given). See above.	**Aim:** To evaluate a school-based PA and nutrition programme to attenuate obesity and promote fitness. Power not stated. See above.	2 years	At year 2 intervention lunches had significantly less fat and sodium and more fibre but 24-hour recall showed significant differences in intake between groups for sodium only. Authors suggest children compensate in energy intake and PA outside school.	Small rewards for volunteers. School food modification.
Gortmaker 1999	RCT By school	1	+	**Setting:** Ten secondary schools in Boston, USA. **Participants:** Girls and boys, grades 6 and 7, mean age 11.7 (SD 0.7) for both intervention and control; 48% female. See above.	**Aim:** To evaluate impact of school-based health behaviour intervention known as PLANET HEALTH on obesity amongst boys and girls in grades 6 to 8. Implemented programme via school curriculum and existing staff resources. Underpinned by behavioural change and social cognitive theory. Promotion of PA, modification of dietary intake	Two school years	Intervention *n* = 641 Control *n* = 654 17% loss to follow-up Intervention increased fruit and vegetable consumption in girls (0.32 servings/day; 95% CI 0.14, 0.5; *p* = 0.003). Intervention resulted in a smaller daily increment in total energy intake among girls (–575 kJ; 95% CI 1155, 0; *p* = 0.05). Measures of extreme dieting behavior remained unchanged (and low) throughout the intervention and were not different between intervention and control schools. Analysis of girls only using self-	See above.

					(decreasing consumption of high-fat foods, increasing fruit and vegetable consumption) and reduction of sedentary behaviours (with a strong emphasis on reducing TV viewing). Thirty-two classroom lessons of 45-min each over 2 school years. Power limited.		report, showed a reduced risk of using self-induced vomiting, laxatives or diet pills to control weight within the previous 30 days.	
Sahota 2001	RCT Cluster, by school	1	+	**Setting:** Ten primary schools in Leeds, UK. **Participants**: 7–11-year-olds, boys and girls, mean age 8 years. *n* (intervention) = 314 *n* (control) = 322	Assessed the impact of a primary school based intervention which included teacher training, modification of school meals, the development of school action plans targeting the curriculum, physical education, tuck shops, and playground activities. Study powered. See above.		*n* (intervention) = 292 *n* (control follow-up) = 303 (at 1-year follow-up for weight) Children in the intervention group reported higher consumption of vegetables (weighted mean difference 0.3 portions/day, 95% CI 0.2, 0.4), but fruit consumption was lower in obese children in the intervention group (–1.0 portions/day, 95% CI 1.8, –0.2).	See above.

Sallis 2003	RCT Cluster, schools randomised by district	1	+	**Setting:** Twenty-four public middle schools (grades 6 to 8) in San Diego County, California. **Participants:** Mean enrolment across 24 schools was 1109 (SD 356) students per school, of whom 49% were female, 44.5%, were non-white, 39.5% received free or reduced school meals and 36.4% were bussed to school. Mean age and mean baseline BMI not reported.	**Aim:** To evaluate the effects of environmental, policy and social marketing interventions on PA and fat intake of middle school students. The primary aims of the intervention were: 1) increase the total energy expenditure from PA by the student population at school; 2) decrease the grams of total saturated dietary fat purchased or brought to school by students. Power not stated. See above.	Two school years.	Number assessed in each group at follow-up not reported. **Fat intake:** The time by condition interaction term was not statistically significant for total ($F = 0.01$, $p = 0.903$) or saturated ($F = 0.08$, $p = 0.781$) fat, indicating no differences in change over time by condition in fat measures at the school level. Effect sizes indicated a near null effect for total ($d = 0.03$) and saturated ($d = 0.13$) fat. There was no intervention effect on fatty foods consumed.	All 24 schools received an incentive to participate (US$1000 for PE equipment), and intervention schools received an additional US$500 for kitchen equipment and US$2000 for PA programmes or equipment.
Story 2003 GEMS-Minnesota	RCT	1	+	**Setting:** Lunchtime clubs in schools in low income areas, Minnesota, USA. **Participants:** 8–10-year-old	**Aim:** To assess feasibility of obesity prevention programme in African American girls. **Intervention:** Lunchtime clubs in	12 weeks	Intervention $n = 26$ Control $n = 28$ Intention to treat analysis No significant difference between groups for dietary intake at 12 weeks.	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to detect a significant intervention effect. Fully powered studies

				African American girls, at least 25th percentile for age and gender BMI, with a parent willing to be involved. **Mean age (years):** Intervention: 9.3 (SD 0.9) Control: 9.4 (SD 0.9) **Sex:** Girls only Intervention *n* = 26 Control *n* = 28	school designed to improve nutrition, PA and self-esteem through a range of activities. The intervention which was conducted twice per week, focused on increasing healthy eating and PA. Intervention meetings, designed in a ‘club meeting’ format, were held twice per week for one hour after school at each of the schools used in the study. The intervention was based on social cognitive theory (Bandura) and targeted key points from three domains: 1) environmental factors such as peer support; 2) personal factors such as knowledge and values; 3) behavioural factors such as goal setting and social reinforcement.		% Energy from fat (parental reported) and low-fat food practices (parental reported) were significantly better in intervention group compared with control.	of two of the GEMS pilots are currently underway.

					Control: The control group served as an 'active placebo', non-nutrition/PA condition and focused on promoting positive self-esteem and cultural enrichment. Participants attended monthly Saturday morning meetings (three meetings over 12 weeks). This included arts and crafts; self esteem activities, creating memory books and a workshop on African percussion instruments. Providers of the intervention included University Staff, Trained African American GEMS staff and school staff. Study not powered (pilot).			
DIET AND PHYSICAL EDUCATION STUDIES TO IMPROVE CARDIOVASCULAR HEALTH								
Luepker	RCT	1	+	**Setting:**	Sample size	3 years	Total *n* = 4109 at 3 years (21%	See above.

1996 (CATCH)	Cluster, by school			Ninety-six public state schools in 12 school districts in California, Louisiana, Minnesota and Texas. **Participants:** Mean age 8.76 years. 2461 of 5106 were girls. Total cohort *n* = 5106 at baseline. Ethnically diverse (white, African American and Hispanic).	determined. See above.		dropout for serum cholesterol measurement at 3 years). % Energy intake from fat fell significantly more in intervention school lunches than control (38.7 to 31.9% in intervention vs. 38.9 to 36.2% in control); self reported % daily energy intake from total fat was significantly reduced in intervention (32.7 to 30.3%) compared with control (32.6 to 32.2%, $p < 0.001$) and total energy intake also significantly reduced in intervention schools ($p < 0.01$).	
Manios 1998, 1999, 2002	CCT (by school)	2	+	**Setting**: Schools in Iraklio and Rethimno (intervention) and Chania (control) Crete, Greece. **Participants**: First-grade primary school children aged 5.5 to 6.5 years; 509 boys and 453 girls.	To evaluate a school-based intervention involving a health and nutrition element and a physical fitness and activity element, on chronic disease risk factors. Power not stated. See above.	6 years	Total 831 available at 6 years, 787 assessed (those who did not change schools and completed). Total energy intake change intervention vs. control: +179 kcal (749 kJ) (*n* = 90) vs. +367 kcal [1535 kJ] (*n* = 86), $p < 0.05$. Total fat intake change intervention vs. control: +5.9 g (*n* = 90) vs. +18.8 g (*n* = 86), $p < 0.05$. Saturated fatty acids change	See above.

				See above.			intervention vs. control: +0.8 g ($n = 90$) vs. +5.1 g ($n = 86$), $p < 0.05$.	
Vandongen 1995	RCT Cluster, by school	1	+	**Setting:** Thirty schools in Western Australia. **Participants:** Age range 10–12 years. 1,147 boys and girls See above.	To evaluate programme of fitness and nutrition alone and combined and school and home-based nutrition programmes to improve cardiovascular health. Delivered by teachers and PE teachers who received in-service training sessions. Study powered See above.	Nine months	971 of 1147 assessed at 9 months for blood pressure, anthropometric and fitness tests. Significant decrease in total fat intake in girls compared with boys in school and home nutrition group (2.9, 95% CI 1.5–4.3) and home nutrition group (3.6, 95% CI 2.1–5.1). When adjusted for baseline values only significant decrease in home nutrition group compared with control. Also significant decrease (unadjusted) in saturated fat intake in girls in school and home nutrition group, home nutrition group, fitness and school nutrition group.	All follow-up measures adjusted for baseline values.
Evidence of efficacy (internal validity) for physical activity outcomes								
PHYSICAL ACTIVITY INTERVENTIONS								
Jamner 2004	CCT Cluster by school	2	+	**Setting:** Two public high schools in Orange County, CA, USA. **Participants:** Fifty-eight female adolescents 25 intervention and	**Aim:** To evaluate the effect of a school-based intervention designed to increase PA among sedentary adolescent females. **Intervention:**	Four months	At follow-up, data were available for 25 intervention participants and 22 control participants The intervention had no significant effect on BMI percentile, 67.28 at baseline and 66.74 at 4 months; % body fat 32.64 at baseline and 31.85 at 4 months.	Study participants overall reported more moderate and less light activity at baseline, as these measures were obtained during summer vacation, whereas follow-up assessments were

				22 control Mean age = 14.94 (SD 0.79) years Mean baseline BMI percentile = 67.28 for intervention completers) mean baseline BMI percentile = 60.47 for control completers. 53% non-Hispanic white, 29% Hispanic, 8% Asian and 3% ‘other’.	Special PE class. The class met five days per week for 60 min each day (approximately 40 min of activity time). Types of activity included aerobic dance, basketball, swimming and tae bo. One day per week of class time was devoted to a lecture or discussion focusing on the health benefits of PA and strategies for becoming more physically active. Not stated who delivered intervention. Power not stated.		Two-day PA recall data: significant effect of the intervention on light ($F = 5.53$, $p = 0.023$), moderate ($F = 7.946$, $p = 0.007$) and total ($F = 4.155$, $p = 0 .043$) activity. The intervention had a significant effect on lifestyle activity, with the intervention group increasing their mean self-reported lifestyle activity from 2.33 (using the sum of affirmative responses to the Stanford Usual Physical Activity Scale) at baseline to 3.19 at 4 months, whereas the control group showed little change (2.58 at baseline and 2.26 at 4 months).	conducted during the school year which may have confounded results.
Pangrazi 2003	CCT By school Control schools were not	2	+	**Setting:** Thirty-five schools in Arizona, USA. **Participants:** 4th grade, mean age for boys and girls was 9.8 (SD	**Aim:** To evaluate the effects of the PLAY intervention. Promotes 30–60 min moderate to vigorous PA daily, 15-min	12 weeks	At 12-weeks the treatment was effective at increasing the PA level of children, especially girls $p < 0.001$. All students: PLAY + PE, and PLAY only groups were significantly more active than C.	Previously adopted in Arizona elementary schools and 24,000 children have received the intervention.

	randomly selected			0.6) years. PLAY + PE: *n* = 183 PE only *n* = 175 PLAY only *n* = 150 No treatment control (C) *n* = 91	activity break each day to teach variety of physical activities, promotes attitudes and behaviours to sustain active habits for life; includes self-monitoring and self-awareness. Teachers received training from county health co-ordinators PLAY is not intended to replace comprehensive PE programme but act as important supplement. The intervention comprised three stages: Step 1: promote play behaviour (first week) teachers and students participated, more walking, less standing, sitting, children were informed about the importance of PA and identified appropriate adult role models.		Girls: PLAY + PE, and PE only groups were significantly more active than C. Boys showed no significant differences in steps across treatment groups as the control boys were already more active than average 10-year-old boys in the area (data from previous study).	

					Step 2: teacher directed activities (3 weeks) games and activities that were enjoyable and could be played outside school. Step 3: encourage self-directed activity (8 weeks) with students aiming to achieve 30 min of activity per day independently of teacher outside school. Treatment and PE schools, children received log sheets similar to the PLAY ones but were asked to record their after school activities (active and sedentary). Teachers trained by county co-ordinators, with programme implemented across Arizona with more than 24,000 children receiving PLAY. Power not stated.			

Pate 2005	RCT Cluster by school	1	+	**Setting**: Twenty-four high schools in 14 South Carolina counties, USA. **Participants**: 2744 girls, 48.7% African American and 46.7% white, mean age 13.6 years, mean BMI 23.1 kg/m^2.	To evaluate school-based PA intervention among high school girls. School personnel headed by a champion implemented programme with training from research staff. Power not stated.	Start of 9th Grade through until Spring? Approx. 6 months?	Intervention: *n* = 863 Control: *n* = 741 Completers only Slightly higher % African American girls lost to follow-up. 45% intervention girls vs. 36% control girls reported vigorous PA during an average of one or more 30 min time blocks per day over a 3-day period. However, most girls in both groups reported daily average of at least two 30-min blocks of moderate to vigorous PA at both baseline and follow-up.	
Robinson 1999	RCT Cluster, by school	1	++	**Setting:** Two public elementary schools in San Jose**,** CA, USA. **Participants:** 3rd and 4th grade students, mean age 8.9 years, 192 boys and girls, 45%-49% girls See above.	To evaluate a school-based intervention to reduce television, videotape and video game use on adiposity. Designed to have 80% power to detect an effect size of 0.20 or greater. See above.	6 months	*n* (intervention follow-up) = 92 *n* (control follow-up) = 100 Three children lost to follow-up in each group. Statistically significant decreases in children's reported television viewing and meals eaten in front of the television in intervention group compared with control. PA metabolic equivalent-weighted, min/week (adjusted for baseline value, age and sex) adjusted change: –16.7 (95% CI –78.6, 45.3), not significant.	Each household received electronic television time manager (control power to TV and video). Schools were matched.
Sallis	RCT	1	+	**Setting:**	To evaluate a school-	2 years	Total 549 children assessed at	Interim results only (2

1993, 1997	Cluster, by school			Seven suburban elementary schools in Southern California, USA. **Participants:** Elementary school children, mean age 9.25 years. Seven schools involved, six schools randomly assigned to the three experimental conditions and one further school added to the control group. 85% non-Hispanic white *n* total (intervention and control at baseline) = 745	based intervention involving PE and self-management (delivered either by specialists or teachers) on weight and adiposity. Programme provided by either certified physical education specialist or teachers trained for total 38 hours in-house over 2 years with substitute teachers provided. Power not stated.		follow-up (305 boys and 244 girls); 26% attrition. Boys (after intervention) *n* control = 101, *n* specialist-led = 91, *n* teacher-led = 113. Girls (after intervention) *n* control = 97, *n* specialist-led = 60, *n* teacher-led = 87. No significant groups differences on weekday or weekend PA outside school using accelerometer (no baseline scores available so results unconditional).	year data from 3-year study). Actual data for BMI and skinfold thicknesses is only presented in graphical form.
Schofield 2005	CCT Cluster by school	2	+	**Setting:** Three high schools in central Queensland, Australia. **Participants:** Low active girls (defined from previous study as those girls who	To pilot efficacy of using pedometer as basis of time efficient yet effective non-curriculum school-based programme Intervention; group meetings once a week for 6 weeks for 30 min each in	12 weeks	Pedometer: *n* = 23 Minutes: *n* = 21 Control: *n* = 24 Mean blinded 4-day step count was significantly different only between pedometer vs. control *p* = 0.03, group with participants in both intervention groups significantly increasing step count across 12 weeks (despite pedometer group	

				took least amount of recorded steps); mean age 15.8 years. **BMI (kg/m^2):** Pedometer intervention: 22.3 (SD 4.1) Minutes intervention: 23.7 (SD 6.6) Control 24.5 (SD 5.5)	groups of 8 either before or after school or in lunch break. Intervention groups received log book to record min in PA or amount of step counts. Actual activity intervention was 12-weeks with weeks 7–12 maintenance phase (no group meetings). **Pedometer intervention:** 1000–2000 step increase daily each week until reached 10,000 steps per day. **Minutes intervention:** Increase by 10–15 min daily each week until reached daily average of 30–60 min/day. Power not stated.		showing significant improvement at 6 weeks). No significant changes in moderate or vigorous PA between any groups. Mean increase 2747 steps per day in pedometer group.	
Simon et al. 2004	RCT	1	+	Children in first-level of middle-	**Aim:** To evaluate the	Ongoing trial entitled	The proportion of intervention adolescents not engaged in	Ongoing.

				school (initially aged 11–12 years) in eight schools in Eastern France were recruited, and were randomised to Intervention (I) or Control (C). 954 adolescents were recruited to the study (92% of eligible); 475 in I schools, 479 in C schools.	impact of a PA intervention in adolescents. **Intervention:** The intervention was directed at changing knowledge and attitudes and at providing social support and environmental conditions that encourage PA of adolescents inside and outside school. It is classified here as a school based intervention, it is not strictly school-based but requires numerous partnerships intervening at different levels (school boards, teachers and medical staff, club educators, families, territorial and community agencies in charge of recreational areas and transportation infrastructure, etc).	'Intervention Centred on Adolescents PA and Sedentary Behaviour' (ICAPS) – this paper reports results from first 6 monthsof trial.	organised PA was reduced by 50% after 6 months, whereas it was unchanged among control students. Participation in leisure-organised PA significantly increased among intervention girls (OR 3.38, 95% CI 1.42, 8.05) and boys (OR 1.73, 95% CI 1.12, 2.66), compared with the control group. In addition, high sedentary behaviour (defined as >3 hours/day TV viewing and computer/video games) was reduced in intervention girls (OR 0.54, 95% CI 0.38, 0.77) and boys (OR 0.52, 95% CI 0.35, 0.76) compared with control group.	PA was assessed with a questionnaire adapted from the 'Modifiable Activity Questionnaire for Adolescents'.

					A mean of 10–12 different weekly activities was provided on I sites. About 50% of adolescents participated in at least one weekly activity. The authors reported that implementation increased progressively throughout the school year, thanks to regular individual contacts and more formal meetings (at least one every 2 weeks). Sample size determined.			
DIET AND PHYSICAL ACTIVITY INTERVENTIONS TO PREVENT OBESITY								
Caballero 2003	RCT Cluster, by school	1	+	**Setting**: Forty-one elementary schools in seven American Indian communities in Arizona, New Mexico, South Dakota, USA. **Participants**: Mean age	**Aim:** To evaluate a school-based multi-component intervention to reduce percentage body fat in American Indian children. Almost the entire intervention was	3 years	*n* (intervention at follow-up) = 727 *n* (control at follow-up) = 682 17% attrition Completer analyses only. Self-reported PA levels were higher among intervention compared with control at end of 3 years (both lower than at baseline though).	Intervention piloted. Compared with CDC reference values, distribution of BMI in study children was shifter towards higher values.

				7.6 ± 0.6 years. Sex not reported. See above.	delivered by school personnel, teachers and food service staff; the Pathways staff focused on research measurements and training and support of school staff. Teachers, food service staff and PE teachers trained annually by SPARK or PATHWAYS instructors and supported within schools. Power not stated.			
Donnelly 1996	CCT By school	2	+	**Setting**: Elementary schools in rural Nebraska, USA. **Participants:** Age 9.2 years. Boys and girls (no figures given). 94% White, 42–44% received free and reduced school lunches. **Mean BMI (kg/m^2):** Intervention: 18.3	**Aim**: To evaluate a school-based PA and nutrition programme to attenuate obesity and promote fitness. Utilised school curriculum and existing staff resources. Research nutrition staff consisted of PhD student in nutrition, registered	2 years	PA in the classroom was significantly greater for intervention than control by 6% but PA outside school was significantly less for intervention than control by 16%. Authors suggest children compensate in energy intake and PA outside school.	Small rewards for volunteers.

				(SD 3.9) Control: 18.5 (SD 3.4) Intervention *n* = 102 Control *n* = 236	dietitian, and several graduate students. PA research staff comprised an exercise physiologist and graduate students. Power not stated. See above.			
Gortmaker 1999	RCT By school	1	+	**Setting:** Ten secondary schools in Boston, MA, USA. **Participants:** Girls and boys, grades 6 and 7, mean age 11.7 (SD 0.7) for both intervention and control. See above.	**Aim:** To evaluate impact of school-based health behaviour intervention known as PLANET HEALTH on obesity amongst boys and girls in grades 6 to 8. Power limited. See above.	Two school years	Intervention *n* = 641 Control *n* = 654 17% loss to follow-up Intervention reduced TV hours among both girls (–0.58 hours; 95% CI –0.85, –0.31; *p* = 0.001) and boys (–0.4 hours; 95% CI –0.56, –0.24, *p* < 0.001). Author concludes that reductions in television viewing predicted obesity change and mediated the intervention effect (in girls but not boys). Among girls, each hour of reduction in television viewing predicted reduced obesity prevalence (OR 0.85; 95% CI 0.75, 0.97; *p* = 0.02). Hours per day spent in moderate to	Obesity definition based on BMI and TSF measure greater than or equal to 85th percentile of age and sex-specific reference data statistically accounted for the potential unit of analysis errors. Blinded outcome assessment was reported. Also reported on the issue of the promotion of unintended side effects (extreme dieting behaviours). Schools experienced

							vigorous PA was not significantly different between intervention and control school.	with interdisciplinary curricula found it easier to implement Planet Health material.
Neumark -Sztainer 2003	CCT Cluster, by school	2	+	**Setting:** Six secondary Schools in twin Cities area, school districts Minnesota, USA. **Participants:** 201 females. Mean age 14.9 (SD 0.9) years in intervention, 15.8 (SD 1.1) years in control. BMI (kg/m^2) at baseline: Intervention vs. control: 27.6 (SD 7.2) vs. 25.9 (SD 5.8). Inclusion criteria: girls with BMI at or above 75th percentile *n* (intervention) = 89	To evaluate an obesity prevention programme that aimed to increase enjoyment and self-efficacy In high-school based girls. See above. Delivered by research team, PE teachers and school counsellors. Power not stated.	7-months total, 16-week intervention plus 8-week maintenance plus follow-up 1-month later	*n* (intervention) = 81 *n* (control) = 99. The only significant variable was a progression in PA stage based on the Stages of Change Model (p = 0.004).	See above.

				n (control) = 112				
Sahota 2001	RCT Cluster, by school	1	+	**Setting:** Ten primary schools in Leeds, UK. **Participants:** 7–11 year olds, boys and girls, mean age 8 years. *n* (intervention) = 314 *n* (control) = 322	Assessed the impact of a primary school-based intervention which included teacher training, modification of school meals, the development of school action plans targeting the curriculum, physical education, tuck shops, and playground activities. Sahota used a population approach underpinned by the Health-Promoting Schools philosophy and the intervention involved the whole school community including parents, teachers and catering staff. 80% power to detect difference in means of a normally distributed outcome measure of at least 1.8 standard		*n* (intervention) = 292 *n* (control follow-up) = 303 (at 1-year follow-up for weight) Sedentary behaviour was higher in overweight children in the intervention group weighted mean difference 0.3, (95% CI 0.0–0.7).	89% of the actions points were implemented in the ten schools and changes were made to the food provision. Both parents and teachers were supportive of the dietary education and promotion of PA. Parental questionnaires (64% returned) detailed suggestions for improvements such as promotion of healthier break time snacks with enforcement by school, material on healthy eating for children and fun PA ideas. Of the 20 teachers invited, 19 attended and were satisfied training, resources and materials offered. Children had higher scores for knowledge, attitudes and were positive about the intervention

					deviations at 5% significance level.			in focus groups. APPLES intervention was successful in producing changes at the school level, in terms of changing the ethos of the schools and the attitudes of the children, but had little effect on children's behaviour other than a modest increase in the consumption of vegetables.
Sallis, 2003	RCT Cluster, schools randomised by district	1	+	**Setting:** Twenty-four public middle schools (grades 6 to 8) in San Diego County, CA, USA. **Participants:** Mean enrolment across 24 schools was 1109 (SD 356) students per school, of whom 49% were female, 44.5%, were non-white, 39.5% received free or reduced school meals and 36.4% were bussed to school.	**Aim**: To evaluate the effects of environmental, policy and social marketing interventions on PA and fat intake of middle school students. Delivered by research staff, teachers, school food service staff and managers. Power not stated. See above.	Two school years	Number assessed in each group at follow-up not reported Intervention schools increased PA over time at a greater rate than control schools. Boys in intervention schools increased about equally in PA in PE and out of PE, but girls in intervention schools increased their activity mainly through PE. Survey data revealed that the intervention had no significant impact on reported PA or participation in sedentary behaviours.	All 24 schools received an incentive to participate (US$1000 for PE equipment), and intervention schools received an additional US$500 for kitchen equipment and US$2000 for PA programmes or equipment.

				Mean age and mean baseline BMI not reported.				
Story 2003 GEMS-Minnesota	RCT	1	+	**Setting:** Lunchtime clubs in schools in low income areas, Minnesota, USA. **Participants:** 8–10-year-old African American girls, at least 25th percentile for age and gender BMI, with a parent willing to be involved. **Mean age (years):** Intervention: 9.3 (SD 0.9) Control: 9.4 (SD 0.9) **Sex:** Girls only. Intervention *n* = 26 Control *n* = 28	**Aim:** To assess feasibility of obesity prevention programme in African American girls **Intervention:** Lunchtime clubs in school designed to improve nutrition, PA and self-esteem through a range of activities. The intervention which was conducted twice per week, focused on increasing healthy eating and PA. Intervention meetings, designed in a 'club meeting' format, were held twice per week for one hour after school at each of the schools used in the study. The intervention was based on SCT (Bandura) and targeted key points	12 weeks	Intervention *n* = 26 Control *n* = 28 ITT analysis No significant difference between groups for PA (accelerometer and questionnaire) at 12 weeks.	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to detect a significant intervention effect. Fully powered studies of two of the GEMS pilots are currently underway.

					from three domains: 1) environmental factors such as peer support; 2) personal factors such as knowledge and values; 3) behavioural factors such as goal setting and social reinforcement. **Control:** The control group served as an 'active placebo', non-nutrition/PA condition and focused on promoting positive self-esteem and cultural enrichment. Participants attended monthly Saturday morning meetings (three meetings over 12 weeks). This included arts and crafts; self-esteem activities, creating memory books and a workshop on African percussion instruments. Providers of the			

					intervention included University Staff, Trained African American GEMS staff and school staff. Study not powered (pilot).			
Warren 2003	RCT Individual	1	+	**Setting**: Three primary schools in Oxford, UK. **Participants**: Children aged 5–7 years (children in Year 1 and Year 2). Sex not reported. See above.	Be Smart was a school and family-based intervention to prevent obesity in children aged 5–7 years. There were four conditions: a nutrition group, a PA group, a combined nutrition and PA group and a control group. The intervention ran for 20 weeks over four school terms (approx. 14 months). Power not stated. See above.	20-week intervention over 14 months	Nutrition intervention at follow-up *n* = 42 PA intervention at follow-up *n* = 42. Combined nutrition and PA intervention *n* = 42. Control *n* = 46. Dropout *n* = 46 for weight Only those who completed were included in analysis (not ITT). Some evidence that PA in playground had improved in the intervention groups but no difference in total activity between groups (including outside school).	See above.
Luepker 1996 (CATCH)	RCT Cluster, by school	1	+	**Setting:** Ninety-six public state schools in 12 school districts in California, Louisiana,	To evaluate a school-based intervention including a home programme for the primary prevention of cardiovascular	3 years	Total *n* = 4109 at 3 years (21% dropout for serum cholesterol measurement at 3 years). Intervention students reported significantly more daily vigorous PA	See above.

				Minnesota and Texas. **Participants:** Mean age 8.76 years 2461 of 5106 were girls. Total cohort *n* = 5106 at baseline. Ethnically diverse (white, African American and Hispanic).	disease. PE specialists and teachers had 1 to 1.5 days of training each school year; training also for cooks and teachers. Sample size determined. See above.		than controls (58.6 vs. 46.5 min, $p < 0.003$).	
Manios 1998, 1999, 2002	CCT By school	2	+	**Setting**: Schools in Iraklio and Rethimno (intervention) and Chania (control) Crete, Greece. **Participants:** First-grade primary school children aged 5.5 to 6.5 years; 509 boys and 453 girls. See above.	To evaluate a school-based intervention, involving a health and nutrition element and a physical fitness and activity element, on chronic disease risk factors. Delivered by school teachers and PE teachers. Power not stated. See above.	6 years	Total 831 available at 6 years, 787 assessed (those who did not change schools and completed). Time in leisure time PA intervention vs. control: +281 ($n = 356$) vs. +174 ($n = 285$) min/week, $p < 0.05$	'Know your body program' also included dental health, drug abuse and accident prevention. Results adjusted for baseline values, sex, BMI, change in height and parental education where appropriate.
Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								

First author	Study design	Research type	Research quality	Study population	Research question and design	Length of follow-up	Main results	Confounders/comments
Smarter Choices – Changing the Way We Travel 2004	Report	N/A	N/A	UK schools	To evaluate alternative modes of transport	N/A	The results of this report suggest that car use can be reduced by 8–15% at engaged schools, but the results are inconsistent. Other benefits may include improved safety and increased awareness of the potential for change in terms of options for alternative modes of transport.	Having a school travel plan coordinator increases the production of school travel plans but there is no evidence that this changes travel patterns or reduces parental fears about traffic danger.
Rowland 2003 Randomised controlled trial of site specific advice on school travel patterns	RCT	N/A	N/A	To evaluate intervention of site-specific advice on school travel patterns	Intervention schools were offered 16 hours of expert assistance over one school year from one of two school travel coordinators who had formal teaching qualifications and road safety experience. Road safety problems and their solutions were identified by meeting with teachers	1 year	Twenty-one London primary schools were randomised. One year post-intervention, nine of eleven intervention schools and none of the control school had travel plans. However, the proportion of children walking,	

					and governors, organising focus groups of parents and pupils, and encouraging the establishment of the school travel working group. The coordinator liaised with relevant parties within the local and health authorities.		cycling, or using public transport on the school journey were similar in intervention and control schools. In the intervention schools, 70% of children walked to school, 24% travelled by car, 6% cycled or used public transport. In the control groups, 71% walked to school, 23% travelled by car, and 7% cycled or used public transport. The proportion of parents who were very or quite worried about traffic danger was similar in the intervention (85%) and control (87%) group. Having a school travel plan coordinator increased the production of school travel plans but there was no evidence that this	

							changed travel patterns or reduced parental fears.	
Department for Education and Skills (2004)	Case study	N/A	N/A		To understand better the influences of re-introduction of National Nutritional Standards for school lunches in 2001 on the provision of food at school lunchtimes.	One time point.	The current National Nutritional Standards for school lunches have failed to promote healthy food choices at lunchtime amongst secondary school pupils in England. In the majority of cases, unrestricted choice of foods at lunchtime was associated with unhealthy food choices. Restricted choice over 1 week (e.g. number of days on which chips were served) was associated with Healthier eating. 82% of schools met all nutritional standards for school meals every lunchtime at the beginning of the service. This had fallen to 47% by	

							the end of service.	
Health Education Trust. A feasibility study into healthier drinks vending in schools (2004)	Feasibility study	N/A	N/A	UK schools	The aim of the feasibility study was to investigate the economic viability of healthier drinks vending provision in secondary schools. Twelve schools participated; schools were chosen to reflect both urban and rural locations and to offer an appropriate mix of size, area and character. The study took a whole school approach. In each school a small working party was set up including senior management, curriculum staff, catering personnel, and representatives from the student council.	N/A	Children will choose healthier options from vending machines, such as mineral water, pure fruit juice and skimmed milk, even when healthy drinks vending machines are set alongside the school's usual vending machine. The key to successful healthy drinks vending is pupil involvement, appropriate location of the vending machine close to the dining area, and continuity of provision (ensuring that the machine is full and in working order).	Evidence of change in total daily consumption of drinks was not assessed. Still awaiting evaluation results from Phase 2. Available at: www.healthedtrust.com
Horne 2004	CBA	2	–	Two inner city schools in London, UK	See above.	See above.	See above.	
James 2004	RCT Cluster by class	1	++	Schools in Christchurch, Dorset, UK.	See above.	See above.	See above.	
Loughridge	CCT	2	+	Secondary	As above.	See above.	See above.	

& Barratt 2005				schools in disadvantaged areas of North Tyneside (north-east of England).				
Metcalf et al. 2005	Cross sectional study – not an intervention	N/A	N/A	154 boys and 121 girls in their first year (aged 4–5 years) at 53 urban primary schools in Avon (part of ALSPAC).	To assess levels of PA of children who walk to school compared with those that are driven. Methods used accelerometry.	N/A	Studied children in urban primary schools in Avon. Being driven to school does not affect the overall PA levels of 5-year-olds. Although the proportion of walkers was highest in the lowest SES group, that pattern of results was unchanged when analysed by each social group. Note: the two groups did not differ significantly in either BMI or sum of skinfold thicknesses.	
Wells & Nelson	CCT	2	+	Primary schools in low to middle	As above.	As above.	As above.	

2005				income areas on the outskirts of London in south-east England.				
Sahota 2001	RCT Cluster, by classroom	1	+	School in Leeds, UK	See above.	See above.	See above.	
Stratton 2000	RCT/CCT Intervention group randomly selected individual children within one school, control children matched from another school.	N/A	N/A	Two schools in an urban industrialised area of north-west England. **Intervention:** 18 boys and 18 girls aged 5 to 7 years. **Control:** 12 boys and 12 girls of similar age, stature and body mass.	To evaluate the effects of moderate to vigorous PA of primary school children of painting a school playground with bright and colourful markings. Playground space 30 × 30 m in intervention and 40 × 20 m in control schools, numbers in playground between 50 and 200; neither school had playground markings at baseline. **Intervention group:** Designed the markings which were then painted in bright fluorescent colours on the tar macadam including castle, dragon, pirate ship, fun trial, hopscotch, snakes	4 weeks	Intervention *n* = 27 Control *n* = 20 **No significant difference in BMI (kg/m^2):** Baseline Intervention: 22.9 Control: 22.4 Post-intervention Intervention: 23.3 Control: 22.9 The intervention did increase children's mean heart rate and levels of moderate and vigorous activity with significant interaction between these variables; no main effect differences	

					and ladders, etc., with only one football allowed. **Control:** No markings and limited equipment.		between groups suggesting factors other than playground markings stimulated PA in control school such as availability of skipping ropes and balls (also both schools significantly increased duration of playtime).	
University of East Anglia. A National Evaluation of School Breakfast Clubs (ABC). Department of Health 2001	Various	N/A	N/A	Schools in East Anglia	A survey of breakfast club provision and the structures put in place to implement the scheme. A cluster RCT to evaluate the effectiveness of breakfast clubs in terms of nutritional, social, psychological and educational outcomes. Case studies to generate detailed information about process and structures and the experiences of those involved.	Various.	There is evidence for a small but important beneficial effect of breakfast clubs in schools on behaviour, dietary intake, health, social interaction, concentration and learning, attendance and punctuality. This positive impact is reaching many families whose members are at risk of, or are actually experiencing, social exclusion. Considerable support for	

					A child and family study using questionnaires and semi-structured interviews to collect information from parents about socio-economic circumstances, the impacts of the scheme on families, and parents' and children's satisfaction with and views about breakfast clubs. Both qualitative and quantitative data were generated over three main phases of data collection during Spring Term 2000, Summer Term 2000 and Spring Term 2001. Data were collected from 235 schools operating breakfast clubs. Thirty schools (6000 children) were selected for the trial.		breakfast clubs was found from the interviews and questionnaires.	
Warren 2003	RCT Individual	1	+	Schools in Oxford, UK.	See above.	See above.	See above.	
Woolfe 2005	Review	2	+	Overview of five school-based dietary	To evaluate feasibility and effectiveness of dietary change	See above.	See above.	See above.

				interventions funded by the Food Standards Agency (UK).	interventions in UK school-based settings.			
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
EPPI-Centre (2003b) Children and healthy eating: a systematic review of barriers and facilitators. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London.	Systematic review	1	++	Various. *n* = 19 intervention studies.	The aim was to evaluate the effectiveness of interventions to increase 4–10-year-old children's fruit and vegetable consumption, and to assess the barriers and facilitators to having a healthy diet.	Various	Teachers found it difficult to fit nutrition education in to the curriculum. They also felt they lacked in skills, training and support to deliver high quality nutrition lessons. However, fruit tuck shops could be valuable to others areas of learning, such as English and art through promotion exercises, and maths via the handling of money. Success of the interventions seemed to depend to a large extent on the enthusiasm of staff and parents.	
EPPI-Centre, (2001a)	Systematic review	1	++	Various. *n* = 7 intervention studies.	The aim was to evaluate the	Various.	Intervention was well received in most cases, although a recurring theme was that schools lacked the time and resources for such	

Young people and healthy eating. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London.					effectiveness of interventions to improve the diets of young people (aged 11–16 years), and to assess the barriers and facilitators to having a healthy diet.		projects. One study noted that young women tended to enjoy the intervention more than young men, and that peer leaders were particularly well received. One intervention met with resistance from teachers and waning enthusiasm from students and parents. In this case, more training for the teachers may have provided more motivation, enthusiasm and skill. Young people's views of barriers and facilitators to healthy eating indicated that effective interventions would: 1) make healthy food choices accessible, convenient and cheap in schools; 2) involve family and peers; 3) address personal barriers to healthy eating, such as preferences for fast food in terms of taste, and perceived lack of will-power.	
EPPI-Centre (2003a) Children and physical activity: a systematic review of barriers and	Systematic review	1	++	Various. *n* = 5 intervention studies (all US-based).	The aim was to evaluate the effectiveness of interventions to increase PA/reduce	Various	In one study, 95% teachers rated the intervention as effective and 65% pupils said they liked the intervention lessons. In another, teachers reported high levels of participation, confidence in the intervention and confidence in themselves to be able to deliver it. Another intervention met with more resistance from school staff, and waning enthusiasm from	

facilitators. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London.					inactivity in children aged 4–10 years, and to assess the barriers and facilitators to their participation in PA.		parents. Interventions should address the barriers and facilitators to participation in PA identified by children, by: 1) providing activities that are enjoyable, in a social atmosphere, giving children some choice, and making children aware of how sedentary activities such as TV watching are; 2) involving parents in interventions; 3) improving children's access to PA opportunities.	
EPPI-Centre (2001b) Young people and physical activity: A systematic review of research on barriers and facilitators. London: EPPI-Centre, Social Science Research	Systematic review	1	++			Various	Enthusiasm for the project amongst staff, parents and pupils varied. The main barrier to implementation was a lack of time and resources. In some schools, though, the intervention measures were well received. Adequate training for teachers expected to give nutrition information is important. Young people's views on barriers and facilitators suggest that interventions should: 1) modify PE lessons to suit their preferences; 2) involve family and peers, and make PA a social activity; 3) increase young people's	

Unit, Institute of Education, University of London							confidence, knowledge and motivation relating to PA; 4) make physical activities more accessible, affordable and appealing to young people.	
James 2004	RCT Cluster by class	1	++	See above.	See above.	See above.	One of the authors delivered the intervention.	Average class size was 22 (SD 5).
Loughridge & Barratt 2005	CCT	2	+	As above.	As above.	As above.	Focus groups were conducted in the control school only, and revealed that students viewed their existing water provision as poor, and wanted sufficient supplies of cooled filtered water at school. Implementation would appear simple, and sustainable (my comments).	
Horne 2004	CBA	2	–	See above.	See above.	See above.	Research staff and school staff. No details.	
Wells & Nelson 2005	CCT	2	+	As above.	As above.	As above.	9% of parents of infants who received free school fruit were not aware that their child did so; conversely 40% of parents of junior children who used to receive free fruit at school were not aware that their child no longer did so. The parents of 483 infant pupils who believed (correctly) that their child was receiving free school fruit were asked a question about	

							whether or not they had changed the amount of fruit they gave to the child. The majority (82%) reported not having changed the amount of fruit they provided for their child.	
Sahota 2001	RCT Cluster, by classroom	1	+	See above.	See above.	See above.	Delivered by teachers but the project team provided training for teachers and the project manager also provided input and support.	
Warren 2003	RCT Individual	1	+	See above.	See above.	See above.	The project team delivered the intervention.	

SEARCH STRATEGIES

1. exp OBESITY/
2. exp Weight Gain/
3. exp Weight Loss/
4. obes$.ti,ab.
5. (weight gain or weight loss).ti,ab.
6. (overweight or over weight or overeat$ or over eat$).ti,ab.
7. weight change$.ti,ab.
8. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
9. body mass.ti,ab.
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. exp Behavior Therapy/
12. exp Social Support/
13. exp Family Therapy/
14. exp Psychotherapy, Group/
15. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
16. (group therapy or family therapy or cognitive therapy).ti,ab.
17. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.
18. counsel?ing.ti,ab.
19. social support.ti,ab.
20. (peer adj2 support).ti,ab.
21. (children adj3 parent$ adj therapy).ti,ab.
22. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23. exp OBESITY/dh [Diet Therapy]
24. exp Diet, Fat-Restricted/
25. exp Diet, Reducing/
26. exp Diet Therapy/
27. exp FASTING/
28. diet$.ti,ab.
29. (low calorie or calorie control$ or healthy eating).ti,ab.
30. (fasting or modified fast$).ti,ab.
31. exp Dietary Fats/
32. (fruit or vegetable$).ti,ab.
33. (high fat$ or low fat$ or fatty food$).ti,ab.
34. formula diet$.ti,ab.
35. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36. exp EXERCISE/
37. exp Exercise Therapy/
38. exercis$.ti,ab.
39. (fitness adj (class$ or regime$ or program$)).ti,ab.
40. (aerobics or physical therapy or physical training or physical education or physical activity or physical inactivity).ti,ab.
41. dance therapy.ti,ab.
42. sedentary behavio?r.ti,ab.
43. 36 or 37 or 38 or 39 or 40 or 41 or 42
44. exp Complementary Therapies/
45. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
46. (hypnotism or hypnosis or hypnotherapy).ti,ab.
47. (acupuncture or homeopathy or homoeopathy).ti,ab.
48. (chinese medicine or indian medicine or herbal medicine or ayurvedic).ti,ab.
49. 44 or 45 or 46 or 47 or 48
50. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
51. (weightwatcher$ or weight watcher$).ti,ab.
52. (correspondence adj (course$ or program$)).ti,ab.
53. (fat camp$ or diet$ camp$).ti,ab.
54. 50 or 51 or 52 or 53
55. exp Health Promotion/
56. exp Health Education/
57. (health promotion or health education).ti,ab.
58. (media intervention$ or community intervention$).ti,ab.
59. health promoting school$.ti,ab.

60. ((school or community) adj2 program$).ti,ab.
61. (family intervention$ or parent$ intervention).ti,ab.
62. (parent$ adj2 (behavio?r or involve$ or control$ or attitude$ or educat$)).ti,ab.
63. 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62
64. exp Health Policy/
65. exp Nutrition Policy/
66. (health polic$ or school polic$ or food polic$ or nutrition polic$).ti,ab.
67. 64 or 65 or 66
68. exp OBESITY/pc [Prevention & Control]
69. exp Primary Prevention/
70. (primary prevention or secondary prevention).ti,ab.
71. (preventive measure$ or preventative measure$).ti,ab.
72. (preventive care or preventative care).ti,ab.
73. (obesity adj2 (prevent$ or treat$)).ti,ab.
74. 68 or 69 or 70 or 71 or 72 or 73
75. exp Controlled Clinical Trials/
76. exp Random Allocation/
77. exp Double-Blind Method/
78. exp Single-Blind Method/
79. exp PLACEBOS/
80. exp *Research Design/
81. exp Intervention studies/
82. exp Evaluation studies/
83. exp Cost Benefit Analysis/
84. (time adj series).tw.
85. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
86. exact{CONTROLLED-CLINICAL-TRIAL}.pt.
87. placebo$.ti,ab.
88. (matched communities or matched schools or matched populations).ti,ab.
89. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
90. (comparison group$ or control group$).ti,ab.
91. matched pairs.ti,ab.
92. (outcome study or outcome studies).ti,ab.
93. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
94. (nonrandomi?ed or non randomi?ed or pseudo randomi?sed).ti,ab.
95. randomi?ed.hw.
96. (cohort or survey: or qualitative).ti,ab.
97. 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96
98. exp Meta-Analysis/
99. meta-analys$.ti,ab.
100. metaanalys$.ab,ti.
101. meta analys$.ab,ti.
102. Cochrane.ab,sh,ti.
103. (review$ or overview$).ti.
104. review$.pt.
105. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
106. pooled analys$.ab,ti.
107. ((data adj2 pool$) and studies).mp. [mp=title, original title, abstract, name of substance, mesh subject heading]
108. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
109. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
110. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
111. 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110
112. (retrospective$ adj2 review$).ab,sh,ti.
113. (case$ adj2 review$).ab,sh,ti.
114. (record$ adj2 review$).ab,sh,ti.
115. (patient$ adj2 review$).ab,sh,ti.
116. (patient$ adj2 chart$).ab,sh,ti.
117. (peer adj2 review$).ab,sh,ti.
118. (chart$ adj2 review$).ab,sh,ti.
119. (case$ adj2 report$).ab,sh,ti.

120. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
121. 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120
122. 121 not (121 and 111)
123. 111 not 122
124. 22 or 35 or 43 or 49 or 54 or 63 or 67 or 74
125. 10 and 124 and 97
126. 10 and 124 and 123
127. 125 or 126
128. animal/
129. human/
130. 128 not (128 and 129)
131. 127 not 130
132. limit 131 to yr=1990–2004
133. exp CHILD/
134. exp ADOLESCENT/
135. exp INFANT/
136. (child$ or adolescent$ or infant$).af.
137. (teenage$ or young people or young person or young adult$).af.
138. (schoolchildren or school children).af.
139. (pediatr$ or paediatr$).af.
140. (boys or girls or youth or youths).af.
141. 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140
142. 132 and 141

DATA SOURCES

AMED
ASSIA
British Nursing Index
CAB Abstracts
CENTRAL (Cochrane Controlled Trials Register)
CINAHL
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
CRD (EED database) http://www.york.ac.uk/inst/crd
DARE
Embase
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC
Food Standards Agency - http://www.food.gov.uk/science/research/
HDA Evidence Base - http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA - http://www.ncchta.org
NICE – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus

For the update search (December 2005) Medline, Cinahl, PsychINFO and Embase were searched.

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Appendix 8

Workplace interventions to prevent obesity

EVIDENCE SUMMARY TABLES

1. BEHAVIOUR MODIFICATION/EDUCATION TECHNIQUES – INCLUDING HEALTH CHECKS AND WORKPLACE-MONITORED DIETS

SUMMARY

Evidence of efficacy for weight management/reduction

Evidence from ten randomised controlled trials (RCTs) and one controlled non-randomised trial (CCT) suggest that worksite behaviour modification programmes such as health screening (a ‘health check’) followed by counselling can result in short-term weight or body fat loss although there was a tendency for weight regain post intervention.

Reductions in body mass/body fat relative to control were noted in eight of the RCTs (Rose 1983 ; Brownell 1985 ; Peterson 1985; Shannon 1987 [data from Erfurt 1991; Gomel 1993 ; Gemson 1995; Hennrikus 1996; Proper 2003]; and one CCT (Cockcroft 1994). There was a wide range of results for the amount of weight lost. The two older studies reported reductions of about1 lb (2.2 kg) per week (Peterson 1985; Shannon 1987 [data from Hennrikus 1996), with a tendency to regain weight for those studies where this was followed up for 6–12 months post intervention (Brownell 1985; Shannon 1987; Gomel 1993). An extended UK-based RCT (Rose 1983) found very small weight reductions in intervention subjects (–0.4% in all men (*n* = 9734) and –0.7% in those at high cardiovascular risk (*n* = 1278) over 5–6 years. A non-randomised UK trial with a weak study design (CCT; Cockcroft 1994) found that those in the advice group lost more weight than those in the control group (*p* = 0.025 for time and advice measures).

A recent UK-based individual RCT looking at a single health check with 5-month follow-up (Hanlon 1995) found no significant difference in body mass index (BMI).

One weak RCT among male blue collar workers in Belgium (Braeckman 1999) resulted in an increase in BMI in the intervention compared with the control group despite reported reduction in energy and percent fat intake.

Evidence of efficacy for diet/physical activity outcomes

There is evidence from a systematic review of trials and six additional RCTs that worksite behaviour modification programmes can lead to improvements in nutrition and physical activity (PA). Evidence of longer term, post intervention benefits is limited.

Nutrition: A systematic review (Janer 2002) found that worksite behaviour modification programmes can show a positive effect on dietary fat intake (ranging from a decrease of 3% to an increase of 1.3% in energy from fat. Programmes can also result in an increase in the consumption of fruit and vegetables, ranging from 0.09 to 0.5 servings per day. Information about long-term effects was limited. The percentage of favourable change maintained at 6 or 12 months with regard to nutrition ranged from 0% to 65%. Successful programmes included a wide range of educational interventions (such as health screening followed by counselling) sometimes accompanied by environmental changes.

Four RCTs with nutrition outcomes were not included in, or were published since, this systematic review. Three RCTs (Sorensen 1996 ; Sorensen 1998; Sorensen 1999) found significant improvements in nutrition and one showed no benefit (Sorensen 2002). Only one trial monitored post intervention effects 1 year after the 2-year intervention (Sorensen 1996) and noted significant decreases in fat intake and increases in fruit and vegetable intake. It appeared from this study that longer, interactive intervention efforts (contests and classes) resulted in more positive outcomes than one-time activities (such as the kickoffs) or more passive efforts (use of printed materials).

Physical activity: There is systematic review evidence (Janer 2002) suggesting significant effects of educational sessions and informative materials on levels of PA. Information on the type of PA in each trial is not provided in the review. Out of nine trials using educational sessions and informative materials, and evaluating outcomes directly related to PA, four reported significant changes. One trial comparing both types of intervention found better results with educational activities focusing on behavioural changes, with 65% of at risk employees exercising weekly, compared with 50% when facilities were offered. Motivationally tailored intervention appeared to be more effective in nearly all the stages of readiness.

Two RCTs not included in, or published since this systematic review noted significant increases in PA in the intervention group (Emmons 1999) or significant increases in both intervention and control groups but no significant difference between groups (Nichols 2000). Only the latter trial had post-intervention follow-up (Nichols 2000; 6 months).

Evidence of corroboration in the UK

Of four intervention studies carried out in the UK (Rose 1983; Hanlon 1995; Cockcroft 1994; Leslie 2002) three (Cockcroft, Leslie and Rose) suggested benefits. In one UK study, individual health checks did not generate threat for most of the participants although the results for weight loss were not significant (Hanlon 1998). In a study addressing barriers to change, men chiefly cited a lack of nutritional information as a barrier to change while women predominantly cited the preferences of family members (Fleming 1997 [4]). Finance was not a factor in this particular study. A single set of case studies suggest that the more successful interventions include an interdisciplinary approach with broad representation including: health and safety and human resources, and implementers from high grades and strategic positions; initiatives integrated into worksite objectives; staff involvement, communication and realistic objectives; activities that go beyond the superficial and address root causes (Health Development Agency 2002).

EVIDENCE TABLE 1: BEHAVIOUR MODIFICATION/EDUCATION TECHNIQUES – INCLUDING HEALTH CHECKS AND WORKPLACE-MONITORED DIETS

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Hanlon 1994, Hanlon 1995	Individual RCT	1	++	Two workplaces in Scotland; one with internal control (engineering factory) and one serving as external control. *n* = 1371 (of 1632 selected). Mean age 44 years. 89% male	**Aim:** To determine the effectiveness of a health check and assess any particular benefits resulting from feedback of plasma cholesterol concentration or coronary risk score or both. Multi-factorial. Single individual healthcheck with trained counsellor giving feedback on blood cholesterol and risk score. 80% power at $p = 0.05$.	Single health check with 5 month follow-up	86% participation. Low attrition: 17% in intervention, 14% in control. No significant difference for BMI between full health check group and internal control ($p = 0.16$). No differences between groups to suggest that feedback of cholesterol concentration or risk score had additional impact on any of the outcomes.	**Health check:** No details of dietary content and diet assessment by self-reported change. Feasibility depends on resources for individual counselling.
Proper 2003	Cluster RCT	1	+	Three municipal services in Enschede, Netherlands. *n* = 299	**Aim:** To investigate effectiveness of an individual counselling intervention at the workplace. Seven	Nine months.	52% recruitment rate. 66% attended six or seven consultations. Significant reduction in % body fat (–0.79% [95% CI –1.43, –	PACE programme. No allocation concealment. No intention to treat (ITT).

				Mean age approx. 40 years. Approx. 65% highly educated. 25.6% female in intervention and 38.5% female in control group.	individual counselling sessions over 9 months to promote PA and nutrition changes plus written information vs. written information only (control). 90% power at $p = 0.05$.		0.16]; $p = 0.015$).	81% health test completion in intervention but only 70% in control group. Post-intervention effects unknown. Generalisable to motivated individuals. Complex and confusing paper.
Gomel 1993	Cluster RCT	1	+	Australian ambulance service. 28 Worksites $n = 488$ 83% male. Mean age 31–33 years.	**Aim:** Comparative efficiency of four programmes designed to decrease cardiovascular risk factors: Health risk appraisal (HRA) with feedback (30 mins); health education (HE) with standard advice (50 mins); behavioural counselling plus HRA and HE (>2 hours over 10 weeks); or all above plus incentives (e.g. lottery draw).	3 and 6 months, and 1 year.	88% participation. Recruitment = 431. 84% follow up at 12 months. BMI increased significantly over four assessments. Increase was on average 4% less for programmes including behaviour modification techniques ($p = 0.04$). Initially significant decrease in % body fat in these groups (when compared with programmes without behaviour counselling, $p = 0.02$) had returned to baseline levels at end of 12 months.	RCT – cluster + No allocation concealment but intention to treat (ITT) analysis.
Peterson	Individual	1	+	High tech	**Aim:**	16 week	80% attrition with professional	Individual but

1985	RCT			manufacturer. Blue collar industry Massachusetts. *n* = 63 24% male Mean percent over ideal weight 36.6% Average age 46.2 years Assembly line workers *n* = 36 Plant managers *n* = 10 Clerical *n* = 5 Unknown *n* = 12	To evaluate weight loss programmes led by volunteers compared with those led by professionals. 12 sessions.	programme plus 4-month follow-up.	leaders, 48% with volunteer leaders. If just completers, professionally led groups lost weight at a faster rate. Overall weight loss for both interventions including dropouts was 3.3 kg (7.3 lb). If just completers there was an overall weight loss of 8.5 kg (18.7 lb). No significance values stated. Professionally led – cost per kg lost index of US$7.88 and US$12.55 at post-test and follow-up respectively. In self-help condition, cost per kg lost index of US$4.38 and US$5.56 at post-test and follow-up.	stratified randomisation based on degree of overweight. Small study and no baseline data provided. No allocation concealment but ITT analysis. High attrition.
Rose 1983	Cluster RCT	1	+	Twenty-four factories (matched as far as possible for size, nature of industry and region, then one in each pair was randomly assigned to intervention condition). UK	**Aim:** To find out how far health education can change the major coronary risk factors in a population. Advice from factory medical departments about cardiovascular risks. Intensive advice for 13% of the population at high risk. Specific	5 or 6 years	5% of intervention site workforce re-examined per annum. The same 10% in control sites analysed biennially. Very small weight reductions in intervention subjects (–0.4% in all men (*n* = 9734) and –0.7% in those at high cardiovascular risk (*n* = 1278), after 5–6 years. No significance values stated.	No allocation concealment. Analysed by cluster (5% of workforce per annum) therefore ITT analysis not possible.

				18,210 men 40–59 years old	interventions for weight loss (for those >15% overweight (medical staff supplemented a little by a central visiting team).			
Shannon 1987	Assessed by Hennrikus 1996 systematic review. – considered an RCT with partial randomisation			**Site one:** Petroleum refinery **Site two:** Chemical plant – both parts of Atlantic Richfield. Forty-seven blue collar from site one, 56 white collar from site two. Wait list control comparison group.	To evaluate the effectiveness of a programme to promote weight loss and improve participant health behaviours and knowledge of nutrition.	Nine-week intervention plus 1-year follow-up.	103/115 participants (89%). 61% in treatment group completed programme. 84% control group had post-test data. Gender and site not related to weight loss. Weight loss in treatment group (mean 0.94 lb [0.43 kg] per week) significantly greater than control. At 1-year follow-up (data on 14 of 32 completers only), six had maintained weight, four had regained some but not all weight and four had continued to lose.	Original paper unavailable. Data extracted from Hennrikus 1996 .
Erfurt 1991	RCT	1	+	Four manufacturing plants, Michigan USA. Mean age 39–43 years 32–36% were above ideal weight	**Aim:** To compare effectiveness of four models at controlling high blood pressure, obesity and cigarette smoking. 1) Control, Health risk appraisal *n* = 2448.	3 years	Sample of 600 selected for re-screening (500 in site 4). 80–84% re-screened. For those employees overweight by 20% or more at baseline, significant differences across sites in mean weight change. Major improvements in risk levels were found with the addition of routine follow-up	Treated as RCT by Janer 2002. No allocation concealment and no ITT though 75–88% of employees screened at baseline and 80–84% re-screened at follow-up.

				In re-screened sample 87–95% were male, and mean age was 43.7–46.3 years. 66–78% white.	2) As 1) plus media promotion, health improvement classes *n* = 1374. 3) As 2) plus support, encouragement *n* = 2089. 4) As 3) plus activities in worksite *n* = 1893.		counselling and a menu of interventions. Sites one and two showed gains (+3.1 and +0.6 lb [+1.41 and +0.27 kg]) and mean reductions in sites three and four (–1.2 and –4.7 lb [–0.54 and –2.13 kg]) ($p < 0.001$). Average weight gain in site one and weight loss in site four statistically significant ($p < 0.01$ and $p < 0.001$).	
Gemson 1995	Individual RCT	1	+	Large financial services firm in New York City. 161 employees who volunteered by a periodic health examination. 81% male. Mean 46.2 years old in health risk appraisal (HRA) and 46.5 in control. 81% white. 50% with College/professional degree in HRA and 60% in control group.	All the volunteers received a physical examination by a registered nurse and completed a questionnaire. Half were then randomised to receive a computerised HRA with counselling. Controls received no report or counselling. No power calculation reported.	Baseline examination and feedback. 6-month follow-up.	53% re-attended in HRA group and 59% in control group. There were no significant differences in weight between the two groups but a trend towards an improvement in the HRA group.	No allocation concealment. No ITT analysis. Poor follow-up.
Cockcroft 1994	CCT	2	+	London teaching hospital. 297	Volunteers who completed the	Baseline screenin	28% re-attended.	Treat as *very weak* CCT.

				volunteers to an invitation to attend a health screening session run by the occupational health/health psychology units. No socio-economic data provided.	screening questionnaire and health measurements were assigned to results only (control) or to receive advice and set targets for changing their lifestyle (intervention).	g and advice. 6-month follow-up.	Those in the advice group lost more weight than those in the control group (BMI [kg/m^2] in advice group was 24.90 at baseline and 24.36 at follow-up, vs. 24.48 at baseline and 24.49 at follow-up in the controls); $p = 0.025$ for time and advice measures.	UK-based but no allocation concealment, no baseline data, No ITT and poor follow-up.
Braeckman 1999	RCT	1	+	Four worksites in Gent Belgium. *n* = 928 100% men, average age 43.7 (range 35–59) years Reported as predominantly blue collar and White.	**Aim:** To evaluate the effect of a short-term, low intensity nutrition intervention on blood lipids, nutrition knowledge and dietary changes. Individual health check with risk feedback, plus mass media and educational sessions. Control group received a written summary of their results without further information or advice although referred to GP if abnormal values.	3 months	Baseline response 83% (*n* = 770). Follow-up response 82% of baseline respondents (*n* = 638). A net reduction in the intake of total energy and the percentage of energy from total fat was reported in the intervention group (–1.42 kcal [5.95 kJ]/day and –1.56% respectively; $p < 0.05$ in both cases) but BMI increased by 0.26 kg/m^2 ($p < 0.001$) compared with control.	No allocation concealment. Small study (only four sites randomised) and some modest baseline differences. No ITT but >82% follow-up.
	Individual RCT	1	+	Department store workers who	**Aim:** To evaluate the	End of 16-week	57.5% attrition in study 1, 42.6% in 2 and 33.8% in 3.	Individual but stratified

				were Union members. New York City, USA. Lower-middle class socioeconomic status (SES). 100% women. *n* = 172 (40 in study 1, 61 in study 2, 71 in study 3). No difference between studies or treatment groups in mean age, weight, or percentage overweight.	effectiveness of three consecutive weight loss programmes of lay vs. professional group leaders, frequent (four × weekly in study one, three × weekly in studies 2 and 3) vs. once weekly meetings, and programmes on/off site.	programme plus 6 months later (study 1) or 1 year later (studies 2/3).	(Attrition rates lower for groups with frequent meetings.) Attrition rates in study 1 lower in groups led by lay therapists (31 and 50%) than professional (75 and 80%) ($p < 0.05$) and in frequent treatment groups (31 vs. 50%, 75 and 82%) ($p < 0.05$). Average weight loss for all subjects completing treatment in study one at 16 weeks was 3.6 kg and at 6 months, 1.2 kg. No significant difference between groups. Post-treatment mean weight loss in study 2 was 9.2 lb (4.17 kg), and 8.6 lb (3.90 kg) at 1-year follow-up. In study 3 weight loss was 7.3 lb (3.31 kg) at post treatment, and 5.9 lb (2.68 kg) at 1-year follow-up. Attrition, weight loss and maintenance similar in lay and professionally led groups in studies 2/3, but costs per pound loss per participant was US$6.35 for the lay leaders and US$18.81 for the professional. No significance values stated.	randomisation based on degree of overweight. No allocation concealment. No ITT analysis. Incorporates Stunkard 1980

Evidence of efficacy (internal validity) for diet/physical activity outcomes								
Janer 2002	Systematic review	1	+	Literature search date unknown (circa 1984–2000) and Medline+ reference list only. Forty-five controlled studies. Fourteen controlled trials with a nutrition outcome and 13 controlled trials with a PA outcome were included .	Review of workplace health promotion trials re major cancer risk factors (diet, obesity and PA amongst other topics). Studies included an educational intervention (such as health screening followed by counselling) and, sometimes, environmental changes.	Various	**From 14 controlled trials with a nutrition outcome:** The increase in vegetable servings per day was reported in three trials and ranged from 0.09 to 0.19. Five studies evaluated fruit intake and four of these obtained statistically significant increases ranging from 0.11 to 0.24 servings per day. In the three studies reporting both fruit and vegetable use, increases ranged from 0.18 to 0.5 servings per day. Changes in fat intake were statistically significant in six of the ten available studies. The magnitude of the change ranged from a decrease of 3.0% to an increase of 1.3% in energy from fat. Five studies included more than one period of follow-up. The percentage of favourable change maintained at 6 or 12 months with regard to the intake increase or reduction ranged from 30 to 65%. **From 13 controlled trials with a physical activity outcome:** Out of nine trials using educational sessions and	Unfocused review question and wide range of types of intervention and outcomes covered. Errors in paper (reference numbers missing in text). Overlap with other reviews and topics – incentives, PA, etc. NB: Shephard 1992 is a case study looking at a PA initiative – see excluded studies. Two studies cited in an older systematic review Roe 1997 are not included: Hanlon 1995 /Hanlon 1994 [17] and Rose 1983 /Bauer 1985. Both are included as individual studies under weight outcomes.

							informative materials and evaluating outcomes directly related to PA, four reported significant changes. Significant changes were reported in three of four trials offering facilities, time and space. One trial comparing both types of intervention found better results with educational activities focusing on behavioural changes, with 65% of at risk employees exercising weekly, compared with 50% when facilities only were offered. A motivationally tailored intervention appeared to be more effective in nearly all the stages of readiness. Information from the review on follow-up is limited. In a non-randomised controlled study reporting a 7-year follow-up, participation was still 13% – the same as at the end of the intervention period (Shephard 1992).	This review includes the Take Heart (Glasgow 1995) and Take Heart II (Glasgow 1997) studies. ***[?]***
Sorensen 1996	Cluster RCT	1	+	Worksites in manufacturing, communications, public service and utilities, USA Blue collar 51% Managerial 22%	**Aim:** To evaluate the effectiveness of the Working Well intervention on Cancer risk factors. Multi-level interventions at	Two-year intervention and 1-year follow-up.	Overall response to baseline survey 69%; 71% response to follow-up. Attrition not stated. Adjusted difference between intervention and control of % energy from fat consumption – 0.35 (SE 0.16)% (*p* < 0.05).	No allocation concealment. ITT analysis by worksite by only about 70% response at each site.

				Clerical 22.4 Multiple 4.5%* Two groups with 54 sites each (28,000 employees).	individual, community and organisational levels including activities, posters and brochures, self assessment and self-help materials, campaigns and contests, direct education and environmental changes.		Adjusted % increase in fruit and vegetable intake 5.6 (SE 1.3)% – consistently higher in intervention and negligible in control (*p* < 0.001). It appeared that longer, interactive intervention efforts (contests and classes) resulted in more positive outcomes than one-time activities (such as the kick-offs) or more passive efforts (use of printed materials).**	Not included in Roe 1997 or Janer 2002. Complicated statistical analysis. The **Working Well** Trial *Information from Abrams 1994. **Information from Patterson 1997.
Sorensen 2002	Cluster RCT	1	+	Fifteen manufacturing worksites (of 41 eligible) in north-east USA, all with probable use of chemical hazards. Baseline variations between groups. 65–71% blue collar (hourly paid) workers. 12.4–15.6% ≤30 years old. 23.5–18.6% 51–	**Aim:** To assess whether health promotion + occupational health and safety intervention vs. standard health promotion (see above) results in significant smoking cessation and increase in fruit and vegetable intake in workers in general and blue collar workers in particular.	Length of intervention 2 years	80% response at baseline (*n* = 9019) and 65% response at completion (*n* = 7327). 5156 responded on both occasions and data presented on this group. No significant differences for mean changes in fruit and vegetable consumption in either group or between groups. No significant difference between men and women in intervention effect (*p* = 0.31) and no difference by job type (data not shown).	The **WellWorks 2** study. Good allocation concealment. Some baseline differences between groups and no ITT analysis. Intervention to address cancer risk rather than obesity prevention and issue under test in occupational health and safety involvement.

				60 years old. 57–66% men.				
Emmons 1999	Individual RCT	1	+	26 worksites in north-east USA of which 22 sites and 2291 workers were included in the final analysis. Circa 57% male, Mean age approx. 42 years, approx. 53% blue collar, approx. 93% white, approx. 83% completed high school.	**Aim:** To present the results regarding behaviour change found among completers of three health behaviour assessments as part of their worksite's participation in the Working Healthy project. A development from the Working Well Trial (see above) but with a focus on PA. Individually focussed activities and changes to catering and exercise environment vs. self-help.	Length of intervention 2.5 years	63% of eligible workers completed baseline survey. 51% completed interim survey. 83% who completed interim also completed final survey. Employees in the cohort were more likely to be male, older, White, and have higher educational levels. Subjects in the intervention condition were significantly more likely to report engaging in physical exercise at the time of the interim assessment ($p < 0.0001$) and the final assessment ($p < 0.03$), reflecting a 30% increase in activity, compared with a 4.3% increase in control. The intervention group showed a marginal increase in fruit and vegetable consumption at the final survey, a 7% increase vs. a 7% reduction in controls ($p < 0.06$ in the univariate model).	The **Working Healthy Project**. No allocation concealment. 51% completion at interim and no ITT analysis. Included in Proper 2003 review.
Sorensen 1999	Cluster RCT	1	+	Twenty-two community health centres in north-east USA.	**Aim:** To evaluate the results of an intervention to	Length of intervention 19.5 months.	Response rate 87% at baseline ($n = 1359$) and 76% at follow-up. 47% response to both.	**Treatwell 5-a-Day** study. No allocation

				n = 1588 84% female. Age range unknown. 59% white/other 23% Latino 18% non-Latino black 80% educated to at least high school. Skill, service, clerical 29.2% Paraprofessional/ technical 20.2% Professional 36.2% Manager 14.3%	increase fruit and vegetable consumption. Three groups: 1) control; 2) worksite intervention – information/education sessions and activities; 3) worksite + family – as 2) but involvement of workers' children to produce a cookbook. Plus environmental changes. 74% power at *p* = 0.05.		After controlling for baseline variations total fruit and vegetable intake increased by 19% in the worksite plus family, 7% in the worksite and 0% in the control (*p* = 0.05). This reflects a one half serving increase in the worksite plus family to control grou*p* (*p* = 0.018). No significant difference between worksite only intervention grou*p* and control (*p* = 0.47). Gender, education and occupation not significantly associated with level of change.	concealment. Self-administered well referenced questionnaire. Community health workers may be more motivated than general population. Only 47% response at follow up and no ITT.
Nichols 2000	Individual RCT	1	+/– (weak)	San Diego, CA, USA. Workers who did not engage in regular PA in two worksites. *n* = 82 Data from final sample (only): majority White women, mean age 42.0 ± 9.7 years.	**Aim:** To evaluate the effects of a 3-month work-site behavioural skills training course on the adoption and 6 month maintenance of PA in middle-aged adults. The intervention group met weekly at the worksite. They were encouraged to participate in a semi-supervised exercise	Three-month interval. Plus 6 month follow-up (9-months post).	78% recruitment (*n* = 64). 73% of these subjects completed the 12-week and 71% completed the 6-month follow-up. Energy expenditure increased for both groups but was marginally greater for the intervention grou*p* (*p* = 0.07). Both groups showed a large increase in moderate and vigorous PA with no significant differences between groups.	No allocation concealment or ITT and <80% follow-up. No baseline data, low power and potential contamination.

					programme at a fitness facility. Controls were given membership of the fitness facility but received no exercise or behavioural training.			
Sorensen 1998	Cluster RCT	1	+/– (weak)	Twenty-four predominantly manufacturing worksites in north-east USA, all using known or suspected carcinogens. *n* = 9648 No social data presented.	**Aim:** To assess effects of health promotion intervention on changes in dietary habits and smoking cessation. Integrated programme with three key elements: 1) joint worker/management planning and implementation; 2) work-site environmental changes and increased availability of healthy foods; 3) targeted health education programmes.	Length of intervention 2 years.	61% response at baseline (5914/9648) and 62% at completion (5406/8667). 2658 responded on both occasions and data presented on this group. Significant differences between intervention and control worksites included reductions in the percentage of energy consumed as fat (2.3 vs. 1.5% and increases in servings of fruit and vegetables (10 vs. 4% increase). No difference in intervention effectiveness by job category for fruit and vegetables and dietary fat outcomes.	The **WellWorks** study. No allocation concealment. Well referenced self-administered semi-quantitative questionnaire. No baseline data though worksites paired according to characteristics before randomisation. Intervention to address cancer risk rather than obesity prevention. Only circa 50% follow-up and no ITT analysis.

Evidence of corroboration (external validity)
Evidence of salience – Is it appropriate for the UK?

First author	Study design	Research type	Research quality	Study population	Research question	Length of follow-up	Main results	Confounders/comments
Hanlon 1995; Hanlon 1994	Individual RCT	1	++	One workplace, Scotland – Engineering factory, as above.	As above.	As above.	As above.	As above.
Leslie 2002	Individual RCT	1	++	Single petrochemical worksite in Scotland, UK.	As above.	As above.	As above.	As above.
Rose 1983	Cluster RCT	1	+	UK factories	As above.	As above.	As above.	As above.
Cockcroft 1994	CCT	2	+	London teaching hospital.	As above.	As above.	As above.	As above. Very weak non-randomised study.
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Hanlon 1998	Observational data from RCT	3	++	One workplace, Scotland – Engineering factory, as above. Mean age 44 years. 89% male	Individual health check – see above.	12-month follow-up.	Subjects who considered themselves to be at risk were more likely to comply with advised behaviour changes. Those who returned for follow-up and had reported one or more of the desired behaviour changes were more likely to be married or cohabiting, none of the other sociodemographic variables was significantly associated with behavioural change.	Characteristics of those who responded to the **Healthcheck** (Hanlon 1995). Self-reported outcomes.

Kelly 1999 (as for Hanlon 1998, above)	Observational data from RCT	3	++	As above.	As above.	As above.	Health checks in this setting, which involved screening for coronary heart disease, did not generate threat for most of the participants. The typical response to the check was positive and one that seemed to prompt an intention to change behaviour in a beneficial way to the individual.	Observational data from the **Healthcheck** study (Hanlon 1995). Self-reported outcomes.
Fleming 1997	Cross-sectional survey	3	+	Employees in seven worksites in the industrial, educational and health sectors in Galway, Ireland. *n* = 2528 38% male 70% men and 77% women ≤30 years.	**Aim:** To obtain a profile of the dietary behaviours of workers and explore potential barriers to change.	N/A	**Response rate:** 69% industry, 91% health sector and 48% education. Men chiefly cited a lack of nutritional information as a barrier to change while women predominantly cited the preferences of family members. Finance was not a factor for any particular social group. Interest in dietary change was especially evident in men in their 30s.	Not UK but Ireland. Self-administered questionnaire. Methodology and analysis unclear.
Health Development Agency 2002	Case Studies	3	+	Sixteen case studies at NHS worksites in the UK implementing the Health at Work (HAW) scheme.	Single semi-structured interviews (60–90 min) with the implementers of HAW at each site.	–	What works? Summary: • An interdisciplinary approach with broad representation including health and safety and human resources; • Implementers from high grades and strategic positions; • Initiatives integrated into worksite objectives; • Staff involvement and realistic objectives; • Communication with all staff;	

							• Activities that go beyond the superficial and address root causes.	
Cockcroft 1995; Cockcroft 1994	Observational data from CCT	3	+	See above.	See above.	See above.	Belief in the effectiveness of lifestyle change in promoting health and anxiety about health can influence uptake of screening.	Very weak non-randomised study.

2. INCREASED WATER PROVISION

SUMMARY

No relevant studies found.

3. HEALTHIER FOOD PROVISION

SUMMARY

Evidence of efficacy for weight maintenance/reduction
Only one intervention, a controlled before and after study (Cook 2001) was found with a weight outcome. The intervention, which consisted of nutrition displays and a monthly 30-min workshop (6-month intervention and 12-month follow-up), found there was no significant self-reported difference in mean BMI or waist circumference.

Evidence of efficacy for diet outcomes
One systematic review (Seymour 2004) concluded that worksite intervention studies targeting healthier food provision by information strategies such as labelling and/or changes in food availability or cost can encourage healthier eating. Two additional RCTs (Beresford 2001; Steenhuis 2004) were included in, or published since, the review. The US study, with measures 3-, 8- and 12-months post-intervention, found an effect of 0.3 servings of fruit and vegetables per day ($p < 0.05$) (Beresford 2001). This intervention (Seattle 5 a Day) built on lessons learnt from the Working Well Trial (included in the Seymour review, 2004). The study in the Netherlands, which looked at combinations of educational and food supply programmes, found no significant effects on consumption data (Steenhuis 2004).

Evidence of corroboration
The only relevant UK study, a controlled before and after study of the Heartbeat Award Scheme (Holdsworth 2004), suggested that worksite interventions can bring about changes to catering provision that may impact on dietary intakes. This study, with measures taken 6 months before and 6 months after the intervention, found significantly more positive change solely in the intervention sites for increase in fruit consumption ($p = 0.029$), reduction in consumption of fried foods ($p = 0.044$) and sweet puddings ($p = 0.042$), and more change to using lower fat milks ($p = 0.037$).

The authors of a cross-sectional survey in England of Heart Beat Award managers and caterers, government and health professionals, recommended improved promotion of the schemes and better integration with other health programmes (The Research Partnership 2000. Additional data from a single set of case studies found that factors most likely to make a canteen-style five-a-day intervention work are commitment from the top, enthusiastic catering management, a strong occupational health lead, links to other on-site health initiatives, free or subsidised produce and heavy promotion and advertisement at point of purchase (Healthlinks 2003).

EVIDENCE TABLE 3: HEALTHIER FOOD PROVISION

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Cook 2001	CBA	2	++	Two South Auckland manufacturing worksites. *n* = 347 at intervention and *n* = 262 in control Voluntary participation and study open to male hourly paid employees. 40% obese at baseline. Huge baseline variations in intervention vs. control sites. Age (mean ± SD) 35.0 ± 11.2 vs. 42.9 ± 11.7 years. European 25.7 vs. 39.7%; ≥ 4 years at	**Aim:** To evaluate effectiveness of health promotion programme targeting dietary behaviours and PA in male hourly-paid workers. Nutrition displays in the cafeteria and monthly 30-min workshop for 6 months. Delayed intervention in control worksite.	After 6-month intervention and at 12 months.	Recruitment 38% at intervention (*n* = 132) and 46% at control (*n* = 121). Follow-up = 94% at 6 months and 89% at 12 months. Statistically significant differences between the intervention and control groups, in mean fat score (*p* = 0.0003), increase in vegetable intake (*p* = 0.007) and PA (*p* = 0.005). There was no significant difference in mean BMI or waist circumference between the groups.	Self-reported nutrition and PA measures. Ethnic variations may limit generalisability to UK.

				high school 50 vs. 29.8%, etc.				
Evidence of efficacy (internal validity) for diet/physical activity outcomes								
Seymour 2004 .	Systematic review	2 (impossible to tell if any included studies were RCTs)	++ (for systematic review overall)	Ten workplace studies, six of which were considered to be a strong or very strong research design.	**Aim:** All articles that included a nutrition intervention with an environmental or policy component conducted in an English-speaking industrialised country.	Various	The authors concluded that of ten worksite intervention studies targeting healthier food provision, most showed statistically significant changes in improved sales of healthier foods. Successful interventions included information strategies (eg labelling) and/or changes in availability and price of healthier foods.	Included studies of 'strong/very strong' research design: Dubois 1996 Jeffery 1993 French 2001 Levin 1996 Schmitz 1986 Wilbur 1981 Some studies had an incentive element.
Steenhuis 2004	Cluster RCT	1	+/– (weak)	The Netherlands. Seventeen worksite cafeterias of large companies or government organizations with mainly white collar workers. *n* = 5425 62% male. Mean age 38 (range 18–64) years. 60% with a high level of education.	**Aim:** To describe a study of effectiveness of two environmental interventions alongside an educational programme in reducing fat intake and increasing fruit and vegetable intake. Four conditions tested: the educational programme; the food	One-month and 6-months post intervention.	30.1% response at baseline. 76.4% of the above group at 1-month post and 61.3% at 6-months post. For the whole study population, no significant effects on consumption data were found for any of the programmes.	No allocation concealment. <80% follow-up with no ITT and some baseline differences. Complex statistical analysis.

					supply programme plus educational; the labelling programme; plus educational and a control group.			
Beresford 2001	Cluster RCT	1	+	Seattle, OR, USA. Twenty-eight worksites with cafeterias. *n* = 2828. Mean age 41.8 years. 58% female. 32% college graduates and a further 23% with postgraduate education. >86% white.	**Aim:** To evaluate the effect of the Seattle 5 a Day worksite programme to increase fruit and vegetable consumption. In each intervention worksite an employee advisory board implemented changes in the cafeteria and targeted individual behaviour (posters, brochures, paycheck inserts, etc.) informed by the stages of change theoretical model.	3-, 8- and 12-months post intervention with cohort of baseline respondents. Two years with cross-sectional data.	Response rate at baseline = 80% on average. At 2-year follow-up response rate = 71% on average. Results from the food frequency questionnaire suggested a fruit and vegetable increase of 0.5 servings per day in the intervention vs. 0.2 in the control worksites, an intervention effect of 0.3 ($p < 0.05$). Other measures of fruit and vegetable consumption, including unobtrusive indicators, supported the effectiveness of the intervention.	**Seattle 5 a Day.** Building on the **Working Well** trial. No allocation concealment. <80% follow-up and no ITT analysis. RCT not included in Seymour 2004 so retained for information.
Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Holdsworth 2004	CBA	2	+	Six workplaces in Leicestershire, UK. (Four intervention,	**Aim:** To evaluate changes in employee eating habits following Heartbeat Award	Measures taken 6 months before and 6 months after	Response rate to post-intervention survey (structured food frequency questionnaire) was 73.2% of possible employees in intervention sites, and 62.6% of possible employees post-intervention.	**Heartbeat Award Scheme** **Excluded from efficacy due to study design.**

				n = 453 employees; two control *n* = 124 employees) Intervention groups: Female 70.5% Age 19–45 years 62.2% Control groups: Female 33.5% Age 19–45 years 63.6% 88.8% of intervention, and 78% of control group in top three social class groups. 92.9% of intervention and 90.3% of control were White.	scheme and to determine if this change was due to the intervention. Four intervention worksites had received Heartbeat Award, Minimum criteria for award was that at least one-third of the dishes on the menu were 'healthy choices'. Control sites had been unsuccessful in receiving award.	intervention.	Significantly more positive change solely in the intervention sites for increase in fruit consumption ($p = 0.029$), reduction in consumption of fried foods ($p = 0.044$) and sweet puddings ($p = 0.042$), and more change to using lower fat milks ($p = 0.037$). No comparative changes in control worksites.	Inappropriate control group thus treated as CBA but retained for information since based in the UK. Self-reported dietary change. Self-selection by more motivated individuals inevitable.
Evidence for implementation – will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Healthlinks 2003	Case studies	3	+	Twelve worksites in Merseyside, UK.	Review of worksites implementing the Take Five initiatives	Various.	The factors most likely to make a canteen style five-a-day intervention work are: • Commitment from the top;	Evaluation report of the **Take Five** initiative.

				Factories *n* = 4 Hospital trusts *n* = 2 Local government *n* = 3 Pharmaceutical *n* = 2 Supermarket *n* = 1	to increase fruit and vegetable intakes in canteens.		- Enthusiastic catering manager; - Strong occupational health lead; - Linked to some other health initiative on site (e.g. Health Focus Group); - Free or subsidised produce; - Heavily advertised and promoted at point of sale.	
The Research Partnership 2000	Cross-sectional survey	3	+	Mailed questionnaire to Heart Beat Award (HBA) scheme managers (*n* = 81), local and health professionals who may or may not be involved in HBA or similar schemes (135), HBA caterers (210), non-HBA caterers (75), local government professionals involved with Best Value (71), Local Agenda 21 (140) or Environmental Health Action Plans, LEHAP (99) in England. No socio-economic details.	**Aim:** To assess the status of the HBA scheme as it completes its tenth year, to assess its value as a public health tool and to consider its future development. Questionnaire survey carried out by consultants (The Research Partnership) on behalf of the Health Education Authority.	N/A	Response rate = 24% (811/3244), with a range from the different groups consulted of 3–38% response, higher amongst those directly involved with HBA schemes (e.g. HBA managers 35%, HBA caterers 38%). Of local authority consultees who had stopped using the scheme, the primary reasons were lack of resources, lack of interest and/or a perceived need for a more locally tailored scheme. The main barriers for those who had not started a scheme were lack of resources and perceived low priority or interest. The main benefits for the local population were thought by organisations/caterers running the scheme to be the increased availability of healthy food choices (97%/89%) and a raising of awareness of health issues (71%/80%). HBA managers saw insufficient national publicity as the	Mailed questionnaire responses only and low response rate. Findings also relevant to Community two review.

							main challenge faced by those running schemes, followed by the difficulty in recruiting caterers to apply and insufficient funding. HBA caterers felt that insufficient customer awareness was the main challenge (mentioned by 85% and 43% gave this the top ranking). The authors concluded that ‘essential’ recommendations were improved promotion and research into potential improvements (integration with other health programmes, multi-agency working, enhanced support and guidance to caterers), while ‘desirable’ recommendations were greater flexibility (perhaps via a graded scheme) and improved regional co-ordination.	

4. INCENTIVES – FINANCIAL, COMPETITION AND OTHER

SUMMARY

Evidence of efficacy for weight maintenance/reduction
Three US-based RCTs (Forster 1985]; Jeffery 1985; Jeffery 1993) suggested that payroll incentive schemes were either only effective in the short term (i.e. during period of intervention) or ineffective for weight control. Follow-up data suggested that where weight was lost this was regained during the period (of 6–12 months) after the intervention (Forster 1985). The schemes included weigh-in, health education/group sessions and the provision of self-motivating materials.

Evidence of efficacy for diet/physical activity
One controlled before and after study (French 2001) concluded that, when prices of low-fat snacks in 55 vending machines were reduced by 10, 25 and 50%, the total number of items sold increased by 9, 39 and 93% respectively. The effect on energy consumption was unknown.

Evidence of corroboration
No UK corroborative studies found.

EVIDENCE TABLE 4: INCENTIVES – FINANCIAL, COMPETITION AND OTHER

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Forster 1985 [220]	RCT	1	+	University of Minnesota, USA employees. *n* = 131 82% women Faculty = 11.5% of group instruction/attendance optional group only. Administrative/techical = 35.7 % overall. Clerical = 57.5% overall. Health promotion practitioner.	**Aim:** To evaluate a weight control programme using financial incentives through payroll deductions; weight loss self-instruction manual and food records for monitoring eating behaviours and calorie intake; weigh ins and group educational sessions 2 × 2 factorial analysis of components.	6-month follow-up. (1-year follow-up in further study.*)	4% participation. Overall attrition 21.4%. Mean weight loss 12.2 lb (5.53 kg) (or 10 lb [4.54 kg] by ITT analysis) was highest in those using self-instruction and not receiving incentives for weight loss, but there was no statistically significant difference between groups. Weight loss was positively associated with attendance at weight ins and educational sessions. Men more likely to achieve goals than women ($p < 0.004$), although small number of men may confound this. (After 1 year, over both studies (Forster (1985) and Jeffery (1985))), 79% regained some weight and 33% regained at least as	Some baseline differences and no allocation concealment. *Forster 1988

							much as they lost. Percentage maintaining post-treatment weight was not statistically significant. Differences between occupational groups of % maintaining post-treatment weight were not statistically significant (*p* = 0.07).*	
Jeffery 1993	RCT	1	+	Minnesota, USA. *n* = 2041 Thirty-two worksites (68.8% private sector in treatment and 56.3% in control). 400–900 employees (55% female in treatment group and 52.9% in control). 41% managerial/professional 41% clerical/sales 18% blue collar Mean BMI for both men and women 10% above actuarial ideals. Professional Health	**Aim:** To evaluate the effectiveness of a work-site health promotion programme in reducing obesity and prevalence of cigarette smoking. Health education classes combined with a payroll-based incentive scheme. Four rounds of 11 bi-weekly sessions over 2 years.	Two years concurrent with intervention.	20% participation in weight control programme. 23% reenrolment. Ineffective for weight and BMI change over 2 years, and no significant differences between treatment and control (all *p* > 0.50). Average weight loss 4.8 lb [2.18 kg] in intervention group. 83% participants in weight control programme were female. 43% were professional, 45% were clerical and 13% were blue collar. Blue collar workers, men and those who were less overweight were less likely to join programme.	No allocation concealment and no ITT but high total response rate (93%). **Healthy Worker Project.**

				Educators.				
Jeffery 1985	RCT	1	+	University of Minnesota, USA employees. *n* = 36 (of 675 invited). Two groups. Female = 86% overall Mean age = 42 years 22% faculty 45% administrative/technical 33% clerical/ Intervention delivered by a Health Promotion practitioner.	**Aim:** Pilot study for above To evaluate the effectiveness of a self-motivation programme of biweekly payroll deductions on weight control. Treatment and delayed treatment. Intervention was a self-motivation programme with incentives through payroll deductions.	6-month intervention + 3-month extension. (1-year follow-up in further study, Forster et al 1998)	6% participation. Attrition 11% in control group. Effective for weight loss in the short term (mean 12.3 lb [5.58 kg]). Weight losses significantly related only to attendance at weigh-ins ($p < 0.001$). Those who re-enrolled for further 3 months were three times more likely to lose weight than those who stopped ($p < 0.005$). Weight regained within 1 year (see above*). There were no statistically significant differences between job categories and age in terms of weight lost. The authors concluded that without continued intervention, worksites do not appear to offer special advantages in aiding weight control (Forster et al. 1988)	Modest baseline differences, no allocation concealment and no ITT analysis. However 94% completed the programme and 88.4% completed more than half the weigh-ins. Generalisable to motivated workers only.
Evidence of efficacy (internal validity) for diet/physical activity outcomes								
French 2001 .	CBA	2	+	Twelve worksites and 12 schools in Minneapolis, USA.	**Aim:** The effects of pricing and promotional strategies on purchases of low-fat snacks from vending	Twelve-month intervention with pricing levels crossed in	When prices of low-fat snacks in 55 vending machines were reduced by 10, 25 and 50%, the total number of items sold increased by 9, 39 and 93% respectively. The effect on	

					machines.	a Latin square design.	energy consumption was unknown.	

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Evidence for Implementation – Will it work in the UK?								
First author	**Study design**	**Research Type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**

5. INCREASED ACTIVE TRAVEL TO AND FROM WORK – INCLUDE PEDOMETERS

SUMMARY

Evidence of efficacy for weight management/reduction
No studies with weight outcomes found.

Evidence of efficacy for diet/physical activity outcomes
There is evidence from one low quality controlled randomised study carried out in the UK (Mutrie 2002) and one before and after study in Finland (Oja 1991) that workplace promotional strategies can increase the number of people travelling actively to work. The UK study (Mutrie 2002) found that the intervention group was almost twice as likely to increase walking to work as the control group at 6 months (125 min walking per week vs. 61 min in the controls at 6 months; odds ratio (OR) 1.93, 95% CI 1.06, 3.52). The intervention (provision of written interactive materials) was not successful at increasing cycling. Of those who received the intervention at baseline, 25% (95% CI 17, 32) had increased their active commuting stage of change to action of maintenance at 12 months.

Evidence of corroboration
One study carried out in the UK.

EVIDENCE TABLE 5: INCREASED ACTIVE TRAVEL TO AND FROM WORK – INCLUDE PEDOMETERS

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/CIs for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
No studies with weight outcomes found.								
Evidence of efficacy (internal validity) for physical activity outcomes								
Mutrie 2002	RCT	1	–	Glasgow University Hospital and Health Board. Three worksites. 64% women. Mean age 38 (range 19–69) years. 76% from socio-economic classes 1–2 (professional and managerial), and most of remainder (20%) in class 3.	**Aim:** To determine if a self-help intervention delivered via written interactive materials could increase active commuting behaviour (walking and cycling). Cognitive behavioural intervention for pre-contemplating workers thinking about, or doing, some regular walking or cycling to work. Receipt of a pack entitled **'Walk in to work out'**. Control group received pack 6 months after intervention group.	One year with 6-month analysis.	Recruitment = 295 assigned to intervention (*n* = 145) or control (*n* = 150). 100% response at baseline. 66% at 6 months and 56% at 12 months. The intervention group was almost twice as likely to increase walking to work as the control group at 6 months (125 min walking per week vs. 61 min in the controls at 6 months; OR 1.93 [95% CI 1.06–3.52]). The pack was not successful at increasing cycling. 25 (95% CI 17–32)% of those who received the intervention at baseline had increased their stage of active commuting stage of change to action of maintenance at 12	Good allocation concealment. No ITT, <80% follow-up and no baseline data.

							months. There were no effects noted from the intervention for gender or age.	
Oja 1991	Before and after	2	+	Paper manufacturing company, Finland. Three sites. *n* = 1200	**Aim:** To evaluate a work–commuting exercise promotion programme. Promotion of active commuting to work through posters, newsletters, etc., with emphasis on safe routes. Improvement of traffic conditions.	6 months	7% of respondents to post-programme questionnaire reported increasing work commuting exercise, particularly among older workers. 20% reported increase in leisure time exercise. No significance stated.	Grading to be confirmed. Methods paper available in Finnish only – to be translated if higher quality studies not obtained from review of wider community interventions.

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study Population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Mutrie 2002	RCT	1	+	Glasgow University Hospital and Health Board.	As above.	As above.	As above.	As above.
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Mutrie 2002	Qualitative data from a	3	++	As above	Five focus groups to look at barriers	6 months	Walkers overcame barriers more than cyclists. Barriers to	

	CCT			*n* = 27 (from 295)	to intervention: Maintenance walkers *n* = 3 men, *n* = 7 women Relapse walkers *n* = 6 women Maintenance cyclists *n* = 1 woman, *n* = 3 men Relapse cyclists *n* = 2 men Total relapse *n* = 2 men, *n* = 5 women		cycling were environmental: pollution, disrepair of cycle paths, lack of covered bike storage and safety. Suggestions for improvements that could be made by management included incentives for active commuting, reminders, encouragement of partial active commuting, safe covered cycle storage and on site showers and changing facilities.	

6. PHYSICAL ACTIVITY PROGRAMMES

SUMMARY

Evidence of efficacy for weight management/reduction
There is inconclusive evidence for the effect of physical activity interventions on body weight, BMI and body fat.

Of four RCTs only one (Pritchard 1997) found a significant effect on body weight between intervention and control groups (Pritchard 1997) with one RCT noting a significant before and after difference in the exercise group (2 kg, $p < 0.025$) with no significant difference in the control group (+0.7 kg; Grandjean 1996). Interventions focused on specific exercise sessions, about three times per week, all aerobics, with exception of Grandjean (1996) who encouraged walking, cycling and jogging. Trials were all very small and generally not of high quality. In addition, the amounts of exercise prescribed did not meet the levels recommended in the Chief Medical Officer's report *At Least Five a Week* (London: Department of Health, April 2004, http://www.dh.gov.uk/assetRoot/04/08/09/81/04080981.pdf).

Evidence of efficacy for physical activity outcomes
Results from a systematic review (Proper 2003) support the implementation of worksite PA programmes.

The overall conclusion of the review, based on five RCTs (two of high quality) and three non-randomised controlled trials was that there was strong evidence for a positive effect of PA programmes on PA. One study designated by the reviewers as a high quality RCT, the Working Healthy project (Emmons 1999), evaluated the effect of the programme at both the midpoint (1.25 years) and the endpoint (2.5 years). It was found that participants had significantly increased their self-reported participation in regular exercise by 10.4 (interim) and 11.9% (end) vs. 2.4 and 1.7% for the reference condition. The other study considered as a high quality RCT (Pritchard 1997) showed a greater increase of energy expenditure in the intervention group compared with the reference and diet group after 12 months(+14.6 vs. 6.5%).

Evidence of corroboration
No UK evidence of corroboration.

EVIDENCE TABLE 7: INCREASED ACTIVE TRAVEL TO AND FROM WORK – INCLUDE PEDOMETERS

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/CIs for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Pritchard 1997	RCT	1	+	Business corporation. Overweight men. *n* = 66 Australia.	**Aim:** To compare total and regional body composition after subjects lost weight through change in diet or exercise. 30 minute aerobic exercise programme (minimum 3 × per week, at 65–75% of maximum heart rate), diet programme (reduced fat) or no intervention control. Bi-monthly meetings for all subjects and monthly counselling for intervention.	12 months	Fifty-eight included in analysis. Change in weight and BMI were significantly different in subjects in the intervention groups compared with control ($p < 0.05$). Change in weight –3.0% in exercise groups and –7.2% in diet group vs. +1.0% in control group. BMI –4.4% in exercise group and 8.2% in diet group vs. +1.0% in control.	No allocation concealment, no ITT but 88% follow-up.
Grønningsäter 1992	RCT	1	+	Insurance workers. Physically inactive.	**Aim:** To study the effects of two types of stress-reduction interventions on physically inactive	10 weeks and 6 months	*n* = 79 randomised into groups. Seventy-six included in 10-week analysis, of which 48.7% were women.	No allocation concealment, no ITT *but* 91% follow-up. No specific body

				$n = 193$ Oslo, Norway. Age range 25–67 years All administrative levels of employees represented.	employees. Aerobic exercise (55 min sessions 3 days per week for 10 weeks, at 70–80% of maximum heart rate) vs. stress management vs. no intervention control.		Seventy-two included at 6-month follow-up. Average attendance 80% women and 76% men in aerobic physical exercise group. No effect on body weight. No significance stated.	weight data given.
Grandjean 1996	RCT	1	+	Westinghouse Corporation, Texas, USA. Thirty-seven female blue collar workers.	Walking, jogging and cycling three times per week for 20–60 min vs. control (no intervention).	24-week intervention. No follow-up.	100% follow-up. Significant effect on body weight (2 kg weight loss, $p < 0.025$) between before and after measures in exercise group. No change in control group (+0.7 kg) but non-significant difference between groups. Difference in % fat between control and exercise groups approached but did not reach statistical significance ($p < 0.056$).	No allocation concealment. 100% follow-up.
Lee 1997	RCT	1	+	Thirty-seven female University workers aged 40–61 (mean 48.4). 76% secretarial/administrative.	Self-administered programme of low-impact aerobic exercise and education vs. control (wait list group invited to attend second 12-week programme). No power calculation.	12-week intervention. 24- and 48-week follow-up.	35/37 included in the analysis. No significant effect on body fat or BMI at 24 weeks compared with earlier measures. BMI was significantly higher in the exercise group at 48 weeks than 0,12 and 24 weeks; insufficient control group data at 48 weeks were available for analysis.	No allocation concealment. No ITT analysis but 94% follow-up.

Cook 2001	CBA	2	++	Two South Auckland manufacturing worksites. *n* = 347 at intervention and *n* = 262 in control. Voluntary participation and study open to male hourly paid employees. 40% obese at baseline. Huge baseline variations in intervention vs. control sites. Age (mean ± SD) 35.0 ± 11.2 vs. 42.9 ± 11.7 years . European 25.7 vs. 39.7%. ≥4 years at high school 50 vs. 29.8%, etc.	**Aim:** To evaluate effectiveness of health promotion programme targeting dietary behaviours and PA in male hourly-paid workers. Nutrition displays in the cafeteria and monthly 30-min workshop for 6 months. Delayed intervention in control worksite.	After 6 month intervention and at 12 months.	Recruitment 38% at intervention (*n* = 132) and 46% at control (*n* = 121). Follow up = 94% at 6 months and 89% at 12 months. Statistically significant differences between the intervention and control groups, in mean fat score ($p = 0.0003$), increase in vegetable intake ($p = 0.007$) and PA ($p = 0.005$). There was no significant difference in mean BMI or waist circumference between the groups.	Self-reported nutrition and PA measures. Ethnic variations may limit generalisability to UK.
Evidence of efficacy (internal validity) for physical activity outcomes								
Proper 2003	Systematic review	1	++	Literature search of English language papers	**Aim of review:** To review the effectiveness of	Various.	The overall conclusion from five RCTs (two of high quality) and three non-randomised controlled	The two trials designated as sound RCTs

				from 1980 to 2000. Twenty-six randomised or non-randomised studies including 15 RCTs and 11 non-RCTs in all. The review included five RCTs (two of high quality) and three non-randomised trials with PA outcomes.	worksite PA programmes on PA, physical fitness and health.		trials was that there was strong evidence for a positive effect of PA programs on PA. The first high quality RCT, the Working Healthy project (Emmons 1999), evaluated the effect of the programme at both the midpoint (1.25 years) and the endpoint (2.5 years). It was found that participants had significantly increased their self reported participation in regular exercise by 10.4% (interim) and 11.9% (end) vs. 2.4% and 1.7% for the reference condition. The other high quality RCT (Pritchard 1997, see above) showed a greater increase of energy expenditure in the intervention group compared with the reference and diet group after 12 months(+14.6 vs. 6.5%).	were: Pritchard 1997 ; Emmons 1999 . Both of which would be designated as CCTs if appraised by NICE/HDA methodology.
Cook 2001 As above.	CBA	2	++	As above.	As above.	After 6-months intervention and at 12 months.	Statistically significant differences between the intervention and control groups, in mean fat score ($p = 0.0003$), increase in vegetable intake ($p = 0.007$) and PA ($p = 0.005$).	Self-reported nutrition and PA measures. Ethnic variations may limit generalisability to UK.

Evidence of corroboration (external validity)

Evidence of salience – Is it appropriate for the UK?								
First author	**Study**	**Researc**	**Researc**	**Study**	**Research**	**Length of**	**Main results**	**Confounders/co**

	design	**h type**	**h quality**	**population**	**question**	**follow-up**		**mments**
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**

7. INCREASED OCCUPATIONAL HEALTH PROVISION AND/OR REFERRAL TO PRIMARY CARE

SUMMARY

No relevant studies found.

8. INCREASED USE OF STAIRS

SUMMARY

Evidence of efficacy for weight management/reduction
No studies found.

Evidence of efficacy for physical activity outcomes
From one interrupted time series study, there is evidence that environmental improvements may increase stair use. Effective actions included re-decoration, motivational signs and music in the stairwell (Kerr 2004). Another interrupted time series study found that posters alone were not effective (Kerr 2001) but a before and after study (Vanden Auweele 2005) that included an email reminder found a temporary improvement while the sign was in place.

Evidence of corroboration
One UK study suggested that posters alone may cause feelings of ‘laziness’ and ‘guilt’ (Kerr 2001).

Cost-effectiveness data
No cost-effectiveness studies found.

EVIDENCE TABLE 8: INCREASED ACTIVE TRAVEL TO AND FROM WORK – INCLUDE PEDOMETERS

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
No studies with weight outcomes.								
Evidence of efficacy (internal validity) for physical activity outcomes								
Kerr 2004	Interrupted time series	2	++	Single five-storey site (Centers for Disease Control and Prevention [CDC]) in Georgia, USA. 74.2% female. Age ≥18 years. 66.4% white, 28.2% African American. 554 permanent employees and 110 temporary.	**Aim:** To assess the impact of stair use of four sequential environmental changes to the stairwell. 1) New carpeting and paint October 1998; 2) Artwork December 1998; 3) Motivational signs September 1999 4) Music in stairwell October 2001.	3.5 years in all.	Both motivational signs and music significantly increased stair use by 8.9% over baseline ($p < 0.05$).	Other factors may have influenced stair use during the study period. The workforce may have been more motivated given their work in a health promotion area.
Kerr 2001	Interrupted time series	2	++	Two accountancy firms (one nine-storey and one four-storey) in the	A1-sized poster reading 'Stay healthy, use the stairs'.	Two-week baseline plus 2-week	There was no significant effect of the poster on stair use in either site. Site one: OR 1.04 (95% CI 0.92, 1.18). Site two: OR 1.22	Very short-term study. The authors

				midlands, UK.		intervention (4-week in second firm). Questionnaire after further week.	(95% CI 0.96, 1.55). The message, however, made 62% and 47% of respondents respectively feel guilty or lazy.	speculated that the feelings of laziness and guilt may have caused workers to reject the message.
Vanden Auweele 2005	Before and after	2	+	131 women in an almost entirely female (131/135) workplace (a socio-cultural organisation) in Belgium. No socio-economic details provided.	**Aim:** To evaluate the impact of two simple interventions aimed at promoting stair use among female employees at a five-floor worksite. After a baseline week an intervention in the first week involved a health sign placed at the junction between the staircase and the elevator. In the second week an email was sent by the worksite's doctor, pointing out the benefits of stair use. The sign was removed 4 days after the observations in the second week. Follow-up data were collected 4 weeks after the second	One-week baseline collection plus one week with sign, plus one further week following email. Follow-up 4 weeks after second intervention week.	In total, 3146 observations were made. Stair use increased significantly from 69% at baseline to 77% during the week after the first intervention ($p < 0.001$). Compared with the first intervention, stair use increased significantly to 85% in the week after the second intervention ($p < 0.001$). However, stair use decreased to 67% at follow up 1 month after the sign was removed and was not significantly different to baseline ($p = 0.52$).	Short term before and after study only. Reliable data collection (observation) but observers were visible.

					intervention week (i.e. 6 weeks post baseline). No power calculation. Higher education intervention. Observers were sport-management students.			

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study Population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Kerr 2001	Interrupted time series	2	++	Two accountancy firms (one nine-storey and one four-storey) in the midlands, UK.	A1-sized poster reading ‘Stay healthy, use the stairs’.	Two-week baseline plus 2-week intervention (4-week in second firm) Questionnaire after further week.	There was no significant effect of the poster on stair use in either site. Site one: OR 1.04 (95% CI 0.92, 1.18). Site two: OR 1.22 (95% CI 0.96, 1.55). The message, however, made 62% and 47% of respondents respectively feel guilty or lazy.	Very short-term study. The authors speculated that the feelings of laziness and guilt may have caused workers to reject the message.

9. STRATEGIES TO INFLUENCE WORKPLACES TO INVEST IN THE HEALTH AND ACTIVITY OF THEIR WORKFORCE (INCLUDES EFFECTS ON EMPLOYEE SICK LEAVE)

SUMMARY

Evidence of efficacy

The evidence base for strategies to influence workplaces is weak. Although there are some indications that sick leave is reduced in workers who have received worksite PA interventions the body of evidence is inconclusive. An RCT found no statistically significant difference although a trend to reduced sick leave was evident (Nurminen 2002). A controlled before and after study (Kerr 1993) found a decrease of sick leave in intervention groups and an increase in controls ($p = 0.04$)

Evidence of corroboration

No evidence for UK corroboration found.

EVIDENCE TABLE 9: STRATEGIES TO INFLUENCE WORKPLACES TO INVEST IN THE HEALTH AND ACTIVITY OF THEIR WORKFORCE (INCLUDES EFFECTS ON EMPLOYEE SICK LEAVE)

The studies included below do not relate to weight, PA or diet outcomes. There is no evidence for efficacy in relation to either of these.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity)								
Nurminen 2002	Individual RCT	1	++	Female laundry workers. Finland. *n* = 260 Intervention = 13 3 Control = 127 Mean age = 40 years 23% intermediate or secondary education. 12% vocational college or university education.	**Aim:** To evaluate the effect of worksite exercise intervention on perceived work ability and sick leave. Both groups had 30 min feedback from physiotherapist with individual exercise prescription and counselling. Intervention grou*p* also had physiotherapist-led exercise training for 1 hour, once per week for 8 months.	3-, 8-, 12- and 15-month follow-up.	Follow-up attendance 90% at 15 months. Approx. 50% of intervention group attended at least two-thirds of exercise sessions. No statistically significant differences in sick leave. Cumulative sick leave in hours at 8, 12 and 15 months was: Intervention: 87, 108 and 154 respectively Control: 82, 96 and 132 respectively	As sick leave information was from Personnel records, no diagnoses of sickness available.
Kerr 1993	CBA	2	++	Bank Headquarters. White collar	**Aim:** To evaluate the effectiveness of an employee fitness	1 year	Statistically significant differences were found between the intervention and control groups on mean total absence.	

				workers. *n* = 152 Amsterdam	programme (EFP) on possible changes in absenteeism, general well-being, self-confidence and perceived physical condition. Four groups. Interventions: 1) Participant in EFP and regular attendance; 2) Participant in EFP and irregular attendance. Controls: 3) Non-participant in EFP and regular exerciser; 4) Non-participant in EFP and non-exerciser.		41.1 and 28.4% decreases in intervention groups and 11.4 and 48.1% increases in control ($p = 0.01$). Statistically significant differences between mean total absence frequency between groups. Decrease in intervention groups and increase in controls ($p = 0.04$).	

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**

SEARCH STRATEGIES

1. exp OBESITY/
2. exp Weight Gain/
3. exp Weight Loss/
4. obes$.ti,ab.
5. (weight gain or weight loss).ti,ab.
6. (overweight or over weight or overeat$ or over eat$).ti,ab.
7. weight change$.ti,ab.
8. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
9. body mass.ti,ab.
10. exp Diet, Fat-Restricted/
11. exp Diet, Reducing/
12. (fruit or vegetable$ or healthy eating or diet$).ti,ab.
13. (high fat$ or low fat$ or fatty food$).ti,ab.
14. exp EXERCISE/
15. (physical activity or physical inactivity or physical fitness).ti,ab.
16. or/1–15
17. exp Behavior Therapy/
18. exp Social Support/
19. exp Psychotherapy, Group/
20. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
21. (group therapy or cognitive therapy).ti,ab.
22. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.
23. counsel?ing.ti,ab.
24. social support.ti,ab.
25. (peer adj2 support).ti,ab.
26. or/17–25
27. exp OBESITY/dh [Diet Therapy]
28. exp Diet, Fat-Restricted/
29. exp Diet, Reducing/
30. exp Diet Therapy/
31. exp FASTING/
32. diet$.ti,ab.
33. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).ti,ab.
34. (low calorie or calorie control$ or healthy eating).ti,ab.
35. (fasting or modified fast$).ti,ab.
36. exp Dietary Fats/
37. (fruit or vegetable$).ti,ab.
38. (high fat$ or low fat$ or fatty food$).ti,ab.
39. formula diet$.ti,ab.
40. or/27–39
41. exp EXERCISE/
42. exp Exercise Therapy/
43. exercis$.ti,ab.
44. (aerobics or physical therapy or physical activity or physical inactivity).ti,ab.
45. (fitness adj (class$ or regime$ or program$)).ti,ab.
46. (aerobics or physical therapy or physical training or physical education).ti,ab.
47. dance therapy.ti,ab.
48. sedentary behavio?r.ti,ab.
49. or/41–48
50. exp Complementary Therapies/
51. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
52. (hypnotism or hypnosis or hypnotherapy).ti,ab.
53. (acupuncture or homeopathy or homoeopathy).ti,ab.
54. (chinese medicine or indian medicine or herbal medicine or ayurvedic).ti,ab.
55. or/50–54
56. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
57. (weightwatcher$ or weight watcher$).ti,ab.

58. (correspondence adj (course$ or program$)).ti,ab.
59. (fat camp$ or diet$ camp$).ti,ab.
60. or/56–59
61. exp Health Promotion/
62. exp Health Education/
63. (health promotion or health education).ti,ab.
64. media intervention$.ti,ab.
65. or/61–64
66. exp Health Policy/
67. exp Nutrition Policy/
68. (health polic$ or food polic$ or nutrition polic$).ti,ab.
69. or/66–68
70. exp OBESITY/pc [Prevention & Control]
71. exp Primary Prevention/
72. (primary prevention or secondary prevention).ti,ab.
73. (preventive measure$ or preventative measure$).ti,ab.
74. (preventive care or preventative care).ti,ab.
75. (obesity adj2 (prevent$ or treat$)).ti,ab.
76. or/70–75
77. exp Controlled Clinical Trials/
78. exp Random Allocation/
79. exp Double-Blind Method/
80. exp Single-Blind Method/
81. exp PLACEBOS/
82. exp Research Design/
83. exp Intervention studies/
84. exp Evaluation studies/
85. exp Cost Benefit Analysis/
86. (time adj series).tw.
87. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
88. exact{CONTROLLED-CLINICAL-TRIAL}.pt.
89. placebo$.ti,ab.
90. (matched communities or matched populations).ti,ab.
91. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
92. (comparison group$ or control group$).ti,ab.
93. matched pairs.ti,ab.
94. (outcome study or outcome studies).ti,ab.
95. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
96. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
97. randomi?ed.hw
98. (cohort or survey: or qualitative).ti,ab.
99. or/77–98
100. exp Meta-Analysis/
101. meta-analys$.ti,ab.
102. metaanalys$.ab,ti.
103. meta analys$.ab,ti.
104. Cochrane.ab,sh,ti.
105. (review$ or overview$).ti.
106. review$.pt.
107. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
108. pooled analys$.ab,ti.
109. ((data adj2 pool$) and studies).mp. [mp = title, original title, abstract, name of substance, mesh subject heading]
110. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
111. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
112. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
113. or/100–112
114. (retrospective$ adj2 review$).ab,sh,ti.
115. (case$ adj2 review$).ab,sh,ti.

116. (record$ adj2 review$).ab,sh,ti.
117. (patient$ adj2 review$).ab,sh,ti.
118. (patient$ adj2 chart$).ab,sh,ti.
119. (peer adj2 review$).ab,sh,ti.
120. (chart$ adj2 review$).ab,sh,ti.
121. (case$ adj2 report$).ab,sh,ti.
122. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
123. or/114–122
124. 123 not (123 and 113)
125. 113 not 124
126. 26 or 40 or 49 or 55 or 60 or 65 or 69 or 76
127. 16 and 126 and 99
128. 16 and 126 and 125
129. 127 or 128
130. animal.sh.
131. human.sh.
132. 130 not (130 and 131)
133. 129 not 132
134. exp workplace/
135. exp working conditions/
136. exp occupations/
137. exp occupation/
138. exp business/
139. exp staff development/
140. exp employee incentive plans/
141. exp incentives/
142. exp management/
143. exp personnel management/
144. exp office management/
145. exp work/
146. exp occupational health/
147. exp occupational health services/
148. exp employer/
149. exp employer-employee relations/
150. exp employer health costs/
151. exp employee assistance programs/
152. exp named groups by occupation/
153. exp ‘occupational health and safety’/
154. employment$.ti,ab.
155. occupation$.ti,ab.
156. (worker$ or employe$ or staff$ or personnel$).ti,ab.
157. (employ$ adj2 (place$ or site$ or locat$ or set$ or environ$)).ti,ab.
158. (work$ adj2 (place$ or site$ or locat$ or set$ or environ$ or condition$)).ti,ab.
159. (work?place$ or work?site$ or work?locat$ or work?set$ or work?environ$).ti,ab.
160. (job$ adj2 (place$ or site$ or locat$ or set$ or environ$)).ti,ab.
161. (job?place$ or job?site$ or job?locat$ or job?set$ or job?environ$).ti,ab.
162. (corporat$ or business$ or public sector$ or private sector$).ti,ab.
163. office$.ti,ab.
164. vocation$.ti,ab.
165. trade$.ti,ab.
166. or/134–165
167. and/133,166
168. limit 167 to yr=1990–2004

DATA SOURCES

Database searches were carried out in October 2004 for papers published from 1990 onwards (1995 onwards for systematic review level evidence).

The following information sources were searched:

AMED (Allied and Complementary Medicine)
ASSIA (Applied Social Sciences Index and Abstracts)
British Nursing Index
CAB Abstracts - Human health and nutrition, agriculture
CENTRAL (Cochrane Controlled Trials Register)
CINAHL (Cumulative Index to Nursing & Allied Health Literature)
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
NHS EED (NHS Economic Evaluation Database) - http://www.york.ac.uk/inst/crd
DARE (Database of Abstracts of Reviews of Effects)
Embase
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC (Educational Resources Information Centre)
Food Standards Agency - http://www.food.gov.uk/science/research/
HDA Evidence Base - http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA (National Coordinating Centre for Health Technology Assessment) - http://www.ncchta.org
NICE (National Institute for Clinical Excellence) – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN (Scottish Intercollegiate Guidelines Network) – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus
Lisa Janzen (Canadian workplace health specialist) contacted.

Update searches

An update search of the same databases was carried out in September 2005 for worldwide intervention and UK corroborative studies. A final search was completed on 1 December 2005 for systematic reviews and controlled trials only in a reduced number of databases: CINAHL, Cochrane, Embase, Medline and PsycINFO.

The search strategies were developed in Medline and adapted for use with the other information sources.

EXCLUDED REFERENCE LIST

Excluded reference	Reason for exclusion
Abood DA, Black DR, Feral D. Nutrition education worksite intervention for university staff: Application of the health belief model. *Journal of Nutrition Education and Behavior* 2003;35(5):260–7.	8-week follow-up.
Addley K, McQuillan P, Ruddle M. Creating healthy workplaces in Northern Ireland: evaluation of a lifestyle and physical activity assessment program. *Occupational Medicine* 2001;51(7):439–449.	Better evidence available.
Aldana SG, Jacobson BH, Harris CJ, Kelley PL. Mobile work-site health promotion programs can reduce selected employee health risks. *Journal of Occupational and Environmental Medicine* 1993;35(9):922–8.	≤1996.
Aldana SG, Merrill RM, Price K, Hardy A, Hager R. Financial Impact of a comprehensive worksite health promotion program. *Preventive Medicine* 2005;40(2):131–137.	Economic analysis. Passed to York.
Alexy B. Workplace health promotion and the blue collar worker. *American Association of Occupational Health Nurses* 1990;38(1):12–6.	Paper not held at British Library. Unable to trace.
Ammerman AS, Lindquist CH, Lohr KN, Hersey J. The efficacy of behavioral interventions to modify dietary fat and fruit and vegetablesetable intake: a review of the evidence. *Preventive Medicine* 2002;35:25–41.	Excluded at Critical Appraisal. Serious concerns about conclusions due to diverse range of settings chosen. Also includes children/adolescents.
Anderson JV, Mavis BE, Robison JI, Stoffelmayr BE. A work-site weight management program to reinforce behavior. *Journal of Occupational and Environmental Medicine* 1993;35(8):800–4.	≤1996.
Anderson DR, Staufacker MJ. The impact of worksite-based health risk appraisal on health-related outcomes: a review of the literature. *American Journal of Health Promotion* 1996;10(6):499–508.	≤1996 and literature review only.
Anderson DR, Whitmer RW, Goetzel RZ et al. The relationship between modifiable health risks and group-level health care expenditures. *American Journal of Health Promotion* 2000;15(1):45–52 .	Discussion of risk factors in relation to healthcare expenditure only.
Angotti CM, Chan WT, Sample CJ, Levine MS. Combined dietary and exercise intervention for control of serum cholesterol in the workplace. *American Journal of Health* Promotion 2000;15(1):9–16.	Outcome was serum cholesterol only.
Aoun S, Johnson L. Diabetes education and screening in worksites in rural Western Australia. *Health* P*romotion Journal of Australia* 2002;13(1):65–8.	Diabetes awareness program in high risk individuals only.
Arao T, Suyama Y, Imaizurni T, Nagamatsu T. Adherence and effectiveness of worksite stair-climbing exercise program on health and physical fitness in white-collar workers. *Bulletin of the Physical Fitness Research Institute* 1997;94:10–23.	Paper not held at British Library. Unable to trace.
Atlantis E, Clow C-M, Kirby A, Fiatarone Singh M. An effective exercise-based intervention for improving mental health and quality of life measures:a randomized controlled trial. *Preventive Medicine* 2004;39:424–34.	Outcomes not relevant to review.
Baer JT. Improved plasma cholesterol levels in men after a nutrition education program at the worksite. *Journal of the American Dietetic Association* 1993;93(6):658–63.	≤1996.
Balfour D, Moody R, Wise A, Brown K. Food choice in response to computer-generated nutrition information provided about meal selections in workplace restaurants. *Journal of Human Nutrition and Dietetics* 1996;9(3):231–7.	≤1996.
Barnes JT. Weight status during and after a 12-week weight loss program	Paper not held at

at the worksite. *Research Quarterly for Exercise and Sport* 2004;75(1):A15–6.	British Library. Unable to trace.
Barratt A, Reznik R, Irwig L, Cuff A, Simpson JM, Oldenburg B, et al. Work-site cholesterol screening and dietary intervention: the Staff Healthy Heart Project. Steering Committee. *American Journal of Public Health* 1994;84(5):779–82.	≤1996.
Barrere CC. Hospital employee cholesterol screening: modification of dietary behavior. *AAOHN Journal* 1994;42(6):261–9.	≤1996.
Beresford SA, Shannon J, McLerran D, Thompson B. Seattle 5-a-Day Work-Site Project: process evaluation. *Health Education and Behavior* 2000;27(2):213–22.	Same trial as Addley (2001)
Bertera RL. Behavioral risk factor and illness day changes with workplace health promotion: Two-year results. *American Journal of Health Promotion* 1993;7(5):365–73.	≤1996.
Biener L, Glanz K, McLerran D, Sorensen G, Thompson B, Basen-Engquist K, et al. Impact of the Working Well Trial on the worksite smoking and nutrition environment. *Health Education and Behavior* 1999;26(4):478–94.	Non-UK corroboration– excluded due to lack of time.
Bishop H. Changes in serum cholesterol after dietary instruction at the workplace. *Journal of the Canadian Dietetic Association* 1990;51(4):491–2.	≤1996.
Blue CL. Adherence to worksite exercise programs:an integrative review of recent research*. AAOHN Journal* 1995;43(2):76–86.	≤1996.
Boudreau F, Godin G, Pineau R, Bradet R. Health risk appraisal in an occupational setting and its impact on exercise behavior. *Journal of Occupational and Environmental Medicine* 1995;37(9):1145–50.	≤1996.
Briley ME, Montgomery DH, Blewett J. Dietary intakes of police department employees in a wellness program. *Journal of the American Dietetic Association* 1990;90(1):65–8.	≤1996.
Briley ME, Montgomery.G.H., Blewett J. Worksite nutrition education can lower total cholesterol levels and promote weight loss among police department employees. *Journal of the American Dietetic Association* 1992;92(11):1382–4.	≤1996.
Brill PA, Kohl HW, Rogers T, Collingwood TR, Sterling CL, Blair SN. The relationship between sociodemographic characteristics and recruitment, retention, and health improvements in a worksite health promotion program. *American Journal of Health Promotion* 1991;5(3):215–21.	≤1996.
Brodie D, Dugdill L. Health promotion at work. *Journal of the Royal Society of Medicine* 1993;86(12):694–6.	≤1996.
Brug J, Steenhuis I, van AP, de VH. The impact of a computer-tailored nutrition intervention. *Preventive Medicine* 1996;25(3):236–42.	6-week study only.
Bruno R, Arnold C, Jacobson L, Winick M, Wynder E. Randomized controlled trials of a non-pharmacologic cholesterol reduction program at the worksite. *Preventive Medicine* 1983;12:523–32.	≤1996.
Bull SS, Gillette C, Glasgow RE, Estabrooks P. Work site health promotion research:To what extent can we generalize the results and what is needed to translate research to practice? *Health Education and Behavior* 2003;30(5):537–49.	Non-UK corroboration– excluded due to lack of time.
Byers T, Mullis R, Anderson J, Dusenbury L, Gorsky R, Kimber C, et al. The Costs and Effects of A Nutritional Education-Program Following Work-Site Cholesterol Screening. *American Journal of Public Health* 1995;85(5):650–5.	≤1996.
Caldwell B. Employers save with wellness programs. Sony introduces targeted incentives in wellness program. Weight watchers goes to work at Milwaukee Company. *Corporate Wellness Resources available. Employee benefit plan review* 1992;46(7):46–51.	≤1996. Non–UK corroboration – excluded due to lack of time.
Chan CB, Ryan DAJ, Tudor-Locke C. Health benefits of a pedometer-based activity intervention in sedentary workers. *Preventive Medicine* 2004;39:1215–22	No control group. Most subjects overweight.

Chang SF. Worksite health promotion – on the effects of an employee fitness program. *Journal of Nursing Research:*2003;11(3):227–30.	Taiwan 8-week follow-up.
Cockcroft A, Gooch C, Ellinghouse C, Johnston M, Michie S. Evaluation of a programme of health measurements and advice among hospital staff. *Occupational Medicine (Oxford)* 1994;44(2):70–6.	≤1996.
Cohen NL, Stoddard AM, Sarouhkhanians S, Sorensen G. Barriers toward fruit and vegetablesetable consumption in a multiethnic worksite population. *Journal of Nutrition Education* 1998;30(6):381–6.	Non-UK corroboration– excluded due to lack of time.
Connell CM, Sharpe PA, Gallant MP. Effect of Health Risk Appraisal on Health Outcomes in A University Worksite Health Promotion Trial. *Health Education Research* 1995;10(2):199–209.	≤1996.
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Croteau KA. A Preliminary Study on the Impact of a Pedometer-based Intervention on Daily Steps. *American Journal of Health Promotion* 2004;18(3):217–20.	8-week follow-up only.
Croteau KA. Strategies used to increase lifestyle physical activity in a pedometer-based intervention. *Journal of Allied Health* 2004;33(4):278–81	8-week follow-up only.
Crouch M, Sallis J, Farquhar J. Personal and mediated health counseling for sustained dietary reduction of hypercholesterolemia. *Preventive Medicine* 1986;15:282–91.	≤1996.
Darrington M. Use of a stage-based nutrition intervention at an industrial workplace: a randomized, controlled trial. *University of Oregon Eugene: Microform Publications*; 1999.	Abstract only. Six week follow up only.
Dennison KF, Galante D, Dennison D, Golaszewski T. A one year post-program assessment of a computer-assisted instruction (CAI) weight management program for industrial employees: lessons learned. *Journal of Health Education* 1996;27(1):38–42.	≤1996.
DiGiacomo Consulting Services. Overview of physical activity programs in the Canadian workplace. Ottawa: DiGiacomo Consulting Services (Ottawa);1993.	Not held at British Library. Unable to trace.
Dubois A, Strychar IM, Champagne F, Leblanc MP, Tremblay C. Report. The effect of a worksite cafeteria program on employees' dietary fat intakes. *Journal of the Canadian Dietetic Association* 1996;57(3):98–102.	≤1996.
Eddy JM, Eynon D, Nagy S, Paradossi PJ. Impact of a physical fitness program in a blue-collar workforce*. Health Values: Achieving High Level Wellness* 1990;14(6):14–23.	≤1996.
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Elbel R, Aldana S, Bloswick D, Lyon J, Elbel R. A pilot study evaluating a peer led and professional led physical activity intervention with blue-collar employees. *Work: Journal of Prevention, Assessment and Rehabilitation* 2003;21(3):199–210.	8-week follow-up.
Elberson KL, Daniels KK, Miller PM. Structured and nonstructured exercise in a corporate wellness program. A comparison of physiological outcomes. *Outcomes Management for Nursing Practice* 2001;5(2):82–6.	Excluded at Critical Appraisal. Poor quality CBA.
Erfurt JC. Improving participation in worksite wellness programs: Comparing health education classes, a menu approach, and follow-up counselling. *American Journal of Health Promotion* 1990;4(4):270–8.	≤1996.
Erfurt JC, Foote A, Heirich MA. The cost-effectiveness of work-site wellness programs for hypertension control, weight loss, and smoking cessation. *Journal of Occupational Medicine* 1991;33(9):962–70.	≤1996.
Erfurt JC, Foote A, Heirich MA. The Cost-Effectiveness of Worksite	≤1996.

Wellness Programs for Hypertension Control, Weight-Loss, Smoking Cessation, and Exercise. *Personnel Psychology* 1992;45(1):5–27.	
Erfurt JC, Holtyn K. Health promotion in small business: what works and what doesn't work. *Journal of Occupational Medicine* 1991;33(1):66–73. [124]	≤1996.
Eriksen HR, Ihlebaek C, Mikkelsen A, Gronningsaeter H, Sandal GM, Ursin H. Improving subjective health at the worksite: a randomized controlled trial of stress management training, physical exercise and an integrated health programme. *Occupational Medicine (Oxford)* 2002;52(7):383–91.	Subjective physical fitness measures only.
Fiske A, Weber Cullen K. Effects of promotional materials on vending sales for low-fat items in teachers' lounges. *Journal of the American Dietetic Association* 2004;104:90–3	4-week intervention only.
France-Dawson M, Holland J, Fullerton D, Kelley P, Arnold S, Oakley A. Review of the effectiveness of workplace health promotion interventions. *London: Social Science Research Unit*; 1994.	Superseded by further EPPI centre review.
French SA. Pricing effects on food choices. *Journal of Nutrition* 2003;133(3):S841S–3.	Paper presented at symposium – same study as French (2001)
French SA. Public health strategies for dietary change: schools and workplaces. *Journal of Nutrition* 2005;135:910–2	Non-systematic literature review.
French SA, Jeffery RW, Forster JL, McGovern PG, Kelder SH, Baxter JE. Predictors of weight change over two years among a population of working adults: the Healthy Worker Project. *International Journal of Obesity and Related Metabolic Disorders* 1994;18(3):145–254.	≤1996.
Fries EA, Ripley JS, Figueiredo MI, Thompson B. Can community organization strategies be used to implement smoking and dietary changes in a rural manufacturing work site? *Journal of Rural Health* 1999;15(4):413–20.	Better evidence available.
Fisher B, Golaszewski T, Barr D. Measuring worksite resources for employee heart health. *American Journal of Health Promotion* 1999;13(6):325–32.	Survey of worksite resources provided.
Garofalo K. Worksite wellness – rewarding healthy behaviors: successful program. *American Association of Occupational Health Nurses* 1994;42(5):236–40.	≤1996.
Gemson DH. Efficacy of computerized health risk appraisal as part of a periodic health examination at the worksite. *American Journal of Health Promotion* 1995;9(6):462–6.	≤1996.
Gemson DH, Sloan RP, Messeri P, Goldberg IJ. A public health model for cardiovascular risk reduction. *Archives Internal Medicine* 1990;150:985–9.	≤1996.
Gill PE, Wijk K. Case study of a healthy eating intervention for Swedish lorry drivers. *Health Education Research* 2004;19(3):306–15	No control group.
Glanz K, Patterson RE, Kristal AR, Feng Z, Linnan L, Heimendinger J et al. Impact of work site health promotion on stages of dietary change: the Working Well Trial. *Health Education and Behavior* 1998;25(4):448–63.	Non-UK corroboration– excluded due to lack of time.
Glasgow RE, Mccaul KD, Fisher KJ. Participation in Worksite Health Promotion - A Critique of the Literature and Recommendations for Future Practice. *Health Education Quarterly* 1993;20(3):391–408.	≤1996.
Glasgow RE, Terborg JR, Hollis JF, Severson HH, Fisher KJ, Boles SM, et al. Modifying dietary and tobacco use patterns in the worksite: the Take Heart Project. *Health Education Quarterly* 1994;21(1):69–82.	≤1996.
Glasgow RE, Terborg JR, Strycker LK, Boles SM, Hollis JF. Take Heart II: Replication of a worksite health promotion trial. *Journal of Behavioral Medicine* 1997;20(2):143–61.	Better evidence available.
Goetzel R, Sepulveda M, Knight K, Eisen M, Wade S, Wong J, et al. Association of IBM's 'A Plan for Life' health promotion program with changes in employees' health risk status. *Journal of Occupational and Environmental Medicine* 1994;36(9):1005–9.	≤1996.
Greene GW, Strychar I. Participation in a worksite cholesterol education	≤1996.

program in a university setting. *Journal of the American Dietetic Association* 1992;92(11):1376–81.	
Griffiths A. The benefits of employee exercise programmes: A review. *Work and Stress* 1996;10(1):5–23.	≤1996.
Groth-Marnat G, Schumaker J. Psychologists in disease prevention and health promotion: A review of the cost effectiveness literature. P*sychology* 1995;32(1):1–10.	≤1996.
Guico-Pabia CJ, Cioffi L, Shoner LG. The Lucent-Takes-Heart cardiovascular health management program. Successful workplace screening. *AAOHN Journal* 2002;50(8):365–72.	Follow-up was for high risk subjects only.
Guldan GS. Effectiveness of a worksite education activity in a factory in China. *Asia-Pacific Journal of Public Health* 1992;6(2):8–14.	≤1996.
Gundewall B, Liljeqvist M, Hansson T. Primary prevention of back symptoms and absence from work: a prospective randomized study among hospital employees. *Spine* 1993 Apr;18(5):587–94.	≤1996.
Hallam JS, Petosa R. The long-term impact of a four-session work-site intervention on selected social cognitive theory variables linked to adult exercise adherence. *Health Education and Behavior* 2004;31(1):88–100.	Excluded at critical appraisal – poor quality CBA.
Hallam JS. A process evaluation of a Social Cognitive Theory based intervention to promote the adoption of exercise behavior of adults at the worksite. *Dissertation Abstracts International Section A: Humanities and Social Sciences* 1996; 56(12-A)	Not held at British Library. Abstract only.
Hallam J, Petosa R. A worksite intervention to enhance social cognitive theory constructs to promote exercise adherence. *American Journal of Health Promotion* 1998;13(1):4–7.	4-week follow-up.
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Harrell JS, Johnston LF, Griggs TR, Schaefer P, Carr EG, Jr, McMurray RG, et al. An occupation based physical activity intervention program:improving fitness and decreasing obesity. *AAOHN Journal* 1996;44(8):377–84.	≤1996.
Hartman TJ, Himes JH, McCarthy PR, Kushi LH. Effects of a low-fat, worksite intervention on blood lipids and lipoproteins. *Journal of Occupational and Environmental Medicine* 1995;37(6):690–6.	≤1996.
Hartman TJ, McCarthy PR, Himes JH. Use of eating pattern messages to evaluate eating behaviors in a worksite cholesterol education program. *Journal of the American Dietetic Association* 1993;93(10):1119–23.	≤1996.
Health Canada. Literature review: Evaluations of workplace health promotion programs. *Canada: Health Canada*; no date given on website (checked May 2006) http://www.thcu.ca/workplace/documents/EvaluationInfoPackFinalWeb.pdf	Literature review only.
Health Development Agency, Industrial Society. Health at work in the NHS: a case study for ambulance trusts. *London: Health Development Agency*; 2002.	Covered by further HEA paper (1999).
Health Education Authority. *Health update: workplace health.* London: Health Education Authority; 1997.	Review of studies – mainly information about current issues.
Health Education Authority. *More to work than this – developing and sustaining workplace health in the NHS.* London: Health Education Authority; 1999.	Report on framework for action.
Health Promotion Goes to Work. *Programs with an Impact.* 1993.	Not held at British Library. Unable to trace.

Heaney CA, Goetzel R. A review of Health – related outcomes of multi-component Worksite Health Promotion Programs. *American Journal of Health Promotion* 1997;11(4):290–308.	Superseded by more recent reviews.
Hebert JR, Stoddard AM, Harris DR, Sorensen G, Hunt MK, Morris DH et al. Measuring the effect of a worksite-based nutrition intervention on food consumption. *Annals of Epidemiology* 1993;3(6):629–35.	≤1996.
Hedberg GE, Wikstrom-Frisen L, Janlert U. Comparison between two programmes for reducing the levels of risk indicators of heart diseases among male professional drivers. *Occupational Environmental Medicine* 1998;55:554–61	Non-randomised trial and RCTs available.
Heirich MA, Foote A, Erfurt JC, Konopka B. Work-site physical-fitness programs – comparing the impact of different program designs on cardiovascular risks. *Journal of Occupational and Environmental Medicine* 1993;35(5):510–17.	≤1996.
Heller RF, Tunstall Pedoe HD, Rose G. A simple method of assessing the effect of dietary advice to reduce plasma cholesterol. *Preventive Medicine* 1981;10:364–70.	≤1996.
Hendriksen IJM, Zuiderveld B, Kemper HCG, Bezemer PD. Effect of commuter cycling on physical performance of male and female employees. *Medicine and Science in Sports and Exercise* 2000;32(2):504–10.	Physical performance outcomes.
Henritze J, Brammell HL, McCloin J. LIFECHECK: a successful, low touch, low tech, in-plant, cardiovascular disease risk identification and modification programme. *American Journal of Health Promotion* 1992;7:129–36.	No control group.
Hillsdon M, Foster C, Naidoo B, Crombie H. Effectiveness of public health interventions for increasing physical activity among adults: a review of reviews. London: Health Development Agency; 2004.	No evidence of worksites increasing PA.
Histon T, Solomon L. Getting out of the office: how one healthcare organization is using a public health approach to address overweight and obesity. *Obesity Research* 2004;12:A166.	Reference abstract incorrect and unable to trace.
Holdsworth M. Does the Heartbeat Award Scheme change employees' dietary attitudes and knowledge? *Appetite* 2000;35(2):179–88.	Health eating attitudes outcome only.
Holdsworth M, Haslam C. A review of point-of-choice nutrition labelling schemes in the workplace, public eating places and universities. *Journal of Human Nutrition and Dietetics* 1998;11(5):423–45.	Review of healthy food choice schemes.
Hunt MK, Lederman R, Stoddard A, Potter S, Phillips J, Sorensen G. Process tracking results from the Treatwell 5-a-Day Worksite Study. *American Journal of Health Promotion* 2000;14(3):179–87.	Non-UK corroboration – excluded due to lack of time.
Irvine AB, Ary DV, Grove DA, Gilfillan-Morton L. The effectiveness of an interactive multimedia program to influence eating habits. *Health Education Research* 2004;19(3):290–305	2-month intervention only.
Jeffery RW, Forster JL, Baxter JE, French SA. An empirical evaluation of the effectiveness of tangible incentives in increasing participation and behavior change in a worksite health promotion program. *American Journal of Health Promotion* 1993;8(2):98–100.	≤1996.
Jeffery RW, French SA, Raether C, Baxter JE. An environmental intervention to increase fruit and salad purchases in a cafeteria. *Preventive Medicine* 1994;23:788–92.	≤1996.
Kao Y, Lu C, Huang Y. Impact of a transtheoretical model on the psychosocial factors affecting exercise among workers. *Journal of Nursing Research* 2002;10(4):303–10.	Non-UK corroboration– excluded due to lack of time.
Katz DL, O'Connell M, Yeh MC, Nawaz H, Njike V, Anderson LM et al. Public health strategies for preventing and controlling overweight and obesity in school and worksite settings:a report on recommendations of the Task Force on Community Preventive Services. MMWR Recomm Rep 2005 Oct 7; Recommendations and Reports. 54(RR–10):1–12. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5410a1.htm	Covers overweight and obese interventions only, claiming paucity of evidence for primary prevention.

Kelder SH, Jacobs DR, Jr, Jeffery RW, McGovern PG, Forster JL. The worksite component of variance: design effects and the Healthy Worker Project. *Health Education Research* 1993;8(4):555–66.	≤1996.
Kerr J, McKenna J. A randomized control trial of new tailored walking campaigns in an employee sample. *Journal of Health Communication* 2000;5(3):265–79.	Mass media influences on stages of change.
Kremers SPJ, Visscher TLS, Brug J et al. Netherlands Research programme weight Gain prevention (NHF- NRG): rationale, objectives and strategies. *European Journal of Clinical Nutrition* 2005;59(4):498–507	Description and rationale for study only. Outcomes expected 2007.
Kristal AR, Glanz K, Tilley BC, Li S. Mediating factors in dietary change: understanding the impact of a worksite nutrition intervention. *Health Education and Behavior* 2000;27(1):112–25.	Non-UK corroboration– excluded due to lack of time.
Kristensen TS. Workplace intervention studies. *Occupational Medicine* 2000;15(1):293–305.	About effectiveness of psychosocial intervention research in workplace in general.
Lando HA, Jeffery RW, McGovern PG, Forster JL, Baxter JE. Factors influencing participation in worksite smoking cessation and weight loss programs: the Healthy Worker Project. *American Journal of Health Promotion* 1993;8(1):22–24.	≤1996.
Lassen A, Thorsen AV, Trolle E, Elsig M, Ovesen L. Successful strategies to increase the consumption of fruits and vegetables: results from the Danish '6 a day' Work-site Canteen Model Study. *Public Health Nutrition* 2004;7(2):263–70.	Non-UK corroboration– excluded due to lack of time.
Leutzinger JA, Ozminkowski RJ, Dunn RL et al. Projecting future medical care costs using four scenarios of lifestyle risk rates. *American Journal of Health Promotion* 2000;15(1):35–44	Discussion of risk factors and relation to health care expenditure only.
Lewis C. Chewing the fat. *Health Service Journal* 2003;13 November:28–31.	Article about NHS strategies to combat obesity.
Liddell JA, Lockie GM, Wise A. Effects of a nutrition education programme on the dietary habits of a population of students and staff at a centre for higher education. *Journal of Human Nutrition and Dietetics* 1992;5(23):33.	≤1996.
Linenger JM, Chesson II CV, Nice DS. Physical Fitness Gains Following Simple Environmental Change. *American Journal of Preventive Medicine*;7(5):298–310	CBA and RCTs are available within this topic.
Linnan L, LaMontagne A, Stoddard A, Emmons K, Sorensen G. Norms and their relationships to health behaviors in worksite settings: An application of the Jackson Return Potential Model. *American Journal of Health Behavior* 2005; 29(3): 258-68	Same study as Sorensen 2002
Linnan LA, Marcus B. Worksite-based physical activity programs and older adults: Current status and priorities for the future. *Journal of Aging and Physical Activity* 2001;9:S59–70.	Non-UK corroboration – excluded due to lack of time.
Linnan LA, Sorensen G, Colditz G, Klar N, Emmons KM. Using theory to understand the multiple determinants of low participation in worksite health promotion programs. *Health Education and Behavior* 2001;28(5):591–607.	Non-UK corroboration.
Lusk SL. Worksite cholesterol screening and diet education programs. *AAOHN Journal* 1998;46(3):147.	One page introduction to reviews.
Maes S, Kittel F, Scholten H, Verhoeven C. 'Healthier Work at Brabantia', a comprehensive approach to wellness at the worksite. *Safety Science* 1992;15(4/6):351–66.	≤1996.
Mageshwari SU, Sunitha V. Development of a software and its impact on weight reduction. *Indian Journal of Nutrition and Dietetics* 1995;(10):238–41.	Unable to trace.
Marcus BH, Emmons KM, Simkin-Silverman LR, Linnan LA, Taylor ER,	Looks at motivational

Bock BC, Roberts MB, Rossi JS, Abrams DB. Evaluation of motivationally tailored vs. standard self-help physical activity interventions at the workplace. *American Journal of Health Promotion* 1998 Mar;12(4):246–53.	readiness.
Marshall AL. Challenges and opportunities for promoting physical activity in the workplace. *Journal of Science and Medicine in Sport* 2004;7(1 Suppl):60–66.	Excluded at Critical Appraisal – poor quality systematic review – limited overlap with Proper.
Marshall A, Bauman A, Patch. Can motivational signs prompt increases in incidental physical activity in an Australian health-care facility? *Health Education Research* 2002;17(6):743–49.	6–8 week follow-up.
McMahon A, Kelleher CC, Helly G, Duffy E. Evaluation of a workplace cardiovascular health promotion programme in the Republic of Ireland. *Health Promotion International* 2002;17(4):297–308.	Non-UK corroboration (programme specific to Ireland).
McPherson KE, Turnball J, Kerri E. Body Image Satisfaction in Scottish Men and Its Implications for Promoting Healthy Behaviors. *International Journal of Men's Health* 2005;4(1): 1–12	Corroborative evidence of relevance to overweight/obese men.
Merom D, Miller Y, Lymer S, Bauman A. Effect of Australia's Walk to Work day campaign on adults' activie commuting and physical activity behaviour. *American Journal of Health Promotion* 2005;19(3):159–62	No control group. 1 day study only.
Michie S, Johnston M, Cockcroft A, Ellinghouse C, Gooch C. Methods and Impact of Health Screening for Hospital Staff. *Journal of Organizational Behavior* 1995;16(1):85–92.	≤1996.
Montgomery DH, Briley ME. Long-term dietary intake changes in police department employees who participated in a worksite nutrition education program. *Topics in Clinical Nutrition* 1995;10(4):78–84.	≤1996.
Moseti HK. An in-depth analysis of the relationship between employee wellness programs and employee health care costs. *Dissertation Abstracts International Section A: Humanities and Social Sciences* 1996;57(6-A)	Abstract only.
Moxley LS. The Development and Impact of an Experimental Student Affairs Employee Wellness Program. *Research in Higher Education* 1990;31(3):211–33.	≤1996.
Mulvihill C, Quigley R. *The management of obesity and overweight. An analysis of the reviews of diet, physical activity and behavioural approaches*. London: Health Development Agency; 2003.	Review of reviews.
Mutrie N, Blarney S, Whitelaw S. *A randomised controlled trial of a cognitive behavioural intervention aimed at increasing active commuting in a workplace setting*. Scotland: Health Education Board for Scotland; 1999.	Superseded by further paper Mutrie (2002)
NHS Centre for Reviews and Dissemination. *Systematic review of interventions in the treatment and prevention of obesity*. York: NHS Centre for Reviews and Dissemination; 1997.	No studies directly related to workplace.
Nicholson C. A controlled trial evaluation of a worksite nutrition education program. *Australian Journal of Nutrition and Dietetics* 1993;50(1):4–8.	≤1996.
O'Connell MP. Health impact of workplace health promotion programs and methodological quality of the research literature. Including commentary by Omenn GS and Chapman LS. *Art of Health Promotion* 1997;1(3):1–8.	Paper not held at British Library. Unab;e to trace.
Okada K. Effects of long-term corporate fitness program on employees health. *Journal of Nutritional Science and Vitaminology* 1991;37:S131–8.	≤1996.
Oldenburg B, Owen N, Parle M, Gomel M. An economic evaluation of four work site based cardiovascular risk factor interventions. *Health Education Quarterly* 1995;22(1):9–19.	≤1996.
Ozminkowski RJ, Goetzel RZ, Santoro J, Saenz BJ, Eley C, Gorsky B. Estimating risk reduction required to break even in a health promotion program. *American Journal of Health* Promotion 2004;18(4):316–25	Cost-effectiveness discussion. Info passed to York for possible tolerance.

Payne N, Jones F, Harris PR. The impact of job strain on the predictive validity of the theory of planned behaviour: an investigation of exercise and healthy eating. *British Journal of Health Psychology* 2005;10:115–31	Questionnare with about 1% response rate – can't generalise.
Peel GR, Booth ML. Impact evaluation of the Royal Australian Air Force health promotion program. *Aviation Space and Environmental Medicine* 2001;72(1):44–51.	Weak retrospective RCT and better RCTs already included.
Peersman G, Harden A, Oliver S, Oakley A. *Effectiveness reviews in health promotion*. London: EPPI-Centre; 1999.	Methodology study.
Pegus C. Effect of the Heart at Work program on awareness of risk factors, self-efficacy, and health behaviors. *Journal of Occupational and Environmental Medicine 2002*;44(3):228–36.	Better evidence available.
Pelletier KR. Clinical and cost outcomes of multifactorial, cardiovascular risk management interventions in worksites: A comprehensive review and analysis. *Journal of Occupational and Environmental Medicine* 1997;39(12):1154–69.	No relevant cost data provided by study.
Pelletier B, Boles M, Lynch W. Change in health risks and work productivity over time. *Journal of Occupational and Environmental* Medicine 2004;46:746–54	No control group.
Pencak M. Workplace health promotion programs. An overview. *Nursing Clinics of North America* 1991;26(1):233–40.	≤1996.
Perlmutter CA, Canter DD, Gregoire MB. Profitability and acceptability of fat- and sodium-modified hot entrees in a worksite cafeteria. *Journal of the American Dietetic Association* 1997;97(4):391–5.	Better evidence available.
Perovich SJ, Sandoval WM. Outcomes of a worksite cholesterol education program over a 5-year period. *Journal of the American Dietetic Association* 1995;(5):589–90.	≤1996.
Pescatello LS, Murphy D, Vollono J, Lynch E, Bernene J, Costanzo D. The cardiovascular health impact of an incentive worksite health promotion program. *American Journal of Health Promotion* 2001;16(1):16–20.	Excluded at Critical Appraisal. Poor quality CBA.
Peters KK. Worksite health promotion with campus maintenance workers. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 1997; 58(5-B)	Not held at British Library. Abstract only.
Peterson TR, Aldana SG. Improving exercise behavior: an application of the stages of change model in a worksite setting. *American Journal of Health Promotion* 1999;13(4):229–32.	9-week follow-up.
Phillips JM, Philbin CA. Worksite weight loss: an effective and fun successful program. *AAOHN Journal* 1992;40(10):496–8.	≤1996.
Pilon BA, Renfroe D. Evaluation of an employee health risk appraisal program. *American Association of Occupational Health Nurses* 1990;38(5):230–5.	≤1996.
Plotnikoff RC, McCargar LJ, Wilson PM, Loucaides CA. Efficacy of an E-mail intervention for the promotion of physical activity and nutrition behavior in the workplace context. *American Journal of Health Promotion* 2005;19(6):422–9.	Excluded at critical appraisal stage.
Pohanka M, Fitzgerald S. Urban sprawl and you. How sprawl adversely affects worker health. *AAOHN Journal* 2004;52(6):242–246	Non-systematic literature review.
Poole K, Kumpfer K, Pett M. The impact of an incentive-based worksite health promotion program on modifiable health risk factors. *American Journal of Health Promotion* 2001;16(1):21–6.	Better evidence available.
Prien KO, Prien EP. A prescribed employee fitness program and job-related attitudes. *Psychological Reports* 2003;93(1):153–9.	Attitudes outcome.
Prior JO, van Melle G, Crisinel A, Burnand B, Cornuz J, Darioli R. Evaluation of a multicomponent worsite health promotion program for cardiovascular risk factors-correcting for the regression towards the mean effect. *Preventive Medicine* 2005;40(3):259–67.	Non-UK study – excluded due to lack of time.
Pritchard JE, Nowson CA, Billington T, Wark JD. Benefits of a year-long workplace weight loss program on cardiovascular risk factors. *Nutrition and Dietetics* 2002;59(2):87–96.	Excluded at Critical Appraisal. Poor quality RCT. No comparative

	baseline data for outcomes.
Prochaska JO, Norcross JC, Fowler JL, Follick MJ, Abrams DB. Attendance and outcome in a work site weight control program – processes and stages of change as process and predictor variables. *Addictive Behaviors* 1992;17(1):35–45.	≤1996.
Pronk N. Worksite health promotion. Systematic reviews on obesity. *ACSM's Health and Fitness Journal* 2005;9(1):34–36	No study design. Discussion paper.
Pohjonen T, Ranta R. Effects of a worksite physical exercise intervention on physical fitness, perceived health status, and work ability among home care workers:five-year follow-up. *Preventive Medicine* 2001;32(6):465–75.	Better evidence available.
Ranieri AM. Promoting regular exercise in an electronic worksite intervention. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 1999; 59(10-B)	Not held at British Library. Abstract only. Four week follow up only.
Research Group of Rome Project of Coronary Heart Disease Prevention. Eight-year follow-up results from the Rome Project of Coronary Heart Disease Prevention. *Preventive Medicine* 1986;15:176–91	Pre-1990 and more recent RCTs.
Rooney B, Smalley K, Larson J, Havens S. Is knowing enough? Increasing physical activity by wearing a pedometer. Wisconsin Medical Journal 2003;102(4):31–6.	8-week follow-up.
Rose G, Heller RF, Pedoe HT, Christie DGS. Heart disease prevention project. *British Medical Journal* 1980;280:747–51.	≤1996.
Ruskin H, Bronner S. Effects of eight years of physical activity on health and behavior of industrial workers. *Journal of the International Council for Health, Physical Education and Recreation, Sport and Dance* 1994;30(4):22–25.	Paper not held at British Library.
Ruskin H, Halfon ST, Rosenfeld O, Tenenbaum G. The effect of a daily exercise program of industrial employees on selected physical fitness components. In: Kaneko M, editor. *Fitness for the aged, disabled and industrial worker*. Champaign, IL: Human Kinetics;1990: 254–9.	Excluded at Critical Appraisal. Poor quality RCT.
Ruzansky AS, Dobson JD. Determining the use and perceived effectiveness of a point-of-purchase cafeteria nutrition education program. *Canadian Journal of Dietetic Practice and Research* 1998;59(2):90–2.	Non-UK corroboration– excluded due to lack of time.
Sasaki S, Ishikawa T, Yanagibori R, Amano K. Change and 1-year maintenance of nutrient and food group intakes at a 12-week worksite dietary intervention trial for men at high risk of coronary heart disease. *Journal of Nutritional Science and Vitaminology* 2000;46(1):15–22.	Outcomes examined for high-risk employees only.
Schafer E, Anderson P. Heart*style: a worksite nutrition education program in a rural setting. *Journal of Nutrition Education* 1998;(1):62–5.	Better evidence available.
Schmitz K, French SA, Jeffery RW. Correlates of changes in leisure time physical activity over 2 years: The healthy worker project. *Preventive Medicine* 1997;26(4):570–9.	Non-UK corroboration– excluded due to lack of time.
Sharpe PA, Connell CM. Exercise beliefs and behaviors among older employees – A health promotion trial. *Gerontologist* 1992;32(4):444–9.	≤1996.
Sheeska JD, Woolcott DM. An evaluation of a theory-based demonstration worksite nutrition promotion program. *American Journal of Health Promotion* 1994;8(4):253, 263–4.	≤1996.
Shephard RJ. A critical analysis of work-site fitness programs and their postulated economic benefits. *Medicine and Science in Sports and Exercise* 1992;24(3):354–70.	≤1996.
Shephard RJ. Do work-site exercise and health programs work? *Physician and Sports Medicine* 1999;27(2):48–50, 55–6, 59–62.	Review of reviews.
Shephard RJ. The benefits of exercise in school and the workplace: cost-effective options. In: Conference proceedings: Vol. 1 Physical Education. Wellington: New Zealand Association for Health, Physical Education and Recreation, 1990:177–94.	Paper not held at British Library. Unable to trace.
Shephard RJ. The costs and benefits of exercise: an industrial perspective. In: Kaneko M, editor. *Fitness for the aged, disabled, and*	≤1996.

industrial work. Champaign, IL: Human Kinetic Publishers; 1990:189–204.	
Shephard RJ. Worksite fitness and exercise programs: a review of methodology and health impact. *American Journal of Health Promotion* 1996;10(6):436–52.	≤1996.
Siggaard R, Raben A, Astrup A. Weight loss during 12 week's ad libitum carbohydrate-rich diet in overweight and normal-weight subjects at a Danish work site. *Obesity Research* 1996;4(4):347–56.	≤1996.
Simpson JM, Oldenburg B, Owen N, Harris D, Dobbins T, Salmon A et al. The Australian National Workplace Health Project: design and baseline findings. *Preventive Medicine* 2000;31(3):249–60.	Baseline evidence only – no published update found.
Simmons D, Fleming C, Cameron M, Leakehe L. A pilot diabetes awareness and exercise programme in a multiethnic workforce. *New Zealand Medical Journal* 1996;109(1031):373–6.	≤1996.
Smith S, Walbourn L, Snelling A. Investigating current trends in worksite weight management programs. *American Journal of Health Promotion* 2000;14(5):333.	Abstract only – not sufficient information.
Sorensen G. Promoting healthy eating patterns in the worksite: The Treatwell intervention model. *Health Education Research* 1991;5(4):505–55.	≤1996.
Sorensen G, Himmelstein JS, Hunt MK, Youngstrom R. A model for worksite cancer prevention: integration of health protection and health promotion in the Wellworks Project. *American Journal of Health Promotion* 1995;10(1):55–62.	≤1996.
Sorensen G, Hunt MK, Cohen N, Stoddard A, Stein E, Phillips J, et al. Worksite and family education for dietary change: the Treatwell 5-a-Day program. *Health Education Research* 1998;13(4):577–91.	Baseline data from Treatwell study. Study reported in Sorensen 1999.
Sorensen G, Linnan L, Hunt MK. Worksite-based research and initiatives to increase fruit and vegetable consumption. *Preventive Medicine* 2004;39(Suppl 2):S94–100.	Expert opinion only.
Sorensen G, Stoddard A, Ockene JK, Hunt MK, Youngstrom R. Worker Participation in an Integrated Health Promotion/Health Protection Program: Results from the WellWorks Project. *Health Education Quarterly* 1996;23(2):191–203.	≤1996.
Sproul AD, Canter DD, Schmidt JB. Does point-of-purchase nutrition labeling influence meal selections? A test in an Army cafeteria. *Military Medicine* 2003;168(7):556–60.	Better evidence available.
Stamler R, Stamler J, Gosch FC, McDonald AM. Primary prevention of hypertension – a randomized controlled trial. *Annals of Clinical Research* 1984;16(Suppl 43):136–42	Pre-1990.
Stange KC, Strogatz D, Schoenbach VJ, Shy C, Dalton B, Cross AW. Demographic and health characteristics of participants and nonparticipants in a work site health-promotion program. *Journal of Occupational and Environmental Medicine* 1991;33(4):474–8.	≤1996.
Steenhuis IH, van Assema P, Glanz K. Strengthening environmental and educational nutrition programmes in worksite cafeterias and supermarkets in The Netherlands. *Health Promotion International* 2001;16(1):21–33.	Non-UK corroboration – excluded due to lack of time.
Steenhuis IH, van Assema P, Glanz K. The effectiveness of nutrition education and labelling in Dutch supermarkets. *American Journal of Health Promotion* 2004;18(3):221–4	Already included in Community Two review.
Tate DF, Wing RR, Winett RA. Using internet technology to deliver a behavioural weight loss program. *Journal of the American Medical Association* 2001;285(9):1172–7	All participants overweight.
Tilley BC, Glanz K, Kristal AR, Hirst K, Li S, Vernon SW, et al. Nutrition intervention for high-risk auto workers: results of the next step trial. *Preventive Medicine* 1999;28(3):284–92.	High-risk employees only.
Tilley BC, Vernon SW, Myers R, Glanz K, Lu M, Sanders K, et al. Planning the next step. Screening promotion and nutrition intervention trial in the work site. *Annals of the New York Academy of Sciences*	≤1996.

1995;768:296–9.	
Terborg JR, Hibbard J, Glasgow RE. Behavior-change at the worksite – does social support make a difference. *American Journal of Health Promotion* 1995;10(2):125–31.	≤1996.
Tessaro IA, Taylor S, Belton L, Campbell MK, Benedict S, Kelsey K, et al. Adapting a natural (lay) helpers model of change for worksite health promotion for women. *Health Education Research* 2000;15(5):603–14.	Non-UK corroboration– excluded due to lack of time.
Thompson B, Shannon J, Beresford SA, Jacobson PE, Ewings JA. Implementation aspects of the Seattle ‘5 a Day’ intervention project: strategies to help employees make dietary changes. *Topics in Clinical Nutrition* 1995;11(1):58–75.	Baseline results only.
Thorsteinsson R, Johannesson A, Jonsson H, Thorhallsson T, Sigurdsson JA. Effects of dietary intervention on serum lipids in factory workers. *Scandinavian Journal of Primary Health Care* 1994;12(2):93–9.	≤1996.
Titze S, Martin BW, Seiler R, Marti B. A worksite intervention module encouraging the use of stairs: results and evaluation. *Sozial-und Praventivmedizin* 2001;46(1):13–9.	Paper not available from British Library in English language.
Tosteson ANA, Weinstein MC, Hunink MGM. Cost-effectiveness of population-wide educational approaches to reduce serum cholesterol levels. *Circulation* 1997;95:24–30.	Serum cholesterol outcome only.
Trent LK. Evaluation of the Navy’s obesity treatment program. *Military Medicine* 1995;160(7):326–30	No control group.
Verrall B. A worksite health promotion intervention improved employees' nutrition. *Evidence-Based Nursing* 2000;3(1):19.	Review of another article.
Voit S. Work-site health and fitness programs: impact on the employee and employer. *Work*:2001;16(3):273–86.	Non-systematic review.
Vuori IM, Oja P, Paronen O. Physically active commuting to work – testing its potential for exercise promotion. *Medicine and Science in Sports and Exercise* 1994;26(7):844–50.	≤1996.
Watson W, Gauthier J. The viability of organizational wellness programs: An examination of promotion and results. *Journal of Applied Social Psychology* 2003;33(6):1297–312.	Non-UK corroboration– excluded due to lack of time.
Wen LW, Orr N, Bindon J, Rissel C. Promoting active transport in a workplace setting: evaluation of a pilot study in Australia. *Health Promotion International* 2005;20(2):123–33	No control group.
Williams S, Michie S, Pattani S, The Nuffield Trust. *Improving the health of the NHS workforce: report of the Partnership on health of the workforce*. London: Nuffield Trust;1998.	Report on improving health in the NHS – not relevant corroborative evidence.
Williams A, Wold J. Nurses, cholesterol, and small work sites: innovative community intervention comparisons. *Family and Community Health* 2000;23(3):59–75.	Better evidence available.
Williams C, Poulter J. Formative evaluation of a workplace menu labelling scheme. *Journal of Human Nutrition and Dietetics* 1991;4(4):251–62.	≤1996.
Wilson MG. A comprehensive review of the effects of worksite health promotion on health-related outcomes: an update. *American Journal of Health Promotion* 1996;11(2):107–8.	≤1996.
Wilson mg, Edmunson J, Dejoy DM. Cost effectiveness of work-site cholesterol screening and intervention programs. *Journal of Occupational Medicine* 1992;34(6):642–9.	≤1996.
Winick C, Rothacker DQ, Norman RL. Four worksite weight loss programs with high-stress occupations using a meal replacement product. *Occupational Medicine (Oxford)* 2002;52(1):25–30.	Better evidence available.
Worick A, Petersons M. Weight-loss contests at the worksite – results of repeat participation. *Journal of the American Dietetic Association* 1993;93(6):680–1.	≤1996.
Yancey AK, McCarthy WJ, Taylor WC, Merlo A, Gewa C, Weber MD, et al. The Los Angeles Lift Off: A sociocultural environmental change intervention to integrate physical activity into the workplace. *Preventive*	Lack of baseline evidence.

Medicine 2004;38(6):848–56.	
Zandee GL, Oermann MH. Effectiveness of contingency contracting: Component of a worksite weight loss program. *AAOHN Journal* 1996;44(4):183–8.	≤1996.

Appendix 9

Community-based interventions to prevent obesity (‘Community 1’)

EVIDENCE SUMMARY TABLES

1. GENERAL PUBLIC HEALTH, OR PUBLIC HEALTH LINKED, INTERVENTIONS FOR THE PRIMARY PREVENTION OF OBESITY

SUMMARY

Evidence of efficacy for weight management/reduction

Twelve randomised controlled trial (RCTs) and one controlled before and after study (CBA) were identified which reported weight outcomes. Results suggest that sustained interventions which focused on diet and activity or provided counselling support were more likely to lead to positive trends in the maintenance of healthy weight/prevention of unhealthy weight gain compared with interventions which focused on physical activity (PA) or diet alone though no firm conclusions can be reached.

Diet and activity

Of the five RCTs which addressed diet *and* activity (Murray 1990; Fries 1993; Jeffrey 1999; Simkin Silverman 2003; Dzator 2004) only one (Simkin Silverman) found a significant prevention of unhealthy weight gain, although Fries and Jeffrey noted positive but non-significant trends. Murray, who compared two eating-management and one weight-loss programme with a PA control group, noted greater weight reduction in the weight loss group immediately after the intervention (10 weeks post-baseline), but this benefit was lost at 1-year follow-up. The latter four studies were based in the USA, one of adult men and women (Murray), one of retirees of both sexes (Fries), one of middle-aged women (Simkin Silverman) and one weak study among younger men and women (Jeffery). All four tended to be among higher socio-economic status (SES) populations. Simkin Silverman was an intensive intervention delivered by behavioural psychologists and nutritionists compared with relatively low-intensity interventions reported by Murray, Jeffrey and Fries. A relatively small RCT of Australian couples (Dzator) found no evidence that the intervention prevented unhealthy weight gain despite reporting improvements in diet.

One relatively large US-based study (Elder 1995) considered the effectiveness of a counselling programme focusing on preventive strategies, including individualised goal-setting for older people. Results appear to suggest that participants were more likely to maintain their weight over a 48-month period than those in the control group.

Diet alone

A CBA trial of a community food skills programme for a mostly female group in eight deprived areas of Scotland (Wrieden 2002) noted a slight decrease in mean weight (–0.6 kg) in the intervention subjects at 6 months post-intervention compared with the slight increase (1.8 kg) seen in control subjects ($p = 0.049$).

Physical activity alone

One US RCT of predominantly older, higher SES, white adults (Stewart 2001) found that information and support provided by trained staff and counsellors resulted in a significant self-reported reduction in body mass index (BMI), compared with no change in BMI among the control group.

Three US-based studies (Coleman 1999; Dunn 1999; Schmitz 2003) found no difference in weight loss between intervention and control groups but did result in significant changes to fat free mass/percentage body fat. Two of these studies were of low intensity (Schmitz focused on strength training, Coleman on daily

30-min walks). One (Dunn) compared ‘exercise on prescription’ with 6-month fitness centre membership for participants. In this study both the intervention and lifestyle group (behavioural intervention to be moderately active on most days) improved their percent body fat.

Two RCTs found no evidence of effect (Pereira 1998; Hillsdon 2002). A low-intensity UK-based study (Hillsdon) among middle-aged adults found no difference in weight between study participants who received a ‘brief negotiation’ or ‘direct advice’ and control group. However, follow-up of participants in this study was poor. Pereira reported no weight differences at 10-year follow-up of US postmenopausal women, although women encouraged to walk as part of the original trial continued to walk significantly more than the control group.

Evidence of efficacy for diet/physical activity outcomes

Dietary outcomes

A high quality systematic review (Pignone 2003) concluded that moderate or high intensity interventions can reduce consumption of saturated fat and increase the intake of fruit and vegetables. Briefer interventions delivered by primary care professionals were also effective but resulted in smaller changes to diet. However, the effect size was to some extent dependent on the number of components included in (i.e. the intensity) of the intervention. Based on complex definitions of effect sizes (for details see Pignone 2003) the authors found that the six studies with three of more components produced medium or large effect sizes.

The findings of the review were supported by three more recent RCTs (Havas 2003; Carpenter 2004; Dzator 2004) and an RCT that was not included in the review (Havas 1998). Carpenter demonstrated improvements to diet in middle-aged women (as measured by a modified healthy eating index) from either group meetings or advice via mail or website with a larger effect from the weekly group meetings. Dzator also found that interactive sessions and/or advice by mail over a 16-week period to couples resulted in improvements to total fat, fibre, and fruit and vegetable intake at 4 months and total fat intake at 12 months follow-up. Marginal improvements were reported in the high intensity versus the low intensity intervention but no significance values were reported.
Two multi-component personalised educational RCTs with lower SES US women, based on social marketing strategies (Havas 1998, 2003), resulted in significant increases in fruit and vegetables in both studies and, also, a reduction in fat and an increase in fibre in the later study (Havas 2003).

Two CBAs were identified (Wrieden 2002; Department of Health 2003), both carried out in the UK. A national before and after evaluation of *Five a Day* pilot projects in five UK communities (Department of Health 2003) concluded that the initiatives stemmed a fall in fruit and vegetable intake against the national trend (a fall in intake in the control group of 0.5 portions per day compared with no change in the intervention group). However a severe lack of methodological detail limits the strength of the conclusions that can be drawn. A community food skills programme for a mostly female group in eight deprived areas of Scotland (Wrieden 2002) resulted in an increase of one portion per week for fruit ($p = 0.047$) immediately post-intervention but this was not sustained at 6-month follow-up.

See also Broader Community Review (Table 1: supermarkets).

Physical activity

One high quality systematic review and nine more recent RCTs considered the effectiveness of interventions to increase PA levels.

The systematic review (Hillsdon 1996) identified a lack of UK-based research but was able to conclude that interventions to encourage walking and non-facility based activity are most likely to lead to sustainable increases in PA (up to at least 2 years). Only two of the more recent RCTs (Jeffery 1999; Schmitz 2003) did not support these conclusions. A small study finding no significant increase in PA among the intervention group (Schmitz) and a further weak RCT where the statistical values were unclear (Jeffery). The majority of studies were among motivated, higher SES groups but were undertaken among both males and females, a range of age groups, and through a range of delivery methods (e.g. mailed information, brief advice, structured programmes and counselling).

Evidence of corroboration in the UK

Of the intervention studies, one RCT focusing on PA (Hillsdon 2002) and two CBAs concentrating on diet change (Wrieden 2002; Department of Health 2003,) were carried out in the UK. In addition, many of the non-UK interventions identified could be generalisable to the UK, particularly for motivated individuals of higher social status.

In terms of implementation, five UK studies were found. Three (Lloyd 1995; Anderson 1998a; Wrieden 2002) considered barriers to dietary change and one considered potential barriers to increasing walking (Vernon 1998). The dietary studies identified practical issues that could reduce the effectiveness of an intervention (e.g. considering concerns around taste, cost, availability and time), but suggest that once these were addressed participants may be receptive to change, particularly in relation to increasing fruit and vegetable consumption. In terms of walking, the most significant barrier was lack of time reflecting findings of RCTs that compliance was likely to be better with less time demanding interventions (i.e. home- rather than facility-based). A weak UK study looking at the role of community recruited and trained nutrition assistants to provide healthy eating advice and support food related activities (Kennedy 1999) found that a fourfold increase in coverage resulted and that the majority of respondents preferred advice from a local person rather than a health professional, perceiving them to be more approachable and easier to access.

EVIDENCE TABLE 1: GENERAL PUBLIC HEALTH, OR PUBLIC HEALTH LINKED, INTERVENTIONS FOR THE PRIMARY PREVENTION OF OBESITY

First author	**Study design**	**Res type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Dzator 2004	RCT Individual	1	+	Couples in Perth, Australia recruited by press and media publicity. Average age 29.4 (SD 8.2) years. No further details other than (in discussion) 'Higher socioeconomic status, based on occupational classification, was over-represented'.	**Aim:** To compare the effects of a diet and PA programme in couples. Couples were randomised to a: (1) programme delivered mainly by mail; (2) a combination of mail and interactive group sessions, or (3) control group. Power calculation: *p* = 0.05 with a power of 80% as a minimum. **Delivered by:** Health promotion professionals, including an exercise physiologist, a clinical nurse and a	16-week intervention. 8-month follow-up (1 year after baseline).	81% completed to 16 weeks (111/137). 59% completed to 1 year (81/137). Diets improved up to 12 months after beginning the 4-month programme, mainly in the interactive group. There were no significant differences for BMI at either four or twelve months in or between any of the groups (*p* = 0.210 at 4 months and *p* = 0.121 at 12 months).	No allocation concealment. Unclear whether the diet and PA questionnaires were validated. Intention to Treat (ITT) used. Motivated (volunteer) and higher SES couples.

					dietitian/nutritionist.			
Schmitz 2003	RCT Individual	1	+	Volunteer female staff and students from the University of Minnesota, USA. Self-reported BMI 20–35 kg/m^2. 100% women aged 30–50 (average 41.8, SD 6.4) years. 90% White, 10% African American or Asian. 85% had completed college.	**Aim:** To assess whether reductions in fat from 15 weeks supervised strength training would be maintained over 6 months of unsupervised exercise. Blocked randomisation by age to a 50-min strength training class twice weekly for 15 weeks followed by 6-month membership to exercise facility or no intervention control **Delivered by:** Supervised training by exercise trainer.	15 weeks supervised, then 6 months unsupervised training.	93% (56/60) of all women completed the study. Twice weekly strength training is behaviourally feasible for busy midlife women and the favourable body composition changes can be maintained over time. Over the total 39 weeks of strength training, the treatment group gained 0.89 kg more in fat free mass (*p* = 0.009), lost 0.98 kg more in fat mass (*p* = 0.06), and lost 1.63% more in percent body fat (*p* = 0.006) compared with control. Strength training did not result in any significant weight loss or waist circumference attenuation; however, there was a significant decrease in percent body fat with intervention compared with control.	Numerous exclusion criteria. No allocation concealment or ITT but 93% follow-up. Participants received US$200 for successful completion of the study. Motivated (volunteer), mostly White and higher SES individuals. This study may also be of relevance to the workplace review.
Simkin-Silverman 2003	RCT Individual	1	++	US study, Pennsylvania. 535 healthy premenopausal volunteer women aged 44–50 (mean age 47, SD 1.9) years with	**Aim:** To examine whether a behavioural intervention aimed at lifestyle changes in diet and PA can prevent the rise in weight and low-density-lipoprotein	54 months.	Attendance was consistently excellent, averaging 90%, with 95% (509/535) attending the 54-month assessment. 80% of intervention participants compared with 45% of controls were at or under baseline weight at 18 months, and 55% compared	Data to 18 months and background information reported in Simkin-Silverman 1998 The Women's Healthy Lifestyle Project. Study had 90% power

				average BMI 20–34 kg/m^2 (approx. half with normal weight at baseline). Participants were predominantly white (% not stated), 85% educated beyond high school and 86% employed.	(LDL)-cholesterol often observed during menopause. Intensive intervention to lower dietary fat and encourage PA and modest weight loss via group meetings and personalised plans. Assessment only control group. **Delivered by:** Behavioural psychologists and nutritionists.		with 26% at 4.5 years (p < 0.001), suggesting that weight gain during peri- to postmenopause can be prevented with a long-term lifestyle dietary and PA intervention. The mean weight chance in the intervention group was 0.1 kg below baseline compared with an average gain of 2.4 kg in the control group.	to detect an effect. Essentially White, well educated and motivated (volunteer) women.
Hillsdon 2002 UK Study	RCT Individual	1	+	Healthy sedentary men and women from two medical centres in Wellingborough, UK. n = 1658 Mean age = 54.9 (range 45–64) years 49% male 9.4% non-White 10.3% higher educated 44.8% no	**Aim:** To compare two low intensity communication styles in a one-to-one intervention: 1) Brief Negotiation (BN) with client centred consultations; 2) Direct Advice (DA) with info on benefits of PA; and encouragement 3) No intervention control.	1 year (Intervention phone calls until 8.5 months.)	32% follow-up in BN group 33% follow-up in DA group 62.5% follow-up in control Those who undertook less that one 30-min occasion of PA per week at baseline were less likely to complete the final log book than those doing at least that amount (odds ratio [OR] 0.29, 95% confidence interval [CI] 0.16, 0.53). No significant between group difference in weight change for BN and DA groups: Mean change from baseline at 12	Randomisation not clearly described but allocation concealment used. Low follow-up but ITT.

				education	Both intervention groups received 30 minute baseline intervention and telephone calls at 2, 6, 10, 18, 26 and 34 weeks relevant to intervention. **Delivered by:** Health promotion specialist.		month follow-up (95% CI): BN: 0.0 (–0.2, 0.2) DA: 0.01 (–0.2, 0.2) Between group difference: –0.03(–0.36, 0.30), *p* = 0.86 (adjusted for baseline BMI, age and energy expenditure). No results stated for difference between intervention vs. control in BMI change.	
Stewart 2001	RCT Individual	1	+	Volunteers from two Medicare health maintenance organisations in the US (California?). 66% female. Mean age 74 (SD 6), range 65–90 years. 8.5% minority groups. 18.9% high school education or less. 22% with graduate degree.	**Aim:** To compare the effectiveness of a choice-based PA programme to increase PA levels of seniors with control group who were offered programme at the end of the year Trained staff assisted participants to develop and maintain a PA regimen that they would be capable of sticking with. Information, support and opportunities for skill building were provided through numerous activities	1-year intervention. No follow-up.	Recruitment 85% (893/1053) of those eligible who responded to invitation. Only 173 were randomised to trial but 95% completion (164/173). Individually tailored programmes to encourage lifestyle changes in seniors may be effective. Self-reported data suggested that the intervention group subjects reduced their BMI from baseline by 0.496 kg/m^2 (*p* = 0.0001), whereas there was no significant change in the control group (*p* = 0.004, not significant).	The CHAMPS II Study, based on social cognitive theory. No allocation concealment or ITT but follow-up = 95%. Validated PA measure. Motivated (volunteer) mostly white, older, female majority and higher SES. Many subjects had health problems.

					(including ten workshops). Regular staff initiated phone calls from a counsellor. **Delivered by:** Trained staff and counsellors.			
Coleman 1999	RCT Individual	1	+	Forty-seven sedentary adult volunteer employees at the University of Buffalo, NY, USA (not engaging in vigorous intensity exercise at least three times per week for at least 20 min per session). Average BMI approx. 25.8 kg/m^2. 84% female, average age approx 43.1 (range 18–55) years. Almost exclusively White, well educated and SES 50–53 on a scale of 8–66.	**Aim:** To test different ways of meeting the recommendations for 30 min of moderate intensity activity on most days of the week. Volunteers were randomised to brisk walking 6days per week in: 1) continuous bout; 2) three 10-min bouts; (3) Any combination so long as each bout was at least 5 min. Academic researchers. **Delivered by:** Activity counsellors.	16-week intervention. 16-week follow-up.	77% (36/47) began study and 89% of those (32/36) completed to 16 weeks. A walking prescription of 30 min per day on most days of the week with the choice to walk in as little as 5-min bouts can improve body composition, as well as help sedentary people maintain these improvements over time. Percentage body fat was significantly reduced from baseline to 32-week follow-up in all groups (p = 0.03) although there was no significant change in body weight. No significant effects observed between groups.	No allocation concealment. No ITT but 85% follow-up. Study likely to be underpowered as small study (47 volunteers only from University). Motivated (volunteer), mostly female, white and high SES. Objective measure of activity using the TriTrac accelerometer as well as self-reported measures. Participants deposited US$50, refunded in segments for completion of assessments and good attendance. This paper may also be of relevance to the workplace review.

Dunn 1999	RCT Individual	1	+	Healthy sedentary men and women (self-reported PA of less than 26 and 24 kcal/day respectively) from Dallas, Texas, USA. Most modestly overweight but none >140% over ideal weight. 50.5% women. Average age 46.0 (± 6.6, range 35–60) years. Stated that 'Highly educated' but no details given.	**Aim:** To compare a lifestyle PA programme with traditional structured exercise. Academic research group. Used the Stages of Change model. The structured exercise group received a traditional exercise prescription for 6 months at a fitness centre individualised to participants after first 3 weeks, followed by meetings and correspondence during follow-up. **Delivered by:** **'**Group leaders' and project staff. Higher education study. The lifestyle group received an intensive behavioural intervention to encourage 30 min moderate intensity	6 months intensive. 18 months maintenance.	Of 122 participants in the lifestyle group 89% (109/122) completed to 6 months and 82% (100/122) to 24 months. Of 115 in the structured group 90% (103/115) completed to 6 months and 78% (90/115) to 24 months. In initially sedentary healthy adults, a lifestyle PA intervention is as effective as a structured exercise programme. Over 24 months, neither group significantly changed their weight from baseline (–0.05 [95% CI –1.05, 0.96], *p* = 0.93] kg) and +0.69 [95% CI –0.37, 1.74] kg, *p* = 0.20, but each group significantly reduced their percentage of body fat from baseline (–2.39 [95% CI –2.92, –1.85]%, *p* < 0.001 and –1.85 [95% CI –2.41, –1.28]%, *p* < 0.001) in the lifestyle and structured activity groups respectively. No significant differences between groups (*p* = 0.17 for % body fat and *p* = 0.32 for weight).	Lacks a no-intervention control group. No allocation concealment but ITT used. Unclear how participants were recruited but probably volunteers. Highly educated. Measurement staff were blinded to allocation.

					PA most days but no fitness centre membership, followed by less regular meetings and correspondence. **Delivered by:** 'Group facilitators'			
Jeffery 1999	RCT Individual	1	+/– (weak)	Men and women recruited from diverse sources, Minnesota, USA. *n* = 1226 18.6% men 40.5% of women were low income (household incomes of US$25000 or less per year). Mean age = 38.4 years 90.7% white 89% with at least some college education Average BMI = 26.7 kg/m².	**Aim:** To evaluate effectiveness of low-intensity intervention to prevent weight gain with age. No-contact Control compared with: 1) education through monthly newsletters (questionnaire postcard included) encouraging paying attention to weight and making small changes in diet and exercise habits; and 2) education + incentives (entry into US$100 lottery if questionnaire postcard returned). Intervention subjects had option for participation in	3 years (Newsletters continued throughout 3 years.)	106 women who become pregnant excluded from the analysis. 809/1120 (72%) completed all data collection visits. Significant increase between intervention groups and control in self-reported frequency of healthy weight loss practices (including reducing energy intake, increasing exercise and fruit and vegetables intake and decreasing fat intake) ($p = 0.01$), related to a reduced rate of weight gain over time. Point estimates for rate of weight gain over three years were slightly lower in both intervention groups than control, but differences between all groups not statistically significant, $p = 0.88$.	No description of randomisation, no allocation concealment or ITT. **Baseline differences:** Mean BMI higher in education-only group. Higher % of whites in two education groups (92% and 93%) than in control (87%). Parallel analyses with subjects completing only partial data (1101/1120 – 98.3%) yielded very similar findings and are not described in paper. Pound of Prevention study.

					community activity every 6 months. Annual study visits for all participants. **Delivered by:** Researchers (although 6-monthly activities delivered by various including nutritionists).			
Pereira 1998	RCT Individual	1	+	Volunteer postmenopausal women from the Pittsburg, Pennsylvania, USA. Average age 57.5 ± 4.2 years. No socio-economic data provided but: 'our population of women was basically of the same … socio-economic status' (quoted verbatim from text).	**Aim:** To test the hypothesis that the women randomised to the walking group of a clinical trial were still walking more 10 years later than the women in the control group. Aim of original trial was to investigate the effect of PA on bone loss. The analysis on that this paper was based looks at increases in activity in the subjects of the above trial and factors associated with compliance. **Delivered by:** Original intervention	2-year intervention? (unclear if intervention continued after 2-year follow-up). 10-year follow-up.	85.6% (196/229) were interviewed by telephone at 10 year follow-up. The median self-reported values for both usual walking for exercise and total walking were significantly higher for walkers compared with controls (for both, $p = 0.01$) but there were no weight differences between groups. **In 1985:** BMI (kg/m^2) in walkers 25.9 (SD 4.84) and in controls 24.4 (SD 4.2). **In 1995:** BMI (kg/m^2) in walkers 25.9 (SD 5.02) and in controls 25.7 (SD 4.86).	Two-year results and background info in Kriska 1986 No allocation concealment. ITT carried out and described in detail in Kriska 1986. Telephone interviewers masked to group assignment.

					delivered by exercise leaders.			
Elder 1995	RCT Individual	1	+	Members of health maintenance organisation (HMO), USA. *n* = 1800 76.8% aged 65–74 years 52.5% female 78.5% had income <US$40,000 per year (approximately £21,000) 65.8% had ≥13-years education.	**Aim:** To evaluate the effectiveness of a preventive services intervention trial compared with control. Intervention was 8-week 2-hour workshops with 25 participants in each delivered in community centres. Workshops on self-care and mental alertness. Goal setting delivered via individualised 15 min counselling sessions. **Delivered by:** 'Facilitators'.	8-week intervention. 12- and 48-month follow-up	84% follow-up in intervention and 82% follow-up in control at 12 months. 44.3% follow-up at 48 months across both intervention and control. Repeated-measures analysis showed that the intervention group experienced little change in body mass in the 48-month period Compared with a consistent, though non-significant rise in body mass levels in the control group (*p* ≤ 0.10).	No ITT. No allocation concealment. Difficult to tell if the only difference between groups was the treatment under investigation. Intervention participants received package of preventive interventions including immunizations and clinical tests as part of a larger trial – selected outcome effects may not be solely attributable to the intervention components. Subjects chose to take part in study after being randomly selected for the programme. Therefore subject motivation may have influenced the findings.
Fries 1993	RCT Cluster	1	+	Bank of America Retirees, California, USA. *n* = 4712 Mean age = 68.2 years	**Aim:** To evaluate the effectiveness of low intensity health promotion programme in terms of reduction of health	24 months (Repeat mailings of self-help materials to intervention throughout this	At 12 months 58% follow-up. At 24 months 47% follow-up. Attrition largely attributable to death, loss of eligibility or moving from state of California.	Baseline difference of 1 lb (0.45 kg) between groups in weight over ideal body weight. Group 1 higher at baseline.

				53% Female Highest work grade level = 13.0 (unclear UK comparison).	risk and medical costs. **Group 1:** Low cost (US$30) individualised programme with risk appraisal (signed by physician) and self-help materials delivered entirely by mail. **Group 2:** Risk appraisal with no feedback for first 12 months, then full programme. **Group 3:** Claims data only – control. Research-led. **Delivered by:** Unclear.	time for group 1 and in final 12 months for group 2.)	Non-significant but favourable trend seen at 12 months for weight over ideal body weight, with the between group difference (between group 1 and group 2) being 1 lb (0.45 kg). Group 1 lost 1 lb (0.45 kg) from baseline and group 2 lost 0 lb (0.00 kg).	No allocation concealment. No ITT. High attrition. Possibly generalisable to retirees.
Murray 1990	RCT individual	1	++	208 Participants recruited from the community by a newspaper advertisement in the 'Twin Cities' (Minnesota). Thus participants were	**Aim:** To evaluate several low-intensity intervention programmes designed for the general public to promote dietary change and reduce	Short-term interventions (varying from 4 to 8 weeks) with analysis at 10 weeks (post test) and 1 year (follow-up) after	5% dropped out and a further 14% attended less than half the lessons but an intention to treat analysis was used. Subjects in the weight management programme lost more weight (approx. 5.5 lb [2.49 kg] per person, $p < 0.05$)	No allocation concealment but ITT used. Participants were self-selected. The study was designed to look at cholesterol rather than weight reduction and

				self-selected. Average age 47 (range 25–70) years, 67% female. 89% had completed some education beyond high school, 60% with college degrees. No racial information.	blood cholesterol levels. Participants were randomised to: 1) eating patterns course (four weekly 2-hour sessions on food selection and preparation) including food-preparation/taste-testing component; 2) an identical course without the food-preparation/taste-testing; 3) weight management programme (eight weekly 1-hour sessions); 4) PA programme (four 2-hour sessions with an emphasis on walking). No power calculation. **Delivered by:** Higher education researchers. Classes taught by nutritionists and dietitians recruited from the community.	baseline.	than the control PA group (approx. 1.9 lb [0.86 kg] per person) at post test but both groups returned to within 1 lb [0.45 kg] of their baseline weights at 1 year follow-up. A cholesterol reduction (circa 4%) was maintained to 1-year follow-up in the dietary/weight loss compared with the control (PA) group.	the PA component was used as the control group, thus severely limiting the value of the RCT for weight outcomes. Participants were blocked by gender and past participation in a weight-loss programme.

Wrieden 2002	CBA	2	+	Eight deprived communities in Scotland. **At baseline:** 88% female. Mean age 32.3 (SD 10.2) (range 16–65) years. 72% rented their accommodation, 33% claimed housing benefit, 46% were on income support and 14% received job seekers allowance. Only 4% were employed full time. 64% manual social class, 11% heads of household had never worked. 77% finished full-time education aged ≤16 years, the intervention group having the highest percentage in this category (84%). In all cases a local community worker recruited people to	**Aim:** To develop, implement and evaluate a transferable community-based, food skills initiative aimed at increasing consumption of fibre-rich starchy carbohydrates, fish, vegetables and fruit and decreasing consumption of fat in adults living in areas of deprivation. During 2000–2001 the CookWell programme (ten weekly 2-hour sessions including data) was run in eight locations throughout Scotland for approx 2–3 months in each community (*n* = 6–10 in each intervention group). The development of the programme was informed by preliminary focus groups within the community.	Three-month intervention plus 6-month follow-up. Quantitative evaluations using food diaries, shopping diaries and questionnaires were carried out in intervention and delayed intervention (control) subjects at baseline, immediately post-intervention (circa 3 months) and 6 months later.	Of 113 subjects initially recruited, 93 (82%) completed the baseline assessments and by the 6-month follow-up 63 (56%) had completed some or all assessments. A slight decrease in mean weight (–0.6 kg) was observed for the intervention subjects at 6-months post-intervention and this was significantly different from the slight increase (1.8 kg) seen in control subjects (*p* = 0.049).	The Cookwell study. Reliability of outcome measures unclear and only 56% follow-up.

				take part.	**Delivered by:** Higher education researchers. No power calculation.			

Evidence of efficacy (internal validity) for diet outcomes								
Pignone 2003	Systematic review	1	++	Literature search 1966 – December 2001. Twenty-one RCTs were included, of which 21 study arms looked at patients not selected/identified by risk factors and 13 looked at patients with identified risk factors. Two trials were carried out in the UK (Roderick 1997; Steptoe 1999). Both studies included subjects with identified risk factors for coronary heart disease or with hypcholesterolaemi	**Aim:** To determine the effectiveness of counselling to promote a healthy diet among patients in primary care settings.	Trials had to be of at least 3 months duration with a minimum retention rate at follow-up of 50%.	Moderate- or high-intensity counselling interventions in primary care settings including use of interactive health communication tools (e.g. telephone messages, computer generated mailings), can reduce consumption of saturated fat and increase intake of fruit and vegetables. Brief counselling of unselected patients by primary care providers appears to produce small changes in dietary behaviour, but its effect on health outcomes is unclear. The authors could find no clear relationship between the risk status of patients and the effect size achieved. Studies using a greater number of components (e.g. dietary assessment, family involvement, social support, counselling, targeted advice, goal	Medline only searched but reference list follow-up and experts consulted. Otherwise a sound review methodology.

				a.			setting) had larger effect sizes. Six studies with three or more components produced medium (*n* = 2 studies) to large (*n* = 4 studies) effects (see Pignone for definitions). **Effect of reducing saturated fat consumption:** Six studies achieved large effect (>3% point reduction), five achieved a medium effect (1.3–3% point reduction) and six achieved a small effect (<1.3% point reduction). For the nine studies reporting change in % energy from saturated fat, net reductions ranged from 0.9–5.3% points. From ten studies for increasing fruit and vegetables consumption, three demonstrated small or no increases (<0.3 servings/day), five showed medium increases (0.3–0.8 servings/day), and two showed large increases (1.4–3.2 servings/day) (range 0–3.4 servings/day increase).	
Carpenter 2004	RCT Individual	1	++	Participants recruited from authors' database of subjects who expressed interest in participating in	**Aim:** To determine the effect of a cognitive and behavioural skills building intervention delivered via:	6-month intervention. No follow-up.	98/189 eligible participants randomised (52%). 95% of this group completed 6 months and ITT used. A behaviourally focused	Very small (pilot) study although methodologically strong. Described the majority of subjects as overweight but no BMI

				health related clinical trials, in Dallas, USA. 64% women, average age 49.6 (SD 11.3), range 29–71 years. 87% white. Circa 10% ≤12 years education, circa 30% >16 years education.	1) a small group in 20 weekly meetings [WM]; or 2) correspondence (20 sessions via mail and interactive web site) [CR]; compared with 3) a usual care control group [UC] on improvement in total diet quality. **Delivered by:** Weekly meetings delivered by two staff co-facilitators.		intervention can improve overall diet quality, especially if delivered through small-group meetings, compared with delivery through mail and interactive websites. The WM group significantly improved their Modified Health Eating Index (MHEI) score compared with the CR (*p* = 0.04) and UC (*p* = 0.002) groups. The CR group's improvement in MHEI score was not significantly different from that of the UC group (*p* = 0.19).	data. Used a *modified* form of a validated dietary measure – MHEI adapted from the US Department of Agriculture's Healthy Eating Index. Mostly white, motivated (volunteer) subjects.
Dzator 2004	RCT Individual	1	+	Couples in Perth, Australia recruited by press and media publicity. Average age 29.4 (SD 8.2) years. No further details other than (in discussion): 'Higher socioeconomic status, based on occupational classification, was over-represented in our study'.	**Aim:** To compare the effects of a diet and PA programme in couples delivered by different mechanisms, with control. Couples were randomised to either: 1) programme delivered mainly by mail ('low intensity'); 2) a combination of mail and interactive group sessions ('high intensity'); or 3) control group.	Sixteen-week intervention, Eight-month follow-up (1 year after baseline),	81% completed to 16 weeks (111/137). 59% completed to 1 year (81/137). Diets improved up to 12 months after beginning the 4-month programme, mainly in the interactive group. Both interventions were more effective than control with statistically significant differences at 4 months for a reduction in total fat (*p* = 0.023), grams of fibre (*p* = 0.037) and fruit and vegetable servings consumed (*p* = 0.019).* At 12 months, only the results for total fat remained	No allocation concealment. Unclear whether the diet and PA questionnaires were validated. ITT analysis used. Motivated (volunteer) and higher SES couples.

					Power calculation: *p* = 0.05 with a power of 80% as a minimum. **Delivered by:** Health promotion professionals, including an exercise physiologist, a clinical nurse and a dietitian/nutritionist.		significant (*p* = 0.013).* *Unclear if these results are comparing intervention groups or intervention and control/ There were only marginal improvements in the high intensity intervention group compared with the low intensity intervention group (no significance values given).	
Havas 2003	RCT Cluster with individual analysis	1	+	2066 women (1055 intervention and 1011 control) served by the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) in Maryland. The majority of participants were black (>50%), <30 years, high school graduates, single, unemployed and with incomes <$15,000.	**Aim:** To decrease the percent of energy derived from fat and to increase fruit, vegetable and fibre intake among low-income women served by the WIC programme. Cluster crossover RCT. Intervention participants had a multidimensional intervention, guided by formative research, which included five interactive nutrition sessions, individualised written materials and phone	6-month intervention with 2-month post-intervention follow-up (8 months) and 1 year later.	Of women meeting criteria, 39% at both intervention and control sites agreed to participate. 71.4% of intervention and 74.7% control participants completed the two months survey and 53.1% and 60.2% respectively completed the 1-year follow-up. Mean differences (intervention-control) in change from baseline were for percent energy from fat – 1.62 ± 0.33% (*p* < 0.0001), for consumption of fruit and vegetables 0.40 ± 0.11 servings (*p* = 0.0003), and for fibre intake 1.01 ± 0.31 g (*p* = 0.001). The changes remained significant at 1-year follow-up for the first two outcomes.	No details of randomisation method or allocation concealment although recruiters were blinded re treatment allocation. Intention to treat analysis carried out. Questionnaire piloted but not validated. ITT analysis but 159 participants (7%) were excluding for reporting 'highly unrealistic calorie [energy] intake'. Each woman was given US$20 for completing the post survey and US$20 for 1-year follow-up survey. Meets criteria for a

					calls. Controls received usual WIC care. No power calculation reported. Intervention provided by peer educators. Higher education researchers.			**social marketing** intervention (see methodology).
Havas 1998	RCT Cluster	1	+	3122 low-income women (enrolled in the federally funded Special Supplemental Nutrition Program for Women, Infants and Children, WIC programme) and their children (control condition *n* = 1679, intervention condition *n* = 1443). Subjects recruited during voucher pick-up [66% acceptance during intervention and 87% acceptance during control phase]. Overall the majority	**Aim:** To increase fruit and vegetable consumption among women served by the WIC programme in Maryland. Power calculation to detect 0.5 helping difference. Randomised crossover design. Randomisation by site, analysis by individual and site. The intervention was informed by focus group research and consisted of three components: nutrition sessions by peer educators; printed materials and visual reminders; and direct	Six-month intervention with 2-month (8-months post baseline) and 1 year later (20 months post baseline) follow-up.	Survey completion at 2 months – 75% intervention; 76% of control. At plus 1 year – 64% intervention; 60% control. ITT used. Two months post-intervention, mean daily consumption had increased by 0.56 ± 0.11 servings in intervention participants and 0.13 ± 0.07 servings in control participants ($p = 0.002$). One year later, mean consumption had increased by an additional 0.27 servings in both intervention and control ($p = 0.004$ between groups).	No details of randomisation method or allocation concealment. ITT analysis carried out. More intervention than control participants were black and/or on food stamps and fewer worked. A major concern is the lower baseline consumption of fruit and vegetables in intervention compared with control participants, although the intervention effect was still significant when this baseline difference was controlled for. Questionnaire piloted but not validated. **Ethnic differences:**

				of subjects were black (>50%), <30 years old. single and unemployed.	mail. The control group received the usual WIC programme, which included <10 min of nutrition education. Intervention provided by peer educators. Higher Education researchers.			Subgroup analysis showed that statistically significant changes occurred only among whites and those with at least a high school education. Barriers leading to non-attendance included lack of transportation, work schedules and lack of interest. Each woman was given US$10 for completing post survey. Meets criteria for a **social marketing** intervention (see methodology).
Department of Health 2003	CBA	2	+/–*	National evaluation of *five-a-day* pilot projects in five areas of the UK. No details provided in the executive summary and none available from project despite two approaches (fiveaday@sh.gsi.gov.uk).	**Aim:** To assess the feasibility of implementing an area-wide approach to increasing fruit and vegetable consumption. The intervention included action to improve access to fruit and vegetables by retailers, food co-	1-year intervention with pre- and post-questionnaires.	Response rate information not available but requested by email (see above). The community initiatives stemmed a fall in fruit and vegetable intake against the national trend. There was a fall in intake in the control group by almost half a portion (although baseline data suggested control group had a higher intake by 1.5 portions compared with intervention sites). Overall the intervention had a positive affect	Five-a-day project. Several baseline differences between the control and intervention populations. *Unless response rate information is made available, this study will be potentially severely confounded. Each of the local evaluation sites developed its own

					operatives and targeted promotional activities in the community and by primary health care professionals. Interventions provided by community based cross-sectoral teams in each area. **Delivered by:** Higher education researchers. No power calculation.		on people with the lowest intakes. Those who ate less than five a day at baseline increased their intake by one portion over the course of the study. In contrast, those who ate five or more a day at baseline decreased intakes by about one portion per day. At follow-up, 35% of people in the intervention areas reported improved access to fruit and vegetables compared with 21% in the control area.	evaluation strategy and tools. Due to the variations in methods, it was not possible to compare the results, or draw general conclusion. This paper is relevant to increasing awareness review.
Wrieden 2002	CBA	2	+	Eight deprived communities in Scotland. **At baseline:** 88% female. Mean age 32.3 (SD 10.2), range 16–65 years. 72% rented their accommodation, 33% claimed housing benefit, 46% were on income support and 14% received job seekers allowance. Only 4% were employed full time.	**Aim:** To develop, implement and evaluate a transferable community-based, food skills initiative aimed at increasing consumption of fibre-rich starchy carbohydrates, fish, vegetables and fruit and decreasing consumption of fat in adults living in areas of deprivation. During 2000–2001 the Cookwell	3-month intervention plus 6-month follow-up. Quantitative evaluations using food diaries, shopping diaries and questionnaires were carried out in intervention and delayed intervention (control) subjects at baseline,	Of 113 subjects initially recruited, 93 (82%) completed the baseline assessments and by the 6-month follow-up 63 (56%) had completed some or all assessments. A mean increase equivalent to one portion per week was seen in the intervention group immediately post-intervention for fruit (*p* = 0.047) but no other significant changes were seen. This change was not sustained at 6-month follow-up. Post-intervention quantitative and qualitative assessments suggested that the percentage of people cooking from basic	The Cookwell study. Reliability of outcome measures unclear and only 56% follow-up.

				64% manual social class, 11% heads of household had never worked. 77% finished full time education aged ≤16 years, the intervention group having the highest percentage in this category (84%). In all cases a local community worker recruited people to take part.	programme (ten weekly 2-hour sessions including data) was run in eight locations throughout Scotland for approx 2–3 months in each community (*n* = 6–10 in each intervention group). The development of the programme was informed by preliminary focus groups within the community. **Delivered by:** Higher education researchers. No power calculation.	immediately post-intervention (circa 3 months) and 6 months later.	ingredients increased in the intervention group compared with the control.	
Evidence of efficacy (internal validity) for physical activity outcomes								
Hillsdon 1996	Systematic review	1	++	Literature search 1966–96. Eleven RCTs included of 12 weeks minimum duration; all from the USA. In terms of the location of exercise, seven trials were home-based and seven	**Aim:** To revise and update a previous systematic review of RCTs of PA promotion in apparently healthy, free living adults.	Studies of 12 weeks minimum duration. Seven of the trials included post-intervention follow-up ranging from 2 months to	Interventions that encourage walking and do not require attendance at a facility are most likely to lead to sustainable increases in overall PA. Levels of PA can be increased and the increase can be maintained for at least 2 years. Regular follow-up, which need not be time consuming and expensive, improves the proportion of people able to maintain initial increases.	**Home-based:** Kriska 1986 Lombard 1995 King 1991 Noland 1989 King 1988 King (different arm) 1988 Godin 1987 **Facility-based:** McAuley 1994

				were facility-based.		12 years: Reid 1979; McAuley 1884; Kriska 1886; King 1988; King 1991; Marcus 1993; Lombard 1995.	Five of the seven home-based trials reported a significant positive outcome of the intervention (Kriska, Lombard, King, Noland, King) but only two of the five facility-based trials (McAuley, King). The small number of trials limits the strength of the conclusions and UK research is needed.	King 1988 MacKeen 1985 Reid 1979 Marcus 1993
Dzator 2004	RCT Individual	1	+	Couples in Perth, Australia recruited by press and media publicity. Average age 29.4 (SD 8.2) years. No further details other than (in discussion): 'Higher socioeconomic status, based on occupational classification, was over-represented in our study'.	**Aim:** To compare the effects of a diet and PA programme in couples. Couples were randomised to a: 1) programme delivered mainly by mail; 2) a combination of mail and interactive group sessions; or 3) control group. **Power calculation:** *p* = 0.05 with a power of 80% as a minimum. **Delivered by:** Health promotion professionals, including an exercise physiologist, a clinical	Sixteen-week intervention Eight-month follow-up (1 year after baseline)	81% completed to 16 weeks (111/137). 59% completed to 1 year (81/137). Both interventions were more effective than control with statistically significant differences at 4 months for exercise days per week (0.7 [SE 0.2]% difference from baseline in both intervention groups and 0.2 [SE 0.2]% difference in control group [*p* = 0.048]) but no difference in the high intervention relative to the low intervention group. At 12 months, there was no significant difference between the intervention and control groups. (High intensity intervention 0.3 [SE 0.2]% change from baseline, low intensity intervention 0.5 [0.2]% change from baseline and control 0.3 [0.2]% change from baseline.)	No allocation concealment. Unclear whether the diet and PA questionnaires were validated. ITT analysis used. Motivated (volunteer) and higher SES couples.

					nurse and a dietitian/nutritionist.			
Schmitz 2003	RCT Individual	1	+	Volunteer female staff and students from the University of Minnesota, USA. Self-reported BMI 20–35 kg/m^2. All women aged 30–50 (average 41.8, SD 6.4) years. 90% White, 10% African American or Asian. 85% had completed College.	**Aim:** To assess whether reductions in fat from 15 weeks supervised strength training would be maintained over 6 months of unsupervised exercise. Blocked randomisation by age to a 50-min strength training class twice weekly for 15 weeks followed by 6-month membership to exercise facility or no intervention control. **Delivered by:** Supervised training by exercise trainer.	Fifteen weeks supervised, then 6 months unsupervised training.	93% (56/60) completed the study. Twice weekly strength training is behaviourally feasible for busy midlife women and the favourable body composition changes can be maintained over time. However, there was no significant difference in PA between intervention and control.	Numerous exclusion criteria. No allocation concealment or ITT but 93% follow-up. Energy intake at baseline was higher in the treatment than the control group. Participants received US$200 for successful completion of the study. Motivated (volunteer), mostly White and higher SES individuals. University employees and researchers – relevant to workplace?
Simkin-Silverman 2003	RCT Individual	1	++	US study, Pennsylvania. 535 healthy premenopausal volunteer women aged 44–50 (mean age 47, SD	**Aim:** To examine whether a behavioural intervention aimed at lifestyle changes in diet and PA can prevent the rise in weight and LDL-	54 months.	Attendance was consistently excellent, averaging 90%, with 95% (509/535) attending the 54-month assessment. At both 6 and 18 months, the intervention group had significantly greater overall activity and energy	Data to 18 months and background info reported in Simkin-Silverman 1998 The Women's Healthy Lifestyle Project.

				1.9) years with average BMI 20–34 kg/m^2 (approx. half with normal weight at baseline). Participants were predominantly white (% not stated), 85% educated beyond high school and 86% employed.	cholesterol often observed during menopause. Intensive intervention to lower dietary fat and encourage PA and modest weight loss via group meetings and personalised plans. Assessment only control group. **Delivered by:** Behavioural psychologists and nutritionists.		expended from walking than controls compared with baseline ($p < 0.05$ for all measures). At 54-months the intervention group had significantly greater overall activity ($p < 0.001$) and less energy intake ($p < 0.01$).	Study had 90% power to detect an effect. Essentially White, well educated and motivated (volunteer) women.
Hillsdon 2002 UK Study	RCT Individual	1	+	Healthy sedentary men and women from two medical centres in Wellingborough, UK. *n* = 1658 Mean age = 54.9 years, range 45–64 49% male 9.4% non-white 10.3% higher educated 44.8% no education	**Aim:** To evaluate effectiveness of low-intensity intervention to prevent weight gain with age. 1) Brief Negotiation (BN) with client centred consultations; 2) Direct Advice (DA) with info on benefits of PA and encouragement) with no intervention control.	1 year (Intervention phone calls until 8.5 months.)	32% follow-up in BN group 33% follow-up in DA group 62.5% follow-up in control. Those who undertook less that one 30-min occasion of PA per week at baseline were less likely to complete the final log book than those doing at least that amount (OR 0.29, 95% CI 0.16, 0.53). ITT revealed that both intervention groups and control group significantly increased PA (energy expenditure in kcal [kJ]/kg per week) from baseline with no significant differences between combined	Randomisation not clearly described but concealment allocation used. Low follow-up but ITT.

					Both intervention groups received 30-min baseline intervention and telephone calls at 2,6,10,18,26 and 34 weeks relevant to intervention Power calculation: Sample size of approx 260 per intervention group (allowing for 10% loss to follow-up) was needed for 76% power to detect a difference of 5 kcal [21 kJ]/kg per week between the two intervention groups, and 87% power to detect a difference of 5 kcal [21 kJ]/kg per week between the combined intervention groups (BN + DA) and the control. **Delivered by:** Health Promotion Specialist.		intervention groups and control group: 3.7% difference (95% CI 4.7, 12.5) (*p* = 0.39), and no significant differences in PA (energy expenditure) between both intervention groups (10.2% difference (95% CI –3.9, 26.1), *p* = 0.16). BN groups who completed the study increased their PA significantly more than controls (24 [95% CI 7, 44]%, *p* < 0.01) No significant difference in energy expenditure between DA completers and control. (Values adjusted for baseline energy expenditure, age, gender, health status, employment, education and home ownership.)	
Stewart 2001	RCT Individual	1	+	Volunteers from two Medicare health maintenance	**Aim:** To examine the effectiveness of a	1-year intervention. No follow-up.	Recruitment 85% (893/1053) of those eligible who responded to invitation. Only 173 were	The CHAMPS II Study, based on social cognitive

				organisations in the US (California?). *n* = 173, randomised of 893 eligible 66% female. Mean age 74 (SD 6, range 65–90) years. 8.5% minority groups. 18.9% high school education or less. 22% with graduate degree.	choice-based PA programme to increase PA levels of seniors, compared with control group who were offered programme at the end of the year. Trained staff assisted participants to develop and maintain a PA regimen that they would be capable of sticking with. Information, support and opportunities for skill building were provided through numerous activities (including ten workshops). Regular staff-initiated phone calls from a counsellor. **Delivered by:** Trained staff and counsellors		randomised to trial but 95% completion (164/173). Individually tailored programmes to encourage lifestyle changes in seniors may be effective. The intervention group increased estimated energy expenditure by 487 kcal (2.04 MJ)/week in moderate or greater intensity activities compared with baseline ($p < 0.001$) and by 687 kcal [2.87 MJ]/week in physical activities of any intensity ($p < 0.001$) compared with baseline. Control group changes were negligible. Between-group analyses found changes were significantly different in both measures ($p < 0.05$).	theory. No allocation concealment or ITT but follow-up = 95%. Validated PA measure. Motivated (volunteer) mostly white, elderly, female majority and higher SES. Many subjects had health problems.
Coleman 1999	RCT Individual	1	+	Forty-seven sedentary adult volunteer employees at the University of Buffalo, NY, USA	**Aim:** To test different ways of meeting the recommendations for 30 min of moderate intensity activity on	16-week intervention. 16-week follow-up.	77% (36/47) began study and 89% of those (32/36) completed to 16 weeks. A walking prescription of 30 min per day on most days of the week with	No allocation concealment. No ITT but 85% follow-up. Small study (47 volunteers only from

				(not engaging in vigorous intensity exercise at least three times per week for at least 20 min per session). Average BMI approx. 25.8 kg/m^2). 84% female, average age approx 43.1 (range 18–55). Almost exclusively White, well educated and SES 50–53 on a scale of 8–66.	most days of the week. Volunteers were randomised to brisk walking 6 days per week in: 1) continuous bout; 2) three 10-min bouts; 3) any combination so long as each bout was at least 5 min. Academic researchers. **Delivered by**: Activity counsellors.		the choice to walk in as little as five min bouts can improve body composition, as well as help sedentary people maintain these improvements over time. Objective and subjective PA measures increased significantly from baseline to the end of the 16-week programme and changes were maintained at the 32-week follow-up for all groups ($p < 0.05$ for all measures).	University). Probably highly motivated, mostly female, white and high SES). Objective measure of activity using the TriTrac accelerometer as well as self-report. Objective measure of activity using the TriTrac accelerometer as well as self-report. Participants deposited US$50, refunded in segments for completion of assessments and good attendance. Semi-workplace intervention?
Dunn 1999	RCT Individual	1	+	Healthy sedentary men and women (self-reported PA of less than 26 and 24 kcal (109 and 100 kJ)/day respectively) from Dallas, TX, USA. Most modestly overweight but	**Aim:** To compare a lifestyle PA programme with traditional structured exercise. Academic research group. Used the Stages of Change	6 months intensive. 18 months maintenance.	Of 122 participants in the lifestyle group 89% (109) completed to 6 months and 82% (100) to 24 months. Of 115 in the structured group 90% (103) completed to 6 months and 78% (90) to 24 months. In initially sedentary healthy adults,	Lacks a no-intervention control group. No allocation concealment but ITT used. Unclear how participants were recruited but probably volunteers. Highly educated.

				none >140% ideal weight. *n* = 235 50.5% women. Average age 46.0 ± 6.6 (range 35–60) years. 'Highly educated' but no details given.	model. The structured exercise group received a traditional exercise prescription for 6months at a fitness centre individualised to participants after first 3 weeks, followed by meetings and correspondence during follow-up. **Delivered by:** **'**Group leaders' and project staff. Higher education study. The lifestyle group received an intensive behavioural intervention to encourage 30 min moderate intensity PA most days but no fitness centre membership, followed by less regular meetings and correspondence. **Delivered by:** 'Group facilitators'.		a lifestyle PA intervention is as effective as a structured exercise programme. At 24 months, adjusted mean changes were 0.84 kcal (3.5 kJ)/kg per day (95% CI 0.42, 1.25), $p < 0.001$, and 0.69 kcal (2.9 kJ)/kg per day (95% CI 0.25, 1.12), $p = 0.002$, for the lifestyle and structured activity groups, respectively. Between-group difference not significant ($p = 0.63$).	Measurement staff were blinded to allocation.

Jeffery 1999 .	RCT Individual	1	+/– (weak)	Men and women recruited from diverse sources, Minnesota, USA. *n* = 1226 18.6% men 40.5% of women were low income (household incomes of US$25000 or less per year (approx. £13,000) Mean age = 38.4 years 90.7% white 89% with at least some college education Mean BMI = 26.7 kg/m²	**Aim:** To evaluate effectiveness of intervention to prevent weight gain with age. No-contact control compared with: 1) education through monthly newsletters (questionnaire postcard included) encouraging paying attention to weight and making small changes in diet and exercise habits; and 2) education + incentives (entry into US$100 lottery if questionnaire postcard returned) Intervention subjects had option for participation in community activity every 6 months. Annual study visits for all participants. **Delivered by:** Researchers (although 6-monthly activities delivered by	3 years (Newsletters continued throughout 3 years.)	106 women who become pregnant excluded from the analysis. 809/1120 (72%) completed all data collection visits. Reported exercise decreased less in the two treatment groups than in control. Statistical significance unclear.	No description of randomisation process. No concealment allocation. No ITT. Baseline differences: Mean BMI higher in education-only group. Higher % of whites in two education groups (92% and 93%) than in control (87%). Parallel analyses with subjects completing only partial data (1101/1120 [98.3%]) yielded very similar findings and are not described in paper. Pound of Prevention study.

					various including nutritionists).			
Pereira 1998	RCT Individual	1	+	Volunteer postmenopausal women from the Pittsburg, Pennsylvania area, USA. *n* = 229, average age 57.5 ± 4.2 years. No socio-economic data provided but: ‘our population of women was basically of the same … socio-econ omic status’ (quoted verbatim from text).	**Aim:** To test the hypothesis that the women randomised to the walking group of a clinical trial were still walking more 10 years later than the women in the control group. Aim of original trial was to investigate the effect of PA on bone loss. The analysis on which this paper was based looks at increases in activity in the subjects of the above trial and factors associated with compliance. **Delivered by:** Original intervention delivered by exercise leaders.	Two-year intervention? (unclear if intervention continued after 2-year follow-up). Ten-year follow-up.	85.6% (196/229 women randomised into the original trial) were interviewed by telephone at 10-year follow-up. The median values for both self-reported usual walking for exercise and total walking were significantly higher for walkers compared with controls (for both, $p = 0.01$), with median differences of 706 and 420 kcal (2.95 and 1.76 MJ)/week respectively.	Two-year results and background info in Kriska 1986 No allocation concealment. ITT analysis carried out and described in earlier publication. Telephone interviewers masked to group assignment.

Evidence of corroboration (external validity)

Evidence of salience – Is it appropriate for the UK?

First	Study	Res	Resea	Study population	Research	Length of	Main results	Confounders/comments

author	design	earch type	rch quality		question and design	follow-up		
Hillsdon 2002 UK Study	RCT Individual	1	+	Healthy sedentary men and women from two medical centres in Wellingborough, UK. See above.	See above.	See above.	See above.	See above.
DOH 2003	CBA	N/a	+/–* ***[where is note?]***	National evaluation of *five-a-day* pilot projects in five areas of the UK.	See above.	See above.	See above.	See above.
Wrieden 2002	CBA	2	+	Community food skills programme in eight deprived communities in Scotland.	See above.	See above.	See above.	See above.

Evidence for implementation – Will it work in the UK?

First author	Study design	Research type	Research quality	Study population	Research question and design	Length of follow-up	Main results	Confounders/comments
Wrieden 2002	CBA	2	+	Eight deprived communities in Scotland. **At baseline:** 88% female. Mean age 32.3 (SD 10.2),	**Aim:** To develop, implement and evaluate a transferable community-based, food skills initiative aimed at increasing consumption of fibre-rich starchy carbohydrates, fish, vegetables and fruit and	Quantitative evaluations were carried out in intervention and delayed intervention (control) subjects at baseline,	Of 113 subjects initially recruited, 93 (82%) completed the baseline assessments and by the 6-month follow-up 63 (56%) had completed some or all assessments.	The Cookwell study. Reliability of outcome measures unclear and only 56% follow-up.

				range 16–65 years. 72% rented their accommodation, 33% claimed housing benefit, 46% were on income support and 14% received job seekers allowance. Only 4% were employed full time. 64% manual social class, 11% heads of household had never worked. 77% finished full time education aged ≤16 years, the intervention group having the highest percentage in this category (84%). In all cases a local community worker recruited people to take part.	decreasing consumption of fat in adults living in areas of deprivation. During 2000–2001 the Cookwell programme (10 weekly 2-hour sessions including data) was run in eight locations throughout Scotland for approx. 2–3 months in each community (*n* = 6–10 in each intervention group). The development of the programme was informed by preliminary focus groups within the community. **Delivered by:** Higher education researchers. No power calculation.	immediately post-intervention and 6 months later (see above). Qualitative interviews were carried out in a sample of intervention and control subjects at the 6-month follow-up.	Participants reported an increase in confidence and pride. The importance of a creche for sessions with familiar workers was crucial to the attendance of participants with young children. Barriers to changing food intake at home included time, demands of caring for young children, taste preferences of family members and dented confidence if a recipe didn't work out well.	
Kennedy 1999	Audit/Evaluation	3	+	Ninety-four members of the community in low-income areas in Bolton, UK. No socio-economic	**Aim:** To explore the role of CNAs in helping to increase coverage of local community dietetic services and to bring about positive changes in the	N/a	50% of the 94 traceable individuals who had been in contact with the CNA for more than a brief session agreed to take	A highly selected group. Questions unclear and exact activities of CNAs unclear. Results could be confounded.

				details were provided of interviewees although 18% of 163 community nutrition assistants (CNAs) contacts lived in deprived areas as classified by census information.	determinants of health eating, within low-income areas of Bolton. The role of the CNAs, who were locally recruited and trained, was to make contact with members of the community, offer introductory talks to groups, run practical activities (e.g. cook and taste), provide healthy eating advice and support food related activities. Members of the community who had been contact with a community nutrition assistant for more than a brief exploratory session took part in the focus group (*n* = 8) and telephone interviews (*n* = 41). No power calculation. **Delivered by:** Higher education researchers.		part. CNAs resulted in a more than fourfold increase in coverage of community nutrition services. More than half (59%, *n* = 41) the respondents selected for telephone interview said they had made changes in their eating habits as a result of contact with the CNAs. When asked about what factors had influenced these changes more than half identified, without prompting, the CNA as having a positive role. The majority of respondents (77%) preferred having a local person rather than a health professional to fulfil this advisory role because local people were perceived as more approachable, easier to access and showing greater empathy.	
Anderson 1998a	Surveys (within RCT)	3	+	Adults recruited at random through a market research agency in Reading	**Aim:** An assessment of perceived barriers to increasing fruit and vegetable consumption as	8 weeks. Questionnaire surveys at	79% of participants randomised completed the study (*n* = 135/170).	Part of the UK *Take Five* study. Short intervention (8 weeks).

				and Glasgow, UK. **Intervention group:** Average age 35.1 (SD 12.4) years, 74% female, 68% non-manual, 11% unemployed. BMI 25.0 (SD 4.5) kg/m^2.	part of a nutrition education intervention. **Delivered by:** Original RCT probably delivered by higher education researchers.	baseline and 8 weeks.	Belief evaluations pre- and post-study indicated that the support of family and friends, food costs, time constraints and shopping practicalities were barriers to greater consumption to increase fruit and vegetable intake. Perceived situational barriers to increasing intakes were limited availability at work canteens, take-aways, friends' houses and at work generally. Following the intervention the number of visits to the shops was perceived as a greater barrier for increasing intakes of fruit and vegetables. Perceived practical opportunities for increasing intakes highlighted drinking fruit juice, taking fruit as a dessert, having fruit as a between meal snack and eating two portions of vegetables with a meal.	Questionnaires, based on the theory of planned behaviour, were pre-tested though not previously validated. Subjects paid compensation (amount not stated) at end of study.
Vernon 1998	Cross-sectional survey	3	+	Members of the general public living in Salisbury , UK who had requested	**Aim:** To evaluate the 'Doorstep Walks' scheme, a pack detailing ten local walks and	N/a	229 questionnaires returned (71% follow-up) and 61% uptake.	Study design did not allow for an analysis by pre-intervention activity level, which limits

				a walking pack. *n* = 322 71% female	benefits of PA, devised by 'Salisbury Walking Forum', an alliance of local groups. Questionnaires issued to collect demographic information and identify motivations and barriers to walking. **Delivered by:** Salisbury walking forum, an alliance of local groups.		By far the most frequently given reason for non-participation (60%) was the shortage of free time, although other barriers were having no one to walk with (15.6%), having no walks near their home (14.4%), being fearful of walking the routes unaccompanied (12.2%, physically unable (11.1%), needed more encouragement (8.9%) and cost restriction (11.1%).	application of the findings.
Lloyd 1995	Surveys (within RCT)	3	+/–	Volunteers in Reading, UK, recruited through newspaper advertisements, aged 18–55 with a BMI of 20–29.9 kg/m^2. **Experimental group:** 22% men, age 35.1 ± 11.3. No socio-economic data provided.	**Aim:** To examine perceived and actual barriers to dietary fat reduction. Subjects were allocated to control or an experimental group receiving instruction on dietary fat reduction. 'Barrier' questionnaires to subjects in the intervention group (*n* = 45) at 4, 8, 12, 16 and 20 weeks. Analysis concentrates on first questionnaire, since more people attempted change in first two weeks than at other times in the study. **Delivered by:**	20-week intervention No post-intervention follow-up.	87% (61/70) subjects completed the study. Over the first 2 weeks of the study, of dietary changes attempted, reducing intake of cakes, biscuits, snacks and cheese was not popular, whereas increasing intake of fruit and vegetables was one of the most well liked changes. Perceived barriers pre-intervention (reduction in taste, ease of shopping and expense) reflected the actual problems encountered. One of the	RCT for efficacy rejected as 1. Unclear data on methodology (e.g. unexplained large number in intervention compared with control group) and weight outcomes. Unclear whether the questionnaire was validated (although referenced) and limited methodological information. Treat as marginal +. Subjects paid £100. on completion of the study.

					State Registered Dietitian or MSc level nutritionist		most consistently reported problems was that of reduction in taste quality of the diet. Other problems included an increase in cost, decrease in convenience, lack of family support for certain changes, and an inability to judge the fat content of the diet.	

2. OPPORTUNISTIC IDENTIFICATION AND LIFESTYLE/EXERCISE ADVICE ON REFERRAL IN PRIMARY CARE SETTINGS FOR PRIMARY PREVENTION OF OBESITY

Evidence of efficacy for weight management/reduction

Nine RCTs reported weight or body composition outcomes, of which three looked at general health advice, one looked at diet interventions alone, and five looked at PA interventions alone. One systematic review looked at exercise training programmes, some of which included diet, in early postmenopausal women.

The results suggest that interventions that provide general advice, addressing both diet and activity, are more likely to prevent unhealthy weight gain than those focusing on diet or activity alone. Of those focusing on PA alone, a more positive outcome was found when interventions were delivered by facilitators from more than one discipline.

General health advice/screening – diet and activity

Three UK based RCTs (Imperial Cancer Research Fund (ICRF) 1994, 1995; Family Heart Study Group (FHSG) 1994**)** were identified with the intensity of intervention based on participants risk score. One RCT (ICRF 1994) found no effect on BMI at 1 year, but a 1.4% reduction in BMI in the intervention group compared with the control at 3 years ($p < 0.005$) (ICRF 1995). The two RCTs from the same study had different control groups. FHSG (1994) reported that the weight of the intervention group was lower by an average 1 kg compared with controls and the proportion of patients with high BMI (≥30 kg/m^2) were lower in intervention than control (no significance values stated). Both interventions were delivered by nurses.

Diet alone

The health check and diet-only RCT (John 2002) reported no difference in weight loss between intervention and control groups ($p = 0.68$) at 6 months.

Physical activity alone

Five RCTs (Taylor 1998; Halbert 2000; Lamb 2002; Elley 2005; Tully 2005) reported weight outcomes in PA interventions. Three RCTs consisted of serially reinforced advice/motivation by telephone after an initial consultation/advice session (Halbert 2000; Lamb 2002; Elley 2005). One study in the UK encouraged intervention participants to attend ‘health walks’ (Lamb 2002), one study in New Zealand looked at a general practitioner (GP) intervention for sedentary 40–79 year-olds and one study in Australia looked at an exercise specialist intervention in a population of older adults (≥60 years; Halbert 2000). Two RCTs looked at exercise advice or prescription alone, both in the UK. One advised non-supervised walking for healthy sedentary people aged 50–65 years (Tully 2005) and one looked at GP exercise referral to a leisure centre for 40–70-year-olds, the majority of whom were overweight or obese (Taylor 1998).

None of the five RCTs showed a significant effect for weight loss at follow-up (of up to 37 weeks depending on study) although positive trends were noted in two studies (Elley, Taylor), one showing a reduction in skinfold thicknesses up to 16 weeks (Taylor). One study (Halbert) showed a significant weight gain in women in the intervention group ($p = 0.01$). Two of the interventions were delivered by facilitators from more than one discipline (Elley: GP/practice nurse and exercise specialist; Lamb: physiotherapist and local health walks coordinator), two were delivered by an exercise specialist alone (Halbert, Taylor) and one was unsupervised (Tully).

The systematic review of exercise training in early postmenopausal women (Asikainen 2004), where some of the interventions were combined with diet, found an improved body composition in 9 of 18 studies. The best effect was in the three studies of overweight women that combined training and diet, but six of the studies with positive results included some women within the normal weight range.

Evidence of efficacy for diet outcomes

One systematic review and four more recent RCTs provide some evidence that interventions can result in changes to dietary intake.

A systematic review (Ashenden 1997; ten studies with diet outcomes, all randomised) reported that dietary advice trials were very mixed in interventions employed and study populations. Of four trials directly assessing dietary change by collecting data on fat and fibre intake, one found very positive results, one found no significant difference on either measure and two found significant differences for one measure but not the other.

Four RCTs published since the systematic review were identified. With the exception of one (Steptoe) the RCTs had predominantly white samples, two were UK-based (Steptoe, John) with one based in a low-income area (Steptoe). Two studies gave dietary advice by physicians in routine consultations (Delichatsios, Beresford), and two were provided by research nurses (Steptoe, John). Three of the RCTs (Delichatsios 2001; John 2002; Steptoe 2003) reported that individually tailored intervention resulted in increases in self-reported fruit and vegetable intake between 3 months (Delichastsios), 6 months (John) and 12 months (Steptoe) between 0.6 portion per day (Delichatsios) to 1.4 portions per day (John) compared with control groups. Steptoe reported increased consumption (at 12 months) in both a nutrition advice and tailored behaviour intervention, but stated significantly higher intake in the tailored behaviour intervention (0.6 portions per day, $p = 0.021$). Beresford (1997) measured changes in fat intake, which were significantly larger at 3 and 12 months in the intervention group.

Evidence of efficacy for physical activity outcomes

Three systematic reviews (Eakin 2000; Eden 2002; Morgan 2005), all retained because of the limited overlap, and including four UK RCTs (Stevens 1998; Taylor 1998; Harland 1999; Lamb 2002), plus one more recent study from New Zealand (Elley 2005), provide some evidence that primary care-based interventions can increase PA levels.

One systematic review concluded that counselling adults in a primary care setting is moderately effective in the short term (Eakin 2000), and one that evidence was ‘inconclusive’ (Eden 2002). Interventions tailored to the participant characteristics and which offered written materials to patients produced stronger results. The most recent systematic review (Morgan 2005) concluded that exercise referral schemes appear to increase PA levels in certain populations, namely those that are not sedentary but already slightly active, older adults and those who are overweight but not obese.

The systematic reviews were unpicked to look at the four UK studies in more detail. One UK RCT which gave physiotherapist run advice sessions to sedentary 40–70-year-olds and encouraged the intervention group to participate in lay led walking schemes reported no significant between group differences in self-reported PA at 12 months and no effect on weight loss (see above). However, when only completers were analysed, the intervention was more effective than advice only (Lamb 2002). Taylor (1998) was an exercise referral scheme intervention with weight outcomes only, discussed above. Harland (1999) was an incentives study (see Table 3) offering vouchers entitling free access to leisure facilities. Increased PA scores were reported at 12 weeks, but this increase was not maintained in the long term (12 months). Stevens (1998) provided a consultation followed by a personalised 10-week programme to sedentary 45–70-year-olds. There was a significant net 10.6% reduction in the proportion of people classed as sedentary in the intervention compared with the control group at 8-months follow-up.

The recent New Zealand-based RCT of oral and written advice from GPs or practice nurses plus motivational phone calls by an exercise specialist reported a significant difference between intervention and control including the proportion undertaking 2.5 hours exercise per week ($p = 0.003$) at 12 months (Elley 2005).

Evidence of corroboration in the UK

Two systematic reviews, seven qualitative studies, two RCTs (one suspended), four cross-sectional surveys, one evaluation and survey and one evaluation of case studies provided evidence of UK corroboration.

Barriers to change

A systematic review (Keller 1999) found that that individual perceptions of self-efficacy (‘I believe I can exercise regularly’) are important and strongly related to exercise behaviour and that clinicians can help facilitate these perceptions. Four additional studies (Horsefall Turner/Wealden District Council 1997; Martin 1999; See Tai 1999; Hardcastle 2001) where participants had been referred to an exercise prescription at a leisure centre revealed a variety of barriers to adherence. These included the importance of social support (all), time (Martin; See Tai; Horsefall Turner) the gym environment and time spent with instructors (Hardcastle, Martin and Horsefall Turner). Other barriers were illness and injury, work pressure, transport, programs not appropriately tailored, lack of money. Knowing where facilities are at the start of the programme increased likelihood of completing a programme by 3.5 times ($p = 0.043$) (See Tai 1999). A qualitative study of guided walks (Ashley 1999) found that *Health Walks* were a sustainable form of exercise, but planning and promotion activities should take into account the seasons and varying needs of walkers (grades of difficulty, evening walks for workers, etc.) as well as emphasising the social benefits.

Data from two RCTs where the intervention was delivered by nurses (Baron 1990; John 2004) reported patients’ barriers to healthy eating included partners and children disliking recommendations and the difficulty of preparation and finding food outside of the home. Only 10% and 8% respectively reported these barriers in the Baron study, but 37 of 40 people reported at least one barrier in John.

Patients’ views of health professional advice

One cross-sectional survey of mainly white, UK patients (Duaso 2002) suggested that significantly more respondents would have liked to have received advice than did ($p < 0.001$). Women found the advice more helpful than men ($p < 0.05$). Hardcastle (2001) demonstrated the importance of encouragement from GPs in promoting PA in addition to participant commitment and confidence. However, a cross-sectional survey (Vernon 1998) on the effectiveness of walking packs found that the major barrier was lack of time (60%) rather than motivation by a GP or health professional (14%). A small qualitative study (Fuller 2003) found that couples viewed general practice as a place for treatment of illness and disease rather than provision of dietary advice. Health was only one of many factors influencing their daily decisions about food and they were concerned about contradictory messages.

Attendance at UK exercise referral schemes

A systematic review of four RCTs and five evaluation studies of UK exercise referral schemes (Gidlow 2005) found that attendance was generally poor. Approximately 80% of participants who took up referral dropped out before the end of the programme. More women than men took up referral (60 vs. 40%) but there was no evidence of higher attendance in women.

Health professionals in primary care

Activity: One evaluation of case studies of PA promotion schemes in primary care (Biddle 1994) revealed that success depends on the qualities of key personnel in contact with participants and establishing a programme depends on the enterprise of an energetic innovator. A qualitative study (Smith 1996) reported that referring practice members saw exercise promotion as a therapeutic as opposed to a preventive option and tight referral criteria was a barrier. Data from a suspended RCT (Fielder 1995) found that barriers to recruiting patients to a GP-led programme included time, overly complicated questionnaires and lack of financial incentive for the health professionals.

Diet: A qualitative study by Fuller (2003) reported that GPs viewed general practice setting as a place for treatment of illness and disease, and their advice was affected by personal preference (younger, females doctors being more enthusiastic). GPs were concerned that dietary advice could damage their relationship with patients. Hopper (1995) reported that practice nurses gave dietary advice more frequently than GPs. Time was the main barrier for GPs to training and offering dietary advice. The primary health care workers surveyed felt that their practice population was not sufficiently motivated to follow dietary advice.

Community pharmacies

Six qualitative studies, two of pharmacy contractors/advisors (Keene 1995; Ursell 1999) and four of community pharmacists (Benson 1995; Moore 1995; Ursell 1999; Coggans 2000) cited time, confidential space, training issues and cost issues (including loss of revenue) as barriers to increasing health promotion. Two of the studies (Benson 1995; Coggans 2000) noted concerns that giving lifestyle advice was ‘interference’.

One qualitative study of consumers (Anderson 1998b) found that only 40% thought it was the usual job of the pharmacist to give health promotion advice although 92% said that they would pick up health information leaflets at the pharmacy. In another study (Coggans 2000) less than 32% reported that they would seek information or help on healthy eating and only 23% would seek help on exercise at the community pharmacy. Conclusions from a Delphi study of health professionals (Coggans 2000) were that factors that facilitate pharmacy staff/customer interaction should be addressed as well as enhancing perceptions of pharmacists as key players in the health care team who provide a confidential service.

EVIDENCE TABLE 2: OPPORTUNISTIC IDENTIFICATION AND LIFESTYLE/EXERCISE ADVICE ON REFERRAL IN PRIMARY CARE SETTINGS FOR PRIMARY PREVENTION OF OBESITY

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Asikainen 2004	Systematic review	1	++	Literature search 1996 – November 2002. Comprehensive search strategy but English language studies only included. Twenty-eight RCTs included, 18 of which had a weight or body fat outcome (1804 subjects in all); three of these were for overweight subjects and combined exercise and diet. Location of studies not described.	**Aim:** To evaluate data on exercise training studies with special reference to improving health in early postmenopausal women.	Duration range for weight loss studies was 12 weeks to 1 year.	Body composition was improved in 9 of 18 studies. The mean weight loss ranged from 2 to 10 kg in 12 weeks to 1 year (note: the best results were accomplished in the three studies with overweight participants that used training and diet). The most effective exercise prescription for losing body fat was 30–60 min of walking or other aerobic training at 45–75% VO_{2max} on 3–5 days per week for 15 weeks to 1 year, or strength training with weight machines twice per week for 1 year. In the training studies where participants were not overweight, adipose tissue was not lost as often as with overweight participants. The authors concluded that health professionals should recommend to sedentary women in early menopause who have fitness or weight concerns, a programme of at least 30 min of daily moderate walking in one to three bouts in addition to resistance exercises	Review found in update search: unpicking not possible within timeframe for completion but six of nine studies with positive outcomes included women within normal weight range. Few studies reported in detail how randomising was performed, if there were power calculations, if staff were blinded, ITT analyses. Some did not report drop out, attendance or injury rates.

							twice per week.	
Elley 2005	RCT Cluster	1	++	All sedentary 40–79-year-old patients visiting general practitioner during study period, in eastern Waikato region of New Zealand. *n* = 878 Mean age = 57.9 years 66.5% female 47% low economic status 28% with post-high school qualification 77% European origin	**Aim:** To assess long-term effectiveness of a clinician based initiative in general practice that provides counselling on PA. GPs and practice nurses prompted by patient to give oral and written advice on PA during usual consultations. Exercise specialist continued support by phone (three calls over 3 months). Control received usual care. **Power calculation:** Sample size of 800 patients from 40 practices (power = 90%). **Delivered by:** GPs/practice nurses and exercise specialist.	12 months	85% follow-up of enrolled patients at 12 months. Very slight BMI (kg/m^2) reduction in both groups but no significant difference between intervention and control for BMI reduction (–0.06 [95% CI –0.24, 0.12], *p* = 0.5).	In the intervention group 385 patients received intervention from general practitioner and 66 patients received intervention from practice nurse.
John 2002 UK Study	RCT Individual	1	++	Healthy participants aged 25–64 years recruited from a primary care health	**Aim:** To evaluate the effectiveness of a brief negotiation	6 months	95% follow-up in both groups. **No difference in weight loss between groups:**	Self-reported values are susceptible to reporting bias, so results should be interpreted with caution.

				centre, Thame, Oxfordshire, UK. *n* = 690 Mean age = 46 years 51% female 49% Social Class I and II 10% Social Class IV and V 'The general practices had few patients from ethnic minorities.'	method to encourage an increase in fruit and vegetables to at least five portions/day. Intervention group received health check followed by 25 min tailored dietary negotiation. Two-week reinforcing phone call and letter sent at 3 months. Control received intervention 6 months later. **Delivered by:** Trained research nurses.		Self-reported weight loss (kg) was 0.6 (SD 2.6) in both intervention and control groups. Adjusted between group difference in change* 0.1 (95% CI –0.4, 0.6), *p* = 0.68. *Adjusted for baseline value and sex.	Same study as John 2004.
Tully 2005	RCT Individual	1	+	Thirty-one healthy, sedentary 50–65-year-olds identified by searching the medical registers of three urban general practices in Belfast, UK, and subsequent selection by questionnaire. Overall recruitment rate = 5.9% (31/527).	**Aim:** To examine the effects of 30 min of self-paced, non-supervised, brisk walking, 5 days per week on the health and fitness of people aged 50–65 years. Intervention group (*n* = 21) instructed to walk briskly for 30 min, five days per week for	12 weeks. No longer-term follow-up.	81% completion and 90% adherence to protocol in intervention group. 90% completion in control group. The mean time spent walking by the intervention group was 27.72 ± 9.79 min/day. No significant changes were found in weight-related measures in either group.	No allocation concealment and no ITT although >80% completion. Participants likely to be highly motivated – overall recruitment rate = 5.9%. The authors noted that reported adherence was high suggesting greater acceptability of a pedometer-driven home-based model (vs. leisure centre exercise protocol).

				No socio-economic details provided.	12 weeks (all in one session or bouts of no less than 10 min). They were asked to record in a diary the time spent walking and the number of steps using a pedometer. Control group (*n* = 10) asked to maintain habitual lifestyle. No power calculation. Intervention delivered by higher education researchers.			
Lamb 2002 UK Study	RCT Individual	1	+	Men and women aged 40–70 years taking <120 min of moderate intensity activity per week. Reading, UK. *n* = 260 48.8% male Mean age = 50.5 (SD 7.8) years	**Aim:** To compare health walks, a community-based lay-led walking scheme versus advice only (from a primary health care professional) in middle-aged adults. Intervention and control took part in a 30 min standardised advice session led by a physiotherapist. Intervention given information about health walks and received up to three	6 months and 1 year	Loss to follow-up at 12 months was approximately 27% in each group. No statistically significant differences between people lost to follow-up and those who remained in the trial. No significant within-group changes from baseline in BMI at 12 months: –0.01 kg/m² reduction in advice group and –0.002 kg/m² reduction in Health walks group. Between group difference –0.009 (95% CI –0.39, 0.194).	Low follow-up, analysis by ITT. Related qualitative study below (Ashley).

					motivational phone calls from a local health walk coordinator. Control received no further intervention. Power calculation: Sample size of 100 people for each group (power = 90%). An additional 30% included to allow for loss to follow-up. **Delivered by:** Physiotherapist and local health walks coordinator.			
Halbert 2000	RCT Individual	1	++	Adults aged ≥60 years who were healthy, sedentary and living in the community. Adelaide, Australia. *n* = 299 Mean age = 67.5 years 46% Male	To determine whether provision of individualised PA advice by an exercise specialist in general practice, reinforced at 3 and 6 months, is effective in modifying PA, compared with no advice control. **Delivered by:** Exercise specialist.	12-month follow-up.	Follow-up of 88%. Over 12 months there were no statistically significant changes from baseline in body weight within either the control or intervention group. Weight decreased in men in the intervention and control groups and in women in the control group but increased in intervention group women ($p = 0.01$). (Values for gender not stated so unclear if significance value for intervention women only.) **Control group values:**	Generalisable to older adults only.

							Baseline = 74 (71.8–76.1) kg and 12 months = 73.6 (71.5–75.8) kg Intervention group values: Baseline = 75.9 (73.8–78) kg and 12 months = 76.0 (73.9–78.1) kg No between group difference stated. ***[ranges or 95%CI?]***	
Taylor 1998	RCT Individual	1	+	142 recruits from 345 men and women, aged 40–70 years and identified as smokers, hypertensive of overweight on medical records in East Sussex general practices. Circa 37% men. No socio-economic details provided.	**Aim:** To examine the effects of a GP exercise referral programme on modifiable coronary heart disease risk factors. The exercise group received a Health Education Authority leaflet on preventing coronary heart disease and was offered 20 half-price sessions over 10 weeks at a leisure centre. Patients engaged in moderate and vigorous aerobic activity in a semi-supervised informal environment. The control group received the leaflet but no further intervention.	Ten-week intervention. Outcomes measured at 0, 8, 16, 26 and 37 weeks.	41% (142) of the 345 invited to enter were randomised. 50% (71) provided data at all assessments, 41% of the exercise and 69% of the control group. 87% of those referred used the prescription and 28% (high adherers) (45% of obese patients) did at least 15 sessions. The exercise group reduced sum of skinfold thicknesses by 8.1 (95% CI 2.9, 13.3)% more than the control group, up to 16 weeks after baseline. High adherers (≥ sessions attended) reduced sum of skinfold thicknesses by 9.2 (95% CI 0.9, 17.5)% more than the control group up to 26 weeks.	Randomisation by random numbers but no allocation concealment. Assessments were not blinded. ITT analysis not carried out other than for the physical self-perception assessment. Baseline measures were broadly similar but there are more obese participants in the intervention group (30 vs. 18%) suggesting a potential weakness in randomisation. Overall there were 83% overweight or obese subjects in the intervention group and 71% overweight or obese subjects in the control group. Objective measures of weight and skinfold thickness. PA (Blair's)

					Intervention provided by higher education researchers. The assessment was by a postgraduate exercise scientist and the outcomes measured by a 'trained researcher'. A power calculation was based on a 4 mmHg blood pressure reduction.			and physical self-perception (PSPP) measures well referenced and probably validated. See also companion corroborative study, Taylor 2005
Imperial Cancer Research Fund 1995 UK Study	RCT Cluster	1	+	Patients aged 35–64 years in 1989 from five urban general practices. Bedfordshire, UK. *n* = 11090 Mean age = 49 years Area chosen for mixed urban and suburban setting, range of heavy and light industry and varied demographic profile.	**Aim:** To determine the effectiveness of health checks (risk factor counselling and negotiation of targets), performed by nurses in primary care, in reducing risk factors for cardiovascular disease and cancer. Control received health check at least 1 year later. Structured dietary assessment. No description of PA component. **Delivered by:** Nurses.	Three years (although mutually arranged (or structured for some risks) follow-up visits during this time, and some randomised to annual health checks).	Comparison of groups within the randomised population. Intervention was 2205 invited for re-examination in 1992–93 after an initial health check in 1989–90. Control group was 1916 randomly allocated an initial health check in 1992–93. Follow-up in control was 81.3% (1916 of 2783 randomised*) of those randomised. Follow-up in intervention was 82.2% (1160 of 2205 randomised*) of those who attended their first health check. *Excluding those who moved from the area. Dietary advice led to a small difference in BMI in intervention groups compared with controls but	Different levels of risk factor received different levels of intensity of intervention. Follow-up sessions for all patients at mutual agreement of nurse and subject. No allocation concealment. ITT analysis carried out.

							failed to reduce the proportion of the population with obesity. At follow-up, mean BMI was lower in intervention group than in control by 1.4% ($p < 0.005$).	
Imperial Cancer Research Fund 1994 UK Study	RCT Cluster	1	+	See above.	See above.	1 year (Although mutually arranged [or structured for some risks] follow-up visits during this time.)	Comparison of groups within the randomised population. Intervention was 2136 patients invited for re-examination in 1990–92 after an initial health check in 1989–90. Control was 3988 attending first check in 1990–92. Follow-up in control was 79.1% (1908 of 2760 randomised, excluding 348 who had moved). Follow-up in intervention was 77.8% of those who attended their first health check (1616 of 2136 randomised, excluding 60 who had moved [= 2076]) At 1 year, no significant difference between groups in BMI (kg/m^2): 0.16 (95% CI –0.06, 0.38). When analysis restricted to attendees a significant difference was found (1.2%) in BMI between intervention and control (significance not stated).	See above. Treated as separate study from above as different control group.
Family Heart	RCT Cluster	1	+	Male patients on GP lists aged 40–	**Aim:** To measure change	1 year	73% response rate to initial questionnaires	No description of randomisation process

Study Group 1994 UK study				59 years in 26 practices in 13 towns, and their partners, UK. *n* = 12472 59.8% male Mean age men = 51.5 years Mean age women = 49 years	in cardiovascular risk factors achievable in families over 1 year by a nurse-led cardiovascular screening and lifestyle intervention in general practice. Intervention received 1.5-hour screening and risk-related lifestyle advice. Internal and external controls received screening 1 year later. **Delivered by:** Nurses.	(Although intervention subjects followed up during this time according to risk score.)	At 1 year, 88% follow-up in intervention males, and 85% follow-up in intervention females. Non-returnees twice as likely to be smokers, more overweight than returnees and with a slightly lower prevalence of diagnosed disease. At 1 year, in the intervention group, weight among returnees was lower by an average 1 kg compared with the internal and external control groups (no significance stated). At 1 year, the proportion of patients with high BMI (≥30 kg/m^2) were lower in the intervention group than in controls (no significance stated).	and no allocation concealment. No ITT analysis re weight outcomes. Follow-up during year dependent on risk score. Substantially more subjects in external control than intervention and internal control. Little baseline data given.

Evidence of efficacy (internal validity) for diet outcomes								
Ashenden 1997	Systematic review	1	+	Literature search year of inception – May 1995. Thirty-seven randomised trials included in all. Ten to modify dietary behaviour.	**Aim:** To explore how effective lifestyle advice provided by GPs is in changing patient behaviour.	Range of follow-up, 3 months to 2 years in ten dietary advice trials.	The dietary advice trials were very mixed in interventions employed and study populations. Of four trials directly assessing dietary change by collecting data on fat and fibre intake only one found positive results, one found no significant difference on either measure and two found significant differences for one measure but not the other. Six trials measured changes in lipid levels (outcome not included in rapid review).	Literature search did not include unpublished trials – may introduce bias. Dietary advice: Logsdon 1989 Cupples 1994 Imperial Cancer Research Fund OXCHECK 1994 Baron 1990* Koopman 1990 Cohen 1991 Beresford 1992

								Campbell 1994 Family Heart Study Group 1994* Tomson 1995 *UK or Irish study
Delichatsios 2001	RCT Cluster	1	+	Adult primary care patients. New England, USA. *n* = 504 (of 1183 eligible) **Intervention:** Mean age = 49.9 ± 12.5 years 77.4% female 83% white 62% with at least a bachelor degree. **Control:** Mean age = 56.8 ± 12.9 years 63.1% female 97% white 56.9% with at least a bachelor degree.	**Aim:** To evaluate a multifaceted nutrition intervention to improve dietary habits among adult primary care patients. Intervention vs. control. Intervention comprised brief personalised recommendations at routine office visits and mailed personalised dietary recommendations, verbal endorsement and motivational phone calls to set targets. US$5 incentive offered for	Three-month follow-up survey (although intervention taking place during this time).	85% follow-up in intervention group. 92% follow-up in control group. Adjusting for age, sex, race and baseline intake, the change in self-reported fruit and vegetable intake in the intervention group was significantly higher than control (0.6 [95% CI 0.3, 0.8] servings/day. No intervention effect on dairy products. (no significance stated).	No allocation concealment. ITT analysis carried out. Some baseline differences. Mean age higher in control group. % of African Americans higher in intervention group. Self-reported outcomes – validated questionnaire. Meets criteria for a **social marketing** intervention (see methodology).

					completion of baseline survey and US$5 for final survey. **Delivered by:** Primary care physician or nurse practitioners and trained telephone counsellors. Nutritionist if necessary.			
Steptoe 2003 UK Study	RCT Individual	1	++	Patients from a primary care centre in a deprived, ethnically mixed, inner city area, UK, aged 18–70 years. *n* = 271 61% female 26% Black 3% Asian 70% White 68% in low-income category. 34% in receipt of benefits.	**Aim:** To measure the effect of brief behavioural counselling in general practice on consumption of fruit and vegetables in adults from a low income population. Two × 15 min counselling (2 weeks apart) on: 1) nutrition counselling (education and	12 months	At 12 months, 81% follow-up in behavioural counselling group, and 80% follow-up in nutrition counselling group. Consumption of fruit and vegetables increased from baseline to 12 months by 1.5 and 0.9 portions per day in behavioural and nutrition groups (mean between group difference 0.6 [95% CI 0.1, 1.1] portions, *p* = 0.021). The proportion of participants eating five or more portions a day increased by 42% with behavioural counselling and 27% with nutritional counselling in the two groups (mean between group difference 15 [95% CI 3, 28]%, *p* = 0.019). There were significant between-group differences suggesting that one	No allocation concealment. ITT analysis carried out. No true control group and low recruitment (12%).

					information); or 2) behavioural counselling (tailored advice). **Delivered by:** Research nurses.		counselling intervention was more effective than the other. Differences were maintained when analysis restricted to 177 participants with incomes ≤£400 per week.	
John 2002 UK Study	RCT Individual	1	++	See above.	See above.	See above.	95% follow-up in both groups. Self-reported daily fruit and vegetable intake increased by a mean 1.4 (SD 1.7) portions in the intervention group and by 0.1 (SD 1.3) portion in the control group (between group difference = 1.4 [95% CI 1.2, 1.6], *p* < 0.0001).* Mean difference of 1.3 (95% CI 0.9, 1.6) daily portions between intervention and control for 'pre-contemplators', 1.6 (95% CI 1.2, 1.9) daily portions for 'contemplators' and 1.3 (95% CI 0.9, 1.7) daily portions for those in 'action' (all *p* values < 0.001). *Adjusted for baseline value and sex.	Self-reported outcomes.
Beresford 1997	RCT Cluster	1	+	Adult patients from six primary care clinics in Puget Sound, Seattle, USA. *n* = 2111* (of 3490 eligible)	**Aim:** To evaluate the effectiveness of a low-intensity dietary intervention in primary care practice in	3 months and 12 months	86.1% follow-up at 12 months. Both groups reduced their self-reported fat intake (% energy from fat) from baseline but at both 3 and 12 months, changes from baseline were significantly larger in the intervention group compared with control.	* As reported in abstract (value of 2121 given in text). Allocation concealment used but no ITT analysis.

				51% ≥ 65 years 68% female 91% White 28% income <US$25,000.	lowering dietary fat intake and raising dietary fibre intake. Physicians gave intervention patients a self-help booklet and brief motivational message during routine appointment. Reminder letter 2 weeks later. Control was usual care. **Delivered by:** Physicians.		**At 3 months:** Mean intervention effect –1.04 (95% CI –1.67, –0.41), $p < 0.01$. At 12 months mean intervention effect –1.20 (95% CI –1.68, –1.73), $p < 0.01$. The corresponding differential change in fat score was –0.046 (95% CI –0.074, –0.018), $p < 0.01$ at 3 months and –0.044 (95% CI –0.073, –0.016), $p < 0.01$ at 12 months.	
Evidence of efficacy (internal validity) for physical activity outcomes								
Eden 2002	Systematic review	1	++	Literature search 1994 – March 2002. Seven RCTs and one CCT included rated as 'good' or 'fair' quality.	**Aim:** To determine whether counselling adults in primary care settings improves and maintains PA levels.		Evidence is inconclusive that counselling adults in the primary care setting to increase PA is effective. Among six controlled trials with a usual care control group, the effects of counselling on PA were mixed with three trials showing statistically significant increases in PA and the remaining three trials showing no effect. Because most studies had at least one methodological limitation, it was difficult to rigorously assess the efficacy of	Included trials: Physically Active for Life 1999 Norris 2000 Smith 2000 Kerse 1999 Change of Heart 1999 Burton 1995 Activity Counseling Trial 2001 Swinburn 1998

							interventions. More evidence is needed.	
Eakin 2000	Systematic review	1	++	Literature search 1980–98. Fifteen RCT or quasi-experimental controlled trials reviewed.	**Aim:** To summarise primary care based interventions for increasing PA and make recommendations for integrating successful strategies into practice.		Primary care-based PA counselling is moderately effective in the short term, although there is considerable variability across studies. Studies in which the interventions were tailored to participant characteristics and which offered written materials to patients produced stronger results. Of ten studies reporting 0- to 11-month post-intervention outcomes, seven reported statistically significant PA outcomes. Of the seven studies reporting post-intervention outcomes at 12 months or longer, three reported statistically significant outcomes.	Included studies: [studies not referenced by Eakin] Goldstein 1999 Bull 1998 *Stevens 1998 *Swinburn 1998 Marcus 1997 Calfas 1996 Dowell 1996 Burton 1995 Elder 1995 Graham Clarke 1994 OXCHECK 1994 Lewis 1993 Logsdon 1989 Kelly 1989 Reid 1979
Morgan 2005	Systematic review	1	+	Literature search to 2002. English language studies only. Nine RCTs included, four of which were from the UK – see comments.	**Aim:** To review current evidence of effectiveness for exercise referral schemes. Studies had to be based in primary care settings.	Limited information in review. Unpicking required (and done for UK studies only).	Exercise referral schemes appear to increase PA levels in certain populations, namely those who are not sedentary but already slightly active, older adults and those who are overweight (but not obese). However, increases in the level of PA may not be sustained over time.	Included since updates older reviews but of lesser quality. No unpublished studies sought and English language studies only included. Little detail of quality methods and appraisal probably undertaken by one reviewer only. UK studies all unpicked: Taylor 1998; Stevens 1998; Harland 1999;

								Lamb 2002
Elley 2005	RCT Cluster	1	++	See above.	See above.	See above.	85% follow-up of enrolled patients at 12 months. Mean total energy expenditure increased by 9.4 kcal (39 kJ)/kg per week (*p* = 0.001) and leisure exercise by 2.7 kcal (11 kJ)/kg per week (*p* = 0.02) or 34 min/week more in the intervention group than in the control (*p* = 0.04). The proportion of the intervention group undertaking 2.5 hours/week of leisure exercise increased by 9.72% (*p* = 0.003) more than in the control group (number needed to treat 10.3).	See above.
Lamb 2002 UK Study	RCT	1	+	See above.	See above.	See above.	Loss to follow-up at 12 months was approximately 27% in each group. No statistically significant differences between people lost to follow-up and those who remained in the trial. There were no significant between group differences (between intervention groups) in self-reported PA at 12-month follow-up by intention to treat analysis (between group difference = 6 [95% CI –5, 16.4])%. In people who completed the trial, health walks was more effective than giving advice only in increasing moderate intensity activity above 120 min/week (between group difference = 13 (95% CI 0.003, 25.9)%, *p* = 0.05).	
Stevens	RCT	1	+	714 people aged	**Aim:**	10-week	1288/2253 approached completed	Randomisation method

1998				45–74 years from two London general practices classed as not active (i.e. sedentary or low/high intermediate activity). Circa 42% men, 54% economically active, 85% white, 29% degree level, 34% no qualifications. All on the surgery lists in the targeted age group were sent a PA questionnaire.	To assess the (cost) effectiveness of a primary care based intervention aimed at increasing levels of PA in inactive people aged 45–74 years. **Intervention subjects:** Consultation with exercise development officer and personalised 10-week programme combining leisure centre and home-based activities. **Control subjects:** Information on local leisure centres. Higher	intervention. Assessment 8 months after randomisation.	questionnaires (57%). 714 were randomised. Of 363 randomised to intervention 35% (126) attended the first consultation and 25% (91) returned for the second consultation at the end of the 10-week programme. There was a net 10.6 (95% CI 4.5, 16.9)% reduction in the proportion of people classified as sedentary in the intervention group compared with the control group, 8 months after baseline. The intervention group also reported an increase in the mean number of episodes of PA per week compared with the control group (an additional 1.52 (95% CI 1.14, 1.95) episodes.	not described. No concealment allocation. Self-reported PA measures but using a validated tool (Blair's 7-day recall). ITT analysis used. Most PA was undertaken away from the leisure centre and the authors concluded that environmental efforts to encourage activities not requiring attendance at a leisure centre may have a greater impact.

					education/health promotion researchers. Intervention by one exercise development officer. No power calculation.			

Evidence of corroboration (external validity)

Evidence of salience – Is it appropriate for the UK?

First author	Study design	Research type	Research quality	Study population	Research question	Length of follow-up	Main results	Confounders/comments
Steptoe 2003 UK Study	RCT Individual	1	++	Patients from a primary care centre in a deprived, ethnically mixed, inner city area, UK.	See above.	See above.	See above.	See above.
John 2002 UK Study	RCT Individual	1	++	Healthy participants aged 25–64 years recruited from a primary care health centre, Thame, Oxfordshire, UK.	See above.	See above.	See above.	See above.
Lamb 2002 UK Study	RCT	1	+	Men and women taking less than 120 min of moderate intensity activity per week. Reading, UK.	See above.	See above.	See above.	See above.
Tully 2005	RCT	1	+	Thirty-one healthy, sedentary 50–65-	See above.	See above.	See above.	See above.

	Individual			year-olds identified by searching the medical registers of three urban general practices in Belfast, UK.				
Taylor 1998	RCT Individual	1	+	142 recruits from 345 men and women, aged 40–70 years and identified as smokers, hypertensive of overweight on medical records in East Sussex general practices.	See above.	See above.	See above.	See above.
Imperial Cancer Research Fund 1995 UK study	RCT	1	+	Patients aged 35–64 years in 1989 from five urban general practices. Bedfordshire, UK	See above.	See above.	See above.	See above.
Imperial Cancer Research Fund 1994 UK study	RCT	1	+	Patients aged 35–64 years in 1989 from five urban general practices. Bedfordshire, UK	See above.	See above.	See above.	See above.
Family Heart Study Group 1994	RCT	1	+	Male patients on GP lists in 26 practices in 13 towns, and their partners, UK.	See above.	See above.	See above.	See above.

Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Gidlow 2005	Systematic review	3	++	Literature search to October 2003 for UK exercise referral interventions. Nine studies met the inclusion criteria: four RCTs and five evaluations of existing schemes.	**Aim:** To explore the attendance of UK exercise referral schemes (ERS), who attends them, why participants drop out of schemes and to compare evaluations of existing ERS with RCTs. Method of participant recruitment was the only marked difference between the two types of study. In RCTs and evaluations, rates of referral uptake and	The durations of the interventions were 10 (*n* = 5), 12 (*n* = 2) or 14 weeks (*n* = 1), although one RCT lasted 2 years despite reporting 10-month outcomes.	Attendance was generally poor; approximately 80% of participants who took up referral dropped out before the end of programmes. More women than men took up referral (60 vs. 40%) but there was no evidence of higher attendance in women. None of the participant characteristics reported were consistently associated with attendance. Most of the reasons for attrition and negative comments from participants related to practical problems associated with attending leisure facilities.	

					attendance were varied but comparable. All interventions were facility-based.			
Keller 1999	Systematic review	3	++	Literature search 1990 – June 1998. Twenty-seven primary and secondary prevention studies included.	**Aim:** To provide a critical systematic review of research using social cognitive theory in exercise research.		Individual perceptions of self-efficacy ('I believe that I can exercise regularly') are important and strongly related to exercise behaviour. Intervention studies demonstrated that participation in an exercise programme promoted self-efficacy and that programmes designed to increase outcome expectations and self-efficacy significantly increased exercise behaviour. Clinicians can facilitate perceptions of self-efficacy by verbal persuasion, modelling exercise behaviour and discussing the positive physical effects of PA.	Worldwide review. Unknown if any of the studies were based in the UK.
John 2004	Qualitative study (from RCT)	3	++	Purposive sample* (of patients not selected as contemplating change) from participants in an RCT examining effectiveness of a nurse-led intervention to increase fruit and vegetables intake. Thame, Oxfordshire, UK.	**Aim:** To examine the barriers to fruit and vegetables consumption after a 6-month trial. Participants asked at initial intervention interview to anticipate barriers and	Interviews carried out 2 weeks after 6-month follow-up.	Barriers anticipated and experienced: • Women reported children and male partners as obstructive to attempts to increase fruit and vegetables consumption. Men reported that partners were supportive. • Additional time needed to prepare food. • Perceived expense of fruit and vegetables. Barriers discovered during intervention: • Problems of getting fruit and vegetables while travelling.	*Sample selected to include those likely to have experienced different barriers. Same study as John 2002.

				n = 40 Mean age 45.9 years 47.5% female Social class I and II = 47.5% Social class III M, III NM, IV and V = 52.5% 72.5% had reported an increase in fruit and vegetables consumption.	discussed barriers at 6-month follow-up. Semi structured interviews carried out at respondents' homes by independent researcher to explore barrier issues in greater depth. **Delivered by:** Intervention by nurses.		• Problems when routine is disrupted at weekends. • 37 of 40 people reported at least one barrier, but 29 of 40 still reported increasing their fruit and vegetable consumption.	
Taylor 2005	Qualitative study (from RCT)	3	+	142 recruits from 345 men and women, aged 40–70 years and identified as smokers, hypertensive of overweight on medical records in East Sussex general practices. Circa 37% men. No socio-economic details provided.	**Aim:** To examine the effects of a GP exercise referral programme on modifiable coronary heart disease risk factors. See Taylor 1998 for details.	Ten-week intervention. Outcomes measured at 0, 8, 16, 26 and 37 weeks.	The exercise group became significantly ($p < 0.05$) more positive about their physical self-worth, physical condition and physical health (but not their physical appearance) than did the control group between baseline and subsequent assessments.	Interviews at eight weeks identified that 50% were positive, 35% had mixed feelings and 15% had only negative comments about the concept of GP referral to a leisure centre-based exercise programme. Concerns included the long waiting time before the introductory session, lack of staff support in a sometimes crowded and noisy exercise room and inconvenient times (off peak hours 09.00–17.00 hours only).

								See Taylor 1998 for quantitative results.
Fuller 2003	Qualitative Study	3	+	GPs *n* = 15 (eight female, seven male) and 30 patients (15 married couples in social class 3, 4 or 5 with young children) from general practices in the Lothian area of Scotland, UK.	**Aim:** To investigate the view of GPs and their patients about healthy eating and the provision of healthy eating advice in general practice. **Delivered by:** N/a.	N/a	GPs and couples saw the general practice setting as a place for treatment of illness and disease. Interviews with couples revealed that health was only one factor that appeared to influence day-to-day decisions about food choice, and that they felt expert messages were contradictory. They felt 'bombarded' by healthy eating information, particularly from the media. GP advice affected by personal preferences and greater enthusiasm was displayed by younger and female doctors. GPs felt that dietary advice may damage their relationship with patients.	Very small sample size, is likely to be underpowered to detect an effect if one exists.
Duaso 2002	Cross-sectional survey	3	+	Patients from a general practice in north-east of England. *n* = 516 (from 3612 eligible) Age range = 17–45 years Characteristics below for responders only (*n* = 316) 59.2% female	**Aim:** To examine patients' recall and perceptions of lifestyle counselling received from practice nurses, and whether patient needs were met. Structured postal	N/A	63% response rate (316 of 516). Those with unhealthy behaviour profiles seem to have received more advice. There appears to be a discrepancy between patients' expectations of lifestyle advice from the practice nurses and the receipt of such advice. Significantly more respondents would have liked to have received advice on diet, weight reduction and exercise than actually received it ($p < 0.001$).	Low response rate. Under-reporting by patients may have occurred due to memory or not recognising advice for what it was.

				Mean age male = 34.1 years and female 33.6 years White, male = 92% Female = 97% In full time employment, male = 98%, female = 72%	questionnaire with letter from GP and stamped self-addressed envelope included. **Delivered by:** Lifestyle counselling by nurses.		On average, patients found the advice received from the practice nurses very/fairly helpful, but significant difference between male and female perceptions: most women found the advice very/fairly helpful while male patients more dubious ($p < 0.05$).	
Hardcastle 2001	Qualitative study	3	++	Older women newly referred by their GP to an exercise programme at a local leisure centre. *n* = 15 Age range = 50–80 years	**Aim:** To explore past and current experiences of PA and perceptions of what blocks/motivates older women to be active. One 20–40 min semi-structured interview in leisure centre cafeteria (based on 'life story' technique), and two follow-up interviews at 5 and 10 weeks. **Delivered by:** Unclear,	10 weeks	80% of the women appeared to have initiated the idea for referral with their GP and the data show an informal network whereby referred women advocate exercise in the community. The data show a lack of commitment, confidence and encouragement from the GPs in promoting PA and referring to exercise programmes. The data show that social support appears to be crucial for some older people, especially regarding instruction and the interpersonal skills of the exercise instructor.	Questions posed during interviews unknown. Very small sample size, is likely to be underpowered to detect an effect if one exists.

					possibly exercise practitioner/instructor.			
Martin 1999	Qualitative data from retrospective analysis	3	+	Finishers (16 male and 26 female) and non-finishers (12 males and 23 females) of a 10-week GP referral exercise prescription programme, Margate, Kent, UK. Mean age = 52.9 years 51% had BMI >25 kg/m^2.	**Aim:** To examine characteristics of finishers and non-finishers of a GP exercise referral scheme. Semi-structured telephone interviews conducted by an independent interviewer **Delivered by:** Unclear.	N/A	Finishers were less reliant on social support and more likely to report tangible health benefits. Non-finishers relied on support from others when attending the gym. Both finishers and non-finishers felt intimidated by others at the gym and felt it was not a comfortable environment for older people. Also, there was feeling in both groups that initial exercise programmes not appropriately tailored. Reasons for non-finishing were mainly illness and injury, but work pressures, time and transport problems were also cited.	Programme had been running for 3 years – responses may be susceptible to recall bias so reliability of results is limited. Content of semi-structured interviews not reported. Results suggest that methodology used was too crude to accurately measure complex characteristics that determine differences between finishers and non-finishers.
See Tai 1999	Cross-sectional survey	3	+	Inner-city general practice patients referred to an exercise prescription at a local leisure centre. *n* = 152 71% female Age range 16–75 years	**Aim:** To examine factors that affect adherence to a GP referral to exercise prescription scheme at a local leisure centre.	N/A	Adherers to exercise programme were significantly older than non-adherers (p = 0.026). Previous barriers to exercise included lack of money, having no energy, not knowing about local exercise facilities, having no partner to exercise with, not being fit enough and having no time. A significantly higher proportion of those who cited 'lack of money' as a barrier	May be of particular relevance to GPs in deprived urban area where high morbidity co-exists with low incomes. Same programme as Smith 1996

					Demographic and barriers data collected at baseline and analysed for adherers and non-adherers. **Delivered by:** Referral by GPs and associated staff. Delivered by trained fitness consultant and referred back to GP.		dropped out of the programme than those who did not cite it as a barrier (55.3 vs. 44.7%, *p* = 0.024). Those who cited 'not knowing about local exercise facilities' as a barrier were 3.5 times more likely to complete the programme (*p* = 0.043).	
Ashley 1999	Qualitative questionnaire study	3	++	336 participants of a Health Walks scheme in Woodley in the Thames Valley and 22 walk leaders. **Walkers:** 78% female. Mean age 58 (SD 10.2), range 27–83 years. 2% unemployed, 47% retired, 11% home-makers. Primarily white (Woodley is 96% White).	**Aim:** To determine the effectiveness of Health Walks in an urban area, specifically looking at how the local development of schemes can be coordinated. Questionnaire study of walkers and walk leaders.	N/A	47% response (*n* = 476) to 768 surveys but only 366 had attended at least one walk and, thus, completed the questionnaire. 22/29 walk leaders (76%) completed questionnaires. The Health Walks programme was a sustainable form of exercise for the majority of participants; 90% said they would continue with the programme. The three main motivators for walk leaders were companionship, ownership of the scheme and appreciation of their commitment to the organisation. Recommendations from the research included:	Study funded by the Countryside Agency and British Heart Foundation. There were a higher proportion of respondents who had completed more than two Health Walks and women than found in Health Walks participants generally. Given the higher proportion of regular attenders, the high percentage saying they would continue walking should be treated with caution.

				Researchers probably from Oxford Brookes University.	**Delivered by:** Volunteer walk leaders.		• take into account the seasons, and varying needs (levels of difficulty, evening walks for workers etc.) in promotion and planning; • emphasise the social aspects; • target participants via general practice, including close links with local health centres; • emphasise the importance of moderate daily activity (e.g. errands by foot rather than by car).	Qualitative study linked to RCT in Lamb
Vernon 1998	Cross-sectional survey	3	+	Members of the general public living in Salisbury, UK, who had requested a walking pack. *n* = 322 71% female	**Aim:** To evaluate the 'Doorstep Walks' scheme, a pack detailing ten local walks and benefits of PA, devised by 'Salisbury Walking Forum', an alliance of local groups. Questionnaires issued to collect demographic information and identify motivations and barriers to walking. **Delivered by:**	N/A	229 questionnaires returned (71% follow-up) and 61% uptake. Few respondents (14%) thought that 'having the walks recommended by a GP or health professional' was an important motivating factor. By far the most frequently given reason for non-participation (60%) was the shortage of free time, although other barriers were having no one to walk with (15.6%), having no walks near their home (14.4%), being fearful of walking the routes unaccompanied (12.2%), physically unable (11.1%), needed more encouragement (8.9%) and cost restriction (11.1%). GP surgeries cited as the single most common place to find out about the initiative.	Study design did not allow for an analysis by activity level, which limits application of the findings.

					Salisbury walking forum, an alliance of local groups.			
Smith 1996	Qualitative study	3	++	Clinical and support staff (23 of 40) in 10 (of 14) general practices involved in referring patients to exercise prescription programme in Inner-London leisure centre. GPs *n* = 16 Practice Nurses *n* = 4 Practice Managers *n* = 4 Receptionist *n* = 1 34.8% male (all GPs)	**Aim:** To identify practices' reasons for joining exercise referral scheme, perceptions of benefit of scheme, selection criteria for referral and reported personal behaviour. Semi-structured interviews carried out at practices. **Delivered by:** N/A	N/A	Referring practice members saw exercise promotion as a therapeutic option, rather than an instrument for primary prevention. Legal implications of referring patients led to over-caution and frustration among referring practice members at not being able to refer the people they considered most in need of the scheme. (Family Health Services Association [FHSA] criteria allowed only 'low risk' patients to be referred). Majority of participants said they participated in some form of sport or leisure activity. The main reason for not doing so was lack of time due to work or social commitments.	May be of particular relevance to GPs in deprived urban area where high morbidity co-exists with low incomes. Same programme as See Tai 1999
Horsefall Turner/Wealden District Council 1997	Evaluation and survey	3	+	Patients referred by GPs to exercise prescription who presented themselves at leisure centre. East Sussex, UK.	**Aim:** To evaluate Wealden District council's Oasis programme of exercise	N/A	1994 (January–July), 21.9% completers. Males more likely to complete than females (27.4 vs. 19.1%). Older patients more likely to complete. Patients referred by GPs who referred the most patients were more likely to complete. Risk category did not affect adherence.	1994. Follow-up of non-adherers stopped when time ran out. 1997 (and 1994?). Data presented on those who were referred and

				1994: *n* = 729 65.4% female >75% aged ≥41 years **1994–1997:** *n* = 627, 66% female Mean age 52 years, range 16–87	referral from GPs to a leisure centre in terms of factors affecting adherence, client views and physiological data. **Two evaluations:** 1994 – Adherence characteristics examined through initial consultation data – non-adherers telephoned. 1997 – questionnaire survey of sample of 192 participants. **Delivered by:** Referred by GP, delivered by programme staff (including fitness instructors and		Principle reasons for non-completion were patient too busy (32.5%) or had become ill or injured (28%). Significant number dropped out due to insufficient supervision or that programme too boring. Other factors were expense and transport. December 1994 – May 1997: 43% completed (47% of males who started and 41% of females). No major differences in completion rates found according to initial fitness or location. Clients referred for medical complaints such as hypertension or arthritis appear to demonstrate better adherence than those referred for stress or weight loss. Adherence significantly better for medium-risk groups compared with high- and low-risk groups. Questionnaire sample biased towards adherers, but general satisfaction with programme. Area identified for improvement was amount of time staff have to spend with clients.	presented themselves at the leisure centre. 1994–1997. Sample selection criteria not given.

					liaison nurse) and referred back to GP.			
Fielder 1995	RCT (suspended)	1	N/A (as trial suspended)	Sedentary patients aged 18–64 years from seven general practices within a 4-mile radius of the local leisure centre. *n* = 38 (out of 900 patients needed to show an effect). RCT suspended.	**Aim:** To assess whether referral to a leisure centre programme was a major factor leading to increased PA. This paper aims to examine data from the RCT to understand failure of trial. **Delivered by:** Referral by GP and fitness assessment presumably from leisure centre staff.	N/A	Slow rate of recruitment into trial. GPs cited the increase in time spent with patients, complicated nature of questionnaire, lack of space for patient to fill in questionnaire and lack of financial incentive for GP as reasons for this.	Suspended RCT as trial did not achieve required sample size.
Hopper 1995	Cross-sectional survey/case study	3	+	Active GP practices in on Sheffield Health Authority's GP practice list. *n* = 100 Primary health care workers	**Aim:** To investigate level of advice given on dietary matters, methods used to give this advice and nutritional		Interviews conducted in 46 of 100 active practices (46% response rate). Practice nurses gave dietary advice more frequently than GPs ($p < 0.05$) and GPs were more likely ($p < 0.05$) to give verbal advice only, whereas practice nurses tended to take a dietary history and give both written and verbal advice. Most GPs	Unknown if questionnaire was validated. Low response rate.

				interviewed $n = 58$. GP $n = 36$ (83% male, mean age 56 years). Practice nurse $n = 22$ (100% female, mean age 35 years).	knowledge and attitudes towards nutrition by Sheffield Primary Health Care Trusts (PHCT), GPs and practice nurses. Structured questionnaire administered by interviewer. **Delivered by:** N/a.		surveyed mentioned the major constraint to offering dietary advice was time. All practice nurses and half of GPs surveyed were interested in attending a nutrition course, but the majority of GPs cited time as a barrier to this. A large proportion of primary health care workers felt that their practice population was not sufficiently motivated to follow dietary advice.	
Ursell 1999	Qualitative study	3	+	Community pharmacists (CPs) ($n = 96$, random sample), lead health authority pharmaceutical advisors and medical directors of public health ($n = 26$) in the West Midlands. No socio-economic information provided. Researchers from the School of Pharmacy, Aston	**Aim:** To examine the attitudes of CPs and those responsible for pharmaceutical policy at health authority level towards a role for community pharmacy in public health provision. Postal questionnaire. **Delivered by:** N/A	N/A.	Overall response rate = 48%. CPs 44%, public health directors 62% and lead pharmaceutical advisors 69%. The proportion of CPs (50%) who perceived the current role of the pharmacist in public health provision to be 'very important' was significantly greater than the corresponding group of policy makers (11%, $p < 0.01$). Lack of time was cited by 62% of CPs as the most important constraint preventing pharmacist involvement in public health promotion while financial issues were considered the most important constraint by 40% of policy-makers. When asked about possible solutions to aid pharmacy involvement, pharmacist	Brief report and very little methodological detail provided. The questionnaire does not appear to have been validated.

				University.			inclusion in primary care group function was considered essential by 27% and 79% of policy-makers and CPs respectively. The need for increased funding (73%, 96% respectively) and appropriate training (67%, 70%) were both highly regarded. The authors tentatively proposed that, given the disparity of views, a clear dialogue on the issue should be established between CPs and policy-makers.	
Anderson 1998b	Qualitative study	N/a	++	Consumers (*n* = 592) interviewed in six pharmacies in Barnet. 74% female. 40% ≥60 years old. 85% white European, 15% unemployed, 35% retired. 90% regular pharmacy users. Researchers probably from Kings College London.	**Aim:** To investigate whether consumers came to the pharmacies for advice on general health matters, read health promotion leaflets and had heard of the Barnet Health Authority High Street Health Scheme (HSHS). **Delivered by:** N/A	N/A.	Many consumers do not currently perceive that there is a role for community pharmacists in health promotion. The GP's surgery was felt to be the most convenient place to get advice about staying healthy, and the GP the best person from whom to get it. The pharmacist was rated second, above the media, although only 15% of respondents had ever asked the pharmacist for general health advice. Only 40% thought that it was the usual job of the pharmacist to give advice about staying healthy although 92% said that they could pick up health information leaflets at the pharmacy. The authors concluded that pharmacist training alone would not change the public's perception of pharmacists. There was no significant variation in responses according to age, race or	Health authority-funded project.

							employment status although women were more likely to get advice from the media.	
Keene 1995	Qualitative study	3	+	Pharmacy contractors based in West Glamorgan. *n* = 48 (of 50)	**Aim:** To examine present state of health education among pharmacists, perceived costs and benefits, and factors to increasing health education activity. Questionnaires with open and closed questions, interviews of up to 1 hour and ethnographic notes. **Delivered by:** Academic and Health Authority researchers.	N/A	Great majority of contractors expressed support for engaging in health promotion but some qualified it with arguments of it being a significant waste of resources and a diversion from core activity of dispensing. Two-fifths of respondents saw time as the strongest constraint against health promotion, one-fifth mentioned space and just under one-third referred to cost. Majority saw training as an essential part of developing pharmacy services, but concerns about co-ordination of training and lack of time for training featured prominently in the comments.	Survey small in scale and range.
Moore 1995	Qualitative study	3	++	Community pharmacists in Kingston and Richmond FHSA, UK.	**Aim:** To identify health promotion activities, and	N/A.	Pharmacists' activities in health promotion were 2.5 times more likely to be reactive rather than proactive. Barriers to health promotion experienced	

				n = 30 (of 34 approached)* *Reasons for refusal include lack of time, illness of pharmacists or unwillingness to participate.	barriers to improving and increasing health promotion activity in community pharmacies. Structured interviews by a research pharmacist. **Delivered by:** N/A		by community pharmacists were lack of time and space, need for a consulting area, desire for payment by the FHSA, need for training, insufficient support from their local health promotion unit, lack of regular contact with health promotion facilitator and the need for more staff.	
Coggans 2000	Qualitative survey, Delphi analysis and literature review	3	++	1) Semi-structured interviews with 60, 30 pharmacists and 30 pharmacy assistants, in community pharmacies in Scotland. 2) Dephi exercise with 25 health professionals. 3) Literature review. Pharmacy customers: 68% female, 7% <20 years, 22% ≥60 years. 19% higher managerial and 7% long-term	**Aim:** To find out what aspects of health promotion are pharmacy customers most receptive to and what methods are appropriate for the delivery of pharmacy health promotion. Research carried out by the Pharmaceutical Services	N/A	Although virtually every customer reported that they were happy to discuss health information with the pharmacist or assistant, <32% reported that they would seek information or help in the community pharmacy on healthy eating and only 23% would seek information or help on taking exercise. Pharmacists were willing and eager to discuss a range of health issues with customers, although there was some reluctance in relation to lifestyle issues, as well as awareness of the limitations arising from lack of privacy. Conclusions from the survey and Delphi study were that factors that facilitate pharmacy staff/customer interaction should be addressed as well as enhancing perceptions of pharmacists as key players in the health care team who provide a confidential service.	

				unemployed.	Division of the Scottish Executive Health Department. **Delivered by:** N/A			
Benson 1995	Qualitative study	3	+	Purposive sample of ten practicing community pharmacists in the UK to obtain geographic and socio-economic range. All white, Anglo-Saxon. Six women, four men. Researcher background unknown (National Pharmaceutical Association/King's College).	**Aim:** To explore pharmacists' perceptions of the nature of their health education role, the practicalities of implementing this role and the obstacles to be overcome. **Delivered by:** N/A	N/A	There was considerable uncertainty about the health education role of pharmacists. There were profound concerns among the respondents that a health education role required 'interference' in patients lives and that health education was often not income generating, a barrier for pharmacies since they run as commercial enterprises. The authors concluded that a paradigm shift would be needed to overcome the barriers of the pharmacist's traditional inclination to a product orientated approach and ethical concerns about interference.	Small sample and all White. Paper lacked methodological detail – example quotes rather than detailed summary provided.
Biddle 1994	Evaluation of case studies	3	+	Structured sample of 50 (of 173) PA promotion schemes in primary health care (20 practice managed and 30 leisure centre managed).	**Aim:** To identify existing PA interventions and any evaluations of them and identify criteria	N/A	Success of PA promotion depends on qualities of key personnel in contact with participants, in particular appropriate training in health promotion techniques and counselling for exercise. Establishing a scheme depends on the enterprise of an energetic innovator.	

				Sample structured in order to get examples from a range of environments and participant profiles. Primary health care facilitators interviewed *n* = 50.	for and barriers to success. Structured questionnaire checklists delivered over the phone (or mailed if lack of time). **Delivered by:** N/A		In most schemes participants are predominantly middle-aged women, often overweight.	
Baron 1990	Survey within RCT	3	+	Patients on the lists of a group general practice in Abingdon, Oxford, UK. Intervention subjects from an RCT investigating the effect of nutrition advice by a nurse in general practice. *n* = 187 52% male Mean age = 41.6 years	**Aim:** To examine difficulties encountered by intervention subjects (queried at 1, 3 and 12 months) with the dietary recommendations. Intervention received 30 min session with nurse aimed at lowering fat and increasing fibre intake. Booklet and two follow-up sessions at 1 and 3 months	3 months and 12 months	89.3% follow-up in intervention group at 12 months. Dietary intervention appeared to be well accepted by the intervention group. 8% thought the recommended regimen was hard to prepare or difficult to find in restaurants. 10% of the intervention group noted that they or their families disliked the recommendations and subjects with this complaint were more likely to drop out of the study.	No allocation concealment. No ITT analysis. Number of subjects evaluated for difficulties encountered with the dietary advice vary because of losses to follow-up and missing data.

					Delivered by: Intervention by nurse.			

3. INCENTIVES

SUMMARY

Evidence of efficacy for weight management/reduction

Only one RCT conducted in the USA (the Pound of Prevention study) reported weight outcomes (Jeffery 1999). This low-intensity intervention to prevent weight gain comprised of education or education with incentives (entry into a US$100 lottery) compared with a control. After a 3-year follow-up significant differences were reported between intervention groups and control with a higher reported frequency in healthy weight loss practices. This was related to a non-significant reduced rate of weight gain over time. No weight gain differences were found between the treatment groups.

Evidence of efficacy for diet/physical activity outcomes

One multifaceted RCT to improve dietary habits among adult primary care patients (Delichatsios 2001) offered an incentive of US$5 for completion of the baseline survey and again for the final survey for those in the intervention group. The intervention group reported a positive effect for fruit and vegetable consumption (an increased of 0.6 servings per day). No effect was found for dairy products.

Two PA incentive interventions (both RCTs – one conducted in the UK and the Pound of Prevention study in the USA) demonstrated a positive short-term effect for PA outcomes. Harland (1999) offered vouchers entitling free access to leisure facilities and reported increased PA scores at 12 weeks and increased vigorous activity in the intervention participants. However, this increase was not maintained in the long-term (12 months). Jeffery (1999) reported that exercise decreased less in the education and education plus incentives groups however statistical significance is unclear.

Evidence of corroboration in the UK

Only one study (Harland) was undertaken in the UK. No other evidence of corroboration was identified.

EVIDENCE TABLE 3: INCENTIVES

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Jeffery 1999	RCT Individual	1	+/– (weak)	Men and women recruited from diverse sources, Minnesota, USA. *n* = 1226 18.6% men 40.5% of women were low income (household incomes of ≤US$25000 per year) Mean age = 38.4 years 90.7% white 89% with at least some college education Mean BMI = 26.7 kg/m².	**Aim:** To evaluate the effectiveness of low-intensity intervention to prevent weight gain with age. No-contact control compared with: 1) education through monthly newsletters (questionnaire postcard included) encouraging paying attention to weight and making small changes in diet and exercise habits; and	3 years (Newsletters continued throughout 3 years.)	106 women who become pregnant excluded from the analysis. 809/1120 (72%) completed all data collection visits. Significant increase between intervention groups and control in self-reported frequency of healthy weight loss practices (including reducing calories, increasing exercise and fruit and vegetables intake and decreasing fat intake) (*p* = 0.01), related to a reduced rate of weight gain over time. Point estimates for rate of weight gain over three years were slightly lower in both intervention groups than control, but differences between all groups not statistically significant, *p* = 0.88.	Also included in Table 1. No description of randomisation process. No allocation concealment. No ITT analysis. **Baseline differences:** Mean BMI higher in education-only group. Higher % of whites in two education groups (92% and 93%) than in control (87%). Parallel analyses with subjects completing only partial data (1101/1120 [98.3%]) yielded very similar findings and are not described in paper. Pound of Prevention Study.

					2) education + incentives (entry into US$100 lottery if questionnaire postcard returned). Intervention subjects had option for participation in community activity every 6 months. Annual study visits for all participants. **Delivered by:** Researchers (although 6 monthly activities delivered by various including nutritionists).			

Evidence of efficacy (internal validity) for diet outcomes								
Delichatsios 2001	RCT Cluster	1	+	Adult primary care patients New England, USA.	**Aim:** To evaluate a multifaceted preventive nutrition intervention to improve	3-month follow-up	85% follow-up in intervention group. 92% follow-up in control group.	No description of randomisation process. No allocation concealment. ITT

				n = 504 (of 1183 eligible) **Intervention:** Mean age = 49.9 ± 12.5 years 77.4% female 83% white 62% with at least a bachelor degree **Control:** Mean age = 56.8 ± 12.9 years 63.1% female 97% white 56.9% with at least a bachelor degree	dietary habits among adult primary care patients. Intervention vs. control. Intervention comprised mailed personalised dietary recommendations, verbal endorsement and motivational phone calls to set targets. US$5 incentive offered for completion of baseline survey and US$5 for final survey. Control comprised no intervention. **Delivered by:** Primary care physician or nurse practitioners and trained telephone counsellors. Nutritionist if necessary.	survey (although intervention taking place during this time).	Adjusting for age, sex, race and baseline intake, the change in fruit and vegetable intake in the intervention group was higher than control (0.6 [95% CI 0.3,0.8] servings/day. No intervention effect on dairy products.	analysis used. Some baseline differences. Mean age higher in control group. Proportion of African Americans higher in intervention group.
Evidence of efficacy (internal validity) for physical activity outcomes								
Harland 1999 UK Study	RCT Individual	1	++	Adults aged 40–64 years attending routine surgeries in one urban general practice in a socio-economically disadvantaged area of Newcastle, UK. *n* = 523 42.5% male 52% employed 10% unemployed	**Aim:** To evaluate the effectiveness of combinations of three methods to promote PA versus a control intervention. Brief (one interview) or intensive (six interviews over 12 weeks) motivational interviewing with or without financial incentive (30 vouchers entitling free access to	12 months	81% response rate at 12 weeks and 85% at 1 year. More participants in the combined intervention groups reported increased PA scores at 12 weeks than controls (38 vs. 16%, difference 22 [95% CI 13, 32]%, $p < 0.001$, with a 55% increase observed in those offered six interviews plus vouchers. Vigorous activity increased in 29% of	One urban general practice in a socio-economically disadvantaged area Less subjects per group in final analysis than required by power calculation, therefore study a little short on power.

				and seeking work 13% unable to work due to illness 72% manual occupational class (III, IV, V)	leisure facilities) and a no intervention control group. Group 1 *n* = 105 – Brief intervention Group 2 *n* = 106 – Brief intervention and vouchers Group 3 *n* = 104 – Intensive intervention Group 4 *n* = 102 Intensive intervention and vouchers 107 participants per group required to detect a difference between success rates of 40% to 60% at 80% power and 5% significance level. **Delivered by:** Interviews by trained health visitor.		intervention participants and 11% of controls (difference 18 [95% CI 10, 26]%, $p < 0.001$) but differences between the four intervention groups were not significant. Short-term increases in activity were not sustained regardless of intensity of intervention.	
Jeffery 1999	RCT	1	+/– (weak)	See above.	See above.	See above.	106 women who become pregnant excluded from the analysis. 809/1120 (72%) completed all data collection visits. Self-reported exercise decreased less in the two treatment groups than in control. Statistical significance unclear.	See above.

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**
Harland 1999 UK study	RCT Individual	1	++	Adults aged 40–64 years attending routine surgeries in one urban general practice in a socio-economically disadvantaged area of Newcastle, UK	See above.	See above.	See above.	
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/comments**

SEARCH STRATEGIES

1.exp OBESITY/
2. exp Weight Gain/
3. exp Weight Loss/
4. obes$.af.
5. (weight gain or weight loss).af.
6. (overweight or over weight or overeat$ or over eat$).af.
7. weight change$.af.
8. ((bmi or body mass index) adj2 (gain or loss or change)).af.
9. body mass.ti,ab.
10. or/1–9
11. exp Behavior Therapy/
12. exp Social Support/
13. exp Family Therapy/
14. exp Psychotherapy, Group/
15. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).af.
16. (group therapy or family therapy or cognitive therapy).af.
17. ((lifestyle or life style) adj (chang$ or intervention$)).af.
18. counsel?ing.af.
19. social support.af.
20. (peer adj2 support).af.
21. (children adj3 parent$ adj therapy).af.
22. or/11–21
23. exp OBESITY/dh [Diet Therapy]
24. exp Diet, Fat-Restricted/
25. exp Diet, Reducing/
26. exp Diet Therapy/
27. exp FASTING/
28. diet$.af.
29. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).af.
30. (low calorie or calorie control$ or healthy eating).af.
31. (fasting or modified fast$).af.
32. exp Dietary Fats/
33. (fruit or vegetable$).af.
34. (high fat$ or low fat$ or fatty food$).af.
35. formula diet$.af.
36. or/23–35
37. exp EXERCISE/
38. exp Exercise Therapy/
39. exercis$.af.
40. (aerobics or physical therapy or physical activity or physical inactivity).af.
41. (fitness adj (class$ or regime$ or program$)).af.
42. (aerobics or physical therapy or physical training or physical education).af.
43. dance therapy.af.
44. sedentary behavio?r.af.
45. or/37–44
46. exp Complementary Therapies/
47. (alternative medicine or complementary therap$ or complementary medicine).af.
48. (hypnotism or hypnosis or hypnotherapy).af.
49. (acupuncture or homeopathy or homoeopathy).af.
50. (chinese medicine or indian medicine or herbal medicine or ayurvedic).af.
51. or/46–50
52. ((diet or dieting or slim$) adj (club$ or organi?ation)).af.
53. (weightwatcher$ or weight watcher$).af.
54. (correspondence adj (course$ or program$)).af.
55. (fat camp$ or diet$ camp$).af.
56. or/52–55

57. exp Health Promotion/
58. exp Health Education/
59. Mass Media/
60. (health promotion or health education).af.
61. (media intervention$ or community intervention$).af.
62. (community adj2 program$).af.
63. (family intervention$ or parent$ intervention).af.
64. or/57–63
65. exp Health Policy/
66. exp Nutrition Policy/
67. (health polic$ or food polic$ or nutrition polic$).af.
68. or/65–67
69. exp OBESITY/pc [Prevention & Control]
70. Primary Prevention/
71. (primary prevention or secondary prevention).af.
72. (preventive measure$ or preventative measure$).af.
73. (preventive care or preventative care).af.
74. (obesity adj2 (prevent$ or treat$)).af.
75. or/69–74
76. exp Controlled Clinical Trials/
77. exp Random Allocation/
78. exp Double-Blind Method/
79. exp Single-Blind Method/
80. exp PLACEBOS/
81. exp Research Design/
82. exp Intervention studies/
83. exp Evaluation studies/
84. exp Cost Benefit Analysis/
85. (time adj series).tw.
86. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).af.
87. exact{CONTROLLED-CLINICAL-TRIAL}.pt.
88. placebo$.af.
89. (matched communities or matched populations).af.
90. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).af.
91. (comparison group$ or control group$).af.
92. matched pairs.af.
93. (outcome study or outcome studies).af.
94. (quasiexperimental or quasi experimental or pseudo experimental).af.
95. (nonrandomi?ed or non randomi?ed or pseudo randomi?sed).af.
96. randomi?ed.hw.
97. (cohort or survey: or qualitative).ti,ab.
98. or/76–97
99. exp Meta-Analysis/
100. meta-analys$.ti,ab.
101. metaanalys$.ab,ti.
102. meta analys$.ab,ti.
103. Cochrane.ab,sh,ti.
104. (review$ or overview$).ti.
105. review$.pt.
106. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
107. pooled analys$.ab,ti.
108. ((data adj2 pool$) and studies).mp. [mp=title, original title, abstract, name of substance, mesh subject heading]
109. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
110. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
111. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
112. or/99–111
113. (retrospective$ adj2 review$).ab,sh,ti.
114. (case$ adj2 review$).ab,sh,ti.

115. (record$ adj2 review$).ab,sh,ti.
116. (patient$ adj2 review$).ab,sh,ti.
117. (patient$ adj2 chart$).ab,sh,ti.
118. (peer adj2 review$).ab,sh,ti.
119. (chart$ adj2 review$).ab,sh,ti.
120. (case$ adj2 report$).ab,sh,ti.
121. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
122. or/113–121
123. 122 not (122 and 112)
124. 112 not 123
125. 22 or 36 or 45 or 51 or 56 or 64 or 68 or 75
126. 10 and 125 and 98
127. 10 and 125 and 124
128. 126 or 127
129. Residence characteristics/
130. Delivery of health care/
131. Community Networks/
132. Social Change/
133. Social Support/
134. Community Health Aides/
135. Community Health Nursing/
136. Community Health Planning/
137. Community Health Services/
138. Community-Institutional Relations/
139. Community Medicine/
140. Community Pharmacy Services/
141. Rural Health Services/
142. Public Health/
143. Public Health Practice/
144. Public Health Nursing/
145. Preventive Health Services/
146. Primary Prevention/
147. (primary prevention or secondary prevention).af.
148. (preventive care or preventative care).af.
149. Physician’s role/
150. Peer Group/
151. Self-Help Groups/
152. Health Personnel/
153. Allied Health Personnel/
154. Mass Media/
155. ((gp$ or general practitioner$ or physician$) adj5 (intervention$ or refer$ or advi$ or train$ or run$)).af
156. ((nurse$ or health visitor$ or pharmacist$ or pharmacy) adj5 (intervention$ or refer$ or led or support$ or advi$ or train$ or run$)).af
157. ((health professional$ or nutritionist$ or dietician$) adj5 (intervention$ or refer$ or led$ or support$ or advi$ or train$ or run$)).af
158. ((peer$1 or lay or professional$1 or community or agenc$) adj5 support).af
159. ((peer$1 or lay or community) adj5 (group$1 or network$1 or program$ or clinic$)).af
160. health promotion/mt
161. (exercise$ prescri$ or exercise$ refer$).af
162. ((nutrition$ or diet$) adj2 advis$).af
163.Community wide.af
164.Social support.af
165.Social network$.af
166. ((lifestyle$ or life style$ adj2 (change$ or advi$)).af
167. or/129–166
168. 128 and 167
169. animal.sh.
170. human.sh.

171. 169 not (169 and 170)
172. 168 not 171
173. limit 172 to yr=1990–2005

DATA SOURCES

Database searches were carried out in January 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence).

The following information sources were searched:

AMED (Allied and Complementary Medicine)
ASSIA (Applied Social Sciences Index and Abstracts)
British Nursing Index
CAB Abstracts - Human health and nutrition, agriculture
CENTRAL (Cochrane Controlled Trials Register)
CINAHL (Cumulative Index to Nursing & Allied Health Literature)
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
CRD (EED database) http://www.york.ac.uk/inst/crd
DARE (Database of Abstracts of Reviews of Effects)
Embase
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC (Educational Resources Information Centre)
Food Standards Agency - http://www.food.gov.uk/science/research/
HDA Evidence Base - http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA (National Coordinating Centre for Health Technology Assessment) - http://www.ncchta.org
NICE (National Institute for Clinical Excellence)– www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN (Scottish Intercollegiate Guidelines Network) – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus

Update searches

An update search of the same databases was carried out in September 2005 for worldwide intervention and UK corroborative studies. A final search was completed on 1 December 2005 for systematic reviews and controlled trials only in a reduced number of databases: CINAHL, Cochrane, Embase, Medline and PsycINFO.

The search strategies (see part c, supporting information) were developed in Medline and adapted for use with the other information sources. Additional papers (*n* = 18) were located from reference lists or in the searches carried out for the broader community review, or were suggested by the Guidance Development Group.

EXCLUDED REFERENCE LISTS

Papers excluded due to lack of time

Paper	Reason for exclusion
Barr SI, Yarker KV, Levy-Milne R, Chapman GE. Canadian dietitians' view and practices regarding obesity and weight management. *Journal of Human Nutrition and Dietetics* 2004;17(6).	Non-UK corroborative – excluded due to lack of time.
Barras C, Bloom *N*, Cook S, Luzhansky Z, Skinner B. Hand in Hand: Encouragement and facilitation of support and self-help group use. *Internet Journal of Health Promotion* August 1996.	Non-UK corroborative – excluded due to lack of time.
Bebetsos E, Chroni S, Theodorakis Y. Physically active students' intentions and self-efficacy towards healthy eating*. Psychological Reports* 2002;91(2):485–95.	Non-UK corroborative – excluded due to lack of time.
Black DR, Blue CL, Coster DC, Chrysler LM. Corporate social marketing: message design to recruit program participants. *American Journal of Health Behavior* 2002;26(3):188–99.	Non-UK corroborative – excluded due to lack of time.
Blackburn GL, Waltman BA. Physician's guide to the new 2005 dietary guidelines: How best to counsel patients. *Cleveland Clinic Journal of Medicine* 2005;72(7); 609-618.	Non-UK corroborative – excluded due to lack of time.
Bryant C, Lindenberger J, Brown C, Kent E, Schreiber JM, Bustillo M, et al. A social marketing approach to increasing enrollment in a public health program: A case study of the Texas WIC program. *Human Organization* 2001;60(3):234–46.	Non-UK corroborative – excluded due to lack of time.
Bull F, Schipper E, Jamrozik K, Phil D. How can and do Australian doctors promote physical activity? *Preventive Medicine* 1997;26(6):866–73.	Non-UK corroborative – excluded due to lack of time.
Clark T, Sleath B, Rubin RH. Influence of ethnicity and language concordance on physician–patient agreement about recommended changes in patient health behaviour. *Patient Education and Counselling* 2005;53(1):87–93.	Non-UK corroborative – excluded due to lack of time.
Clemmens D, Engler A, Chinn PL. Learning and living health: College students' experiences with an introductory health course. *Journal of Nursing Education* 2004;43(7):313–8.	Non-UK corroborative.
Croft JB, Temple SP, Lankenau B, Heath GW, Macera CA, Eaker ED, et al. Community intervention and trends in dietary-fat consumption among black-and-white adults. *Journal of the American Dietetic Association* 1994;94(11):1284–90	Non-UK corroborative – excluded due to lack of time.
Davis LL, Broome ME, Cox RP. Maximizing retention in community-based clinical trials. *Journal of Nursing Scholarship* 2002;34(1):47–53	Non-UK corroborative – excluded due to lack of time.
Drayton-Brooks S, White N. Health promoting behaviors among African American women with faith-based support. *ABNF Journal* 2004;15(5):84–90.	Non-UK corroborative – excluded due to lack of time.

Dwyer JJ, Hansen B, Barrera M, Allison KR, Ceolin-Celestini S, Koenig D, et al. Maximising children's physical activity: an evaluability assessment to plan a community-based, multi-strategy approach in an ethno-racially and socio-economically diverse city. *Health Promotion International* 2003;18:199–208.	Non-UK corroborative – excluded due to lack of time.
French SA NS. Reducing barriers to participation in weight-loss programs in low-income women. Journal of the *American Dietetic Association* 1998;98(2):198–200..	Non-UK corroborative – excluded due to lack of time.
Goodman RM, Steckler A, Hoover S, Schwartz R. A critique of contemporary community health promotion approaches: Based on a qualitative review of six programs in Maine. *American Journal of Health Promotion* 1993;7:208–20..	Non-UK corroborative – excluded due to lack of time.
Greene GW, Fey-Yensan N, Padula C, Rossi S, Rossi JS, Clark PG. Differences in psychosocial variables by stage of change for fruits and vegetables in older adults. *Journal of the American Dietetic Association* 2004;104(8);1236–43..	Non-UK corroborative – excluded due to lack of time.
Guion LA. Partnerships for Progress: summer youth nutrition programs. *Journal of Extension* 1998;36(6)	Brief narrative evaluation of seven youth nutritional programmes. Non-UK corroborative excluded due to lack of time.
Harris JE, Hamaday V, Mochan E. Osteopathic family physicians' attitudes, knowledge, and self-reported practices regarding obesity. *Journal of the American Osteopathic Association* 1999;99(7):358–65.	Non-UK corroborative – excluded due to lack of time.
Hawk C, Long CR, Perillo M, Boulanger KT. A survey of US chiropractors on clinical preventive services. *Journal of Manipulative and Physiological Therapeutics* 2004;27(5).	Non-UK corroborative – excluded due to lack of time.
Honda K. Factors underlying variation in receipt of physician advice on diet and exercise: Applications of the behavioral model of health care utilization. *American Journal of Health Promotion* 2004;18(5):370–77	Non-UK corroborative – excluded due to lack of time.
Huang J, Yu H, Marin E, Brock S, Carden D, Davis T. Physicians' weight loss counseling in two public hospital primary care clinics. *Academic Medicine* 2004;79(2): 156–61.	Non-UK corroborative – excluded due to lack of time.
Hunt JR, Kristal A, White E, Lynch JC. Physician recommendations for dietary change: their prevalence and impact in a population-based sample. *American Journal of Public Health* 1995;85(5):722–6.	Non-UK corroborative – excluded due to lack of time.
Jackson CL. Lifestyle counselling in general practice. Waste of time or challenge of skill? *Medical Journal of Australia* 1992;157(6):396–8.	Non-UK corroborative – excluded due to lack of time.
Kayman S, Bruvold W, Stern JS. Maintenance and relapse after weight loss in women: behavioral aspects. *American Journal of Clinical Nutrition* 1990;52(5):800–807.	Non-UK corroborative – excluded due to lack of time.
Kelleher CC, Fallon UB, McCarthy E, Dineen BD, O'Donnell M, Killian M et al. Feasibility of a lifestyle cardiovascular health	Non-UK corroborative – excluded

promotion programme for 8–15 year olds in Irish general practice: results of the Galway Health Project. *Health Promotion International* 1999;14:221–9.	due to lack of time.
Keller I, Legetic B. Training Chilean primary health care professionals in nutrition for non-communicable disease prevention. *Revista Panamericana de Salud Republica – Pan American Journal of Public Health* 2004;16(4):242–9.	Non-UK corroborative – excluded due to lack of time.
Kreuter MW, Scharff DP, Brennan LK, Lukwago SN. Physician recommendations for diet and physical actiivity: which patients get advised to change. *Preventive Medicine* 1997;26(6):825–33.	Non-UK corroborative – excluded due to lack of time.
Kreuter MW, Chheda SG, Bull FC. How does physician advice influence patient behavior? Evidence for a priming effect. *Archives of Family Medicine* 2000;9(5):426–33.	Non-UK corroborative – excluded due to lack of time.
Lazovich D, Curry SJ, Beresford SAA. Implementing a dietary intervention in primary care practice: a process evaluation. *American Journal of Health Promotion* 2000;15(2):118–25.	Non-UK corroborative – excluded due to lack of time.
Lee Y-S. Gender differences in physical activity and walking among older adults. *Journal of Women and Aging* 2005;17(1/2):55–70.	Non-UK corroborative.
Lee JS, Kritchevsky SB, Tylavsky FA, Harris T, Everhart J, Simonsick EM et al. Weight-loss intention in the well-functioning, community-dwelling elderly: associations with diet quality, physical activity, and weight change. *American Journal of Clinical Nutrition* 2004;80(2):466–74.	Non-UK corroborative – excluded due to lack of time.
McGuire MT, Jeffrey RW, French SA, Hannan PJ. The relationship between restraint and weight and weight-related behaviors among individuals in a community weight gain prevention trial. *International Journal of Obesity and Related Metabolic Disorders* 2001;25(4):574–80.	Non-UK corroborative – excluded due to lack of time.
Messecar DC, Salveson CA, Monkong S. Feasibility of a virtual health and wellness center for the Oregon Air National Guard. *Military Medicine* 2002;167(1):38–43..	Non-UK corroborative – excluded due to lack of time.
Mihalynuk TV, Knopp RH, Scott CS, Coombs JB. Physician informational needs in providing nutritional guidance to patients. *Family Medicine* 2004;36(10); 722-26 .	Non-UK corroborative – excluded due to lack of time.
Monge-Rojas R, Garita C, Sanchez M, Munoz L. Barriers to and motivators for healthful eating as perceived by rural and urban Costa Rican adolescents. *Journal of Nutrition Education and Behaviour* 2005;37(1):33–40.	Non-UK corroborative – excluded due to lack of time.
Murtagh EM, Boreham CAG, Nevill A, Hare LG, Murphy MH. The effects of 60 minutes of brisk walking per week, accumulated in two different patterns, on cardiovascular risk. *Preventive Medicine* 2005;41(1):92–7.	Excluded at critical appraisal. Potentially severely confounded study. 1–
Ness K, Elliott P, Wilbur V. A peer educator nutrition program for seniors in a community development context. *Journal of Nutrition Education* 1992;24(2):91–4.	Non-UK corroborative – excluded due to lack of time.

Nomaguchi KM, Bianchi SM. Exercise time: Gender differences in the effects of marriage, parenthood, and employment. *Journal of Marriage and Family* 2004;66(2):413–430.	Non-UK corroborative – excluded due to lack of time.
Nothwehr F. Attitudes and behaviors related to weight control in two diverse populations. *Preventive Medicine* 2004;39(4)***I;*** **674-80**.	Non-UK corroborative – excluded due to lack of time.
Owen N. Strategic initiatives to promote participation in physical activity. *Health Promotion International* 1996;11(3):213–8.	Non-UK corroborative – excluded due to lack of time.
Schnirring L. Survey suggests a decline in obesity counselling: physicians analyze reasons. *Physician and Sportsmedicine* 2004;32(6):18–20, 40.	Non-UK corroborative – excluded due to lack of time.
Sciamanna CN, DePue JD, Goldstein MG. Nutrition counseling in the Promoting Cancer Prevention in Primary Care Study. *Preventive Medicine* 2002;35(5):437–46.	Non-UK corroborative – excluded due to lack of time.
Sherwood NE, Morton N, Jeffery RW, French SA, Neumark-Sztainer D, Falkner NH. Consumer preferences in format and type of community-based weight control programs. *American Journal of Health Promotion* 1998;13(1):12–8.	Non-UK corroborative – excluded due to lack of time.
Tu W, Stump TE, Damush TM, Clark DO. The effects of health and environment on exercise-class participation in older, urban women. *Journal of Aging and Physical Activity* 2004;12:480–96.	Non-UK corroborative.
Verheijden MW, Bakx JC, Delemarre ICG et al. GPs ‘assessment of patients’ readiness to change diet, activity and smoking. *British Journal of General Practice* 2005;55(515).	Non-UK corroborative – excluded due to lack of time.
Whitaker RC, Sherman SN, Chamberlin LA, Powers SW. Altering the perceptions of WIC health professionals about childhood obesity using video with facilitated group discussion. *Journal of the American Dietetic Association* 2004;104(3):379–86.	Non-UK corroborative – excluded due to lack of time.
Wilson PM, Rodgers WM. The relationship between perceived autonomy support, exercise regulations and behavioural intentions in women. *Psychology of Sport and Exercise* 2004;5:229–42.	Non-UK corroborative.
Wyatt HR, Peters JC, Reed GW, Barry M, Hill JO. A Colorado statewide survey of walking and its relation to excessive weight. *Medicine and Science in Sports and Exercise* 2005; 37(5); 724–730.	Non-UK corroborative.

Excluded reference list

Paper	**Reason for exclusion**
Review: Computerized reminders increase the rate of use of most preventive services. *ACP Journal Club* 1997;126:80.	Review of ambulatory care study.

Review: Most obesity treatment methods are ineffective over the long term. *ACP Journal Club* 1999;131:20.	Review of [143].
Abdul-Ghani MA, Sabah M, Minuchin O, Vardi P, Raz I, Wainstein J. Primary prevention of type 2 diabetes: How do we do it? *Israel Medical Journal* 2004;6:305–7.	Non-systematic literature review.
Ahrens RA, Hower M. Effects of weight reduction interventions by community pharmacists. *Journal of the American Pharmacists Association* 2003; 43(5):583–9.	Overweight and obese subjects only.
Altman DG. Sustaining interventions in community systems: On the relationship between researchers and communities. *Health Psychology* 1995;14(6):526–36.	Expert opinion/discussion paper
Ammerman AS, Lindquist CH, Lohr KN, et al. The efficacy of behavioral interventions to modify dietary fat and fruit and vegetable intake: a review of the evidence. *Preventive Medicine* 2002;35:25–41.	Excluded at critical appraisal: - quality systematic review
Anderson C. Community pharmacy health promotion activity in England: a survey of policy and practice. *Health Education Journal* 1996; 55: 194–202.	No relevant results
Anderson C. Health promotion by community pharmacists: perceptions, realities and constraints. *Journal of Social and Administrative Pharmacy* 1998;15:10–22.	Six respondents only, and replicates results of larger included studies (Keene [324] and Moore [325]).
Andersen RE, Franckowiak, SC, Bartlett, SJ, Fontaine, KR. Physiologic changes after diet combined with structured aerobic exercise or lifestyle activity. *Metabolism: Clinical and Experimental* 2002;51(12):1528–33.	Overweight and obese subjects only.
Andersen RE, Bartlett SJ, Moser CD, Evangelisti MI, Verde TJ. Lifestyle or aerobic exercise to treat obesity in dieting women. *Medicine and Science in Sports and Exercise* 1997;29(Suppl 5):S46.	Abstract only. Obese subjects only.
Anderson A, Cox D. Five a day – challenges and achievements. *Nutrition and Food Science* 2000;30(1):30–34.	Very low quality study. Better evidence available
Anderson AS. How to implement dietary changes to prevent the development of metabolic syndrome. *British Journal of Nutrition* 2000;83(Suppl 1):S165–8.	Narrative overview. Relevant papers obtained.
Anderson JV, Bybee DI, Brown RM, et al. 5 a Day fruit and vegetable intervention improves consumption in a low income population. *Journal of the American Dietetic Association* 2001;101:195–202.	Population already in an intervention programme (WIC)
Aoun S, Rosenbery M. Are rural people getting Heartsmart? *Australian Journal of Rural Health* 2004;12:81–8.	Does not meet inclusion criterion. No control group.
Armitage CJ. Evidence that implementation intentions reduce dietary fat intake: a randomized trial. *Health Psychology* 2004; 23(3):319–23.	Does not meet inclusion criterion. One month follow-up.
Baranowski T, Mendlein J, Resnicow K, Frank E, Cullen KW, Baranowski J. Physical activity and nutrition in children and youth: An overview of obesity prevention. *Preventive Medicine*	Narrative overview. Relevant papers obtained.

2000;31(2):S1–10.	
Baranowski T, Baranowski JC, Cullen KW, De Moor C, Rittenberry LHD. 5-a-day achievement badge for African-American boy scouts: Pilot outcome results. *Preventive Medicine* 2002;34:353–63.	Two-month follow-up
Baranowski T, Baranowski JC, Cullen KW, Thompson DI, Nicklas TA, Zakeri IE, et al. The Fun,Food and Fitness Project (FFFP): The Baylor GEMS pilot study. *Ethnicity and Disease* 2003;13:S30–9.	All African American children. Relevant to Black and Ethnic Minority review.
Baranowski T, Simons-Morton B, Hooks P, Henske J, Tiernan K, Dunn JK, et al. A center-based program for exercise change among Black-American families. *Health Education Quarterly* 1990;17:179–96.	Family and Black and Minority Ethnic Group (BMEG) intervention. Relevant to other review.
Barnard ND, Scialli AR, Turner-McGrievy G, Lanou AJ. Acceptability of a low-fat vegan diet compares favorably to a step II diet in a randomized, controlled trial. *Journal of Cardiopulmonary Rehabilitation* 2004;24(4):229–35.	Overweight and obese subjects only.
Baron M. Fighting obesity: part 1: review of popular low-carb diets. *Health Care Food and Nutrition Focus* 2004;21(10):1–6.	Non-systematic literature review.
Batch JA, Baur LA. Management and prevention of obesity and its complications in children and adolescents. *Medical Journal of Australia* 2005;182:130–5.	Non-systematic literature review.
Bautista-Castano I, Doreste J, Serra-Majem L. Effectiveness of interventions in the prevention of childhood obesity. *European Journal of Epidemiology* 2004;19:617–22.	Largely relevant to Schools and informed Teeside. Unpicked for community studies.
Baxter T, Milner P, Wilson K, Leaf M, Nicholl J, Freeman J, et al. A cost effective, community based heart health promotion project in England: prospective comparative study. *British Medical Journal 1997*;315:582–5.	More relevant to Community 2 review.
Beech BM, Klesges RC, Kumanyika SK, Murray DM, Klesges L, McClanahan B, et al. Child- and parent-targeted interventions: The Memphis GEMS pilot study. *Ethnicity and Disease* 2003;13(Suppl 1):S78–87.	BMEG and family intervention. Relevant to other reviews.
Bessell TL, McDonald S, Silagy CA, Anderson JN, Hiller JE, Sansom LN. Do internet interventions for consumers cause more harm than good? A systematic review. *Health Expectations* 2002;5(1):28–37.	Wide range of studies – only one with weight outcome. Relevant study obtained.
Biem HJ, Turnell RW, D'Arcy C. Computer telephony: automated calls for medical care. *Clinical and Investigative Medicine-Medecine Clinique et Experimentale* 2003;26(5):259–68.	Review with only four potentially relevant papers – all checked and none met inclusion criteria.
Blair SN, Collingwood TR, Reynolds R, Smith M, Hagan RD, Sterling CL. Health promotion for educators: impact on health behaviors, satisfaction, and general well-being. *American Journal of Public Health* 1984;74:147–9.	School-based intervention.
Blair SN, Applegate WB, Dunn AL, Ettinger WH. Activity	Superseded by systematic review

Counseling Trial (ACT): rationale, design and methods. Medicine and Science in Sports and Exercise 1998;30(7):1097–106.	evidence.
Blue CL, Black DR. Synthesis of intervention research to modify PA and dietary behaviours. *Research and Theory for Nursing Practice: An International Journal* 2005;19(1):25–61.	Unpicked – all studies BMEG or overweight subjects.
Borhani NO. Significance of physical activity for prevention and control of hypertension. *Journal of Human Hypertension* 1996;10(Suppl 2):S7–11.	All subjects required to have 'high normal' diastolic blood pressure.
Bowden JM, Shaul MP, Bennett JA. The process of changing health risk behaviors: an Oregon rural clinic experience. *Journal of the American Academy of Nurse Practitioners* 2004;16(9):411–7.	Before and after study. Better evidence available.
Bowen DJ, Beresford SA. Dietary interventions to prevent disease. *Annual Review of Public Health* 2002;23:255–86.	Non-systematic review. Relevant papers obtained.
Bracht N, Finnegan JR, Rissel C, Weisbrod R, Gleason J, Corbett J, et al. Community ownership and program continuation following a health demonstration project. *Health Education Research* 1994;9:243–55.	Statewide intervention and not suitable for local implementation: Minnesota Heart Health Programme.
Braddy BA, Orenstein D, Brownstein JN, Cook TJ. PATCH: An example of community empowerment for health. *Journal of Health Education* 1992;23:179–182.	Evaluation of PATCH Programme.
Browne D. Exercise by Prescription. *Journal of the Royal Society of Health* 1997;117(1):52–55.	Conference paper - general discussion of exercise prescription.
Brownson RC, Smith CA, Pratt M, Mack NE. Preventing cardiovascular disease through community-based risk reduction: the Bootheel Heart Health Project. *American Journal of Public Health* 1996;86(2):206–13.	Country-wide intervention and not suitable for local implementation.
Brug J, Campbell M, van Assema P. The application and impact of computer-generated personalized nutrition education: a review of the literature. *Patient Education and Counseling* 1999;36:145–56.	Overview. Relevant papers obtained.
Brunton G, Harden A, Rees R, Kavanagh J, Oliver S, Oakley A. *Children and physical activity: A systematic review of barriers and facilitators*. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London; 2003.	Only three non-school linked studies – check for broader community.
Burke V. Health promotion in couples adapting to a shared lifestyle. Health Education Research 1999;14(2):269–88.	Pilot for Burke (2003).
Burke V. Physical activity and nutrition programs for couples: a randomized controlled trial. *Journal of Clinical Epidemiology* 2003;56(5):421–32.	Same study as Dzator (2004)..
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S. Changes in cognitive measures in a randomized controlled trial of a health promotion program for couples targeting diet and physical activity. *American Journal of Health Promotion*	Same study as Dzator (2004)..

2004;18(4):300–11.	
Butterfoss FD, Goodman RM, Wandersman A. Community coalitions for prevention and health promotion. *Health Education Research* 1993;8:315–30.	Discussion paper on Community Coalitions.
Buttriss J. Doctors and the provision of advice on nutrition. *Nutrition and Food Science* 1996; July/August: 9–13.	Very low quality study. Better evidence available.
Buttriss J, Stanner S, McKevith B, Nugent A, Kelly C, Phillips F, et al. *A critical review of the psychosocial basis of food choice and identification of tools to effect positive food choice: a summary*. Report No. 9017. UK: British Nutrition Foundation, 2004.	Non systematic review-relevant papers obtained. Check community 2 and workplace database.
Caballero B. Obesity prevention in children: opportunities and challenges. *International Journal of Obesity* 2004;28:S90–5.	Non-systematic literature review.
Cadman L, Wiles R. Nutrition advice in primary care: Evaluation of practice nurse nutrition training programmes. *Journal of Human Nutrition and Dietetics* 1996;9(2):147–56.	Training of nurses.
Calfas KJ, Long BJ, Sallis JF, Wooten WJ. A controlled trial of physician counseling to promote the adoption of physical activity. *Preventive Medicine* 1996;25(3):225–33.	4–6 week follow-up.
Calfas KJ, Sallis JF, Oldenburg B, French M. Mediators of change in PA following an intervention in primary care: PACE. *Preventive Medicine* 1997;26(3):297–304.	6 week follow-up.
Cameron R. Toward the development of self-help health behaviour change programs: weight loss by correspondence. Canadian *Journal of Public Health* 1990;81(4):275–9.	Overweight and obese subjects only.
Campbell K. Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews* 2004; 4.	One community-based study only.
Campbell MJ, Browne D, Waters WE. Can general practitioners influence exercise habits? Controlled trial. *British Medical Journal* 1985;290:1044–6.	Superseded by systematic review.
Campbell MK, Devellis BM, Strecher VJ, Ammerman AS, DeVellis RF, Sandler RS. Improving dietary behavior: The effectiveness of tailored messages in primary care settings. *American Journal of Public Health* 1994;84(5):783–7.	Superseded by systematic review evidence.
Carroll R, Ali N, Azam N. Promoting physical activity in South Asian Muslim women through 'exercise on prescription'. *Health Technology Assessment* 2002; 6(8): 1-108.	BMEG subjects only. Relevant to other review.
Caserta MS GP. Older women's feelings about exercise and their adherence to an aerobic regimen over time. *Gerontologist* 1998;38(5):602–609.	Overweight and obese women only.
Centres for Disease Control and Primary Prevention Working Group. Primary prevention of type 2 diabetes mellitus by lifestyle intervention: implications for health policy. *Annals of Internal*	Non-systematic literature review.

Medicine 2004;140:951–7.	
Chen AH, Sallis JF, Castro cm , et al. A home-based behavioural intervention to promote walking in sedentary ethnic minority women: Project WALK. *Journal of Women's Health: Research on Gender, Behavior, and Policy* 1998;4:19–39.	BMEG – relevant to other review.
Ciliska D, Miles E, O'Brien M, Turl C, Tomasik HH, Donovan U, et al. *Effectiveness of community interventions to increase fruit and vegetable consumption in people four years of age and older*. Canada: Effective Public Health Practice Project; 1999.	Only two relevant papers – obtained.
Clifford PA, Tan, SY, Gorsuch,RL. Efficacy of a self-directed behavioral health change program: weight, body composition, cardiovascular fitness, blood pressure, health risk, and psychosocial mediating variables. *Journal of Behavioral Medicine* 1991;14(3):303–23.	CCT. Better evidence available.
Coakley J, White A. Making decisions – gender and sport participation among British adolescents. *Sociology of Sport Journal* 1992;9(1):20–35.	Relevant to broader community. Paper filed in Community 2.
Cochrane T, Davey R. Evaluation of exercise prescription for 25 general practices and a large leisure complex in Sheffield. Journal of Sports Science 1998;16(1):17–18.	Small preliminary findings paper - can't locate any further papers.
Coday M. Health Opportunities with Physical Exercise (HOPE): social contextual interventions to reduce sedentary behavior in urban settings. Health Education Research 2002;17(5):637–47.	Preliminary report. Church affiliated. Include in broader community.
Colchio K, Zybert P, Basch CE. Effects of after-school PA on fitness, fatness, and cognitive self-perceptions: a pilot study among urban, minority adolescent girls. *American Journal of Public Health* 2000;90(6):977–78.	Non-UK BMEG.
Coleman KJ GEC. An objective measure of reinforcement and its implications for exercise promotion in sedentary Hispanic and Anglo women. *Annals of Behavioral Medicine* 2000;22(3):229–36.	Validation evaluation of a measure for the assessment of exercise + sedentary activity choices.
Conn VS, Minor MA, Burks KJ, Rantz MJ, Pomeroy SH. Integrative review of PA intervention research with aging adults. *Journal of the American Geriatric Society* 2003;51:1159–68.	Superseded by more recent systematic review.
Coups EJ, Gaba A, Orleans T. Physician screening for multiple behavioural health risk factors. *American Journal of Preventive Medicine* 2004;27(2S):34–41.	Discussion of risk factors only.
Cox DN, Anderson AS, Reynolds J, McKellar S, Lean ME, Mela DJ. Take Five, a nutrition education intervention to increase fruit and vegetable intakes: impact on consumer choice and nutrient intakes. *British Journal of Nutrition* 1998;80:123–131.	Superseded by systematic review evidence.
Crawford D. Can anyone successfully control their weight? Findings of a three year community-based study of men and women. *International Journal of Obesity and Related Metabolic Disorders* 2000;24(9):1107–10.	Same trial as Jeffery (1999).
Crockett SJ, Heller KE, Skauge LH, Merkel JM. Mailed-home	Superseded by systematic review

nutrition education for rural seniors: a pilot study. *Journal of Nutrition Education* 1992;24(312):315.	evidence.
Crookes P, Davies S, McDonnell A, Shewan J. Practice nurses and the prevention of cardiovascular disease and stroke: a literature review to promote evidence-based practice. Part II: hypertension, raised blood cholesterol, lack of exercise and obesity. *Clinical Effectiveness in Nursing* 1997;1(4):198–205.	Review of link between PA and obesity and cardiovascular disease – no relevant outcomes.
Crouch D. How nurse intervention is tackling child obesity. *Nursing Times* 2004;100(31):26.	Review of school-based study.
Cullen KW, Bartholomew LK, Parcel GS. Girl scouting: An effective channel for nutrition education. *Journal of Nutrition Education* 1997;29(2):86–91.	Relevant to broader community review. Paper filed in community 2.
Cummins S, Macintyre S. A systematic study of an urban foodscape: The price and availability of food in Greater Glasgow. Urban Studies 2002;39(11):2115–30.	Survey of food availability – relevant to broader community.
Cutler JA. Randomized clinical trials of weight reduction in nonhypertensive persons. *Annals of Epidemiology* 1991;1(4):363–70.	High diastolic blood pressure required in subjects.
Dallow C.B., Anderson J. Using self-efficacy and a transtheoretical model to develop a PA intervention for obese women. *American Journal of Health Promotion* 2003;17(6):373–81.	Obese subjects only.
De Bourdeaudhuij L, Brug J. Tailoring dietary feedback to reduce fat intake: An intervention at the family level. *Health Education Research* 2000;15:449–62.	6-weeks follow-up only.
De Bourdeaudhuij L, Brug J, Vandelanotte C, Van Oost P. Differences in impact between a family-versus an individual-based tailored intervention to reduce fat intake. *Health Education Research* 2002;17:435–49.	10-weeks follow-up only.
Deal LW. The effectiveness of community-health nursing interventions – a literature-review. *Public Health Nursing* 1994;11(5):315–23.	Discussion Paper (including City and Level Health promotion).
DeHaven MJ, Hunter IB, Wilder L, Walton JW, Berry J. Health programs in faith-based organizations: Are they effective? *American Journal of Public Health* 2004;94(6):1030–6. [32]	Church intervention – include in broader review. Paper filed in community 2.
De Pinto C. Childhood obesity. A review of causes, prevention and the role of the primary care provider. *Maryland Medicine* 2004; Summer: 9–14.	Non-systematic literature review.
Del Prete L., English C, Caldwell M, Banspach SW, Lefebvre C. Three-year follow-up of Pawtucket Heart Health's community-based weight loss programs. *American Journal of Health Promotion* 1993;7(3):182–7.	Cross sectional survey. Better evidence available.
DiPietro L. Physical activity in the prevention of obesity: current evidence and research issues. *Medicine and Science in Sports and Exercise* 1999;31(Suppl 1):S542–6..	Non–systematic review. Relevant papers obtained.

Dittmar H, Blayney M. Women's self-reported eating behaviours and their responses to food and non-food television advertisements. *European Eating Disorders Review* 1996;4(4):217–31.	Eating disorders (anorexia and bulimia).
Dobbins M, Beyers J. *The effectiveness of community-based heart health projects: A systematic overview update*. Canada: Effective Public Health Practice Project; 1999.	Superseded by more recent systematic review.
Donnelly JE, Hill JO, Jacobsen DJ, Potteiger J, Sullivan DK, Johnson SL, et al. Effects of a 16-month randomized controlled exercise trial on body weight and composition in young, overweight men and women: the Midwest Exercise Trial. *Archives of Internal Medicine* 2003 June 9;163(11):1343–50..	All subjects overweight and obese.
Donnelly JE, Smith B, Jacobsen DJ et al. The role of exercise for weight loss and maintenance. *Best Practice and Research Clinical Gastroenterology* 2004;18(6):1009–29.	Non-systematic literature review.
Douketis JD, Feightner JW, Attia J, Feldman WF. Periodic health examination, 1999 update: 1. Detection, prevention and treatment of obesity. *Canadian Medical Association Journal* 1999;160(4):513–25.	Review of studies of mostly obese patients: Relevant papers obtained.
Dunn AL, Andersen RE, Jakicic JM. Lifestyle PA interventions: History, short- and long-term effects, and recommendations. *American Journal of Preventive Medicine* 1998;15(4):398–412.	Possible systematic review of interventions in a variety of settings. Relevant papers obtained and check for broader community.
Dunn AL, Garcia ME, Marcus BH, Kampert JB, Kohl HW, Blair SN. Six-month physical activity and fitness changes in Project *Active*, a randomized trial. *Medicine and Science in Sports and Exercise* 1998;30(7):1076–83.	Final results paper (Dunn [350]) already included.
Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HW, Blair SN. Reduction in cardiovascular disease risk factors: 6-month results from Project *Active. Preventive Medicine* 1997;26:883–92.	Final results paper (Dunn [350]) already included.
Dunt D, Day N, Pirkis J. Evaluation of a community-based health promotion program supporting public policy initiatives for a healthy diet. *Health Promotion International* 1999;14(4):317–27.	Community/city-level intervention and not suitable for local implementation.
Eaton CB, Menard LM. A systematic review of physical activity promotion in primary care office settings. *British Journal of Sports Medicine* 1998;32:11–6.	Superseded by more recent systematic reviews
Ebrahim S, Smith GD. Systematic review of randomised controlled trials of multiple risk factor interventions for preventing coronary heart disease. *British Medical Journal* 1997;314(7095):1666–1674.	Patient at risk and health professional intervention = clinical group.
Edmunds LD. Parents' perceptions of health professionals' responsese when seeking help for their overweight children. *Family Practice* 2005;22:287–92.	Discusses overweight and obesity only.
Edmunds L, Bowler I. Partners in action. *Health Service Journal* 1995;February 9:27.	Review of Biddle (1994).

Eng E, Young R. Lay health advisors as community change agents. *Family and Community Health* 1992;15:24–40..	Discussion paper and planning model.
Engberg, M. General health screenings to improve cardiovascular risk profiles: a randomized controlled trial in general practice with 5-year follow-up. *Journal of Family Practice* 2002;51(6):546–52.	Impact of health screening.
Epstein LH. Integrating theoretical approaches to promote physical activity. *American Journal of Preventive Medicine* 1998;15(4):257–65.	Discussion of integration of theoretical approaches to promote PA.
Epstein LH, Gordy CC, Raynor HA, Beddome M, Kilanowski CK, Paluch R. Increasing fruit and vegetable intake and decreasing fat and sugar intake in families at risk of childhood obesity. *Obesity Research* 2001;9(3):171–8.	Family intervention. Relevant to other review.
Eriksson KF LF. No excess 12-year mortality in men with impaired glucose tolerance who participated in the Malmo Preventive Trial with diet and exercise. *Diabetologia* 1998;41(9):1010–16.	Men with impaired glucose intolerance.
Eriksson J. Prevention of Type II diabetes in subjects with impaired glucose tolerance: the Diabetes Prevention Study (DPS) in Finland. Study design and 1-year interim report on the feasibility of the lifestyle intervention programme. *Diabetologia* 1999;42(7):793–801.	Only subjects with impaired glucose tolerance.
Evans AT, Rogers LQ, Peden JGJ, Seelig CB, Layne RD, et al. Teaching dietary counseling skills to residents: patient and physician outcomes. The CADRE study group. *American Journal of Preventive Medicine* 1996;12:259–65.	High risk sample only.
Fagard RH. Physical activity in the prevention and treatment of hypertension in the obese. *Medicine and Science in Sports and Exercise* 1999;31(11)(Suppl 1):S624–S630.	Hypertension outcomes.
Fitzgibbon ML, Stolley MR, Kirschenbaum DS. An obesity prevention pilot program for African-American mothers and daughters. *Journal of Nutrition Education* 1995;27:93–99. [	BMEG subjects only – relevant to other review.
Fletcher A, Rake C, Health Education Authority. *Effectiveness of interventions to promote health eating in elderly people living in the community: a review*. London: HEA; 1998.	Not all studies included in analysis are relevant – potentially relevant papers checked.
Ford BS, McDonald TE, Owens AS, Robinson TN. Primary care interventions to reduce television viewing in African-American children. *American Journal of Preventive Medicine* 2002;22(2):106–109.	Four-week follow-up. BMEG subjects only.
Foreyt JP, Goodrick K. Evidence for success of behavior modification in weight loss and control. *Annals of Internal Medicine* 1993;119**(7 part 2)**: 698–701.	Brief overview of evidence for success of behaviour modification in weight loss and control. No relevant included papers.
Foreyt JP, Poston WS. What is the role of cognitive-behavior therapy in patient management? *Obesity Research* 1998;6(Suppl 1):S18–22.	Non-systematic overview. Relevant references obtained. Intervention – clinical treatment (CBT).

Foreyt JP. Attributes of successful approaches to weight loss and control*. Applied and Preventive Psychology* 1995;3(4):209–15..	Discussion paper/summary of evidence.
Forster JL, Jeffery RW, Schmid TL, Kramer FM. Preventing weight gain in adults: A pound of prevention. *Health Psychology* 1988;7:515–25.	Pilot study for Jeffery (1999).
Fortmann SP, Winkleby MA, Flora JA, Haskell WL, Taylor CB. Effect of long-term community health education on blood pressure and hypertension control: The Stanford Five-City Project. *American Journal of Epidemiology* 1990;132(4):629–66.	City-Wide Intervention and not suitable for local implementation. Stanford 5-city project.
Fowler-Brown A, Kahwati LC. Prevention and treatment of overweight in children and adolescents. *American Family Physician* 2004;69:25918.	Relevant to school/pre school reviews.
Frable PJ, Dart L, Bradley P. The healthy weigh/El Camino Saludable: A community campus partnership to prevent obesity*. Journal of Interprofessional* Care 2002; 18(4): 447-49	Does not meet inclusion criterion. No control group.
French SA HL. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. *International Journal of Obesity and Related Metabolic Disorders*. 2000; 24(10):1353–9.	Fast food restaurant use: broader community.
Gahagan S. Child and adolescent obesity. *Current Problems in Pediatric Adolescent Health Care* 2004;34:6–43.	Non systematic literature review
Garcia AW, Sahay A, Grimes C, Henry J, Newkirk N, Kuntzleman C. Physical fitness status of over 2800 preadolescents from a diverse high-risk population. *Journal of Applied Sports Psychology* 1997;9:S94.	Abstract only – unable to trace associated paper.
Gerber JC, Stewart DL. Prevention and control of hypertension and diabetes in an underserved population through community outreach and disease management: a plan of action. *Journal of the Association for Academic Minority Physicians* 1998;9(3):48–52.	Description of community outreach programme. No relevant outcomes.
Ghalamkari H, Rees J, Saltrese-Taylor A. Evaluation of a pilot health promotion project in pharmacies: (3) Clients' further opinions and actions taken after receiving health promotion advice. *Pharmaceutical Journal* 1997;258:909–12.	No interpretable relevant data available.
Gibbins RL, Riley M, Brimble P. Effectiveness of programme for reducing cardiovascular risk for men in one general practice. *British Medical Journal* 1993;306:1652–6.	Before and after study. Better evidence available.
Gibson EL, Wardle J, Watts CJ. Fruit and vegetable consumption, nutritional knowledge and beliefs in mothers and children. *Appetite* 1998;31(2):205–28.	Mother and child corroboration. Relevant to other review.
Glanville J, Glenny AM, Melville A, O'Meara S. The prevention and treatment of obesity. *Effective Health Care* 1997;3(2):1–12.	Only three relevant papers, mainly treatment focussed. Obtain papers (Check for broader community).
Glenny AM, O'Meara S, Melville A, Sheldon TA, Wilson C. The treatment and prevention of obesity: a systematic review of the	Review of studies with overweight and obese subjects – includes

literature. *International Journal of Obesity and Related Metabolic Disorders* 1997;21(9):715–37.	clinical interventions.
Goldberg JH, Kiernan M. Innovative techniques to address retention in a behavioural weight-loss trial. *Health Education Research* 2005;20(4):439–47.	Discussion of retention in trial of overweight/obese participants
Goldstein MG, Whitlock EP, DePue J. Multiple behavioural risk factor interventions in primary care. Summary of research evidence. *American Journal of Preventive Medicine* 2004;27(2S):61–79.	Non-systematic literature review.
Goodman RM, Wheeler FC, Lee PR. Evaluation of the Heart to Heart Project: lessons from a community-based chronic disease prevention project. *American Journal of Health Promotion* 1995;9(6):443–55.	Evaluation of a ‘a city-wide‘ and not suitable for local implementation, chronic disease prevention project Florence, South Carolina.
Gorbach SL, Morrill-LaBorde A, Woods MN *et al.* Changes in food patterns during a low-fat dietary intervention in women. *Journal of the American Dietary Association* 1990;90:802–9.	All subjects at elevated risk for breast cancer.
Gorin A, Phelan S, Tate D et al. Involving support partners in obesity treatment. *Journal of Consulting and Clinical Psychology* 2005;73(2):341–3.	Participants all overweight.
Gould M, Iliffe S, Thorogood M, University College London Medical School. Department of Primary Health Care, London School of Hygiene and Tropical Medicine. Department of Public Health Policy HPSU. *Promoting physical activity through primary health care: an evaluation of the Health Education Authority‘s guide*. London, UCLMS/LSHTM; 1994.	Not held at British Library. Unable to obtain.
Gorin A, Phelan S, Tate D, Sherwodd N, Jeffery R, Wing R. Involving support partners in obesity treatment. *Journal of Consulting and Clinical Psychology* 2005;73(2):341–3.	Participants all overweight.
Gould MM, Thorogood M, Iliffe S, Morris JN. Promoting PA in primary care: measuring the knowledge gap. *Health Education Journal* 1995;54:304–11.	Doctor and nurse knowledge and training needs regarding PA advice.
Grant S, Todd K, Aitchison TC, Kelly P, Stoddart D. The effects of a 12-week group exercise programme on physiological and psychological variables and function in overweight women. *Public Health* 2004;118:31–42.	Participants all overweight.
Gray DP. Dietary advice in British general practice. *European Journal of Clinical Nutrition* 1999;53(Suppl 2):S3–8.	Discussion/overview. Relevant papers obtained.
Groth-Marnat G, Schumaker J. Psychologists in disease prevention and health promotion – A review of the cost-effectiveness literature. *Psychology* 1995;32(1):1–10.	Discussion paper. Relevant papers obtained.
Haase A, Steptoe A, Phil D, Sallis JF, Wardle J. Leisure-time physical activity in university students from 23 countries: associations with health beliefs, risk awareness, and national economic development. *Preventive Medicine* 2004;39:182–90.	UK corroborative information is minimal.
Hackman RRM, Wagner EL. The senior gardening and nutrition	Superseded by systematic review

project: development and transport of a dietary behavior change and health promotion program. *Journal of Nutrition Education* 1990;22:262–70.	evidence.
Hakala P. Weight reduction programmes at a rehabilitation centre and a health centre based on group counselling and individual support: short- and long-term follow-up study. *International Journal of Obesity and Related Metabolic Disorders* 1994 Jul;18(7):483–9.	All obese subjects.
Halbert JA, Silagy CA, Finucane P, Withers RT, Hamdorf PA. Recruitment of older adults for a randomized, controlled trial of exercise advice in a general practice setting. *Journal of the American Geriatric Society* 1999;47(4):477–81.	Further data from Halbert (2000).
Hankey CR, Eley S, Leslie WS, Hunter CM, Lean MEJ. Eating habits, beliefs, attitudes and knowledge among health professionals regarding the links between obesity, nutrition and health. *Public Health Nutrition* 2004;7(2):337–43.	Survey of knowledge beliefs and attitudes / eating habits of health profs (for treatment of overweight people).
Hardeman W, Griffin S, Johnston M, Kinmonth AL, Wareham NJ. Interventions to prevent weight gain: a systematic review of psychological models and behaviour change methods. *International Journal of Obesity* 2000;24:131–43.	Only four of ninr studies relevant. Relevant papers obtained.
Hariri S. *Multimedia health promotion in community pharmacy*. Department of Pharmacy, King‘s College London; 1998.	Outcomes not relevant to review.
Harland J, White M, Drinkwater C, et al. The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *British Medical Journal* 1999;319:828–32.	Duplicate of Harland (1999).
Harris HE, Ellison GTH, Clement S. Do the psychosocial and behavioral changes that accompany motherhood influence the impact of pregnancy on long-term weight gain? *Journal of Psychosomatic Obstetrics and Gynecology* 1999;20:65–79.	Causation not intervention. Influences of the impending pregnancy on long-term weight gain.
Harrison RA, Roberts C, Elton PJ. Does primary care referral to an exercise programme increase physical activity one year later? A randomized controlled trial. *Journal of Public Health (Oxford)* 2005 Mar;27(1):25–32.	All subjects either obese, high coronary heart disease risk, previous myocardial infarction or diabetic.
Hartman TJ, McCarthy PR, Park RJ, Schuster E, Kushi LH. Results of a community-based low-literacy nutrition education program. *Journal of Community Health* 1997;22:325–41.	City-wide intervention and not suitable for local implementation. Sample already in an intervention programme.
Harvey-Berino J, Pintauro S, Buzzell P, Di Guilio M, Gold BC, Moldovan C, et al. Does using the Internet facilitate the maintenance of weight loss? *International Journal of Obesity and Related Metabolic Disorders* 2002;26(9):1254–60.	All subjects overweight and obese.
Harvey-Berino J. The feasibility of using Internet support for the maintenance of weight loss. *Behavior Modification* 2002 Jan;26(1):103–16.	All subjects overweight and obese.
Hassell K, Rogers A, Noyce P, Nicolaas G. *The public’s use of community pharmacies as a primary health care resource*.	Study looking at pharmacies’ management of minor ailments

Community Pharmacy Research Consortium; 1998.	and illnesses. No relevant data.
Hays NP, Starling RD, Liu X et al. Effects of an ad libitum low-fat high-carbohydrate diet on body weight, body composition and fat distribution in older men and women. *Archives of Internal Medicine* 2004;164:210–17.	Participants all overweight.
Health Education Authority. *Effectiveness of physical activity promotion schemes in primary care*. Report No. 14. London: HEA; 1998.	Full report obtained.
Health Promotion Authority Wales. *Pharmacy health care scheme survey (Wales).* Wales: Health Promotion Authority Wales; 1991.	Not available from British Library. Unable to locate.
Health Select Committee. *Inquiry into obesity*. Written evidence submitted by the Pharmaceutical Services Negotiating Committee (PSNC). Aylesbury Buckinghamshire: PSNC, April 2003.	Discussion of obesity treatment.
Hedberg **GE, Wikstrom-Frisen L, Janlert U.** Comparison between two programmes for reducing the levels of risk indicators of heart diseases among male professional drivers. *Occupational and Environmental Medicine* 1998;55(8):554–61.	Workplace relevant – to check in workplace database.
Heller RF, Walker RJ, Boyle CA, O'Connell DL, Rusakaniko S, et al. A randomised controlled trial of a dietary advice program for relatives of heart attack victims. *Medical Journal of Australia* 1994;161:529–31.	Superseded by systematic review evidence
Henriksen N, Sogaard AJ, Fylkesnes K. The Finnmark Intervention Study: design, methods and effects of a 2 year community-based intervention. *European Journal of Public Health* 1995;5:269–76.	City-wide intervention and not suitable for local implementation.
Henritze J, Brammell HL, McCloin J. LIFECHECK: a successful, low touch, low tech, in-plant, cardiovascular disease risk identification and modification programme. *American Journal of Health Promotion* 1992;7:129–36.	Relevant to workplace but exclude since no control group.
Henry LL, Royer L. Community-based strategies for pediatric nurses to combat the escalating childhood obesity epidemic. *Pediatric Nursing* 2004;30(2):162–4.	Overview of potential strategies.
Hensrud DD. Tackling obesity in a 15-minute office visit. *Postgraduate Medicine* 2004;115(1):59–61.	General discussion re obese patient.
Heshka S, Greenway F, Anderson JW, Atkinson RL, Hill JO, Phinney SD, et al. Self-help weight loss versus a structured commercial program after 26 weeks: A randomized controlled study. *American Journal of Medicine* 2000;109(4):282–7.	Subjects all overweight and obese in clinical setting.
Hesketh A, Lindsay G, Harden R. Interactive health promotion in the community pharmacy. *Health Education Journal* 1995;54:294–303.	Subjects had upper gastrointestinal disease.
Hills D, Health Development Agency. *Evaluation of community-level interventions for health improvement: a review of experience in the UK*. London: Health Development Agency; 2004.	Review looking at experience of evaluating community interventions in the UK.
Hillsdon M, Thorogood M, Antiss T, Morris J. Randomised	Superseded by more recent

controlled trials of physical activity promotion in free living populations: a review. *Journal of Epidemiology and Community Health* 1995;49:448–53.	systematic review.
Hillsdon M. Promoting physical activity: issues in primary health care. *International Journal of Obesity and Related Metabolic Disorders* 1998;22(Suppl 2):S52–4.	Non-systematic review. Relevant papers obtained.
Hillsdon M, Foster C, Naidoo B, Crombie H. *The evidence on the effectiveness of public health interventions for increasing physical activity among adults: A review of reviews*. London: Health Development Agency; 2004.	Review of reviews. Relevant papers obtained.
Hinkle AJ. Community-based nutrition interventions: reaching adolescents from low-income communities. *Annals of the New York Academy of Sciences* 1997;817:83–93.	Theoretical rationale/overview of the California Adolescent Nutrition and Fitness (CANFit) Program – non-profit, grant-funding organisation.
Hjalmarson A, Rossner S, Ostenson CG. Supervised physical activity in Sweden: in theory and practice. *Patient Education and Counseling* 2000;39(2.3):281–4.	Descriptive evaluation of PA programmes in Sweden.
Hourihan F, Krass I, Chen T. Rural community pharmacy: A feasible site for a health promotion and screening service for cardiovascular risk factors. *Australian Journal of Rural Health* 2003;11:28–35.	Screening. Advice and/or referral to GP.
Hu G, Lakka TA, Barengo NC, Tuomilehto J. PA, physical fitness and risk of type 2 diabetes. *Metabolic Syndorme and Related Disorders*. 2005; 3(1):35–44. [	Discussion of risk factors only.
Humphreys K, Ribisl KM. The case for a partnership with self-help groups. *Public Health Reports* 1999;114(4):322–25 and 328–329.	General discussion of self-help groups.
Iliffe S, Tai S, Gould M, et al. Prescribing exercise in general practice. *British Medical Journal* 1994;309:494–5.	Editorial.
Imperial Cancer Research Fund OXCHECK Study Group. Prevalence of risk factors for heart disease in OXCHECK trial: Implications for screening in primary care. *British Medical Journal* 1991;302(6784):1057–60.	Duplicate of Imperial Cancer Research Fund OXCHECK Study Group (1991).
Imperial Cancer Research Fund OXCHECK Study Group. Prevalence of risk factors for heart disease in OXCHECK trial: Implications for screening in primary care. *British Medical Journal* 1991;302(6784):1057–60.	Descriptive data analysis only no data point before/after.
Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: Results of the OXCHECK study after one year. *British Medical Journal* 1994;308(6924):308–12.	Duplicate of Muir (1994).
Irwin ML, Tworoger SS, Yasui Y et al. Influence of demographic, physiologic and psychosocial variables on adherence to a yearlong moderate-intensity exercise trial in postmenopausal women. *Preventive Medicine* 2004;39:1080–86.	All participants overweight.

Isacsson A, Lindholm LH, Schersten B, Eklund E, Bjorkman S, Jarhult B, et al. Community intervention against non-insulin dependent diabetes mellitus (NIDDM) and cardiovascular disease: A study based on Swedish health care. *Cardiovascular Risk Factors* 1996;6(3):164–71.	Cross-sectional survey (*n* = 3). Higher level evidence available.
Jakicic JM, Otto AD. Motivating change: modifying eat and exercise behaviors for weight management. *ACSM's Health and Fitness Journal* 2005;1(6):6–12.	Non-systematic literature review.
Jackson C, North Yorkshire Specialist Health Promotion Service, North Yorkshire Health Authority. *Exercise by prescription: evaluation report.* Harrogate: North Yorkshire Specialist Health Promotion Service; 1997.	Uncontrolled before and after study. Better studies (RCTs) available.
Jacobsen DJ, Donnelly JE, Snyder-Heelan, K, Livingston,K. Adherence and attrition with intermittent and continuous exercise in overweight women. *International Journal of Sports Medicine* 2003;24(6):459–64.	Overweight and obese subjects only.
Jago R, Baranowski T. Non-curricular approaches for increasing physical activity in youth: a review. *Preventive Medicine* 2004;39(1):157–163.	Safe routes to school – include in broader community review.
James J. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. *British Medical Journal* 2004;328(7450):1237–39.	School based. Relevant to other review.
Jason LA, Greiner BJ, Naylor K, Johnson SP, Van Egeren L. A large-scale, short-term, media-based weight loss program. *American Journal of Health Promotion* 1991;5(6):432–7.	Statewide, mass media intervention and not suitable for local implementation.
Jebb S, Sritharan N. A nurse's role in promoting weight loss and encouraging healthier lifestyles. *Professional Nurse* 2005;20(7):25–29.	Non-systematic review/discussion paper.
Jeffery RW, Wing RR, Sherwood NE, Tate DF. Physical activity and weight loss: does prescribing higher physical activity goals improve outcome? *American Journal of Clinical Nutrition* 2003;78(4):684–9.	Overweight and obese subjects only.
Jeffery RW, Gerber WM, Rosenthal BS, et al. Monetary contracts in weight control: effectiveness of group and individual contracts of varying size. *Journal of Consulting and Clinical Psychology* 1983;51:242–8.	All overweight and obese subjects.
Jeffery RW, Bjornson-Benson WM, Kurth CL, Johnson SL. Effectiveness of monetary contracts with two repayment schedules of weight reduction in men and women from self-referred and population samples. *Behavior Therapy* 1984;15:273–9.	All overweight and obese subjects.
Jeffery RW. Minnesota studies on community-based approaches to weight loss and control. *Annals of Internal Medicine* 1993;119(7 Pt 2):719–21.	Non-systematic overview of statewide interventions and not suitable for local implementation.
Jeffery RW. Community programs for obesity prevention: the Minnesota Heart Health Program. *Obesity Research*	Statewide intervention and not suitable for local implementation:

1995;3(Suppl 2):S283–8.	Minnesota Heart Health Program.
Jeffery RW, French SA. Preventing weight gain in adults: design, methods and one year results from the Pound of Prevention study. *International Journal of Obesity and Related Metabolic Disorders* 1997;21(6):457–64.	Earlier write-up of Jeffery (1999).
Jeffery RW, Gray CW, French SA, Hellerstedt WL, Murray D, Luepker RV, et al. Evaluation of weight reduction in a community intervention for cardiovascular disease risk: changes in body mass index in the Minnesota Heart Health Program. *International Journal of Obesity and Related Metabolic Disorders* 1995;19(1):30–9.	Statewide intervention and not suitable for local implementation: Minnesota Heart Health Program.
Jeffery RW, Wing RR, Thorson C, Burton LR. Use of personal trainers and financial incentives to increase exercise in a behavioural weight-loss program. *Journal of Consulting and Clinical Psychology* 1998;66:777–83.	Overweight and obese subjects only.
Jeffery RW. Public health strategies for obesity treatment and prevention. *American Journal of Health Behavior* 2001;25(3):252–9.	Non-systematic literature review.
John JH, Yudkin PL, Neil HAW, Ziebland S. Does stage of change predict outcome in a primary-care intervention to encourage an increase in fruit and vegetable consumption? *Health Education Research* 2003;18(4):429–38.	Stage of change sub-group analysis for John (2002).
Johnston LF, Warwick J, De Ste Croix M, Crone D, Sidford A. The nature of all 'inappropriate referrals' made to a countrywide physical activity referral scheme: Implications for practice. *Health Education Journal* 2005;64(1):58–69.	UK corroborative: look at medical reasons for referral and exercise schemes.
Jorgensen T, Borch-Johnsen K, Thomsen TF, Ibsen H, Glumer C, Pisinger C. A randomized non-pharmacological intervention study for prevention of ischaemic heart disease: baseline results Inter99*. European Journal of Cardiovascular Prevention and Rehabilitation* 2003;10(5):377–86.	All subjects at a high risk of HIV.
Kahn EB, Ramsey LT, Brownson RC, Heath GW, Howze EH, Powell KE, et al. The effectiveness of interventions to increase physical activity – A systematic review. *American Journal of Preventive Medicine* 2002;22(4):73–108.	Superseded by better quality systematic review.
Kanders BS, Ullman-Joy P, Foreyt JP, Heymsfield SB, Heber D, Elashoff RM, et al. The Black American Lifestyle Intervention (BALI): a weight loss program for working class African American women. *Journal of the American Dietetic Association* 1994;94:310–12.	BMEG subjects only. Relevant to other review.
Kane RL, Johnson PE, Town RJ, Butler M. A structured review of the effect of economic incentives on consumers' preventive behavior. *American Journal of Preventive Medicine* 2004;27(4):327–52.	Studies from various settings. Relevant studies obtained. Check workplace and broader community.
Karvetti RL HP. A seven-year follow-up of a weight reduction programme in Finnish primary health care. *European Journal of Clinical Nutrition* 1992;46(10):743–52.	Primary care – overweight subjects only.

Keene JM, Cervetto S, Willson A. Health promotion in the community pharmacy. *Pharmaceutical Journal* 1994;246:240–42.	Quantitative results from [324]
Keller J. Should doctors be more proactive in advising patients to exercise? *IDEA Fitness Journal* 2004; September: 16.	Editorial/discussion doc
Kelley K, Abraham C. RCT of a theory-based intervention promoting healthy eating and PA amongst out-patients older than 65 years. *Social Science and Medicine* 2004;59(4):787–97..	Two-week follow-up only.
Kelsey K, Earp JL, Kirkley BG. Is social support beneficial for dietary change? A review of the literature. *Family and Community Health* 1997;20(3):70–82.	Discussion paper on social support.
Kemmler WK, Lauber D, Engelke K, Weineck J. Effects of single- vs. multiple-set resistance training on maximum strength and body composition in trained postmenopausal women. *Journal of Strength and Conditioning Research* 2004;18(4):689–94.	Subjects were well trained women with osteopenia.
King AC, Rejeski WJ, Buchner DM. PA interventions targeting older adults. A critical review and recommendations. *American Journal of Preventive Medicine* 1998;15:316–333.	No hard data for PA outcomes available.
King AC, Sallis JF, Dunn AL, Simons-Morton DG. Overview of the Activity Counseling Trial (ACT) intervention for promoting PA in primary health care settings. *Medicine and Science in Sports and Exercise* 1998;30(7):1086–96.	Earlier write up of Marcus (1998).
King AC, Friedman R, Marcus B, Castro C, Forsyth L, Napolitano M, et al. Harnessing motivational forces in the promotion of physical activity: the Community Health Advice by Telephone (CHAT) project. *Health Education Research* 2002;17:627–36.	Protocol for RCT. Author emailed to confirm status of trial. Author confirmed trial results are currently under review with a journal.
Kirk-Gardner R, Steven D. Hearts for Life: a community program on heart health promotion. *Canadian Journal of Cardiovascular Nursing* 2003;13(1):5–10.	Before and after study. Better evidence available.
Kirk SF, Harvey EL, McConnon A, Pollard JE, Greenwood DC, Thomas JD, Ransley JK. A randomised trial of an Internet weight control resource: the UK Weight Control Trial. *BMC Health Services Research* 2003;3(1):19.	Pre-trial protocol.
Klem ML Viteri JE, Wing RR. Primary prevention of weight gain for women aged 25–34: the acceptability of treatment formats. *International Journal of Obesity and Related Metabolic Disorders:* 2000;24(2):219–25.	CCT. Better evidence available.
Kligman EW, Pepin E. Prescribing physical activity for older patients. Geriatrics 1992;47(8): 33-34, 37-44 and 47..	Expert opinion.
Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM, Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 2002;346(6):393–403.	Persons at risk of diabetes (elevated plasma glucose concentration) – comparison with drug therapy.
Kocken PL, Voorham AJJ. Interest in participation in a peer-led senior health education program. *Patient Education and*	Same study as Kocken (1998).

Counselling 1998;34:5–14.	
Kocken PL, Voorham AJJ. Effects of a peer-led senior health education program. *Patient Education and Counseling* 1998;34:15–23.	Peer-led health promotion programme – no relevant outcomes.
Koplan JP, Liverman CT, Kraak VI. Preventing childhood obesity: Health in the balance: Executive summary. *Journal of the American Dietetic Association* 2005;105(1):131–8..	Discussion paper.
Kremers SPJ, Visscher TLS, Brug J. Netherlands Research programme weight gain prevention (NHF-NRG): rationale, objectives and strategies. *European Journal of Nutrition* 2055;59(4):498–507.	Rationale only, study will report in 2007.
Kriska AM, Delahanty LM, Pettee KK. Lifestyle intervention for the prevention of type 2 diabetes: translation and future recommendations. *Current Diabetes Reports* 2004;4(2):113–8.	Sample has impaired glucose tolerance.
Kyle A. Are practice nurses an effective means of delivering dietary advice as part of health promotion in primary health care?: Evaluation of practice nurse training in Somerset. *Journal of Human Nutrition and Dietetics* 1993;6(2):149–62.	Nurse training and knowledge of dietary and nutrition issues.
Laaksonen DE, Lindstrom J, Lakka TA, et al. Physical activity in the prevention of type 2 diabetes. *Diabetes* 2005;54:158–65.	Study population with impaired glucose tolerance in the care of health professionals.
Lasater TM, Sennett LL, Lefebvre RC, DeHart KL, Peterson G, Carleton RA. Community-based approach to weight loss: the Pawtucket ‘weigh-in’. *Addictive Behaviors* 1991;16(3/4):175–81.	Major government initiative and citywide intervention and not suitable for local implementation.
Lassner JB. Does social support aid in weight loss and smoking interventions? Reply from a family systems perspective. *Annals of Behavioral Medicine* 1991;13(2):66–72.	Social support family and Spouses only.
Lawlor D, Hanratty B. The effect of physical activity advice given in routine primary care consultations: a systematic review. *Journal of Public Health Medicine* 2001;23(3):219–26.	Very low quality systematic review. Better evidence available.
Leigh JP, Richardson N, Beck R, Kerr C, Harrington H, Parcell CL, et al. Randomized controlled study of a retiree health promotion program: the Bank of America Study. *Archives of Internal Medicine* 1992;152(6):1201–6.	Same study as Fries (1993).
Lewis VJ, Blair AJ, Booth DA. Outcome of group therapy for body-image emotionality and weight-control self-efficacy. *Behavioural Psychotherapy* 1992;20(2):155–65.	Before and after study. Better evidence available.
Lewis BS, Lynch WD. The effect of physician advice on exercise behavior*. Preventive Medicine* 1993;22(1):110–21.	<3 months follow-up.
Linenger JM, Shesson CV, Nice DS. Physical fitness gains following simple environmental change*. American Journal of Preventive Medicine* 1991;7:298–310..	Workplace (Navy sample) - check workplace database.
Lindstrom J, Peltonen M, Tuomilehto J. Lifestyle strategies for weight control: Experience from the Finnish Diabetes Prevention	Study already excluded, all subjects had impaired glucose

Study. *Proceedings of the Nutrition Society* 2005;64(1):81–8.	tolerance.
Little P, Slocock L, Griffin S, Pillinger J. Who is targeted for lifestyle advice? A cross-sectional survey in two general practices. *British Journal of General Practice* 1999;49(447):806–10.	Non-relevant outcomes for UK corroborative evidence.
Little P, Kelly J, Barnett J, Dorward M, Margetts B, Warm D. Randomised controlled factorial trial of dietary advice for patients with a single high blood pressure reading in primary care. *British Medical Journal* 2004;328(7447):1054–7.	Subjects with single high blood pressure reading.
Little P, Dorward M, Gralton S. A randomised controlled trial of three pragmatic approaches to initiate increased physical activity in sedentary patients with risk factors for cardiovascular disease. *British Journal of General Practice* 2004;54(500):189–96.	Less than 3-months follow-up.
Lobstein T, Baur L, Uauy R. Obesity in children and young people:a crisis in public health. *Obesity Reviews* 2004;5(Suppl 1):4–85.	Non systematic literature review.
Logsdon DN, Lazaro CM, Meier RV. The feasibility of behavioral risk reduction in primary medical care. *American Journal of Preventive Medicine* 1989;5:249–56.	CCT. Better evidence available.
Lord JC, Green F. Exercise on prescription: does it work? *Health Education Journal* 1995;54(4):453–64.	Primary care based – at risk and ‘overweight‘ subjects only.
Luepker RV, Murray DM, Jacobs DR, Mittelmark MB, Bracht N, Carlaw R, et al. Community education for cardiovascular-disease prevention – risk factor changes in the Minnesota Heart Health-Program. *American Journal of Public Health* 1994;84(9):1383–93.	State-wide intervention and not suitable for local implementation: Minnesota Heart Health Programme.
Lutz SF, Ammerman AS, Atwood JR, Campbell MK, DeVellis RF, et al. Innovative newsletter interventions improve fruit and vegetable consumption in healthy adults. *Journal of the American Dietetic Association* 1999;99:705–9.	Superseded by systematic review evidence.
Marcoux BC. Social networks and social support in weight loss. *Patient Education and Counseling* 1990;15(3):229–38.	‘Social support‘ of friends, neighbours and family.
Marcus AC, Heimendinger J, Wolfe P, Fairclough D, Rimer BK, Morra M, et al. A randomized trial of a brief intervention to increase fruit and vegetable intake: A replication study among callers to the CIS. *Preventive Medicine* 2001;33(3):204–16.	Superseded by systematic review evidence. Highly motivated sample.
Marcus BH, Owen N, Forsyth LH, Cavill NA, Fridinger F. Physical activity interventions using mass media, print media, and information technology. *American Journal of Preventive Medicine* 1998;15(4):362–78.	Very low quality systematic review. Relevant papers obtained and also possibly relevant for Broader community.
Marcus BH, Bock BC, Pinto BM, Forsyth LH, Roberts MB, Traficante RM. Efficacy of an individualized, motivationally-tailored physical activity intervention. *Annals of Behavioral Medicine* 1998;20(3):174–180.	CCT. Better evidence available.
Marteau TM, Kinmouth AL, Thompson S, Pyke S. The psychological impact of cardiovascular screening and intervention in primary care: a problem of false reassurance? *British Journal*	Psychological impact of screening.

of General Practice 1996;46:577–82.	
Maskarinec G, Chan CLY, Meng L, Franke AA, Conney RV. Exploring the feasibility and effects of a high-fruit and -vegetable diet in healthy women. *Cancer Epidemiology, Biomarkers and Prevention* 1999;8:919–24.	Superseded by systematic review evidence.
Mason V. *Young people and sport in England 1994: The views of teachers and children*. London: The Sports Council; 1995.	Schools based corroboration study – relevant to schools review.
Mayer JA, Jermanovich A, Wright BL, Elder JP, Drew JA, Williams SJ. Changes in health behaviors of older adults: the San Diego Medicare Preventive Health Project. *Preventive Medicine* 1994;23(2):127–33.	Same study as Elder (1995).
McCormick SE, Clarke CI. Prevention and management of overweight/obesity in the community. *Nutrition Bulletin* 2004;29(3):274–9.	Conference report. Check references for broader community review.
McLean N, Griffin S, Toney K, Hardeman W. Family involvement in weight control, weight maintenance and weight-loss interventions: A systematic review of randomised trials. *International Journal of Obesity* 2003;27(9):987–1005.	Review of studies with all overweight subjects in primary care public health settings.
McTiernan A, Ulrich CM, Yancey D, Slate S, Nakamura H, Oestreicher N, et al. The Physical Activity for Total Health (PATH) Study: rationale and design. *Medicine and Science in Sports and Exercise* 1999 Sept;31(9):1307–12..	Rationale and design for PATH Study.
Melnyk MG, Weinstein E. Preventing obesity in black women by targeting adolescents: a literature review. *Journal of the American Dietetic Association* 1994;94(5):536–40.	Literature review of BMEG subjects. Relevant to other review.
Mernitz H, McDermott AY. Exercise and the elderly: A scientific rationale for exercise prescription. *Journal of Clinical Outcomes Management* 2004;11(2):106–16.	Non-systematic review. No relevant outcomes.
Merzel C, D'Afflitti J. Reconsidering community-based health promotion: Promise, performance, and potential. *American Journal of Public Health* 2003;93(4):557–74.	Systematic review of statewide interventions and not suitable for local implementation.
Michie S, Johnston M, Cockcroft A, Ellinghouse C, Gooch C. Methods and impact of health screening for hospital staff. *Journal of Organizational Behavior* 1995;16(1):85–92.	Methods and impact of screening.
Miles A. Using the mass-media to target obesity: an analysis of the characteristics and reported behaviour changes of participants in the BBC's 'Fighting Fat, Fighting Fit' campaign. *Health Education Research* 2001;16(3):357–72.	Mass-media campaign and not suitable for local implementation.
Morss GM, Jordan AN, Skinner JS et al. Dose-response to exercise in women aged 45–75 yr (DREW): Design and rationale. *Medicine and Science in Sports and Exercise* 2004;***36(2)***:336–44.	Overweight and obese participants only. Trial design only.
Mullen PD, SimonsMorton DG, Ramirez G, Frankowski RF, Green LW, Mains DA. A meta-analysis of trials evaluating patient education and counseling for three groups of preventive health	Patients in clinical settings. Relevant to clinical group.

behaviors. *Patient Education and Counseling* 1997;32(3):157–73.	
Munro J. *A randomised controlled trial of exercise in over-65-years-olds: experience from the first year*. Hamburg: Health Promotion Publications; 1997:264–67.	Excluded at critical appraisal. No methodological information.
Murie J, Tuohy AP, Carroll D. Impact of a health promotion program on multiple risk-factors for CHD – A preliminary evaluation. *Scottish Medical Journal* 1994;39(1):12–6.	Before and after study. Better evidence available.
Nader PR. The role of the family in obesity prevention and treatment. *Annals of the New York Academy of Sciences* 1993;699:147–53.	Non-systematic overview. Relevant references obtained.
Nawaz H, Katz D. American College of Preventive Medicine practice policy statement: Weight management counseling of overweight adults. *American Journal of Preventive Medicine* 2001;21(1):73–8.	US Policy Document.
Naylor PJ, Simmonds G, Riddoch C, Velleman G, Turton P. Comparison of stage-matched and unmatched interventions to promote exercise behaviour in the primary care setting. *Health Education Research* 1999;14(5):653–66.	Superseded by systematic review evidence.
Neale AV. Behavioural contracting as a tool to help patients achieve better health. *Family Practice* 1991;8(4):336–42.	80% (*n* = 144/179) of total sample consisted of subjects classified as having ‘high cholesterol’.
Neumark-Sztainer D. Physical activity within a community-based weight control program: program evaluation and predictors of success. *Public Health Reviews* 1995;23(3):237–51.	Overweight and obese subjects only.
Newton RL, Perri MG. A randomized pilot trial of exercise promotion on sedentary African-American adults. *Ethnicity and Disease* 2004;14(4):548–57.	BMEG subjects only. Relevant to other review.
Nguyen HQ, Carrieri-Kohlman V, Rankin SH, Slaughter R, Stulbarg M. Internet-based patient education and support interventions: a review of evaluation studies and directions for future research. *Computers in Biology and Medicine* 2004;34:95–112.	Contains only one relevant study – Tate (2001). – already considered for workplace review.
Noble L. Dietitians and the practice nurse. *Practice Nursing* 1998;9(12):33–36.	Discussion paper only.
Norman GJ, Mills PJ. Keeping it simple: Encouraging walking as a means to active living. *Annals of Behavioral Medicine* 2004;28(3):149–151..	No study design. Discussion document.
Norris SL, Grothaus LC, Buchner DM, et al. Effectiveness of physician-based assessment and counseling for exercise in a staff model HMO. *Preventive Medicine* 2000;30:513–23.	Superseded by systematic review evidence.
Nowson CA, Worsley A, Margeison C, Jorna M, Godfrey SJ, Booth A. Blood pressure change with weight loss is affected by diet type in men. *American Journal of Clinical Nutrition* 2005;81:983–89.	All participants overweight or obese
O’Meara S, Glenny A, Sheldon T, Melville A, Wilson C.	Description of the methodology of

Systematic review of the effectiveness of interventions used in the management of obesity. Proceedings from the ASO and BDA symposium held on 25 November 1997 at St. Bartholomew's Hospital, London. *Journal of Human Nutrition and Dietetics*1998;11(3):203–6.	a systematic review, not review itself.
O'Toole ML, Sawicki MA, Artal,R. Structured diet and physical activity prevent postpartum weight retention. *Journal of Women's Health* 2003;12(10):991–8.	Post-partum women only.
Ohrig E, Geiss HC, Haas GM, Schwandt P. The Prevention Education Program (PEP) Nuremberg: design and baseline data of a family oriented intervention study. *International Journal of Obesity and Related Metabolic Disorders* 2001;25(Suppl 1):S89–92.	School and family intervention. Relevant to other review.
Parra-Medina D. Successful recruitment and retention strategies for a randomized weight management trial for people with diabetes living in rural, medically underserved counties of South Carolina: the POWER study. *Journal of the American Dietetic Association* 2004;104(1):70–5.	People with diabetes.
Pate RR, Trost SG, Mullis R, Sallis JF, Wechsler H, Brown DR. Community interventions to promote proper nutrition and physical activity among youth. *Preventive Medicine* 2000;31:S138–49.	Discussion paper/expert opinion. Relevant papers obtained.
Pate RR, Ward DS, Felton G, et al. Effects of a community-based intervention on physical activity and fitness in rural youth. *Medicine and Science in Sports and Exercise* 1997;29:S157. [	Relevant to schools review.
Patrick K, Sallis JF, Long B. A new tool for encouraging activity: project pace. *Physician and Sport Medicine* 1994;22(11):45-55.	Description of project PACE.
Pavlovich WD, Waters H, Weller E, Bass EB. Systematic review of literature on the cost-effectiveness of nutrition services. *Journal of the American Dietetic Society* 2004;104:226–32..	Three weight loss studies included but all with obese patients only.
Perry CL. Getting beyond technical rationality in developing health behaviour programs with youth. *American Journal of Health Behavior* 2004;28(6):558–68.	Non-systematic literature review.
Petrella RJ, Koval JJ, Cunningham DA, Paterson DH. Can primary care doctors prescribe exercise to improve fitness? The Step Test Exercise Prescription (STEP) project. *American Journal of Preventive Medicine* 2003;24(4):316–22.	No relevant outcomes (VO_{2max} and physical fitness).
Petrella RJ, Lattanzio CN. Does counselling help patients get active? Systematic review of the literature. *Canadian Family Physician* 2002;48:72–80.	Overlap with other systematic reviews already included.
Petrella RJ, Koval JJ. Prescription of exercise by physicians improves fitness in elderly people. *Evidence-Based Healthcare* 2003;4(7):172–3.	Commentary on other papers.
Pickett KE, Pearl M. Multilevel analyses of neighbourhood socioeconomic context and health outcomes: a critical review. *Journal of Epidemiology and Community Health* 2001;55(2):111–22.	No relevant outcomes.

Pinto B, Goldstein M, Marcus B. Activity counseling by primary care physicians. *Preventive Medicine* 1998;27(4):506–13.	Behaviour change models/discussion paper.
Pinto BM, Friedman R, Marcus BH, Kelley H, Tennstedt S, Gillman MW. Effects of a computer-based, telephone-counseling system on physical activity. *American Journal of Preventive Medicine* 2002;23(2):113–20.	All subjects overweight and obese.
Potter JD, Graves KL, Finnegan JR, Mullis RM, Baxter JS, Crockett S, et al. The cancer and diet intervention project: a community-based intervention to reduce nutrition-related risk of cancer. *Health Education Research* 1990;5(4):489–503.	Grocery Store Mass media – relevant to broader community.
Price S. Understanding the importance to health of a balanced diet. *Nursing Times* 2005;101(1):30–1.	No study design. Discussion paper.
Prochaska JO, Velicer WF, Redding C et al. Stage-based expert systems to guide a population of primary care patients to quit smoking, eat healthier, prevent skin cancer, and receive regular mammograms. *Preventive Medicine* 2005;41:406–416.	Does not meet inclusion criteria since assesses stage of change. Also complex intervention targeting smoking, sun exposure, mammography relapse as well as high fat diet.
Pronk NP, Boucher JL, Gehling E, Boyle RG, Jeffery RW. A platform for population-based weight management: Description of a health plan-based integrated systems approach. *American Journal of Managed Care* 2002;8(10):847–57.	Baseline data and methods description
Quinn MT. Training lay health educators to conduct a church-based weight-loss program for African American women. *Diabetes Education* 2001;27(2):231–8.	Relevant review evidence table excluded due to lack of evidence.
Rapoport L. Evaluation of a modified cognitive-behavioural programme for weight management. *International Journal of Obesity and Related Metabolic Disorders* 2000;24(12):1726–37.	Sample consisted of overweight subjects only. Weight loss not an outcome of focus. Intervention clinical treatment – cognitive-behavioural treatment (CBT).
Read A, Ramwell H, Storer H, Webber J. A primary care intervention programme for obesity and coronary heart disease risk factor reduction. *British Journal of General Practice* 2004;54(501):272–8.	Overweight subjects only – primary care run.
Rees R, Harden A, Shepherd J, Brunton G, Oliver S, Oakley A. *Young people and physical activity*. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London; 2001.	Systematic review of young people and PA. Relevant papers obtained.
Reger B, Wootan MG, Booth-Butterfield S, Smith H. 1% or less: a community-based nutrition campaign. *Public Health Reports* 1998;113(5):410–423.	More relevant to broader community.
Reilly JJ. Physical activity and obesity in childhood and adolescence. *Lancet* 2005;366:268–9..	Comment/editorial.
Resnick B, Magaziner J, Orwig D, Zimmerman S. Evaluating the components of the Exercise Plus Program: rationale, theory and implementation. *Health Education Research* 2002;17(5):648–58.	Hip fracture recovery.

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Wilson DK, Friend R, Teasley N, Green S, Reaves IL, Sica DA. Motivational versus social cognitive interventions for promoting fruit and vegetable intake and physical activity in African American adolescents. *Annals of Behavioral Medicine* 2002;24:310–9.	School-based. Relevant to other review.
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Wing RR, Jeffery RW, Pronk N, et al. Effects of a personal trainer and financial incentives on exercise adherence in overweight women in a behavioural weight loss program. *Obesity Research* 1996;4:457–62.	All overweight and obese subjects.
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Winkleby MA, Feldman HA, Murray DM. Joint analysis of three US community intervention trials for reduction of cardiovascular disease risk. *Journal of Clinical Epidemiology* 1997;50(6):645–58.	City-wide intervention and not suitable for local implementation.
Winnett RA, Tate DF, Anderson ES, Wojcik JR, Winett SG. Long-term weight gain prevention: A theoretically based internet approach. *Preventive Medicine* 2005;41:629–41.	Non-systematic literature review.

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Zabinski MF, Calfas KJ, Gehrman CA, Wilfley DE, Sallis JF. Effects of a physical activity intervention on body image in university seniors: Project GRAD. *Annals of Behavioral Medicine* 2001;23(4):247–52.	Body image outcome. Not relevant.
Zabinski MF, Celio AA, Wilfley DE, Barr TC. Prevention of eating disorders and obesity via the internet. *Cognitive Behaviour Therapy* 2003;32(3):137–50.	Literature review. Relevant papers obtained
Zwiauer KF. Prevention and treatment of overweight and obesity in children and adolescents. *European Journal of Pediatrics* 2000;159(Suppl 1):S56–68.	Narrative review.
The Pharmaceutical Services Negotiating Committee (PSNC). Health Select Committee Inquiry into Obesity. Aylesbury Buckinghamshire: PSNC*,* 2003	Discussion of obesity treatment.

Contents

Appendix 10

THE EFFECTIVENESS OF BROADER COMMUNITY-BASED INTERVENTIONS TO PREVENT OBESITY

EVIDENCE SUMMARY TABLES

EVIDENCE TABLE 1: SUPERMARKETS AND SHOPS

- **Point of choice (point-of-purchase) prompts**
- **Educational videos**
- **Group teaching sessions**
- **Mass media and supermarket**
- **Food 'deserts' – within corroborative section**

SUMMARY

Evidence of efficacy for weight management/reduction
No studies were found that reported weight outcomes.

Evidence of efficacy for diet/physical activity outcomes
Dietary outcomes

Point-of-purchase: Two good quality reviews with limited overlap (Roe 1997; Seymour 2004) concluded that informational point-of-purchase strategies in supermarkets can increase the purchase of targeted items. Both reviews looked at all types of research study. Seymour (2004) noted that the longer (2-year) multi-component studies showed the greater intervention effects but no data were provided. Roe (1997) noted that point-of-choice programmes supported by informational brochures and local promotion had a positive effect on sales of at least some items in two of the three good quality studies while the intervention was in place. The magnitude of the effect ranged from 1–2% of total market share of healthier food items. The third study showed no effect on sales.

Two randomised controlled trials (RCTs) of point-of-purchase interventions in supermarkets have been found to date (Kristal 1997; Steenhuis 2004). One found no decrease in total fat intake (Steenhuis 2004) and the other found no increase in fruit and vegetable consumption (Kristal 1997), although Kristal noted a borderline statistically significant 8.4% increase ($p < 0.07$) in the percentage of intervention store shoppers in the action or maintenance stage of dietary change. Unpicking to extract data from any other RCTs included in the systematic reviews was carried out. No RCTs were included and none of the studies appeared to meet the rapid review criteria of control group and 3-months follow-up.

Educational videos: Two studies of educational videos included in the systematic review by Roe (1997) resulted in a reduction in fat intake of purchases of 4–5% while the intervention and feedback were provided.

Computer-based intervention: An RCT to assess the direct and mediated impact of a self-administered, computer-based intervention on supermarket shoppers (Anderson 2001) found that the treatment group was more likely than the control group to attain goals for fat at the end of the intervention ($p < 0.001$) and follow-up ($p < 0.05$), although the low initial response and compliance rate suggest that these results could be from a motivated subgroup. There was a trend towards goal attainment for fibre and fruits and vegetables post-intervention ($p < 0.1$), but this was not significant.

All the interventions were in supermarkets and none of the studies was carried out in the UK. Most of the subjects in the three RCTs were women, as might be expected in this setting.

Physical activity
No studies were found that reported physical activity (PA) outcomes.

Evidence of corroboration in the UK
In terms of corroboration, nine UK-based corroborative studies were found, only two of which had a direct bearing on the point-of-purchase interventions summarised above.

Point-of-purchase
The study by Knox (2001) combined a cross-sectional survey and interviews to determine those factors most important for successful reduced-fat product development and to seek consumers' views on perceived barriers to reduced fat intake. 69.3% of consumers felt that nutritional information on food products was helpful. Those in lower socio-economic groups appeared more likely to find information on products more difficult to understand (p = 0.021), whilst those in higher socio-economic groupings appeared more likely to attribute confusion to conflicting dietary advice (p = 0.002). Confusing nutritional labelling information and conflicting dietary advice were barriers to making informed decisions. 59% of consumers were of the view that reduced fat foods were inferior in taste compared with full fat products, and over 90% considered taste to be the most important criteria in the selection of both meat and dairy products.

A qualitative study of 14 low-income middle-aged women (Dibsdall 2002) reported that while the women found media messages (from television [TV] and radio programmes, magazines or newspapers) surrounding healthier eating confusing they were aware of and agreed with the basic recommendations for a healthier diet. Participants reported good control of food availability and budgets but buying 'more' foods such as more fruits and vegetables was beyond their budgetary control. Irrespective of the healthiness of their diet, the participants displayed a basic lack of motivation to change eating behaviours.

Food deserts
Six publications addressed the specific issue of 'food deserts'. A before and after study (Wrigley 2003) and companion qualitative studies (Whelan 2002; Wrigley 2004) looking at the effect of the opening of a supermarket in a deprived, previously poor-retail-access community in Leeds, and a cross-sectional comparison of dietary intake vs. retail access in Newcastle upon Tyne (White 2004). Neither study provides evidence of a 'food desert' effect on dietary intake. In Newcastle the data did not demonstrate a relationship between most indicators of healthier eating and factors relating to the local retail environment. Knowledge and relative affluence were the key indicators. Individuals in the lowest socio-economic quintile were less aware of current healthy eating messages than those in the top quintile. Poor knowledge was consistently associated with less healthy eating, as well as with other measures of a less healthy lifestyle (e.g. low levels of PA and smoking) (White 2004). In Leeds, the affect of improved retail provision did not improve population intakes of fruit and vegetables although the group that switched to the new store increased their consumption by 0.23 portions per day (Wrigley 2003).

A potentially biased study in Northern Ireland (Furey 2001) found that 11% of consumers self-reported a concern regarding food poverty issues and the authors concluded that some non-car owners and lower income family units cannot achieve a healthy affordable diet. Another study carried out in England (Caraher 1998) found that one-third of women, compared with 7.7% of men, cited transport as a major factor limiting their choice of food. Cost rather than quality is the major issue for those in lower income brackets when deciding where to shop (Furey 2001; Whelan 2002). One study found, however, that this constraint applied to younger women only while older women tended to be less worried about the cost of food and more enthusiastic regarding buying foods that would be perceived as healthier (Whelan 2002). For the elderly, the main issues related to physical access constraints (Whelan 2002).

A very weak cross-sectional evaluation of a fruit and vegetable home delivery scheme found that 74% of participants reported eating more fruit and vegetables while on the scheme and 42% reported that they were eating more fruit and vegetables after than before the scheme (Ali 2001).

EVIDENCE TABLE 1: SUPERMARKETS AND SHOPS

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Overall strength of evidence of efficacy for weight outcomes = no evidence found								

Evidence of efficacy (internal validity) for diet outcomes								
Point of choice/purchase prompts								
Seymour 2004	Systematic review	2	++	Literature search from 1970 to June 2003. Thirty-eight studies reviewed including ten grocery store interventions of which the authors regarded six as strong or very strong research designs, including one RCT; i.e. most studies graded research type 2.	**Aim:** All articles that included a nutrition intervention with an environmental or policy component conducted in an English-speaking industrialised country.	The studies varied in length from 1 week to 2 years.	The general conclusions of this wide-ranging review of point-of-purchase behaviour were that interventions in 'limited access' sites (i.e. where few other choices were available) had the greatest effect on sales of targeted (healthier) food choices. Eight interventions used only information strategies and, of these, five reported increased sales of targeted items. There was little evidence to suggest that any particular combination of information strategies was more successful than any other. The longer (2-year) multi-component informational studies showed the greatest intervention effects. The remaining two interventions used strategies of availability, access or incentives as well as information (Kristal 1997, see below and Curhan 1974). Curhan	None of the studies appeared to be in a UK setting. Although a good review the evidence tables lacked detail in terms of significance values and the quality assessment methods used.

							compared four interventions of which the most successful was increasing produce display space to 200% of original allocation; this significantly increased sales (from 28–59% depending on the type of produce).	
Roe 1997	Systematic review	1	++	Literature search to 1996. Seventy-six studies (37 RCTs, 29 cohort studies, nine uncontrolled before and after studies, one crossover study of three parallel interventions). **Supermarket settings:** One RCT, three controlled cohort studies judged to be of good quality, one RCT and one uncontrolled study judged to be moderate quality and two poor quality cohort studies, i.e. most studies graded research type 2. Seven studies were based in the USA and one in Canada.	To review health promotion interventions to promote healthy eating in the general population. Little information on who provided interventions. Information is provided for only two studies – one study delivered by the authors and the other by a dietitian.	Follow-up periods were minimal or non-existent. Six of eight studies assessed the impact immediately after the intervention while two studies followed-up outcomes 4 weeks post-intervention. No summary information for supermarket settings. Where assessed, effects generally only lasted as long as the intervention was in place.	Point-of-choice programmes supported by informational brochures and local promotion had a positive effect on sales of at least some low fat or 'healthier' items (items that aid reduction in fat intake and/or increased fibre, fruit and vegetable intake) in two of the three good quality studies while the intervention was in place. The magnitude of the effect ranged from 1–2% of total market share. The third study showed no effect on total sales of low fat or 'healthier' items (i.e. aid reduction in energy, fat and dietary cholesterol intake). (Good quality studies: Ernst 1986; Rodgers 1994; Levy 1995.) Two studies of educational videos (Winett 1988, 1991) resulted in a decrease in the fat content of purchases of 4–5% energy while the intervention and feedback were provided. The educational videos used various forms of modelling, goal-setting and feedback addressing nutrition education, personal control of diet, options for new purchases.	Good quality but relatively dated systematic review. No UK trials in supermarket settings.
Steenhuis 2004	RCT Cluster	1	+	2203 clients of 13 Dutch supermarkets.	**Aim:** To assess the effect of nutrition education with or without shelf	Six-month intervention with questionnaires	48% response to pre-questionnaire, 80% (of this 48%) responded to the 2-month and 83% to the 6-month post-	No allocation concealment. Self-reported fat intake by questionnaire. Intention

				Clients were 80% female, medium education, mean age 46 years, mean BMI 24.3 kg/m^2.	labelling on reduced fat intake. Supermarkets were randomised to: 1) no intervention (control); 2) education alone (posters, brochure, recipe cards, self-help manual etc.); 3) education with shelf-labelling of low-fat products. **Delivered by:** University researchers. No power calculation.	at 1 month pre- and 2 and 6 months post-intervention.	intervention questionnaires. No significant effects were found for the educational intervention, alone or with the labelling, compared with control, on total fat intake and the psychosocial determinants of eating less fat.	to treat (ITT) poorly addressed. All supermarkets followed up but variable questionnaire responses. Meets criteria for a **social marketing** intervention (see methodology).
Kristal 1997	RCT Cluster	1	+	Eight supermarkets in Iowa, USA. No demographic differences between stores. 84% of respondents were women, even age distribution, 18 to ≥65 years old, 28% considered themselves ‘farm families’.	**Aim:** To evaluate whether a supermarket point-of-purchase intervention could increase shoppers’ consumption of fruit and vegetables. Four stores were randomised to an educational intervention (flyers, signs, recipes, coupons, food demos, store staff dressed as vegetables) and four to control. **Delivered by:** Probably a	Eight-month intervention and 1-year follow-up (i.e. 4 months post-intervention).	**Overall response rates to exit interviews:** 59.8% in intervention (I) and 67.2% in control (C) stores, and similar at baseline and follow-up. Response rates to take home survey 74.5% (I), 72.3% (C) at baseline and 77.5% (I & C) at follow-up. Compared with change in control shoppers, the percentage of intervention store shoppers in the action or maintenance stage of dietary change increased by 8.4% but this was non significant ($p < 0.07$), and there was no corresponding increase in fruit and vegetable consumption.	No allocation concealment. No ITT analysis. Not included in the review by Matson–Koffman (reason unknown – may have been excluded by the authors or missed by the search strategy).

					combination of higher education research and supermarket employees. No power calculation.			
Computerised intervention								
Anderson 2001	RCT individual	1	+	USA supermarkets, probably Virginia but not stated. Participants were 96% female, 92% White, mean income of US$35,000 and mean education of 14.8 ± 2.1 years. Participants (self-selected) were recruited in five supermarkets during face-to-face contact followed by a mail-back of enrolment materials. An expression of interest was acknowledged when a shopper returned at least some part of the enrolment packet.	**Aim:** To explore the extent to which treatment effects were mediated by social cognitive variables using measures of self-efficacy (for buying, preparing, eating and serving lower fat and higher fibre foods and more fruits and vegetables) and outcome expectations shown to explain nutrition behaviour among food shoppers).* Based on a self-administered, computer-based intervention on nutrition behaviour in supermarket food shoppers. Individuals randomised to tailored information and regulation strategies delivered in 15 brief weekly segments, or control.	15-week intervention plus 6-months follow-up.	795 expressed interest and 363 recruited. At end of intervention all controls and 87% intervention group completed questionnaires. At follow-up 62% control and 49% intervention provided full questionnaire and receipt data. The treatment group was more likely than the control group to attain goals (i.e. personalised nutritional goals set during the intervention) for reducing fat intake at the end of the intervention ($p < 0.001$) and at 6-month follow-up ($p < 0.05$). There was a trend towards goal attainment for increasing fibre and fruit and vegetables intake post-intervention ($p < 0.1$) but this was not significant.	Nutrition for Life (NFL) computerised intervention. No allocation concealment. No ITT. Subjects were highly motivated. Participants received US$10 for completing enrolment forms, US$10 for baseline, US$15 for post-test food frequency questionnaires (FFQs) and Food Beliefs Surveys and US$20 for follow-up FFQs. Participants also received US$5 per week for returning annotated food shopping receipts during baseline, US$7 per week during the intervention and US$10 per week during follow-up. *Social cognitive theory suggests nutrition goal-setting and self-regulation may directly improve participants’

					Delivered by: Higher education researchers and supermarket employees delivered intervention. Computerised element self-delivered. No power calculation.			nutrition-related behaviour.

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders /comments**
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders /comments**
Point of choice/purchase								
Knox 2001	Cross-sectional survey and qualitative interviews	3	+	**Product development personnel:** Qualitative interviews (*n* = 47) with key food product development personnel from 27 food companies throughout Northern Ireland and England. **Consumers:** Qualitative interviews (*n* = 90) followed by survey (*n* = 1004) of customers in retail	**Aim:** 1) To determine those factors most important for successful reduced fat product development; and 2) to gain insight into the consumer view of reduced fat foods and to determine barriers to the uptake of reduced fat foods from the consumer	N/a Cross-sectional plus interviews.	**Consumer qualitative:** Ninety-six approached, 90 interviewed (60 in Northern Ireland and 30 in England) in store and 68 (75.5%) returned for a debriefing interview on exiting the store. **Consumer survey:** More than 3000 people approached, 2148 refused to participate (32.8% response rate). **Qualitative:** Uptake or rejection of reduced fat	Sample characteristics for the key food product development personnel and details of interviews not provided Low response rate to questionnaire. Largely female

				outlets in Northern Ireland and England. **Qualitative sample:** 90% female, age distribution slightly skewed towards the 40s. **Survey sample:** 77.5% female, age was normally distributed. **Qualitative:** 34.4% housewives or retired. **Survey:** Sample slightly biased towards the lower middle class and upper working class. 64.8% held GCEs or about with a large proportion holding no formal qualification (20.6%).	perspective Product development personnel described their experiences to provide insight into problems encountered re development, launch and marketing of reduced fat products.* **Consumer qualitative:** 10–15 min interview re food choices. **Survey tool:** Dietary views and attitudes. Participants were interviewed prior to commencing shopping and were asked upon leaving the store if they thought the interview had influenced their purchases and were requested to provide the researcher with a copy of their till receipt (i.e. interviewed before		foods influenced by health concerns, ‘goodness of fit’ with dietary health strategies, particularly weight reduction, perceived inferior sensory attributes of the products and scepticism towards reduced fat foods and fat claims. Although none of those who said they were influenced by the interview had bought reduced fat products, 5% of respondents said they had thought more about their purchases as a result of the interview. 66% of those re-interviewed on leaving the store believed that the interview would not influence subsequent purchases. **Survey:** 69.3% of respondents felt that nutritional information on food products was helpful. Lower socio-economic groups appeared more likely to find information difficult to understand (*p* = 0.021), whilst those in higher economic groupings were significantly more likely to attribute confusion to conflicting dietary advice (*p* = 0.002). Reported barriers to uptake of reduced-fat food products – confusing nutritional labelling information and conflicting dietary advice makes it difficult to make informed decisions. Authors commented that participants were sceptical of advice offered and	sample and likely to be motivated. Compliance for consumer qualitative interviews was high (94%) although the sample consisted of 81 females and nine males. Compliance for the consumer survey was very low at 33%. *Qualitative interviews with product development available but not considered of relevance to this review.

					bought groceries). **Delivered by:** Higher education researchers probably. No power calculation.		claims made for reduced fat foods. 59% indicated that reduced-fat foods were inferior in taste and over 90% felt that taste was the most important criteria in selecting meat and dairy products. Those reporting barriers more likely to be male, young, sceptical to products and claims, report lack of will power and concerns on expense. Uptake associated with being female, older, belief that reduced fat products are healthier, concern about health and body weight, and adopting a dietary health strategy).	
Dibsdall 2002	Qualitative	3	+	Fourteen middle-aged women from a low-income Housing Association in Norwich. Women had a mean age of 51.3 years, all had some profession other than housewife although only seven were in full-time, low-paid employment.	To provide an in-depth account of the beliefs and experiences pertaining to food and health from a specific group of low-income women. Letters were sent to residents inviting them to take part in a health study. Individual semi-structured 50 min interviews were conducted by one researcher. Long-term health (particularly cancer) and healthy eating, (particularly fruit	Interviews between July and September 2000 No follow-up.	Women reported being confused by messages surrounding healthy eating. However, participants were aware of and agreed with the basic recommendations for a healthier diet, high in fruits and vegetables and low in fats, sugars, and salts. ‘Fresh’, ‘natural’ and ‘organic foods’ were seen as healthier, whereas processed food and foods containing chemical additives were perceived as less healthy, even possible causes of cancer. Participants reported good control of food availability and budgets, but that purchasing organic foods and buying ‘more’ foods such as more fruits and vegetables was beyond their budgetary control. Irrespective of the healthiness of their diet, the participants displayed a basic lack of motivation to change eating	Small sample size and low response rate to invitations to participate (9%) may have led to the possibility of selection biases. NB. Authors state that they expected the low response rate from the letters inviting study participation ‘given the commitment required from respondents,

					and vegetable consumption), were explored. Audiotaped interviews were transcribed verbatim, coded and analysed by two people and themes were identified for each interview. **Delivered by:** Higher education researchers. No power calculation.		behaviours.	the lack of incentive and the knowledge that individuals from low income groups in the UK generally refuse such invitations'.
Food deserts								
Wrigley 2003	Before and after study	2	+	Local authority housing estate area of Leeds (Seacroft) – within the top 5% most deprived wards in England. Essentially a low-income, compoundly deprived, White area. **Respondents at baseline:** 82% female. 9% 17–24 years and 22% ≥65 years. 20% in full time work, 24.7% employed at home, 5.5% unemployed. 72.5% GCSE or below. 16.5% income of <£5000 per annum, 13% >£20,000 and 17.5% refused information. Household	**Aim:** To assess the impact of a retail provision intervention (the opening of a retail centre including a Tesco store in the locality) on food consumption patterns, and by extension diet-related health, in a deprived, previously poor-retail-access community. Two waves of study in June/July 2000 (before, approximately	Before and after study.	Of 3000 households contacted, 1009 respondents completed the 'before' wave of the survey (34%) and 615 completed the 'after' wave (21%, or 61% of the baseline respondents). Of respondents completing both waves, 45% switched to the new store, claiming ease of access and convenience. Those who didn't switch were concerned about the expense of the store (28%) and its large size and layout (21%). Across the 615 respondents who completed both waves, mean consumption of fruit and vegetables increased insignificantly by 0.4 portions per day (from 2.88 to 2.92). The group that switched to the new store (*n* = 276) increased their	Survey was pre-tested. Power calculation used although detail unclear. Attempts to get representative sample were made. Links with Whelan 2002 . Authors confirmed (3 June 2005) that 'the bias introduced as a result of the attrition (between

				deprivation score: 0, (least deprived) 25.5%; 1, 29.4%; 2, 30.2%; 3, 11.9%; 4 (most deprived), 1.5%.	5 months before the opening of the new store) and in June/July 2001 (after, 7–8 months beyond the opening of the new store). Seven-day food-consumption diary, plus interviewer-administered household questionnaire. **Delivered by:** Fieldwork by market research team and survey designed by university researchers, market research team and J. Sainsbury. Power calculation used but statistical power not stated.		consumption by 0.23 (2.66 to 2.89; *p* = 0.034) portions per day compared with those who did not switch (*n* = 339) (–0.13; 3.07 to 2.94, *p* = 0.178).	waves 1 and 2 which they checked very carefully) was fairly minimal'.
Whelan 2002	Qualitative	3	++	Residents in the Seacroft area of Leeds, a 'food desert' prior to a major improvement in food retail accessibility. Thirty-three women and two men aged 18–40 years. Area mainly deprived housing estates with a 'smattering' of private housing.	**Aim:** To explore individual food shopping behaviour, consumption patterns and attitudes towards a healthy diet. Five focus groups (between five and ten members)	N/a. Focus groups.	Recruitment rate unknown. Younger women, especially those with low incomes, were more concerned about cost rather than the quality of the food bought. This often led to foods being bought exclusively in budget stores, which may have imposed important constraints on what was available to purchase. When asked 'What influenced the foods they bought', older women tended	Recruitment and complete details of sampling frame not reported. Links with Wrigley 2003 . The focus groups were not composed

					sampled opportunistically. **Delivered by:** Higher education researchers. No power calculation.		to be less worried about the cost of food and more enthusiastic regarding buying foods that would be perceived as healthier. For the elderly, the main issues related to physical access constraints.	of members of the main Seacroft sample. Author confirmed 5 July 2005.
Wrigley 2004	Qualitative	3	++	Residents in the highly deprived Seacroft area of Leeds. Recruitment was conducted by experienced fieldworkers and five of eight groups consisted of residents who had switched their main food shopping source in the post-intervention period to the new store. Forty-nine participants comprised eight focus groups in age gradients 17–34 years (*n* = 4), 35–54 years (*n* = 2), >45 years (*n* = 1) and >55 years (*n* = 1). Focus groups were predominantly composed of socio-economic group D/E. Focus groups were conducted in September 2002 (a little over 1 year on from the main post-intervention household-questionnaire surveys and 1 year 10 months	**Aim:** To explore the impact of increased physical access to full-range retailing in the area, assess the views of the residents who had switched their main food sources as a result of the intervention compared with those who had not and to investigate the perceptions of the impact of the intervention on food consumption habits and their potential to eat a more healthy diet. **Delivered by:** Higher education researchers. No power calculation.	N/a. Focus groups.	77% of those recruited attended with the exception of groups 1 and 2. Walking to the 'main' food source, with its associated flexibility and cost-savings, had become a viable option for the majority of focus group participants and physical access coping strategies had significantly altered. However, economic access constraints (with the exception of certain direct reductions in the transport costs of food shopping) had for many remained fundamentally unaltered. Overall, there was little evidence (if any) from the focus groups concerning the impact of the new store on the potential of participants to eat a more healthy diet. What evidence there was suggested that a minority of participants were using the transport cost savings associated with improved access to full-range food retail provision to buy fresh food.	Focus groups 1 and 2 (younger switchers) where nine individuals had been recruited for each group only four and three respectively attended. Total number recruited unclear. Participants give small monetary incentive to attend the focus groups. Focus group residents not drawn from the main Seacroft sample (author confirmed 6 July 2005).

				from the opening of the new store) at a variety of venues in the vicinity of the intervention store and lasted approximately 75–90 min. Groups were moderated by a qualitative researcher. Each session was audio taped, transcribed and analysed by the moderator using standard content analysis.				
White 2004	Cross-sectional survey	3	++	Representative sample of households and individuals in Newcastle upon Tyne and all retail outlets selling food, as well as data on access to retail outlets and socio-economic data. Retail outlets were surveyed to get details on type, size and opening hours plus the range, cost and quality of 33 commonly eaten food items. Surveyed sample were >16 years old, 59% women, 95% White European and 37% in full-time employment. The sample of households was slightly biased towards higher socio-economic status,	**Aim:** To determine the relationship between dietary intake and socio-economic factors at individual, household and neighbourhood levels and retail access to a 'healthy' and affordable diet, to determine if food 'deserts' exist and, if so, to describe their characteristics. Food Standards Agency report. **Delivered by:** Higher education researchers. No power calculation.	N/a. Cross-sectional survey with multi-level modelling.	5044 individuals (of 6162, 83% response rate) in 3153 households (of 17801 contacted – 18% response rate) completed the main surveys. 560 retail outlets (of 658 approached, 85% response) were surveyed. Individuals in the lowest socio-economic quintile were less aware of current healthy eating messages than those in the top quintile. Poor knowledge was consistently associated with less healthy eating, as well as with other measures of a less healthy lifestyle (e.g. low levels of PA and smoking). The availability of the full range of foods, the 'healthy' and the 'unhealthy' baskets was not socio-economically patterned by area and there were no significant cost variations. The data did not demonstrate a relationship between most indicators of healthier eating and	Unknown if questionnaire validated but otherwise a good study. Low household response rate indicates selection bias toward those of higher socio-economic status.

				and of individuals to older age groups and women, compared with the Newcastle population as a whole. An initial random sample of 11,266 private households was selected using the Post Office's Postcode Address File (PAF). Each selected household was sent a questionnaire pack, addressed to the householder and a pre-paid envelope. The main food shopper was asked to complete the questionnaire. As a result of a poorer than anticipated response rate a further sample of 6535 households was selected using the same procedure 3 months later. Respondents were asked if they and other household members were willing to take part in the individual survey. Those who agreed were added to the Phase 2 study sample list and sent an individual questionnaire.			factors relating to the local retail environment. The authors concluded that key predictors of healthy eating are primarily dietary knowledge, relative affluence and a 'healthy' lifestyle, so it seems unlikely that those people whose diet is 'less healthy' than desirable would eat more healthily if supplied with improved retail provision.	
Furey 2001	Range of qualitative/ quantitative methods	3	+	A range of research methodologies were employed in locations throughout Northern	**Aim:** To identify possible locations of food deserts in Northern	N/a	The authors concluded that certain user groups in Northern Ireland (non-car owners and lower-income family units) cannot	A good range of research methods were used and

				Ireland. Of the (stratified random sample of) food shoppers interviewed half were from rural and half from urban locations. 77% were female and the majority were aged ≥65 years. The social class status was skewed towards the lower socio-economic classes because the fieldwork was largely conducted in housing estates and 51% fell into the unemployed, casual worker, housewife or retired groups with only 12% professing themselves as social class A or B.	Ireland, quantify their characteristics, establish which consumer groups are affected and make recommendations to negate the effects of food deserts. Quantitative methods included a consumer questionnaire, comparative shopping exercises, and shopping diaries. Qualitative methods included consumer focus groups and interviews with retail managers. **Delivered by:** Higher education researchers. No power calculation.		achieve an affordable, healthy diet – possibly to the detriment of their health status. 11% of Northern Ireland consumers self-reported a real concern regarding food poverty issues, suggesting simultaneous financial constraints on food choice as well as the market-inflicted physical access difficulties. 82% noticed how their seemed to be fewer food stores than previously, while two thirds argued the town centre food store was more convenient than the edge of town.	combined. Little detail of study questions was provided, nor was there a discussion of the researchers' viewpoint or potential limitations of the study. Potential for bias cannot be ruled out.
Caraher 1998	Cross-sectional survey	3	+	The Health Education Authority's (HEA) 1993 Health and Lifestyles survey. 5553 interviews with 16–74-year-olds at a random sample of addresses in England, stratified by NHS region.	Corroborative evidence to look at the issues of access to food and the influences people face when shopping for a healthy food	N/a	9% of social group I and II respondents report no concern with what they eat compared with 24.9% in class III manual and 21.2% in classes IV and V. A higher proportion of individuals in the lower income brackets (11% lowest vs. 7% highest income	Results were weighted as far as possible to allow for potential bias due to the policy of interviewing

				The Registrar General's six-group social class classification was used.	basket. No power calculation. **Delivered by:** Data from the HEA survey carried out by Market & Opinion Research International (MORI).		bracket) and people aged ≥55 years use local shops (10.5 vs. 7.9% 35–54-year-olds). The major issue for those in the lowest income bracket in deciding where to shop is cost (47.3%) whereas speed and convenience is the key issue for the highest income groups (69.4% of the highest income group). The quality of food and the range of healthy foods were cited by less than 10% of respondents as factors in deciding where to shop. 12.7% of men compared with 5.4% women cited not knowing how to cook as a restriction on their choice of food. When asked about factors they felt limited their choice of food, a third of women compared with 7.7% of men cited transport as a factor.	only one person per household and to compensate for the under-representation of certain age groups. Self-reported data.
Fruit and vegetable delivery scheme								
Ali 2001	Cross-sectional survey	3	+	Two London estates. Fifty-one households ('51 individual members'), recruitment details not reported. 66% respondents were aged between 25 and 59 years, 16% male, 39% in work (full or part time). 24% White, White British, or English. 18% Black African, 10% Caribbean/Black, Afro-Caribbean/Caribbean 47% on state benefits.	**Aim:** To explore whether fruit and vegetable delivery schemes met a need on the estates and to see what lessons could be learned to help future projects. Survey with qualitative and quantitative sections to evaluate two 6-week pilot fruit and vegetable delivery schemes. Survey	N/a. Cross-sectional	Fifty-one households completed information about circumstances survey, 75% (*n* = 38) completed the views and experiences survey. 74% of people who filled in survey questionnaires said they ate more fruit and vegetables while on the scheme. 42% of people of filled in survey questionnaires said that they were eating more fruit and vegetables after than before the scheme. 45% of people who filled in the	Data analysis may not be rigorous. Some conclusions drawn through use of additional unreported data. Self-reported fruit and vegetable intake.

					conducted after the pilot scheme (time difference not reported). **Delivered by:** Evaluation group led by the project worker and a Health First researcher. No power calculation.		questionnaire listed convenience/ease of access to fruit and vegetables as a benefit. 97% said they would use a new scheme if it was set up.	

EVIDENCE TABLE 2: RESTAURANTS AND CAFÉS

- **Point-of-purchase prompts**
- **Non promotional information**
- **Price changes**
- **Manipulation of nutrient content/increased availability of nutritious foods**

Note: Overlap with workplace and school interventions in systematic reviews.

SUMMARY

Evidence of efficacy for weight management/reduction
No studies were found that reported weight outcomes.

Evidence of efficacy for diet/physical activity outcomes
Dietary outcomes

Point-of-purchase: Four systematic reviews were found. They looked at all types of research study, 28 primary studies in all, and had limited overlap. Two were good quality (Roe 1997; Seymour 2004) and two much lower quality (Holdsworth 1998; Matson-Koffman 2005). All the reviews concluded that informational point-of-purchase or choice strategies increased the consumption of targeted items. Seymour (2004) reported that most of the restaurant studies reported some significant increased sales of targeted menu items but no data were provided. Roe (1997) concluded that point of choice promotions led to an increase in sales of promoted items by 2–12% total market share but the effect generally only lasted as long as the intervention was in place. Since the reviews lacked detailed information, unpicking was carried out. Of the 28 primary studies, none met the rapid review inclusion criteria (a control group and at least 3-months follow-up).

A single RCT was found that was not included in any of the reviews and was carried out in the UK (Stubenitsky 2000). This found that provision of an acceptable lower fat, lower energy main course dish in a restaurant setting had a direct effect on fat and energy intake, was not compensated for in other components of the meal and was not affected by consumer knowledge of the ‘lower fat’ nature of the dish (through menu text). For the group choosing the target dish who were served the full fat version, their total energy and fat intakes during the meal was increased compared with those served the lower fat option [$F(3,80) = 5.27$, $p = 0.0002$ and $F(3,80+13.82$, $p \leq 0.0001$].

Physical activity
No studies were found that reported PA outcomes.

Evidence of corroboration in the UK:
Five UK corroborative studies were found of relevance to eating out.

In a cross-sectional survey of 14-year-olds in London (Watt 1996) the most frequently cited factor perceived as being helpful to promote future changes in general eating habits was strong will power (83.3%). Other important factors included wider availability of healthy foods (67.3%), support from family (66.7%), advice from doctors (58.2%), cheaper healthy foods (53.3%) and better food labelling (50.0%). Between the social classes, a difference emerged for friends’ support, information booklets, wider availability of healthy foods, costs of healthy foods and own will power, with these being considered more helpful by individuals from non-manual households ($p < 0.05$). A companion qualitative study (Watt 1997) found that 'healthy foods' were considered to be largely irrelevant, unappealing and expensive by most young people interviewed, and not readily available outside their own homes. In contrast 'fast foods' were considered part of their independent lives, commonly eaten with friends, associated with enjoyment and relaxation, ready available, appealing and inexpensive. Parental disapproval appeared to be part of their appeal.

From a questionnaire study of public eating places (Warm 1997) reported that Heartbeat Awards (HBA) premises compared with controls were more likely to report that they offered what they perceived as a healthy dish ($p < 0.001$) and they also recorded an increase in purchases of brown rice ($p < 0.001$) and more low-fat spreads ($p < 0.05$,for public eating places). The data were self-reported and there is potential for bias. Another study of HBA public eating premises (Holdsworth 1997) found that the main influences were quality of food (72.2%), affordable prices (60%), good service (53.3%), variety of choice (48.5%) and location (42%). The availability of healthy food choices (30%) was least often selected, but nearly twice as many women (34%) as men (17.2%) said that this influenced their choice of eating-place ($p = 0.014$). Availability of healthy food choices was more important to those aged ≥45 years (40.5 vs. 25.5% of ≤45-year-olds; $p = 0.016$).

A qualitative study of community cafés in Glasgow (Simons 2004) made the following recommendations for increasing healthy choice sales: the need for a strong lead to provide coordination and support; café staff should be actively involved, trained and supported; promotion to be encouraged and best practice shared between cafes; healthy options to be competitively priced and to include 'special offer' incentives.

EVIDENCE TABLE 2: RESTAURANTS AND CAFÉS

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
No evidence found.								
Evidence of efficacy (internal validity) for diet outcomes								
Seymour 2004	Systematic review	2	++	Literature search from 1970 to June 2003. Thirty-eight studies reviewed including five restaurant interventions, only one with a strong research design but no RCTs.	**Aim:** All articles that included a nutrition intervention with an environmental or policy component conducted in an English-speaking industrialised country.	The studies varied in length from 4 weeks to 1 year	The general conclusions of this wide-ranging review of point-of-purchase behaviour were that interventions in 'limited access' sites (i.e. where few other choices were available) had the greatest effect on food choices. The authors reported that most of the restaurant studies reported some significant increased sales of targeted menu items. Not enough information was provided to assess the exact number with significant positive results. All used some form of information strategy (such as symbols or labels to promote low fat items) and, overall, providing information in the restaurant setting appeared to be associated with increased purchase of targeted items, suggesting that the specific strategies were not as important as the act of intervening.	None of the studies appeared to be in a UK setting. Although a good review the evidence tables lacked detail in terms of significance values and the quality assessment methods used.
Roe 1997	Systematic review	2	++	Literature search to 1996. **Catering settings:** Fifteen studies (one RCT, eight	To review health promotion interventions to promote healthy eating in the general population.	Range of timescales. Two weeks to 6 months in catering settings.	Point of choice promotions used in five of fifteen studies and all four of the restaurant studies, used signs to encourage selection, backed up with written educational and promotional	Good quality but relatively dated systematic review. No UK trials in restaurant settings. The

				uncontrolled before and after studies, five cohort studies, one crossover study of three parallel interventions) in all including community, school and work outlets (three judged to be of good quality) but only four in public restaurants (none judged to be good quality) – i.e. most studies graded type 2.	Information on who delivered the interventions not provided.		materials such as posters, information boards, fliers and table tents (nb: assumed that table tents are three-dimensional table displays). These led to an increase in sales of promoted items by 2–12% but the effect generally only lasted as long as the intervention was in place.	restaurant studies were all assessed as moderate quality (three uncontrolled studies and one crossover study) – i.e. no restaurant RCTs. **Restaurant studies:** Mayer 1986 Colby 1987 Wagner 1988 Albright 1990 **University studies:** David-Chervin 1985 Meiselman 1994 (study 1) Meiselman 1994 (study 2)
Matson-Koffman 2005]	Systematic review	2	+	1970 – October 2003 (more comprehensive search from 1990). Sixty-five pre-1990 and 64 in 1990 or later intervention studies of all research types (authors report as 26 experimental studies, 51 quasi-experimental studies and 50 non-experimental studies). Of the nutrition studies, 33 looked at the availability of nutritious foods and	To review the literature to determine whether policy and environmental interventions can increase people's PA or improve their nutrition. Studies published pre-1990 are only briefly summarised. Study designs for individual studies are not reported and are referred to as 'large scale trials'.	Not stated for pre-1990 studies. Follow-up periods for studies published between 1990 and 2003 ranged from 4 weeks to 10 years to three years for post-1990 studies.	From this narrative review (with some data on post-1990 but no data provided on pre-1990 studies) the authors made the following recommendations: • Use point-of-purchase strategies, including menu and shelf labelling, to increase purchases and consumption of healthier foods. • Promote policies and environmental supports that increase supply and access to healthier foods and beverages in vending machines, restaurants and cafeterias, including more fruits and	Supermarket and restaurant studies were combined (see also Evidence Table 1). Recent but confusing review of varied study types and outcomes. No unpublished studies included. Study quality assessed but doesn't appear to have been taken into account in the summary. The analysis of results was different for pre and post-1990 studies. Follow-up periods have not been reported for all of the studies

				29 at point-of-purchase strategies in supermarkets and restaurants. Studies pre-1990 only briefly summarised. Study designs of individual studies not reported and referred to as 'large scale trials'. None of the restaurant studies were RCTs. For post-1990 studies, 48 were conducted in the USA, three UK, three Australia, two Canada, one Sweden, one Finland, one Switzerland, and two not reported.			vegetables and reasonably priced, good tasting, heart healthy items with lower fat and sugar content.	No post-1990 UK studies. Pre-1990 unknown. PA data not extracted as better review.
Holdsworth, 1998	Systematic review	2	+	Literature search date unknown. Twenty-one nutrition labelling schemes at the point-of-purchase published between 1978 and 1993 (13 pre-1990 and eight 1990 or later). Of the 21 studies six (three prescriptive, two descriptive and one prescriptive replaced by a	To review point-of-choice nutrition labelling schemes in catering establishments to describe the variety of schemes and determine the characteristics of effective interventions, including both descriptive and prescriptive labelling.	Range of timescales. Eight weeks to 12 months in public eating places and 4 weeks to 16 months in universities.	Most of the studies reviewed demonstrated some positive short-terms benefits from schemes although it is unclear which is the most effective labelling format, i.e. labelling of healthier food choices or providing nutrient information.	Literature search dates have not been reported. Varied study types and outcomes. No details of the methods used for quality appraisal. Number of papers identified and methods of the selection process not reported. Many of the interventions were of short duration, had short-term follow-up

				consumer driven scheme) were conducted in public eating places and four (descriptive labelling) in university settings. None of the restaurant studies were RCTs.				periods and few had a control group. The majority of the schemes were from the USA. **Public eating places:** Scott 1979 Dubbert 1984 Wagner 1988 Albright 1990 Heartbeat Award Scheme 1990 Green 1993
Stubenitsky 2000	RCT	1	+	279 members of the public booking a meal at a restaurant during the week in which the study was being held. Mixed age group but majority 'somewhat older than average age' – 11.6% ≤34 years old, 22.8% 35–49 years old, 25% 50–64 years old, 40.6% ≥65 years old. Silver service training restaurant at a City College Hotel School in Norwich. Actually refers to	To examine the influences of nutritional information and consumer characteristics on meal quality expectations, food selection and subsequent macronutrient intakes of consumers offered a reduced-fat option in a restaurant. Subjects seated in different parts of the restaurant were presented with menus differing only in printed information accompanying one target dish – smoked haddock with Welsh rarebit. Four groups:	Questionnaires handed out after ordering and before meal was served; repeated after meal was finished with modified wording relating to actual perception of meal just eaten; and final questionnaire re attitudes and beliefs towards eating 'healthy eating' options in a catering environment, 'completed following the entire meal'.	Subjects in the older age group differed in absolute terms from those in younger groups but this did not significantly influence the direction of any of the outcome measures. Menu information had no effect on total energy and fat intake among the three groups receiving the RF (reduced fat) target dish The proportion of subjects choosing alternative options was not influenced by the presence of information on the menu ($p \geq 0.05$). For the FFB group choosing the target dish, their total energy and grams of fat intake was increased compared with those served the lower fat option [$F(3,80) = 5.27$, $p = 0.0002$ and $F(3,80) = 13.82$, $p \leq 0.0001$]. No consistent pattern in	No allocation concealment. ITT analysis used. Subjects in this study tended to be older than average, which might have some influence on results although direction of outcome measures was the same in all age groups. Most of the subjects were regular visitors to this restaurant, hence uniformly high pre-meal expectations based on prior experience. Nutritional calculations were based on amount and type of food served, as practical considerations meant leftovers could not be

				two separate weeks in June and October 1996 but results appear to have been aggregated between the two as no distinction is made.	1) Full-fat blind (FFB) – no additional information, full-fat food served. 2) Reduced-fat blind (RFB) – no additional information, reduced-fat food served. 3) Reduced-fat informed (RFI) – 'this is a lower fat option' – reduced-fat food served. 4) Reduced-fat informed with details (RFID) – 'This lower fat option is prepared with reduced-fat cheese and skimmed milk' – reduced-fat version served. **Delivered by:** Training school. No power calculation.		differences between pre-meal (expectation) ratings and post-meal (actual) ratings between the four groups. FFB group had significantly lower expected liking, taste and texture rating than the other three groups [$F(3,80) = 3.98$, $F(3,80) = 6.52$ and $F(3,80) = 3.9$; all $p < 0.05$]. Did not find differences in overall meal fat and energy intake of subjects informed versus not informed of their main course dish (RFI vs. RFB). Provision of menu information did not have a significant effect on pre-meal expectation ratings. Provision of an acceptable lower fat, lower energy main course dish in a restaurant setting had a direct effect on fat and energy intake, which was not compensated for in other components of the meal, and was not affected by consumer knowledge of the 'lower fat' nature of the dish (through menu text). Measures of meal expectations, actual acceptance and perceived matching of expectations were also not affected by this information.	measured. Accuracy of actual intake data would have been enhanced by this but effect would be expected to be small compared with that observed for meal composition. Unclear whether questionnaires were validated. Self-reported behaviour.

<table>
<tr><td colspan="9">Evidence of corroboration (external validity)</td></tr>
<tr><td colspan="9"></td></tr>
<tr><td colspan="9">Evidence of salience – Is it appropriate for the UK?</td></tr>
<tr><td>First author</td><td>Study design</td><td>Research type</td><td>Research quality</td><td>Study population</td><td>Research question and design</td><td>Length of follow-up</td><td>Main results</td><td>Confounders/ Comments</td></tr>
</table>

Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/ comments**
Simons 2004	Qualitative	3	+	Customers and staff at 13 community cafés in greater Glasgow, plus stakeholders in the project. No socio-demographic details provided.	**Aim:** To assess the effectiveness of the five components of the Scottish Healthy Choices Award intervention in the 13 cafés that took part in the pilot. Each café was visited for a full day by a researcher and as many customers, staff and volunteers interviewed as possible. Interviews were also undertaken with 12 stakeholders (Greater Glasgow NHS Board, mobile chefs, NHS Health Scotland, Project management team etc.) face-to-face or by telephone. **Delivered by:** Collaboration of NHS, city and local organisations in Glasgow. Evaluation carried	N/a	A large number of recommendations for the scheme were made including: the need for a strong lead to provide coordination and support; café staff should be actively involved, trained and supported; promotion to be encouraged and best practice shared between cafes, healthy options to be competitively priced and to include ‘special offer’ incentives.	Uncontrolled evaluation study – effectively a series of case studies with stakeholder interviews.

					out by independent consultants. No power calculation.			
Holdsworth 1997	Cross-sectional survey	3	+	Eleven eating places in Leicestershire with the HBA (one hotel, two leisure centres, two public houses, two restaurants, four cafés), all in rural locations. Customers completing the questionnaire were adults aged 16–80 years, two-thirds <45 years, 78.5% were female and 97.4% were White. One-third was from social class group 1, and one-third from group 4, and only 13.2% in the HBA target group 3.	**Aim:** To evaluate customers' perspectives of the HBA Scheme in 11 public eating places. A self-completed structured questionnaire was administered to all customers at the establishments on the day the researcher visited. **Delivered by:** Evaluation was carried out by University researchers. No power calculation.	N/a	Of 377 customers approached, 271 completed questionnaires (72%). The response rate varied between establishments from 47.5% to 100%. The main influences on choice of eating place were quality of food (72.2%), affordable prices (60%), good service (53.3%), variety of choice (48.5%) and location (42%). The availability of healthy food choices (30%) was least often selected but nearly twice as many women (34%) as men (17.2%) said that this influenced their choice of eating place ($p = 0.014$). Availability of healthy food choices was more important to those aged ≥45 years (40.5 vs. 25.5% of the <45-year olds; $p = 0.016$).	Most outcomes related to awareness – possible relevance to awareness review.
Watt 1997	Qualitative	3	++	Eighty-one adolescents aged 13 or 14 years (Year 9) from four schools in inner London. Purposive sample from respondents to a cross-sectional survey to provide a range of experiences of dietary	A cross-sectional survey of school children in Camden. A set of interviews to explore young people's perceptions of food.	N/a	No-one selected refused to be interviewed. The most prominent food-classification system used by this sample of inner city Year 9 children involved the dichotomisation of foods into either 'fast food'	Companion paper to Watt 1996. A well described piece of qualitative research with a robust

				change. 41 female, 40 male. No further data other than provided by Watt 1996.	**Delivered by:** Higher education researchers. No power calculation.		or 'healthy food'. 'Fast foods' were generally considered to be high in fat and/or cholesterol and some considered them to be high in fat and sugar while others stressed the additives and preservatives contained in the foods. 'Healthy food' was generally considered to be low in fat with a good balance of vitamins and other nutritional items. 'Healthy foods' were considered to be largely irrelevant, unappealing and expensive by most young people interviewed, and not considered readily available outside their own homes. In contrast 'fast foods' were considered part of their independent lives, commonly eaten with friends, associated with enjoyment and relaxation, ready available, appealing and inexpensive. Parental disapproval appeared to be part of their appeal.	methodology.
Watt 1996	Cross-sectional	3	+	485 Year 9 students at four schools in Inner London. Subjects were 60.3% male, mean age 14.3 years, 52% lived in manual households, 62%	**Aim:** To assess the patterns of dietary behaviour and experiences of change. Knowledge, skills and beliefs about	Survey between May and July. No follow-up.	The most frequently cited factor perceived as being helpful to promote future changes in general eating habits was strong will power (83.3%). Other important factors included wider availability of	Self-reported survey data collected in 1994. School students – potential

				White and 37% lived with a single parent.	food and health were also investigated. Students self-completed questionnaires comprised of six sections covering socio-demographic information, food frequencies, eating patterns, food skills, dietary behaviour changes and knowledge and attitudes towards food and health at school during May–July 1994. **Delivered by:** UCL Medical School researchers. No power calculation.		healthier foods (67.3%), support from family (66.7%), advice from doctors (58.2%), cheaper healthier foods (53.3%) and better food labelling (50.0%). Between the social classes, a difference emerged for friends' support, information booklets, wider availability of healthy foods, costs of healthy foods and own will power, with these being considered more helpful by individuals from non-manual households ($p < 0.05$) than manual.	relevance to schools review.
Warm 1997	Evaluation	3	++	Public eating places (including hotels, guest houses, public houses and leisure centres), workplace canteens/restaurants and education establishments 'within the former Wessex region' – more specific details are not reported.	To compare the differences between premises with and without the HBA (current catering practices including their purchasing, promotion and availability of healthy food options and cooking procedures).	N/a	497 HBA premises and 495 control premises without the award were sent postal questionnaires. Response rates were 76% (n = 380) and 62% (n = 306) respectively. 39% of those surveyed were public eating places. 76% of premises believed they offered healthier meals, although most premises did not have to	Greater response rate from establishments holding award. Bias may have been introduced by award-holders in over reporting the provision of healthy foods and by

					Delivered by: Regional group in Wessex Regional Health Authority. Unclear precisely who sent out or analysed the questionnaires.		change either their purchasing or cooking practices in order to achieve the levels required to receive the award. HBA premises compared with controls more likely to offer what they perceived as a healthy dish ($p < 0.001$) and recorded an increase in purchases of brown rice ($p < 0.001$) and more low-fat spreads ($p < 0.05$ for public eating places). Although 81% of HBA premises compared with 55% of controls indicated that they actively promoted healthy eating ($p < 0.001$ for comparison), public eating places were the least likely to do so. Both HBA and control premises indicated that there had been an increased demand for more healthy food over the last 5 years with active premises seeing a larger increase in demand than control sites (76 vs. 61%, $p < 0.001$). This change in demand for healthy food had led to more than 90% of premises altering the food served. Increased customer demand was proposed as a motivation to possibly selling more healthy food in	providing more healthy choices than non-respondents. Unannounced site visits could have assessed the extent of potential biases but were not conducted. Self-reported behaviour. Unclear if questionnaire validated.

							the future (58 and 66% for HBA and controls, respectively).	

EVIDENCE TABLE 3: RELIGIOUS ORGANISATION-BASED

SUMMARY

Evidence of efficacy for weight management/reduction

No studies were found that reported weight outcomes.

Evidence of efficacy for diet/physical activity outcomes

Dietary outcomes

Only one study was found that included White as well as Black and ethnic minority groups (BMEGs). Solely BMEG studies will be considered in a future review.

Physical activity

No studies were found that reported PA outcomes.

Evidence of corroboration in the UK

No UK corroborative studies were found.

EVIDENCE TABLE 3: RELIGIOUS ORGANISATION-BASED

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)/**comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Weight outcomes = no evidence with weight outcomes								
Evidence of efficacy (internal validity) for diet outcomes								

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Evidence for Implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**

EVIDENCE TABLE 4: ENVIRONMENTAL CHANGES AND FACILITIES TO PROMOTE PHYSICAL ACTIVITY

- **Active travel vs. car travel**
- **Stair-climbing**
- **Access to space and facilities for physical activity**
- **Safer routes to school**

Note: According to the rapid review parameters, only intervention studies with a control group are included in evidence tables. In two topic areas of this review, stair climbing and walking/cycling trails, the only available evidence comes largely from uncontrolled before-and-after studies with a high potential for bias and, in the case of stair climbing studies, largely short term. Since this is the best available evidence on topics of relevance to the obesity prevention guidelines, they have been included in this review for information and comment by the Guidance Development Group (GDG).

SUMMARY

Evidence of efficacy for weight management/reduction

No studies were identified with weight outcomes.

Evidence of efficacy for diet/physical activity outcomes

Physical activity

Active travel vs. car travel: One good quality systematic review (Ogilvie 2004, including nine UK studies) concluded that targeted behavioural change programmes with tailored advice can change the travel behaviour of motivated subgroups, resulting, in the largest study, in a shift to walking and cycling from car use by about 5% of all trips at a population level compared with a shift towards car use by 2% in the control groups. The review indicated that single studies of commuter subsidies and a new railway station also showed positive effects. The balance of best available evidence about publicity campaigns, engineering measures and other interventions suggested that they have not been effective.

Point-of-decision prompts to stimulate stair-climbing: Two systematic reviews, one good quality (Kahn 2002, including two UK studies) and one more recent but lower quality (Foster 2004b, including eight UK studies) concluded that educational materials such as posters and stair riser banners have a weak positive effect on stimulating stair climbing. Foster 2004b found that most studies saw a short-term effect for up to 3 months though one study saw an effect (+29%) 6 months after baseline. Kahn (2002) noted a range of effect sizes (observed a net increase in stair use compared with baseline levels) from a 5.5 to 128.6%. Three before and after studies were published since these reviews, two in the UK (Adams 2002; Webb 2005) and one in Australia (Marshall 2002). Studies found either no increase in stair use (Adams 2002) or a short-term increase (Marshall 2002; Webb 2005). Marshall (2002) found that stair use dropped to baseline levels 10 weeks into the 12-week intervention. A very weak study (Webb, 2005) compared a 2-week phase of stair riser banners with an identical message followed by 2- weeks with different messages. Stair use increased significantly during both phases compared with baseline but there was no significant different between the two phases. A further study with a very weak study design comparing stair- to escalator-use in a Stockholm rail station (Faskunger 2003) found that, with only one ascending escalator, 35.2% of the population decided to climb the stairs. With two ascending escalators, stair use dropped to 18.2% ($p = 0.000$).

Creation of space for physical activity: One good quality systematic review (Kahn 2002 , all US studies of varying designs) found strong evidence that creation of or enhanced access to places for PA combined with informational outreach activities is effective in increasing levels of PA. Examples of interventions were access to fitness equipment in fitness or community centres and creation of walking trails. One more recent controlled before and after (CBA) trial carried out in the USA (Brownson 2004) and two more recent before and after studies of multi-purpose trails, one in the USA (Evenson 2005) and one in Australia (Merom 2003) have been published. A study of six communities with walking trails compared with comparison communities (Brownson 2004) reported no statistically significant intervention effects although two subgroups showed trends to a positive net change in rates of 7-day total walking in the intervention communities; people with high school degrees or less and people living in households of lower annual incomes (≤US$20,000). Evenson (2005) found that 2 months following the building of a multi-use trail, there was no demonstration in increase of PA amongst adults living within 2 miles (1.6 km) of the trail. Conversely Merom (2003) found that a promotional campaign for a local trail reached and influenced cyclists living within 1.5 km of the trail.

Safer routes to school: One RCT (Rowland 2003) found that assistance from a school travel coordinator did not change children's travel patterns or substantially affect parental fears about the safety of the journey to school. At 1-year follow-up the adjusted odds ratio (OR) for walking, cycling or using public transport in intervention schools was almost identical to that in control schools (0.98, 95% confidence interval [CI] 0.61,1.59).

Evidence of corroboration in the UK

Active vs. car travel
A cross-sectional survey (Foster 2004a) found that, for UK women, the perceived safety of walking during the day and lack of shops within walking distance were significant barriers to walking. Environmental perceptions were not related to the number of women walking for more than 150 min per week whereas having a park within walking distance was significantly associated with this measure in men. Data from two sets of case studies (Sustrans 2004, Department of Transport 2003) provide evidence for improvements in active travel as a result of: (1) improving the walking and cycling environment (e.g. traffic calming, good crossings, lighting); (2) providing better facilities (e.g. cycle stores, traffic free routes); and (3) influencing behaviour (e.g. involving the community, educational schemes, guides, maps and leaflets). Experience from a mass media campaign in Scotland (Wimbush 1998) suggested that a TV advertisement and helpline encouraged motivated individuals (callers to the helpline) to walk more but there was no effect on the population as a whole.

Two years after implementation of the City of London's congestion charging scheme (Transport for London 2005) it was estimated that 5000–10,000 former car journeys (10–20%) had transferred to cycling, walking, motorcycle, taxi or car share since implementation. Before and after street surveys found that walking and public transport were perceived to have improved in comfort and overall quality. Cycle and powered two-wheeler safety were perceived to have improved.

Point-of-decision prompts to stimulate stair-climbing: A large number of stair-climbing studies have been carried out in the UK that provide weak evidence of effectiveness and these are summarised above. Evidence from a worldwide systematic review (Kahn 2002, including two UK studies) suggested that tailoring the prompts either by specifying the benefits of stair use or by customising the sign to appeal to specific populations (e.g. ethnic groups, obese people) may increase intervention effectiveness and that signs were effective for both men and women (three studies). One UK study (Adams 2002) found evidence that prompts could be guilt-inducing (see also workplace review).

Creation of space for physical activity
One systematic review of consultation studies (Cole-Hamilton 2002) and four individual studies (Coakley 1992; Hillman 1993, 1996; Davis Mulvihill 2000) were found.

The systematic review of 93 consultation studies in England (Cole-Hamilton 2002) found that barriers to play for school-age children are fears for their own safety, in particular: bullies; dirty unkempt play areas and parks; the lack of things to do; traffic; lack of facilities for disabled children. Children using staffed provision like: staff who listen; staff who are funny, friendly and fair; having a say in what they do; staff who can deal with conflicts between children.

A qualitative study of English children (Mulvihill 2000) concluded that barriers to PA for 5–11-year-olds were lack of their and parents' time and, for some, expense. Parental barriers were lack of time, lack of safety and the poor condition of local parks. Children aged 11–15 years old stressed the importance of the social aspects of PA and cited cost and lack of transport in rural areas as barriers. A reduction in PA in young women was notable and cited barriers included feeling intimidated by young men, lack of time and lack of self-confidence. Safety was the main parental concern and parents believed that PA declined in females of this age.

A weak report of cross-sectional surveys of English 7–11-year-olds (Hillman 1993) noted that in 1971, three-quarters of 7–11-year-olds were allowed to cross roads on their own. By 1990 this had fallen to one-half. 50% were allowed to use buses in 1971 compared with one in seven by 1990. Bicycle ownership increased from two-thirds in 1971 to 90% in 1990 but only one-quarter was allowed to use them on the roads compared with two-thirds in 1971. Nearly four times as many children were driven to school in 1990 compared with 1971. Boys were allowed far more independence than girls; three in five of the boys could cross roads alone, compared with two in five girls **in 1990.** The primary concerns of parents were danger from traffic, children's reliability and fear of molestation.

A qualitative study of young people in London (Coakley 1992) concluded that young women were less likely than young men to see sport as compatible with adulthood. Financial constraints had a significant impact on sport participation in both sexes. Young women mentioned parental constraints and the influence of boyfriends as affecting their leisure choices whereas young men tended to 'do what they wanted'. For 13–16-year-olds encouragement from parents was particularly important; for people >16 years old adult advocates and role models were more likely to be important. Decisions about sport participation reflected past experiences and were often associated with feelings of discomfort and embarrassment in young women.

A cross-sectional and focus group study of 9–11- and 13–14-year-olds (Davis 1996) found that children were aware of the health promotion messages but felt considerable environmental constraints. Many were not allowed to play outdoors, use local parks or cycle to school – or they did not feel comfortable doing so. Girls especially were restricted in how late they were allowed out. In the children's views, traffic danger, 'stranger danger' and social and cultural factors interact to create barriers to keeping healthy and active. Neither study looked at attitudes to dance, yoga or other 'non-sport' forms of PA.

Safer routes to school: There is good corroborative evidence from the UK that Safer Routes to School (SRTS) schemes can be effective (i.e. at odds with one identified RCT). A series of before and after studies in Worcestershire (Parker 2003) found that, when both a school travel plan (STP) and SRTS programmes were in place, there was a 3% increase in walking, a 4% reduction in single-occupancy car use and a 1.5% increase in car sharing. Bus and cycle use remained largely static. A selected series of 30 case studies of school travel initiatives in the UK (Department for the Environment, Transport and the Regions 1999) found, in the ten schools that reported data, an overall increase in cycle use and decrease in car travel. Effects on walking and bus travel were variable. Another scheme (Jones 2001) found a considerable increase in walking and cycling to school 3 years after the intervention. From baseline, bus use increased considerably (from 44 to 53% to school and from 50 to 56% home) while walking (23–26%, 27–29%) and cycling (3–7%, 3–7%) also increased.

Cross-sectional and focus group surveys (DiGuiseppi 1998; Derek Halden Consultancy 1999; Dixey 1999, 1998; Jones 2001) provide powerful evidence that children would like to walk, cycle or take the bus to school but perceived and actual dangers have led to increased vigilance by parents and reduced activity in children.

One ongoing longitudinal study (EarlyBird, Metcalf 2004) found that being driven to school did not affect the overall PA of 5-year-olds.

A Scotland-wide study of SRTS schemes (Derek Halden Consultancy 1999) included the following recommendations: encourage publicity that identifies for local communities that their involvement can make a real difference; note that many of the measures that can be taken forward within schemes are effective, simple and cheap to implement; reinforce the need to achieve wide ownership at the outset and a good understanding among partners of their complementary aims; ensure that there are clearly defined roles for the project champion; emphasise that projects should be designed for sustainability and publicise success stories.

EVIDENCE TABLE 4: ENVIRONMENTAL CHANGES AND FACILITIES TO PROMOTE PHYSICAL ACTIVITY

Definitions

Physical activity

Any force exerted by skeletal muscle that results in energy expenditure above resting level. The term PA therefore includes the full range of human movement, from competitive sport and exercise to active hobbies, walking, cycling, or activities of daily living. PA per se is a complex, multi-dimensional behaviour.

Exercise

Planned bouts of PA usually pursued for personal health and fitness goals. Exercise is a subset of PA, which is volitional, planned, structured, repetitive and aimed at improvement or maintenance of any aspect of fitness or health.

Sport

A subset of PA, which involves structured competitive situations governed by rules. In Europe, sport is often used in a wider context to include all exercise and leisure PA. The Council of Europe European Sports Charter 1993 defines sport as '… all forms of PA which, through casual or organised participation, aim at expressing or improving physical fitness and mental well-being, forming social relationships or obtaining results in competition at all levels'.

MET

MET stands for 'metabolic equivalent task'. 1 MET = a person's metabolic rate (rate of energy expenditure) when at rest. MET values are assigned to activities to denote their intensity and are given in multiples of resting metabolic rate. For example, walking elicits an intensity of 3–6 METs, depending on how brisk the walk is.

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
No intervention studies with weight outcomes.								

Evidence of efficacy (internal validity) for diet outcomes								
Evidence of efficacy (internal validity) for physical activity outcomes								
Active travel vs. car travel								
Ogilvie 2004	Systematic review	1	++	Literature search from earliest date to December 2002. Twenty-two controlled or uncontrolled prospective and controlled retrospective studies included (three RCTs, seven controlled non-randomised trial [CCTs], 11 uncontrolled and one controlled prospective study).	To assess what interventions are effective in promoting a population shift from using cars towards walking and cycling and to assess the health effects of such interventions.	Study lengths varied from 1 to 60 months.	Targeted behavioural change programmes can change the behaviour of motivated subgroups, resulting (in the largest study) in an increase of around 5% of all trips undertaken by walking and cycling. Single studies of commuter subsidies and a new railway station also showed positive effects. The balance of best available evidence about publicity campaigns, engineering measures (such as 20 mph zones or bypasses [England], extending existing cycle route networks [The Netherlands, Germany], new cycle routes [England], downtown auto-restricted zone [Boston, MA, USA]) and other interventions suggests that they have not been effective. The targeted behavioural change programmes (six studies of four interventions) offered an intervention	**UK trials:** Barrell 1995 Hodgson 1998 Social Research Associates 1999 Mutrie 2000, 2002, Babtie Group 2001 Sustrans 2002a, 2000b Rowland 2003 Only three RCTs included but still treated as type 1 research.

							to a motivated subgroup only or information and advice tailored to peoples' particular requirements, or both (e.g. leaflets, time tables, maps, trial free bus or bike passes, personal travel diaries).	
Point-of-decision prompts								
Centres for Disease Control and Prevention 2001 - Summary Report Kahn 2002	Systematic review	2 Before and after studies only.	++	Literature search 1980–2000, English language publications only. Ninety-four studies included of which five were on point-of-decision prompts to encourage stair use (all before and after studies).	A systematic review of community interventions to increase PA.	No information on intervention lengths provided.	There is sufficient evidence that point-of-decision prompts are effective in increasing levels of PA, as measured by an increase in the percentage of people choosing to take the stairs rather than an elevator or escalator. Range of effect sizes (observed increase in stair use compared with baseline levels) from a 5.5% net increase to 128.6%. Findings from several of the studies suggest that tailoring the prompts either by specifying the benefits of stair use or by customising the sign to appeal to specific populations (e.g. ethnic groups, obese people) may increase intervention effectiveness. Signs were effective for both men and women (three studies). None of the studies measured outcomes other than the percentage of people using the stairs, and none attempted to ascertain possible permanence of their reported effects.	Good review and quality assessment undertaken. Point-of-decision prompts for stair use: Two UK studies (Blamey 1995; Kerr 2000), both of which were included in the review by Foster (2004b). Summary also available as Centres for Disease Control publication 2001. Studies conducted in shopping centres, train/bus stations and university Library.
Foster 2004b	Systematic review	2 Before and after studies only.	+	Literature search from earliest date – December 2001. Sixteen uncontrolled before and after studies of educational	A systematic review of studies that used environmental interventions to increase health-enhancing PA.	Length of intervention and follow-up mostly not stated but text suggests that the majority	A number of before and after studies suggest a weak effect of educational materials (e.g. posters and stair riser banners) on stimulating stair climbing. Most studies have seen a short-term effect for up to three months and one study saw an	No unpublished studies sought. No critical appraisal undertaken of included studies. **UK studies:**

				materials on stair use (eight based in the UK).		were more than 3 months.	effect (+29%) 6 months after baseline (Kerr 2001c).	Blamey 1995 Mutrie 1996 Kerr 2000, 2001a, 2001b, 2001c, 2001d, 2001e
Webb 2005	Before and after (interrupted)	2	–	A shopping mall in England with a 24-step staircase and adjacent escalators. 32,597 ascending pedestrians observed. 54% were women, 80% appeared younger than 60 years and 21% were classified as non-White.	**Aim:** To systematically compare the effects of stair riser banners featuring eight different messages with the effects of banners that repeated a single message. No power calculation. Higher education researchers. Same message: Eight banners saying 'Keep fit' interspersed with three saying 'Take the stairs' were fitted to alternate stair risers. Different messages: 'Stay healthy', 'Free exercise', 'Work your legs', 'Daily exercise', 'Keep fit', 'Easy exercise', 'Be active', 'Exercise your heart'.	Two-weeks of baseline observation followed by 2 weeks when banners with the same message were displayed and a further 2 weeks when banners with different messages.	Stair climbing increased significantly between baseline and the intervention period (OR 2.45, 95% CI 2.14, 2.40) from 7.0% using the stairs at baseline, compared with 14.2 and 13.6% respectively, in the single- and multiple-message phases. There was no significant difference between the single message and multiple message condition. Throughout the study, males, White persons, those <60 years and those without baggage climbed the stairs more than their counterparts (all *p* < 0.001). However, no significant interactions occurred between demographic characteristics and either intervention phase.	Very short-term before and after study only. No post-intervention follow-up, although analysis suggested no significant changes in stair or escalator use over successive weeks of the intervention. Activity was measured by observation with 95% interobserver agreement. Number of observations for each period not reported so not possible to confirm the % increases claimed by the authors. Poor study and not included in evidence statements.
Adams 2002	Before and after (time series)	2	+	All users of the stairs and lifts in the medical school of the University of Newcastle upon Tyne.	**Aim:** To use a theoretically based, systematic approach to design and evaluate a stair promotion	The posters were in place for 4 weeks with data collected at baseline and	No increase in stair use was measured in response to the intervention. Stair use comprised 20.1% of all upward journeys pre-intervention, 20.6% at week 1 and 19.5% at week 4 (*p*>0.05).	Time series studies inherently low quality, although a fair and unobtrusive method of observation was

					intervention in conjunction with the target group. **Intervention:** A time-series study building on lessons learnt from users' views on attitudes to stair climbing (from 73 semi-structured interviews; methodology not provided) and to the most acceptable and potentially effective messages and slogan. **Delivered by:** Researchers at the University. **Power:** Eight hours of observation to detect a 50% increase in stair use = 90% power.	at weeks 1 and 4.	Interviews post-intervention suggested that the posters were considered good but probably not effective, they were informative and guilt-inducing, and encouraging people to climb five flights of stairs was overambitious. Although the authors aimed to leave the posters in place for at least 12 weeks and to collect data at baseline and at weeks 1, 4 and 12 the intervention was terminated after the fourth intervention week. As no significant difference was detected between stair use at baseline and at one or four weeks, authors hypothesised that a delayed effect at 12 weeks would be unlikely.	employed (observation from fifth floor, with simultaneous observation from inside stairwell and from one of the lifts, of distance and direction of all journeys made over a 45-min period). There was unauthorised removal of 29/39 posters during the intervention.
Marshall 2002	Before and after (interrupted)	2	+	Australian hospital. No population data provided.	**Aim:** To evaluate whether a stair-promoting intervention could increase the use of the stairs over the elevator in a healthcare facility. The intervention included motivational signs and footprints. Numbers using the	Time series design over 12 weeks. Data were collected before, during and after displaying a signed intervention during weeks 4–5 and 8–9.	Stair use significantly increased from baseline after the first intervention phase (weeks 4–5) (1%, *p* = 0.02; OR 1.05, 95% CI 1.01, 1.10), but stair use decreased back towards baseline levels after the intervention was removed (between weeks 6 and 7). Stair use did not significantly change from baseline after re-introduction of the intervention (weeks 8–9). Lastly, stair use decreased below the initial baseline	Uncontrolled time series study is an inherently weak design. Data collection included unobtrusive monitoring and looks reliable. Power calculation carried out but no sign of application.

					stairs were recorded by an objective, unobtrusive motion-sensing device and research assistant observation; self-report data from hospital staff working on floors four and five were also collected. **Delivered by:** University researchers. No power calculation.		level during the final weeks of evaluation (weeks 10–12). There was no significant change in self-reported stair use by hospital staff.	Total number of observations not provided.
Faskunger 2003	Observational field study	2	+/–	Observation of 1614 people using the stairwell (51 steps) and escalator during rush hour in a Stockholm suburb train station. No details of Study population.	To investigate stairwell and escalator use in a train station where the setting was modified during the intervention (one or two ascending escalators) to increase understanding of how PA could be promoted in such an environment. **Delivered by:** University researchers. No power calculation.	One-hour observation of commuters (*n* = 1614) in a situation with one (*n* = 854) or two (*n* = 760) ascending escalators.	With only one ascending escalator, 35.2% of the population decided to climb the stairwell. With two ascending escalators, stairwell use dropped to 18.2% (*p* = 0.000). Some people taking the escalator decided to walk up it, however (data not provided).	Uncontrolled study design and brief data collection (1-hour observation only). No baseline data. May be highly confounded.
Space for physical activity								
Kahn 2002	Systematic review	2	++	Literature search 1980–2000, English language publications only.	A systematic review of community interventions to increase PA.	No information on length of follow-up.	There is strong evidence that creation of or enhanced access to places for PA combined with informational outreach activities is	Good review and quality assessment undertaken.

				Ninety-four studies included (type not specified so assumed no RCTs) of which ten looked at creation of or enhanced access to places for PA combined with informational outreach – community-wide campaigns or mass-media campaigns.			effective in increasing levels of PA. Examples of interventions were access to fitness equipment in fitness or community centres and creation of walking trails. Informational outreach interventions included point-of-decision prompts, see above, and mass media campaigns. Outcome measures varied but from five studies reporting the effect on frequency of PA the median increase was 48.4 (interquartile range 21.0–83.8)%. The intervention was effective for diverse populations including Black ethnic groups (two studies).	**Enhanced access to space:** No UK studies (all USA) and eight were carried out in the workplace.
Brownson 2004	CBA	2	+	Six rural intervention communities in Missouri and six comparison communities in Arkansas/Tennessee with similar socio-demographic characteristics. Female 77% in intervention, 74% in control sites. Age group ≥18 years old. White race 70% intervention, 64% control; Black 29%, 34%; other 1%, 2%. Education < high school 29%, 21%; college graduate 14%,	**Aim:** To determine whether a multi-level ecologic intervention is effective in increasing PA at the community level and to examine intervention effectiveness for various high-risk groups (e.g. persons of lower income). The intervention was developed with community input and included tailored newsletters based on information provided by participants, walking clubs, fun and awareness days, walk-a-thons, etc.	Baseline and follow-up survey at approximately 2-year intervals with intervention between times.	No information given on participation rate for completion of form leading to tailored newsletter or refusal rates to random phone questionnaire. A community-wide change in walking rates in rural communities was not documented. Although two subgroups showed trends to a positive net change in rates of 7-day total walking in the intervention communities; people with high school degrees or less and people living in households of lower annual incomes (≤US$20,000) no studied group showed a statistically significant net intervention effect.	The Bootheel Heart Health Project. Controlled before and after study only. Intervention was less intense than planned. No participation/attrition information. Self-reported outcomes. Data appear to be from separate cross-sectional surveys rather than cohorts.

				17%.	Telephone survey using random-digit dialling to households with working phones. **Delivered by:** Intervention by an academic team working with community coalitions and local governments. Questionnaire administered by trained interviewers. No power calculation.			
Evenson 2005	Before and after	2	+	366 randomly selected adults (≥18 years) living within 2 miles (3.2 km) of a segment of a multi-use trail in Durham, central North Carolina. Most participants were in good health, had ≥16 years of education; approximately two-thirds were women, one-third were non-Hispanic Black and two-thirds lived within 1 mile (1.6 km) of the trail.	A prospective evaluation of the impact of building a multi-use trail (i.e. cycle path), in terms of change in PA levels among nearby residents. **Delivered by:** University researchers. No power calculation.	Data collected 2 years before and 2 months after opening of trail.	Baseline (2 years pre-trail construction) response rate 47.2% (*n* = 685 out of 2125). At follow-up 63.7% of those who responded at baseline completed the interview (*n* = 436 but 48 had moved away and 22 lived >2 miles (3.7 km) from the trail, leaving *n* = 366). Two months following the building of a multiuse trail, there was no demonstration in increase of PA amongst adults living within 2 miles (3.2 km) of the trail.	Good before and after study but inherently weak design and poor response rate. Some differences between those who completed the baseline and the follow-up survey (more likely to be non-Hispanic White and male). Did not appear to include promotion of trail.

Merom 2003	Before and after	2	+	Adults aged 18–55 years of age who lived around a newly constructed Rail Trail (part of the NSW state-wide 'BikePlan' but designed for walking as well as cycling) in Sydney, Australia. Adults were randomly sampled from an 'inner' area within 1.5 km of the trail and an 'outer' area, bike owners only, 1.5–5 km from the trail. Two-thirds of the sample were inner-city residents, 57% male. 54% had a more than high school education, 34% from a non-English speaking background. In the outer area there were more males (64%), reflecting bike ownership.	**Aim:** To assess the impact of a local promotional campaign (including press advertisements with maps, radio promotion, brochure and map distribution, around a newly constructed Rail Trail in Western Sydney. Pre- and post-campaign telephone surveys were used. Objective concurrent monitoring of daily bike counts was carried out. Promotional campaign delivered by the NSW Road and Traffic Authority. **Delivered by:** Evaluation carried out by Health Service Epidemiology Unit/NSW University. No power calculation.	3 months. No follow-up.	At baseline, 65% sampled households agreed to participate and 568 (73%) completed the baseline interview. 450 (79%) of the cohort completed both interviews. The campaign reached and influenced cyclists in the inner area. Inner cyclists increased mean cycling time by 0.19 (SD 1.5) hours while outer cyclists decreased cycling time (–0.24 [SD 1.6] hours). Mean daily bike counts in the monitored areas increased significantly after the trail launch ($p < 0.001$).	Good before and after study although inherently weak study design.
Safer routes to school								
Rowland 2003	RCT cluster	1	++	Children aged 6–7 or 9–10 years in 21 primary schools in London (Camden and Islington). Sex ratio unknown.	**Aim:** To evaluate the effect of site specific advice from a school travel coordinator on school travel patterns.	One-year intervention plus 1-year follow-up.	21/41 schools (51.2%) agreed to participate and were randomised. The survey questionnaires were administered to parents of children aged 6–7 or 9–10 years and had an 85% response rate.	The study size and duration were constrained by time and resources. it is not clear whether any practical road

				54% White, 18% Black, 15% Asian, 15% other.	Intervention schools (*n* = 11) received 16 hours of expert assistance over one school year. Road safety issues were identified by meetings with teachers and governors, organising focus groups of parents and pupils and encouraging the establishment of a school travel working group. It is unclear where the intervention was conducted. **Delivered by:** School travel coordinators (funded by Camden and Islington Health Action Zone). No power calculation.		Assistance from a school travel coordinator did not change children's travel patterns or substantially affect parental fears about the safety of the journey to school. At 1-year follow-up the adjusted OR for walking, cycling or using public transport in intervention schools was not significantly different to that in control schools (0.98, 95% CI 0.61, 1.59).	safety/engineering solutions were implemented (e.g. speed reduction, crossing patrols – see corroborative evidence).

Evidence of corroboration (external validity)								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Active vs. car travel								
Ogilvie 2004	Systematic review	1	++	Literature search from earliest date to December 2002. Twenty-two controlled or uncontrolled prospective and controlled retrospective	See above.	See above.	See above.	**UK trials:** Barrell 1995 Hodgson 1998 Social Research Associates 1999 Mutrie 2000, 2002 Babtie Group 2001 Sustrans 2002a, 2002b

				studies included, nine from the UK.				Rowland 2003
Point of decision prompts								
Webb 2005	Before and after (interrupted)	2	+	A shopping mall in England with a 24-step staircase and adjacent escalators. 32,597 ascending pedestrians observed.	See above.	See above.	See above.	See above.
Foster 2004b	Systematic review	2 Before and after stud-ies only	+	Literature search from earliest date – December 2001. Sixteen uncontrolled before and after studies of educational materials on stair use.	See above.	See above.	See above.	Eight included studies carried out in the UK: Blamey 1995 Mutrie 1996 Kerr 2000, 2001a, 2001b, 2001c, 2001d, 2001e
Adams 2002 [	Before and after (time series)	2	+	All users of the stairs and lifts in the medical school of the University of Newcastle upon Tyne.	See above.	See above.	See above.	See above.
Safer routes to school								
Rowland 2003	RCT cluster	1	++	Investigation of site-specific advice on school travel patterns; 21 primary schools in London (Camden and Islington). 54% White, 18% Black, 15% Asian, 15% other.	See above.	See above.	See above.	See above.

Evidence for Implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Active vs. car travel								
Transport	Audit/ev	3	+	General London	**Aim of**	Scheme	Comparing 2003 with 2002, there was an	The effects

for London 2005	aluation			population and commuters	**congestion charging:** To reduce congestion, to make radical improvements in bus services, to improve journey time reliability to car users, to make distribution of goods and services more efficient. Net revenues of £90 million were generated in 2004/5 and have been largely spent on improved bus services. **Delivered by:** Government. No power calculation.	introduced in February 2003. Annual evaluations.	increase of 37% in the number of people entering the charging zone by bus. In 2004 a further 12% increase compared with 2003 was registered. A decrease of 7% of underground journeys to the congestion zone was noted in 2003 but this recovered to 2002 levels in 2004. An increase in two-wheeled travel (pedal cycle and powered two-wheeler) was reported but no figures are provided. Of an estimated 40,000–45,000 car journeys transferred to other methods (60–70% of former terminating car movements), it was estimated that 5,000–10,000 journeys (10–20%) transferred to cycle, walk, motorcycle, taxi or car share since the introduction of the scheme. Before and after street surveys found that walking and public transport were perceived to have improved in comfort and overall quality. Cycle and powered two-wheeler safety were perceived to have improved. Negative and positive responses to the scheme were voiced and it was difficult to isolate the perceived impacts on the local neighbourhood and quality of life. In general the scheme was perceived to have been more successful than expected.	on PA are incidental to the aims of the scheme and limited information has been gathered.
Foster 2004a	Cross-sectional survey	3	+	Survey of 4265 nationally representative English adults aged 16–74 years.	To examine the relation between adults' perceptions of the social and physical environment and their self-reported walking behaviour. **Delivered by:** Department of	N/a Cross-sectional survey by 30-min interview.	In women, perceived safety of walking during the day (OR 0.53, 95% CI 0.31, 0.88) and no shop within walking distance (OR 0.72, 95% CI 0.52, 0.99) were associated with any reported walking occasions. Perceptions of the environment were not related to women walking ≥150 min/week. In men, having a park within walking distance was associated with walking ≥150 min/week (OR 2.22, 95% CI 1.18, 4.35). No other significant associations were found.	Unclear if questionnaire was validated, self-reported data, although reliable statistics and the sample was probably

					Health 3-year health promotion campaign. Trained interviewers from a social marketing company interviewed participants at home. No power calculation.			representative.
Sustrans 2004	Selective case studies	3	+	Various locations in England. No socio-demographic details.	A Sustrans action plan for increasing walking and cycling based on good practice guidance in three areas from 50 case studies in England. **Delivered by:** Case studies selected by Sustrans.	Varies for each case study.	The action plan provides evidence through the descriptions of 50 case studies for successful outcomes as a result of: 1) Improving the walking and cycling environment (e.g. introducing safety and security measures such as traffic calming, charging for cars, pedestrian crossings, CCTV, cycle lanes, lighting, cleaner streets). 2) Providing better facilities for walking and cycling (e.g. cycle stores, seats, drinking fountains, traffic free routes). 3) Influencing travel behaviour (e.g. educational/promotional schemes, led walks/cycle rides, guides, walking/cycling incentive schemes, cycle proficiency training).	Selected case studies with limited description of methodology although some studies include PA outcome measures.
Department of Transport 2003	Series of case studies	3	+/–	UK-wide case series. No population data given.	A collection of case studies of community projects that illustrate (in the authors' words) that 'for virtually every aspect of walking policy and promotion of walking there is … a good idea	Data not provided.	Using illustrations from case studies where the amount of walking was increased, the authors summarised good practice in developing pedestrian schemes as including: • an evaluation and audit of pedestrian needs; • community involvement; • good road crossings; • signs (e.g. high quality maps) and lighting; • home zones – making the road a shared area for both cars and pedestrians; • car user charging;	Very brief selected descriptions of case studies with no methodological information and very little in the way of data.

					that works'. **Delivered by:** Case studies selected by Department of Transport.		- walking schemes (rural areas, to work, to school).	
Wimbush 1998	Evaluation incorporating before and after	2	+	Scotland-wide mass media campaign. **Nationwide pre- and post-survey:** Representative of Scottish population. 'Fitline' callers (a free, direct-response telephone helpline service): 59% female. All ages included, 8% <16 years; 20% >55 years. 40% manual and 60% non-manual. Only 15% inactive at baseline.	**Aim:** To evaluate a national campaign involving a 40-second TV advertisement, a telephone helpline (with information pack for callers) and encouragement to local radio stations to run programmes. Target population people aged 30–55 years, who were not regular exercisers. Evaluation involved pre- and post-campaign population surveys and baseline and follow-up surveys (at 10 weeks and 1 year) of a random sample (*n* = 700) of helpline callers	Mass media campaign for 4 weeks in autumn 1995 with second four week burst in spring 1996. National evaluation pre- (June 1995) and post- (June 1996) campaign. Fitline callers at baseline (time of first call) and 10 weeks and 1 year after initial call.	Response rate to baseline survey individual questions varied from 62–86%. Of 700 randomly selected and consenting callers, 490 (70%) interviewed at 10 weeks and 283 (58%) at 1 year. In the population surveys, although knowledge and awareness increased, there was no change in the number of days in the last week on which respondents had spent at least 30 min walking, the mean number of days being 4.26 in June 1995 and 4.13 in June 1996. Among Fitline callers, 48% of the respondents claimed to be more physically active than they had been at last contact, 46% were exercising at the same level and 7% were less active.	Uncontrolled before and after a weak study design. Fitline callers are likely to be highly motivated, so will not be representative of the general population. All outcomes self-reported.

					who consented to be followed up. **Delivered by:** Campaign by the Health Education Board for Scotland and Government national survey. Fitline caller surveys by University researchers. No power calculation.			
Space and motivation for physical activity								
Mulvihill 2000 [	Qualitative	3	++	Paired interviews and focus groups with 163 children (aged 5–15 years) and 52 parents in six geographical areas of England – at schools, youth clubs and a shopping mall. Combination of urban/suburban and rural sites in Manchester, Durham, Leicester, Birmingham, London and Devon. A purposive sample was selected (guided by teachers) to reflect the diversity of socio-economic background, ethnicity and PA levels. The authors claimed a bias towards lower socio-economic groups (as	**Aim:** To provide, using qualitative methods, information concerning the reported perceptions of, motivations for, and barriers to PA among young people aged 5–15 years. **Delivered by:** Fieldwork carried out by higher education researchers. No power calculation.	N/a	**Children aged 5–11 years:** PA was considered pleasurable and good for you. Parents determined whether or not children walked to school and how far they were allowed to cycle. They also facilitated attendance at out of school activities. Barriers to activity were seen by the children as the lack of their own, and parents, time. Expense was a barrier for a small number. **Parents of children aged 5–11 years:** Parents perceived their children as energetic and PA as highly beneficial but requiring more work by the parents. Time was considered a barrier, including whether children walked to school or not. Parents also agreed that organised PA was expensive but lack of funds were not a barrier. Lack of safety and the poor condition of local parks were barriers. **Children aged 11–15 years:** The transition from primary to secondary	High quality study but lack of detail on sampling methods and no summary of Study population (though information provided for each site in appendices).

				measured by receipt of free school meals), lower levels of PA and young women aged 13–15 and data were provided, spread across four appendices with no summary analysis.			school led to a reduction in PA in young women, some of whom felt that teachers did not always treat them seriously in sports. Social aspects of PA (hanging out, shopping, dancing) were important. Young women felt intimidated and embarrassed by young men when playing sport and felt the latter generally played too vigorously. Young men preferred to play with their own sex as girls were seen as having a poorer ability and lower interest. Barriers included cost and lack of late transport in rural areas. Barriers for girls included feeling self-conscious and lack of time. Choices at this age were not influenced by parents. **Parents of children aged 11–15 years:** A number of parents felt they had to encourage their children to be physically active though others regarded their children as very active. Safety was a parental concern particularly at night. General belief that interest in PA declines with age, especially in girls.	
Cole-Hamilton 2002	Systematic review of observational studies	3	++	In May–July 2001 the Children's Play Council contacted organisations in England known to have undertaken Best Value Reviews of children's play and asked for copies of any consultations with school-age children and young people about children's free time. 108 reports were received (93 consultations and >13,000 subjects) and analysed for common themes and interests of	**Aim:** To review the attitudes and activities of children and young people to look at their free time activities in general and at their views of provision. The research was carried out by the Children's Play	N/a	Children play in the streets, local parks and recreation fields, open spaces and play areas. They like physically active outdoor and indoor pursuits, meeting friends, quiet activities, a choice of activities. Barriers to play for children are: fears for their own safety, in particular bullies; dirty unkempt play areas and parks; the lack of things to do; traffic; lack of facilities for disabled children. Children using staffed provision like: staff who listen; staff who are funny, friendly and fair; having a say in what they do; staff who	Excellent summary of themes from 93 separate studies. However, no analysis of results in terms of gender, age, ethnicity.

				children, young people and parents. (An additional systematic review was also carried out for publications from 1995 onwards looking for evidence to substantiate the arguments for play and is reported in this publication.)	Council, an alliance of national and regional organisations and local authorities.		can deal with conflicts between children.	
Hillman 1993	Cross-sectional survey	3	+/–	English school children aged 7–11 years in five areas. No further detail provided.	Two cross-sectional surveys in 1971 and 1990. **Delivered by:** Unknown. No power calculation.	N/a	In 1971, three-quarters of 7–11-year-olds were allowed to cross roads on their own. By 1990 this had fallen to one-half. One in two were allowed to use buses in 1971 compared with one in seven by 1990. Bicycle ownership increased from two-thirds in 1971 to 90% in 1990 but only one-quarter were allowed to use them on the roads compared with two-thirds in 1971. Nearly four times as many children were chauffeured to school in 1990 compared with 1971. Boys were allowed far more independence than girls, three in five of the boys could cross roads alone, compared with two in five girls (in 1990?). The primary concerns of parents were danger from traffic, children's reliability and fear of molestation.	A very weak paper with no methodological detail and no citations to follow-up. **Consider exclusion?**

Coakley 1992	Qualitative	3	++	Thirty-four men and 26 women aged 13–23 years (only three older than 18 years) from an industrial area south-east of London. 85% were White, native [sic] Britons, 15% were Black, Indian or Asian. About 75% from working class families, remainder from middle class families. Half of the interviewees were chosen because of their active involvement in sport and half identified by teachers or program organisers as dropouts or non-participants.	Qualitative study by semi structured interview (45 min) in conjunction with a media-marketing campaign by the British Sports Council in 1985 to 'sell' sport participation to young people, especially 14–18-year-olds working-class youth who had quit or never participated in sport. **Delivered by:** Study commissioned by the regional Sports Council and higher education researchers carried out the interviews. No power calculation.	N/a	Most young people chose leisure activities they thought would prepare them for adult roles or to do adult things (i.e. be independent and autonomous). Young women were more likely to conclude that sport had nothing to do with adulthood while young men were more likely to see sport as compatible with adulthood. Participation was more likely if it was seen as an avenue for extending or displaying competence. Financial constraints had a significant impact on sport participation in both sexes. Young women mentioned parental constraints and the influence of boyfriends as affecting their leisure choices whereas young men tended to 'do what they wanted'. For 13–16-year-olds encouragement from parents was particularly important; for people over 16 years adult advocates and role models were more likely to be important. Decisions about sport participation reflected past experiences and were often associated with feelings of discomfort and embarrassment in young women.	Generally a good study. Attitudes to non-'sport' forms of PA (e.g. dance/yoga) were not considered.
Davis 1996	Questionnaire and focus group – qualitative	3	+	9–11- and 13–14-year-old pupils from four schools in areas of Birmingham with an 'above-average concentration of heads of households in lower occupational classes'. One primary and one	**Aim:** To build an understanding of children's and young people's perceptions of risk and patterns of decision making on transport.	N/a	Children were aware of the health promotion messages that walking and cycling were 'healthy' and that being active was important but felt considerable environmental constraints on their activities. Many were not allowed to play outdoors, use local parks or cycle to school – or they did not feel comfortable doing so. Girls especially were restricted in how late they	Little clarity on data analysis provided and focus group members were not randomly selected. Attitudes to PA

				secondary in the inner suburbs and one primary and one secondary in the outer suburbs.	Semi-structured questionnaire completed by 492 pupils and focus-group discussions with one group from each class taking part in the questionnaire. **Delivered by:** University researchers (health and transport research group). No power calculation.		were allowed out. In the children's views, traffic danger, 'stranger danger' and social and cultural factors interact to create barriers to keeping healthy and active.	from sport and non-sport (e.g. dance/yoga) were not considered.
Safer routes to school								
Parker 2003	Series of before and after studies	2	+	Schools in Worcestershire. No population details provided. Example safer route to school (SRTS) measures were engineering improvements – lighting, crossings, junction changes, traffic calming, footway enhancements, improved school entrances, bus waiting areas. Example STP measures were secure cycle parking, lockers and storage, dry waiting areas, educational	An evaluation using uncontrolled before-and-after methods of 87 SRTS schemes and eight STPs implemented across the county. **Delivered by:** County Council. In all cases, the development and implementation was undertaken with all members of the school community, including questionnaire surveys of pupils at	Ongoing.	From before and after travel surveys at a 1-year interval (using a 'hands up' design) at schools with SRTS measures alone, there was an increase in walking but at the expense of other sustainable travel methods and single occupancy car use also increased. Where STP and SRTS programmes were in place there was a 3% increase in walking, a 4% reduction in single-occupancy car use and a 1.5% increase in car sharing. Bus and cycle use remained largely static.	Series of before and after case studies and no controls (other than SRTS only schools). It is not possible to tell if the changes recorded are a direct result of the STP/SRTS programmes. Annual surveys will be undertaking at schools and longitudinal data will be available at a later date.

				materials (project work, assignments), cycle proficiency training, car sharing, promotional materials (newsletters, posters), rescheduled bus time-tables, maps.	each school. No power calculation.			
Jones 2001	Before and after study and surveys	2	+	Secondary school in East Grinstead, West Sussex. No socio-demographic details.	**Aim:** To develop a SRTS scheme by asking the pupils themselves what problems were deterring them from walking, cycling or using public transport to get to school. The scheme included sheltered cycle parking for upper school, new pedestrian and cycle access, enhanced signing, speed reduction, footway and carriageway maintenance and was implemented and informed by baseline, and 1- and 3-year post-intervention pupil surveys. **Delivered by:** West Sussex County Council.	Ongoing scheme with 1- and 3-year follow-up.	Response rate unknown. At baseline 28% of pupils travelled to school, and 18% travelled home from school by car. Three years after the intervention, these values had dropped to 13 and 7%. Bus use increased considerably (from 44 to 53% to school and from 50 to 56% home), while walking (23–26%, 27–29%) and cycling (3–7%, 3–7%) also increased. At the 3 year survey, cycling was cited as the preferred mode of transport for boys, while girls expressed a preference for the bus. ‘Too dangerous’ was the reason 12% of pupils give for not walking and 14% for not cycling – yet fewer than 7% of the walkers and cyclists themselves said it was dangerous.	Uncontrolled before and after study. Sampling methods for the surveys and response rates unknown. Intervention seems to be a comprehensive, multi-component scheme.

					No power calculation.			
Derek Halden Consultancy 1999	Case studies and surveys	3	++	Scotland-wide. SRTS is a UK-wide campaign. SRTS plans tend to include the following measures: • improved safety and accessibility for walkers and cyclists (e.g. pedestrian crossings, speed cameras, maps); • measures to enhance personal skills of children (e.g. pedestrian and cycle skills training, cycle maintenance training, road safety in curricula); • measures to enhance participation (e.g. publicity, community involvement in promotion/implementation, project evaluation).	**Aim:** To prepare an inventory of SRTS in Scotland and to prepare draft guidance for best practice on such schemes. **Delivered by:** Evaluation by private consultancy commissioned by the Scottish Office Central Research Unit. No power calculation.	Ongoing schemes.	Council and cycle charity (Sustrans, Spoke) questionnaires delivered to all 32 Scottish Unitary Councils, Sustrans the national sustainable transport charity and Spokes the cycle campaign group. 32/34 replied = 94%. Questionnaires were also sent to practitioners taking forward 89 active projects, *n* = 152. 127/152 replied = 84%, but only 51 fully completed since many projects not sufficiently advanced to answer all questions (covering 36 of 89 active projects = 40%). Overall practitioners considered that the presence of vehicles in the vicinity of the school, particularly those of parents of school children, is the major concern, and that improving safety and accessibility for walkers was the main aim, particularly for children crossing busy roads. The authors recommendations for SRTS guidance included: • encourage publicity that identifies for local communities that their involvement in SRTS can make a real difference; • note that many of the measures that can be taken forward within schemes are effective, simple and cheap to implement; • reinforce the need to achieve wide ownership at the outset and a good understanding among partners of their complementary aims; • ensure that there are clearly defined roles for the project champion; • emphasise that projects should be designed for sustainability; • publicise success stories.	Good corroborative evaluation with case studies supported by survey data.

Department of Employment, Training and Rehabilitation 1999	Case series	3	+	Thirty case studies (15 urban, seven inner city, eight rural) of existing school travel initiatives in the UK selected from 92 schools identified through work by Sustrans and the University of Westminster. The 50 schools were selected to give a range of catchment areas, school types, travel patterns, travel plan initiatives and 30 of these were chosen for detailed study.	**Aim:** Case studies of selected school travel initiatives. Questionnaire and interviews with local authorities, school teachers (and sometimes governors), travel mode split survey. The school travel plans varied but common initiatives were engineering changes including traffic calming, car banning and safe routes, improved facilities (e.g. cycle parks), education/promotion **Delivered by:** Schools. No power calculations.	Ongoing.	Only ten of the case studies reported before and after travel arrangements and a common result was an increase in the number of students cycling to school. Of the ten schools, walking increased in four, decreased in six; cycling increased in eight and stayed the same in two; bus travel increased in three, decreased in two and stayed the same in four. Car travel increased in one, decreased in six and stayed the same in three.	Selected case studies. 30 selected from 92. Different sets of data collected within each case study. No overall summary and very difficult to compare results and draw conclusions
Dixey 1999 Dixey 1998	Two surveys plus interview	3	++	Seven primary schools in housing estates on the fringes of Leeds. Sex and age range unknown. Described as predominantly White and working class areas with a mix of council and private housing; relatively disadvantaged with a range of social problems (including high	**Aim:** To present findings of a study regarding supervised journeys, actual and preferred modes of travel, and parent's perceptions of danger. Data were collected from children and parents in 1995 and	1 year.	Response rate unknown (though 75% quoted for the childrens's' questionnaire). 1043 children's and 758 parents' questionnaires returned in 1995, 933 children's and 544 parents' in 1996. From the questionnaire results, the parents and children differed significantly from each other in how they would prefer to get to and from school. Almost 40% would prefer to cycle. A quarter would prefer to travel by car, which is similar to the proportion that does. More	Unclear how many people were surveyed; unclear if survey tool validated. However, combination of quantitative and

				traffic areas) drug users, strangers and litter in the estate used for the qualitative research). Intervention provided by Leeds Road Safety Unit.	1996 to inform an educational road safety education programme (no description). A questionnaire was used (teacher supervised for the children) – questions/details of survey not reported. Interviews were also carried out with 32 mothers of primary school children in one of the estates, (1-hour semi-structured interview). **Delivered by:** University research evaluation. Interviews by professional interviewer.		parents would prefer to use a car than do so. From the qualitative research it appeared that a high profile given to the vulnerability of children in public places has resulted in parents becoming ever vigilant and subjecting children to increased surveillance. Parents had practical ideas about making their environment safer. There was considerable consensus that there were inadequate facilities for young people. Increased school security was also seen to have improved general feelings of safety.	qualitative research and overall good quality study. Nearly one-half of the questionnaire respondents had no paid employment and one-third did not own a car. Of 52 mothers surveyed, 11 had no partner, 19 had no paid employment.
Metcalf 2004	Longitudinal survey	3	++	154 boys and 121 girls in their first year (aged 5 years) at 53 urban primary schools in the UK. Socio-economic details collected but not reported. Recruitment details not provided.	**Aim:** To measure the activity cost of the school run in young children in the EarlyBird study. The children wore uniaxial accelerometers during waking hours for five consecutive schooldays and the weekend. Mode of transport and school	N/a	No attrition reported. Being driven to school does not affect the overall PA of 5-year-olds. Twice as many children walked to school as were driven by car with no significant gender bias – median time 7 min; median distance 0.7 km. Total weekly activity of children walking to school compared with those travelling by car was identical ($p = 0.97$) and the additional activity reported by walkers during the school journey was only 2% of the total weekly activity.	Recruitment details were not provided. Objective measure of PA – uniaxial accelerometers worn during waking hours. The EarlyBird study is

					journey time were assessed by questionnaire and with the RAC's online route planner. Power calculation – 80% to detect a significant difference of 12% school journey activity and 8% total weekly activity.		The authors stated that although the proportion of walkers was highest in the lowest socio-economic group (C 78%, B 63%, A 62%) the pattern was unchanged across groupings. The two groups did not differ in either BMI or sum of skinfold thicknesses.	longitudinal and data for older children will be available in due course.
DiGuiseppi 1998	Cross-sectional	3	++	Survey of primary school children in two inner London boroughs (Camden and Islington). Excluding independent schools (data unavailable), respondents were 54% White, 18% Black, 14% Asian, 15% other, and similar to the school populations.	**Aim:** To survey the travel patterns of urban primary school children to inform the development of strategies to reduce school-related car travel. **Delivered by:** Survey carried out by university researchers, funded by the two London boroughs and the local Health Authority. No power calculation.	N/a	Thirty schools (97%) agreed to participate. Of 2476 enrolled children, 2086 (84%) returned usable questionnaires. Adults accompanied 84% of children to and from school. Most children (61%) were rarely or never allowed out without an adult for school or leisure. Only 3% of bicycle owners were allowed to cycle on main roads. 90% of parents were very or quite worried about abduction or molestation and 89% were very or quite worried about traffic. The strongest predictors of car travel to school were car ownership, greater distance to school, attendance at an independent school, and parental worry about abduction. The authors concluded that parents who currently drive their children might forgo the car for safe, convenient alternatives that address their fears.	Good quality cross-sectional survey.
Thomas 2004	Qualitative	3	–	Series of interviews around the UK with children aged 10–11 years.	**Aim:** To establish childrens' attitudes to their environment and how this affects them.	N/a	In order of frequency and emphasis, children cited traffic, strangers/criminals, being lost, bullying, trains and terrorism as dangers. The overall level of deprivation impacted on children's access to quality space. The authors concluded that new ways should be	Potentially highly flawed study. No methodology description

					Four locations (with large Pakistani, African-Caribbean/Black African, White and disadvantaged populations). **Delivered by:** Unclear (see confounders). No power calculation		found to facilitate environmental education through out of school learning and green school design and children from disadvantaged backgrounds should be given more opportunities to access quality public space.	. Roles of researchers unclear (Demos, 'green alliance'). Results appear consistent across the minority/disadvantaged groups included in study.

EVIDENCE TABLE 5: MULTI-COMPONENT CITY-/COUNTY-/STATE-WIDE INTERVENTIONS WITH POTENTIAL FOR LOCAL IMPLEMENTATION

SUMMARY

Overall, five CBA studies were identified (Osler 1993; Shelley 1995; Baxter 1997; O'Loughlin 1999; Huot 2004) of which one (Baxter) was based in the UK. All five were multi-component interventions aimed at reducing cardiovascular risk factors (including smoking) in adults and employing a range of educational and behavioural strategies such as workshops, seminars, point of choice, educational materials and local multi-media components. Three were broadly city-wide (O'Louglin, Baxter, Osler) and two were county-/state-wide (Huot, Shelley), one with suburban and rural components (Huot). Two looked at lower income populations (O'Loughlin, Baxter).

There was very little evidence of benefit from these interventions in terms of weight, diet and/or PA outcomes.

Evidence of efficacy for weight management/reduction

Three CBA studies measured weight outcomes (O'Loughlin, Baxter, Shelley). O'Loughlin and Baxter looked at lower income populations. None of the studies noted a significant reduction in weight or BMI in the intervention compared with the control communities although Shelley recorded a trend towards weight reduction in the intervention group.

Evidence of efficacy for diet/physical activity outcomes

Four CBAs measured dietary outcomes (Huot, O'Loughlin, Baxter, Osler). Three measured no difference in dietary outcomes between the intervention and control areas (Huot, O'Loughlin, Osler). The UK study (Baxter) observed a single significant change, in that 8.7% more people drank low-fat milk in the intervention population ($p < 0.001$). The authors believed that this change in was largely attributable to a 'wake up to semi-skimmed milk' promotion – leaflets were delivered to 11,000 households over a 2-year period.

Three CBAs measured PA outcomes (O'Loughlin, Baxter, Osler). None of the studies detected a difference between control, although two (O'Loughlin, Osler) noted an increase in PA in both intervention and control populations.

Evidence of corroboration in the UK

One of the studies (Baxter) was carried out in Rotherham, UK.

Cost-effectiveness data

Baxter estimated the cost per life-year gained as £31 in 1997 (but this was based on a reduction in smoking of 6.9% as well as an increase in semi-skimmed milk consumption of 8.7%).

EVIDENCE TABLE 5: MULTI-COMPONENT CITY-/COUNTY-/STATE-WIDE INTERVENTIONS WITH POTENTIAL FOR LOCAL IMPLEMENTATION

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
O'Loughlin 1999	CBA	2	+	St Henri, Montreal, Canada – adults in a low-income, inner city neighbourhood with a population of 25,000. Independent sample survey and longitudinal survey of 52% of independent sample. At baseline in independent sample: *n* = 849 in intervention and *n* = 825 in control. Mean age (years) 38.8 (12.8) in intervention and 36.9 (11.7) in control. 47.3% male in intervention and 52.8% male in control. 72.9% completed high school in intervention and 77.4% in control. 28.4% with insufficient household income	**Aim:** To evaluate the impact of a 4-year community based cardiovascular disease prevention program among adults aged 18–65 years in a low-income inner city neighbourhood. 'Coeur en santé St-Henri' included smoking cessation workshops, nutrition education, menu-labelling and point of choice education, mailed print education materials and screening. No power calculation provided. **Delivered by:** Coeur en santé St-Henri 'run from an ordinary public health department'. Unclear who delivered	Four-year intervention. Three-year follow-up from baseline for repeat independent sample survey and 5-year follow-up from baseline for longitudinal survey (18 months post-intervention).	**Independent sample survey:** Baseline: 79.3% response rate in intervention: 77.8% response rate in control. Follow-up: 70.6% response rate in intervention and 67.2% response rate in control. **Longitudinal survey:** Intervention: 423/849 = 50% follow-up. Control: 396/825 = 48% follow-up. The participation rate in activities was only 2–3%. There were few community-wide programme benefits. In the independent sample there were no statistically significant differences between intervention and control in the OR of BMI ≥27 kg/m^2 (*p* = 0.466) at follow-up. In the longitudinal cohort survey the percentage of subjects with mean BMI ≥27 kg/m^2 increased in intervention by 9.5% and in control by 9.3 (OR 1, 95% CI 0.7,	Reliance on self-report, use of telephone surveys, loss to follow-up in the longitudinal cohort study, and contamination of control site. Also relevant to awareness-raising review.

				in intervention and 33.8% in control Subjects from random samples selected from residential telephone directories.	interventions.		1.6)%.	
Baxter 1997	CBA	2	+	Adults aged 18–64 years in Rotherham, UK. Two intervention areas with a high incidence of coronary heart disease (Swinton and Wath) were compared with a control area (Maltby) with a similar record for coronary heart disease and socio-economic composition. Jarman deprivation scores (and values)/unemployment rates (and values) for intervention areas of Swinton = 12 (1.5)/10 (11.3) and Wath = 9 (–1.2)/7 (10.4) compared with control area Maltby = 14 (3.5)/12(11.8).	**Aim:** To determine whether a community-based coronary heart disease health promotion project was associated with changes in lifestyle risk factors and to estimate whether such an approach was cost-effective. Subjects for the separate cross-sectional surveys at baseline and post-intervention (4 years) randomly selected from the Rotherham Family Health Services Authority register. Power calculation assumed 2% smoking reduction over 3 years. No power calculation for weight control. **Delivered by:**	Four years with surveys at baseline and 4 years.	Response rates to questionnaire 82–86%. There were no weight benefits. Overweight increased in all areas between baseline and follow-up and there were no significant differences in weight change between the intervention and control areas.	The Action Heart health promotion intervention: Incorporating elements of behavioural change (e.g. weight control clinic, stop smoking groups), education (course, leaflets, library resources), empowerment (action heart clubs), medical (screening checks), social change (institutional action heart charter). Questionnaire validated in previous research (references provided). Socio-economic differences between study and control sites so study essentially before and after. Self-reported outcomes. Excellent response rate.

					Health Authority/higher education researchers.			
Shelley 1995	CBA	2	+	Adults in the county of Kilkenny, south-east Ireland (*n* = approximately 70,000) and reference county with shared demographics. **Intervention sample:** Baseline: *n* = 792 (53.3% male, 42.9% aged 35–44 years, 29.4% aged 49–54 years, 27.7% aged 55–64 years). Follow-up: *n* = 802 (50.2% male, 44.4% aged 35–44 years, 31.9% aged 45–54 years, 23.7% aged 55–64 years). **Reference sample:** Baseline: *n* = 604 (51.7% male, 40.2% aged 35–44 years, 32.1% aged 45–54 years, 27.7% aged 55–64 years). Follow-up: *n* = 631	**Aim:** To assess the results of the Kilkenny Health Project in terms of the effect on the major cardiovascular risk factors. Outcomes evaluated by means of population surveys of independent samples in Kilkenny and in equivalent control community. Programme included leaflets, training seminars for health, education and catering personnel, nutrition counselling service and coverage in local media. **Power calculation:** The sample size (900 in intervention and 600 in reference communities) gives a power of 80%, at a two-sided significance level of 5%, to detect differences between the two communities	Five-year health promotion project, with measurements at baseline and 5 years later.	'The final response rates for the surveys were in the range of 70–75% of the self-selected sample' (no data provided). Mean BMI increased by 0.4 kg/m² in men in the intervention area compared with by 1.0 kg/m² in the controls ($p < 0.01$). For women increases were 0.4 and 1.3 kg/m² respectively ($p < 0.01$) in women. The end result was a net but non-significant reduction in BMI gain in both males and females in the intervention compared with the control communities.	Baseline survey in reference group may have taken place after intervention started (1986). Possible contamination of reference group by national media (see above). Self-selected sample. Different cross-sectional samples. No intervention control (although may have seen some national media: 'national media used as little as possible in the early years of the project'.

				(49% male, 43.3% aged 35–44 years, 32.5% aged 45–54 years, 24.2% aged 55–64 years) No socio-economic details provided. Self-selected recruitment – sample of 2000–3000 subjects selected from the register of electors and subjects asked if they wanted to participate. Chosen to ensure spread of age and sex.	of at least 20% in the prevalence of any risk factor. **Delivered by:** Survey nurses.			
Evidence of efficacy (internal validity) for diet outcomes								
Huot 2004	CBA	2	+	Suburban and rural communities in Montreal, Canada. Adults were all parents targeted through their grade 4–6 children at school. Control communities were selected with similar socio-economic data. Pre- and post-analysis was through independent samples and there	**Aim:** To evaluate the dietary impact of multiple community-based cardiovascular disease prevention programmes by means of a validated, self-administered FFQ. **Suburban programme:** Local media articles, taste-testing sessions, meetings/conferences, games in local stores, walking clubs.	Five-year intervention with baseline and 4-year assessment.	Response rates varied among sites from 65% to >80%. Only 4% of the suburban intervention community participated in activities. 19% of the rural group said they had participated in a heart health activity while 15% of the control group also reported involvement, indicating contamination. The interventions did not have any measurable effect on dietary behaviours either within or between groups.	The urban programme was school-based and is not summarised here. Clear differences between the pre and post-test groups could have seriously confounded the results. The Ammerman FFQ was validated with 70 adults and a test/pre-test reliability of 0.78 recorded. Self-reported weight and PA reported in companion paper? – no reference given.

				were variations in socio-economic data at post- compared with pre-test (see confounders). Pooled data (very similar for intervention and control groups): circa 55% female. Mean age circa 40 (SD circa 5.7) years. Primary school education or less at baseline circa 13% and follow-up circa 6%. College or above education at baseline circa 36% and at follow-up circa 46%. Separate data were not provided for rural and suburban communities.	**Rural programme:** Local newspaper articles, screening sessions for hypertension/cholesterolaemia, supermarket tours, healthy recipe booklets, food tasting and cookery sessions, conferences, walking clubs. No power calculation. **Delivered by**: Suburban – unknown. Rural – local volunteers. Evaluation by higher education researchers.		The suburban sites showed improvements in diet in both experimental and control groups while the rural sites showed deterioration in both groups (all non significant). The authors proposed several possible explanations for lack of effect including the difficulty of involving the community in events, cross contamination, problems with the dietary measure and bias from the study design.	
O'Loughlin 1999	CBA	2	+	Adults in St Henri, Montreal, Canada – low-income, inner-city neighbourhood with a population of 25,000. Independent sample survey and longitudinal survey. At baseline in independent survey – *n* = 849 in intervention and	**Aim:** To evaluate the impact of a 4-year community-based cardiovascular disease prevention programme among adults aged 18–65 years in a low-income inner city neighbourhood. 'Coeur en santé St-	Four-year intervention. Three-year follow-up from baseline for repeat independent sample survey and 5-year follow-up from baseline for longitudinal survey (18-	**Independent sample survey:** Baseline: 79.3% response rate in intervention, 77.8% response rate in control. Follow-up: 70.6% response rate in intervention and 67.2% response rate in control. **Longitudinal survey:** Intervention: 423/849 = 50% follow-up	Reliance on self-report, use of telephone surveys, loss to follow-up in the longitudinal cohort study, and contamination of control site. Also relevant to awareness raising review.

				n = 825 in control. Mean age: 38.8 (SD 12.8) in intervention and 36.9 (SD 11.7) years in control. 47.3% male in intervention and 52.8% male in control. 72.9% completed high school in intervention and 77.4% in control. 28.4% with insufficient household income in intervention and 33.8% in control. Subjects from random samples selected from residential telephone directories.	Henri' included smoking cessation workshops, nutrition education, menu-labelling and point-of-choice education, mailed print education materials and screening. No power calculation provided. **Delivered by:** Coeur en santé St-Henri 'run from an ordinary public health department'. Unclear who delivered interventions.	months post-intervention).	Control: 396/825 = 48% follow-up The participation rate in activities was only 2–3% and there were few community wide programme effects. In the independent sample there were no statistically significant differences between intervention and control in the ORs of high-fat/junk food consumption at follow-up ($p = 0.442$). In the longitudinal cohort survey there were no significant declines in the prevalence of high fat/junk food consumption in either community.	
Baxter 1997	CBA	2	+	Adults aged 18–64 years in Rotherham, UK. Two intervention areas with a high incidence of coronary heart disease (Swinton and Wath) were compared with a control area (Maltby) with a similar record for coronary heart disease and socio-	**Aim:** To determine whether a community-based coronary heart disease health promotion project was associated with changes in lifestyle risk factors and to estimate whether such an approach was cost-effective. Subjects for the	Four years with surveys at baseline and 4 years.	Response rates to questionnaire 82–86%. Low-fat milk consumption increased in both intervention and control areas from baseline to follow but 8.7% more people drank low-fat milk ($p < 0.001$) in the intervention area compared with the control area. No other statistically significant changes between the areas were detected. The authors believed that the change in low-fat milk consumption was largely	The Action Heart health promotion intervention: Incorporating elements of behavioural change (e.g. weight control clinic, stop smoking groups), education (course, leaflets, library resources), empowerment (action heart clubs), medical (screening checks), social change (institutional action heart charter).

				economic composition. Jarman deprivation scores (and values)/unemployment rates (and values) for intervention areas of Swinton = 12 (1.5)/10 (11.3) and Wath = 9 (–1.2)/7 (10.4) compared with control area Maltby = 14 (3.5)/12 (11.8).	separate cross-sectional surveys at baseline and post-intervention (4 years) were randomly selected from the Rotherham Family Health Services Authority register. Power calculation assumed 2% smoking reduction over 3 years. No calculation re diet outcomes. **Delivered by:** Health Authority/higher education researchers.		attributable to a 'wake up to semi-skimmed milk' promotion as part of the intervention – leaflets were delivered to 11,000 households in the intervention area over a 2-year period.	Questionnaire validated in previous research (references provided). Socio-economic differences between study and control sites so study essentially before and after. Self-reported outcomes. Excellent response rate.
Osler 1993	CBA	2	+	Adults in two municipalities in rural Denmark. Control municipality had comparable population parameters. **Intervention:** *n* = 1010 (1989) and *n* = 1003 (1990). 52% female, 84% married or cohabiting, 56% with more than 3 years education and 20% with none. Age range 20–	**Aim:** To assess the effect of a community-based cardiovascular disease prevention project on awareness and health behaviours. Activities (fitness tests, exercise, smoking cessation programmes, safety education and demonstration of how to buy healthy food). Heart Week organised after 6 months with	Intervention throughout 12 months? One-year follow-up from baseline (6 months from 'Heart week').	51% of total sample (intervention and control) responded to cross-sectional surveys in 1989, and 59% of total sample responded in 1990. Response rate lowest amongst men aged 20–24 years and highest amongst women aged 44–65 years. Unmarried and divorced people under-represented in sample. 39% of respondents ate less fat with no difference between intervention and control area. Sex (Female?) ($p < 0.001$) and health beliefs (own effort is	Low response rate. Evaluation of study possibly not sufficiently sensitive to detect an acceleration of an already observed upturn in health behaviour in Denmark. Integration of programme into community social organisations didn't appear to work. Difficult to recruit volunteers and elements of group activities and face-to-face interaction were of limited proportions and based on self-selection,

				65 years, 78% between 25 and 54 years old. **Control:** *n* = 1092 (1989) and *n* = 1109 (1990) 50% female, 83% married or cohabiting, 54% with more than 3 years education and 19% with none. Age range 20–65 years, 75% between 25 and 54 years old.	activities and mass media (cinema, newspaper and radio) campaign. **Delivered by:** Volunteers organised by a paid project coordinator, led by a steering committee with members of the Health Council under the local Health Administration. No power calculation provided.		important) ($p < 0.001$) predicted attained changes in fat consumption.	and the project ended up as a pure mass media campaign.
Evidence of efficacy (internal validity) for physical activity outcomes								
O'Loughlin 1999	CBA	2	+	Adults in St Henri, Montreal, Canada – low-income, inner city neighbourhood with a population of 25,000. Independent sample survey and longitudinal survey. At baseline in independent sample *n* = 849 in intervention and *n* = 825 in control. Mean age 38.8 (12.8) years in intervention and 36.9 (11.7) years in control. 47.3% male in intervention and 52.8% male in	**Aim:** To evaluate the impact of a 4-year community-based cardiovascular disease prevention program among adults aged 18–65 years in a low-income inner city neighbourhood. 'Coeur en santé St-Henri' included smoking cessation workshops, nutrition education, menu-labelling and point of choice education, mailed print education materials	Four-year intervention. Three-year follow-up from baseline for repeat independent sample survey and 5-year follow-up from baseline for longitudinal survey (18 months post-intervention).	**Independent sample survey:** Baseline: 79.3% response rate in intervention, 77.8% response rate in control. Follow-up: 70.6% response rate in intervention, 67.2% response rate in control. **Longitudinal survey:** Intervention: 423/849 = 50% follow-up. Control 396/825 = 48% follow-up. Participation rate in activities was only 2–3% and there were few community-wide programme effects. In the independent sample survey models for physical inactivity, the adjusted OR for infrequent leisure time PA	Reliance on self-report, use of telephone surveys, loss to follow-up in the longitudinal cohort study, and contamination of control site.

				control. 72.9% completed high school in intervention and 77.4% in control. 28.4% with insufficient household income in intervention and 33.8% in control Subjects from random samples selected from residential telephone directories.	and screening. No power calculation provided. **Delivered by:** Coeur en santé St-Henri 'run from an ordinary public health department'. Unclear who delivered interventions.		in intervention was 1.9 compared with 2.8 in control, indicating that PA increased more in control group, but this did not reach statistical significance (p = 0.063). In the longitudinal cohort survey there were no significant declines in the prevalence of physical inactivity between communities, both of which reported an increase in PA (+16.3% in the intervention and +13.5% in the control communities).	
Baxter 1997	CBA	2	+	Adults aged 18–64 years in Rotherham, UK. Two intervention areas with a high incidence of coronary heart disease (Swinton and Wath) were compared with a control area (Maltby) with a similar record for coronary heart disease and socio-economic composition. Jarman deprivation scores (and values)/unemployment rates (and values) for intervention areas	**Aim:** To determine whether a community based coronary heart disease health promotion project was associated with changes in lifestyle risk factors and to estimate whether such an approach was cost-effective. Subjects for the separate cross-sectional surveys at baseline and post-intervention (4 years) were randomly selected from the Rotherham Family Health Services Authority register. Power calculation	Four years with surveys at baseline and 4 years.	Response rates to questionnaire 82–86%. No PA changes were detected between baseline and follow-up in either the intervention or the control group.	The Action Heart health promotion intervention: incorporating elements of behavioural change (e.g. weight control clinic, stop smoking groups), education (course, leaflets, library resources), empowerment (action heart clubs), medical (screening checks), social change (institutional action heart charter). Questionnaire validated in previous research (references provided). Socio-economic differences between study and control sites so study essentially before and after. Self-

				of Swinton = 12 (1.5)/10 (11.3) and Wath = 9 (–1.2)/7 (10.4) compared with control area Maltby = 14 (3.5)/12(11.8).	assumed 2% smoking reduction over 3 years. No power calculation for PA outcomes. **Delivered by:** Health Authority/higher education researchers.			reported outcomes. Excellent response rate.
Osler 1993	CBA	2	+	Adults in two municipalities in rural Denmark. Control municipality had comparable population parameters. **Intervention:** *n* = 1010 (1989) and *n* = 1003 (1990). 52% female, 84% married or cohabiting, 56% with more than 3 years education and 20% with none. Age range 20–65 years, 78% between 25 and 54 years old. **Control:** *n* = 1092 (1989) and *n* = 1109 (1990). 50% female, 83% married or	**Aim:** To assess the effect of a community-based cardiovascular disease prevention project on awareness and health behaviours. Activities (fitness tests, exercise, smoking cessation programmes, safety education and demonstration of how to buy healthy food). Heart Week organised after 6 months with activities and mass media (cinema, newspaper and radio) campaign. **Delivered by:** Volunteers organised by a paid project coordinator, led by a steering committee	Intervention throughout 12 months? One-year follow-up from baseline (6 months from ‘Heart week’).	51% of total sample (intervention and control) responded to cross-sectional surveys in 1989, and 59% of total sample responded in 1990. Response rate lowest amongst men aged 20–24 years and highest amongst women aged 44–65 years. Unmarried and divorced people under-represented in sample. 28% did more exercise with no difference between intervention and control area. 13% and 15% reported being physically inactive in intervention and control areas at baseline. At follow-up 20% reported being physically inactive in both areas. Age ($p = 0.01$) and health beliefs (own effort is important) ($p < 0.001$) predicted attained changes in PA.	Low response rate. Evaluation of study possibly not sufficiently sensitive to detect an acceleration of an already observed upturn in health behaviour in Denmark. Integration of programme into community social organisations didn’t appear to work. Difficult to recruit volunteers and elements of group activities and face-to-face interaction were of limited proportions and based on self-selection, and the project ended up as a pure mass media campaign.

				cohabiting, 54% with more than 3 years education and 19% with none. Age range = 20–65 years, 75% between 25 and 54 years.	with members of the Health Council under the local Health Administration. No power calculation provided.			

Evidence of corroboration (external validity)

Evidence of salience – Is it appropriate for the UK?

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/Comments**
Baxter 1997	CBA	2	+	Adults aged 18–64 years in Rotherham, UK.	See above.	See above.	See above.	See above.

Evidence for implementation – Will it work in the UK?

Overall strength of evidence of corroboration =

First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**

SEARCH STRATEGIES

1. exp OBESITY/
2. exp Weight Gain/
3. exp Weight Loss/
4. obes$.ti,ab.
5. (weight gain or weight loss).ti,ab.
6. (overweight or over weight or overeat$ or over eat$).ti,ab.
7. weight change$.ti,ab.
8. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
9. body mass.ti,ab.
10. or/1-9
11. exp Behavior Therapy/
12. exp Social Support/
13. exp Family Therapy/
14. exp Psychotherapy, Group/
15. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
16. (group therapy or family therapy or cognitive therapy).ti,ab.
17. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.
18. counsel?ing.ti,ab.
19. social support.ti,ab.
20. (peer adj2 support).ti,ab.
21. (children adj3 parent$ adj therapy).ti,ab.
22. or/11-21
23. exp OBESITY/dh [Diet Therapy]
24. exp Diet, Fat-Restricted/
25. exp Diet, Reducing/
26. exp Diet Therapy/
27. exp FASTING/
28. diet$.ti,ab.
29. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).ti,ab.
30. (low calorie or calorie control$ or healthy eating).ti,ab.
31. (fasting or modified fast$).ti,ab.
32. exp Dietary Fats/
33. (fruit or vegetable$).ti,ab.
34. (high fat$ or low fat$ or fatty food$).ti,ab.
35. formula diet$.ti,ab.
36. or/23-35
37. exp EXERCISE/
38. exp Exercise Therapy/
39. exercis$.ti,ab.
40. (aerobics or physical therapy or physical activity or physical inactivity).ti,ab.
41. (fitness adj (class$ or regime$ or program$)).ti,ab.
42. (aerobics or physical therapy or physical training or physical education).ti,ab.
43. dance therapy.ti,ab.
44. sedentary behavio?r.ti,ab.
45. or/37-44
46. exp Complementary Therapies/
47. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
48. (hypnotism or hypnosis or hypnotherapy).ti,ab.
49. (acupuncture or homeopathy or homoeopathy).ti,ab.
50. (chinese medicine or indian medicine or herbal medicine or ayurvedic).ti,ab.
51. or/46–50
52. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
53. (weightwatcher$ or weight watcher$).ti,ab.
54. (correspondence adj (course$ or program$)).ti,ab.
55. (fat camp$ or diet$ camp$).ti,ab.
56. or/52-55
57. exp Health Promotion/
58. exp Health Education/
59. mass media/
60. (health promotion or health education).ti,ab.

61. (media intervention$ or community intervention$).ti,ab.
62. (community adj2 program$).ti,ab.
63. (family intervention$ or parent$ intervention$).ti,ab.
64. or/57-63
65. exp Health Policy/
66. exp Nutrition Policy/
67. (health polic$ or food polic$ or nutrition polic$).ti,ab.
68. or/65-67
69. exp OBESITY/pc [Prevention & Control]
70. exp Primary Prevention/
71. (primary prevention or secondary prevention).ti,ab.
72. (preventive measure$ or preventative measure$).ti,ab.
73. (preventive care or preventative care).ti,ab.
74. (obesity adj2 (prevent$ or treat$)).ti,ab.
75. or/69-74
76. exp Controlled Clinical Trials/
77. exp Random Allocation/
78. exp Double-Blind Method/
79. exp Single-Blind Method/
80. exp PLACEBOS/
81. exp Research Design/
82. exp Intervention Studies/
83. exp Evaluation Studies/
84. exp Cost Benefit Analysis/
85. (time adj series).tw.
86. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
87. exact{CONTROLLED-CLINICAL-TRIAL}.pt.
88. placebo$.ti,ab.
89. (matched communities or matched populations).ti,ab.
90. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
91. (comparison group$ or control group$).ti,ab.
92. matched pairs.ti,ab.
93. (outcome study or outcome studies).ti,ab.
94. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
95. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
96. randomi?ed.hw.
97. (cohort or survey: or qualitative).ti,ab.
98. or/76-97
99. exp Meta-Analysis/
100. meta-analys$.ti,ab.
101. metaanalys$.ab,ti.
102. meta analys$.ab,ti.
103. Cochrane.ab,sh,ti.
104. (review$ or overview$).ti.
105. review$.pt.
106. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
107. pooled analys$.ab,ti.
108. ((data adj2 pool$) and studies).mp.
109. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
110. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
111. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
112. or/99-111
113. (retrospective$ adj2 review$).ab,sh,ti.
114. (case$ adj2 review$).ab,sh,ti.
115. (record$ adj2 review$).ab,sh,ti.
116. (patient$ adj2 review$).ab,sh,ti.
117. (patient$ adj2 chart$).ab,sh,ti.
118. (peer adj2 review$).ab,sh,ti.
119. (chart$ adj2 review$).ab,sh,ti.
120. (case$ adj2 report$).ab,sh,ti.
121. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.

122. or/113-121
123. 122 not (122 and 112)
124. 112 not 123
125. 22 or 36 or 45 or 51 or 56 or 64 or 68 or 75
126. 10 and 98 and 125
127. 10 and 124 and 125
128. 126 or 127
129. Residence characteristics/
130. Community Health Planning/
131. Community Health Services/
132. Community-Institutional Relations/
133. Public Health/
134. Environment Design/
135. City planning/
136. Social Environment/
137. Housing/
138. Restaurants/
139. restaurant$.ti,ab.
140. neighbo?rhood$.ti,ab.
141. community wide.af.
142. built environment$.ti,ab.
143. shop$.ti,ab.
144. supermarket$.ti,ab.
145. vending machine$.ti,ab.
146. food desert$.ti,ab.
147. church$.ti,ab.
148. urban environment$.ti,ab.
149. (barriers adj10 food).ti,ab.
150. guide to community preventive services.ti,ab.
151. (youth club$ or gym$ or leisure cent$ or leisure service$).ti,ab.
152. or/129-151
153. 128 and 152
154. animal.sh.
155. human.sh.
156. 154 not (154 and 155)
157. 153 not 156
158. limit 157 to yr=1990-2005

DATA SOURCES

The following information sources were searched during April 2005:

AMED (Allied and Complementary Medicine)
ASSIA (Applied Social Sciences Index and Abstracts)
British Nursing Index
CAB Abstracts - Human health and nutrition, agriculture
CENTRAL (Cochrane Controlled Trials Register)
CINAHL (Cumulative Index to Nursing & Allied Health Literature
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
NHS EED (NHS Economic Evaluation Database) - http://www.york.ac.uk/inst/crd
DARE (Database of Abstracts of Reviews of Effects)
Embase
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC (Educational Resources Information Centre)
Food Standards Agency - http://www.food.gov.uk/science/research/
HDA Evidence Base - http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.org
Medline
NCCHTA (National Coordinating Centre for Health Technology Assessment) - http://www.ncchta.org
NICE (National Institute for Clinical Excellence) – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN (Scottish Intercollegiate Guidelines Network) – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus
Urbadisc

Update searches
An update search of the same databases was carried out in September 2005 for worldwide intervention and UK corroborative studies. A final search was completed on 1 December 2005 for systematic reviews and controlled trials only in a reduced number of databases: CINAHL, Cochrane, Embase, Medline and PsycINFO.

The electronic search strategies (see part c, supporting information) were developed in Medline and adapted for use with the other information sources. Additional papers were identified from reference lists and (*n* = 7) by members of the GDG.

EXCLUDED REFERENCES

Papers excluded: non UK-corroborative

Paper	Reason for exclusion
Addy CL, Ainsworth BE, Kimsey D, Kirtland KA, Sharpe P, Wilson DK. Associations of perceived social and physical environmental supports with physical and walking behaviour. *American Journal of Public Health* 2004;94(3):440–3.	Non-UK corroborative – excluded due to lack of time.
Anonymous. The national bicycling and walking study. Case study number 1: Reasons why bicycling and walking are not used more extensively as travel modes. US Department of Transportation. Washington DC; 1994.	Non-UK corroborative – excluded due to lack of time.
Appleyard BS. Planning safe routes to school. *Planning* 2003;69(5):34–7.	Non-UK corroborative – excluded due to lack of time.
Ashton B, Hehir A. Working with private partner organizations to address public health nutrition issues: a case study*. Nutrition and Dietetics* 2002;59:43–7.	Non-UK corroborative – excluded due to lack of time.
Ball K, Crawford D, Warren N. How feasible are healthy eating and physical activity for young women? *Public Health Nutrition* 2004;7(3):433–41.	Non-UK corroborative – excluded due to lack of time.
Bauman AE, Humpel N, Leslie E, Marshall AL, Owen N, Sallis JF. Association of location and perceived environmental attributes with walking in neighbourhoods. *American Journal of Health Promotion* 2004;18(3):239–42.	Non-UK corroborative – excluded due to lack of time.
Benson W. Strategies and willingness of rural restaurateurs to promote healthy foods. *Canadian Journal of Public Health* 1995;86(3):181–4.	Non-UK corroborative – excluded due to lack of time.
Blanchard CM, McGannon KR, Spence JC et al. Social ecological correlates of physical activity in normal weight, overweight, and obese individuals. *International Journal of Obesity* 2005;29(6):720–6.	Non-UK corroborative – excluded due to lack of time.
Boarnet MG, Anderson CL, Day K, McMillan T, Alfonzo M. Evaluation of the California Safe Routes to School legislation: urban form changes and children's active transportation to school. *American Journal of Preventive Medicine* 2005;28(2)(Suppl 2):134–40.	Non-UK corroborative – excluded due to lack of time.
Braza M, Seeley A, Shoemaker W. Neighborhood design and rates of walking and biking to elementary school in 34 California communities. *American Journal of Health Promotion* 2004;19(2):128–36.	Non-UK corroborative – excluded due to lack of time.
Brownson RC, Housemann RA, Brown DR et al. Promoting physical activity in rural communities: walking trail access, use and effects. *American Journal of Preventive Medicine* 2000;18(3):235–41.	Non-UK corroborative – excluded due to lack of time.
Centers for Disease Control and Prevention. *Kids walk to school: a guide to promote walking to school.* Washington DC: Department of Health and Human Services; 1999.	Non-UK corroborative – excluded due to lack of time.
Cho MH. The strength of motivation and physical activity level during leisure time among youth in South Korea. *Youth and Society* 2004;35(4):480–94.	Non-UK corroborative – excluded due to lack of time.
Clark DO, Nothwehr F. Exercise self-efficacy and its correlates among	Non-UK corroborative –

socio-economically disadvantaged older adults. *Health Education and Behaviour* 1999;26(4):535–46.	excluded due to lack of time.
Clarke A, Dornfeld M. *National bicycling and walking study. FHWA case study no. 19: Traffic calming, auto-restricted zones and other traffic management techniques – Their effects on bicycling and pedestrians.* Report no. FHWA-PD-93-028. Washington DC: Federal Highway Administration; 1994.	Non-UK corroborative – excluded due to lack of time.
Corti B, Donovan RJ, Holman CDJ. Factors influencing the use of physical activity facilities: results from qualitative research. *Health Promotion Journal of Australia* 1996;6(1):16–21.	Non-UK corroborative – excluded due to lack of time.
Cotugna N, Vickery CE. Development and supermarket field testing of videotaped nutrition messages for cancer risk reduction. *Public Health Reports*. 1992;107(6):691–4.	Non-UK corroborative – excluded due to lack of time.
Cox R, Parker G, Watson A et al. Dietary cancer risk of low-income women and change with intervention. *Journal of the American Dietetic Association*. 1995;95:1031–4.	Non-UK corroborative – excluded due to lack of time.
Darbyshire P, McDougall C, Schinder W. We have to live in the future*.* *Early Child Development and Care* 2004;174(3):369–87.	
Duncan HH, Travis SS, McAuley WJ. An emergent theoretical model for interventions encouraging physical activity (mall walking) among older adults. *Journal of Applied Gerontology* 1995;14(1):64–77.	Non-UK corroborative – excluded due to lack of time.
Duncan M, Mummery K. Psychosocial and environmental factors associated with physical activity among city dwellers in regional Queensland. *Preventive Medicine* 2005;40(4):363–72.	Non-UK corroborative – excluded due to lack of time.
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Frank LD, Engelke PO, Schmid TL. *Health and community design: the impact of the built environment on physical activity.* Washington DC: Island Press; 2003.	Non-UK corroborative – excluded due to lack of time.
Frazao E. *America's eating habits: changes and consequences.* Washington, DC: USDA/Economic Research Services 1999.	Non-UK corroborative – excluded due to lack of time.
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Gehl J, Gemzoe L. *Public spaces, public life*. Copenhagen: Danish Architectural Press; 1999.	Non-UK corroborative – excluded due to lack of time . NB: Reference from paper suggested by GDG.
Giles-Corti B, Donovan RJ. The relative influence of individual, social and physical environment determinants of physical activity. *Social Science and Medicine* 2002;54:1793–1812.	Non-UK corroborative – excluded due to lack of time
Go for Green/Environics. *National survey on active transportation: summary report*. Ottawa, Canada: Go for Green/Environics; 1998.	Non-UK corroborative – excluded due to lack of time
Godbey G, Graefe A, James, SW. The benefits of local recreation and park services: a nationwide study of the perceptions of the American public. Pennsylvania: Pennsylvania State University;1992.	Non-UK corroborative – excluded due to lack of time
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Green J, Waters E, Haikerwal A et al. Social, cultural and environmental influences on child activity and eating in Australian migrant communities. *Child Care Health and Development*. 2003;29(6):411–8.	Non-UK corroborative – excluded due to lack of time.
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Mitchell SA, Olds RS. Psychological and perceived situational predictors of physical activity: a cross-sectional analysis*. Health Education Research* 1999;14:305–13.	Non-UK corroborative – excluded due to lack of time.
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O'Loughlin J, Ledoux J, Barnett T. La Commande du Coeur (‘Shop for your Heart’): a point-of-choice nutrition education campaign in a low-income urban neighbourhood. *American Journal of Health Promotion* 1996;10(3):175–8.	Non-UK corroborative – excluded due to lack of time.
Pikora T, Giles-Corti B, Bull F, Jamrozik K, Donovan R. Developing a framework for assessment of the environmental determinants of walking and cycling. *Social Science and Medicine* 2003;56(8):1693–1703.	Non-UK corroborative – excluded due to lack of time.
Pucher J. Urban transport in Germany: providing feasible alternatives to the car. *Transport Reviews* 1998;18(4):285–310.	Non-UK corroborative – excluded due to lack of time.
Pucher J, Dijkstra L. Promoting safe walking and cycling to improve public health: lessons from the Netherlands and Germany. *American Journal of Public Health* 2003;93(9):1509–16.	Non-UK corroborative – excluded due to lack of time.
Reed JA, Ainsworth BE, Wilson DK, Mixon G, Cook A. Awareness and use of community walking trails. *Preventive Medicine* 2004;39(5):903–8.	Non-UK corroborative – excluded due to lack of time.
Reicks M, Mills J, Henry H. Qualitative study of spirituality in a weight loss program: Contribution to self-efficacy and locus of control. *Journal of Nutrition Education and Behaviour* 2004;36(1):13–19.	Non-UK corroborative – excluded due to lack of time.

Rouffignat J, Vallee A. Changes in eating habits and urban-environment – development of the restaurant industry in metropolitan-area of Quebec City. *Canadian Geographer – Geographe Canadien* 1990;34(3):194–208.	Non-UK corroborative – excluded due to lack of time.
Rutt CD. Individual, social, and environmental correlates of physical activity and body mass index in El Paso, Texas. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2004; 65; 6-B)	Non-UK corroborative – excluded due to lack of time.
Sallis JF, Hovell MF, Hofstetter CR. Predictors of adoption and maintenance of vigorous physical activity in men and women. *Preventive Medicine* 1992;21:237–51.	Non-UK corroborative – excluded due to lack of time.
Sallis JF, Johnson KJ, Calfas S, Caparosa S, Nichols JF. Assessing perceived physical environment variables that may influence physical activity. *Research Quarterly for Exercise and Sport* 1997;68:345–51.	Non-UK corroborative – excluded due to lack of time.
Sanderson B, Littleton MA, Pulley LV. Environmental, policy, and cultural factors related to physical activity among rural, African American women. *Women and Health* 2002;36(2):75–90.	Non-UK corroborative – excluded due to lack of time.
Scott D, Munson W. Perceived constraints to park usage among individuals with low incomes. *Journal of Park and Recreation Administration* 1994;12:52–69.	Non-UK corroborative – excluded due to lack of time.
Scott J, Wadley D, Ziviani J. Walking to school: incidental physical activity in the daily occupations of Australian children. *Occupational Therapy International* 2004;11(1):1–11.	
Sharpe PA, Granner ML, Hutto B, Ainsworth BE. Association of environmental factors to meeting physical activity recommendations in two South Carolina counties. *American Journal of Health Promotion* 2004;18(3):251–7.	Non-UK corroborative – excluded due to lack of time.
Shepherd SK, Sims LS. Employing cognitive response analysis to examine message acceptance in nutrition education. *Journal of Nutrition Education* 1990;22(5):215–9.	Non-UK corroborative – excluded due to lack of time.
Shriver K. Influence of environmental design on pedestrian travel in four Austin neighborhoods. *Transportation Research Record* 1997;1578:64–75.	Non-UK corroborative – excluded due to lack of time.
Simmons D, McKenzie A, Eaton S et al. Choice and availability of takeaway and restaurant food is not related to the prevalence of adult obesity in rural communities in Australia. *International Journal of Obesity* 2005;29(6):703–10.	Non-UK corroborative – excluded due to lack of time.
Sirard JR, Ainsworth BE, McIver KL, Pate RR. Prevalence of active commuting at urban and suburban elementary schools in Columbia, SC. *American Journal of Public Health* 2005;95(2):236–7.	Non-UK corroborative – excluded due to lack of time.
Steenhuis IHM, Van Assema P, Glanz K. Strengthening environmental and educational nutrition programmes in worksite cafeterias and supermarkets in the Netherlands. *Health Promotion International* 2001;16(1):21–33.	Non-UK corroborative – excluded due to lack of time.
Stone G. 'Walk it, bike it, bus it': perceptions of active modes of transport. *World Transport Policy and Practice* 2003;9(3):15–25.	Non-UK corroborative – excluded due to lack of time.
Story M, Neumark-Sztainer D, French S. Individual and environmental influences on adolescent eating behaviors. *Journal of the American Dietetic Association* 2002;102:S40–51.	Non-UK corroborative – excluded due to lack of time.
Sutherland M, Hale CD, Harris GJ. Community health promotion: the	Non-UK corroborative –

church as partner. *Journal of Primary Prevention* 1995;16(2):201–16.	excluded due to lack of time.
Timperio A, Crawford D, Telford A, Salmon J. Perceptions about the local neighborhood and walking and cycling among children. *Preventive Medicine* 2004;38(1):39–47.	Non-UK corroborative – excluded due to lack of time.
Timperio A, Salmon J, Telford A, Crawford D. Perceptions of local neighbourhood environments and their relationship to childhood overweight and obesity. *International Journal of Obesity* 2005;29(2):170–5.	Non-UK corroborative – excluded due to lack of time.
Titze S, Stronegger W, Owen N. Prospective study of individual, social, and environmental predictors of physical activity: women's leisure running. *Psychology of Sport and Exercise* 2005;6:363–76.	Non-UK corroborative – excluded due to lack of time.
Tully AM. Ireland's national dairy council's '3-a-day' campaign: the Irish perspective*. British Nutrition Foundation* 2005;30:182–5.	Non-UK corroborative – excluded due to lack of time.
Vereecken CA, Van Damme W, Maes L. Measuring attitudes, self-efficacy, and social and environmental influences on fruit and vegetable consumption of 11- and 12-year-old children: reliability and validity. *Journal of the American Dietetic Association* 2005;105:257–61.	Non-UK corroborative – excluded due to lack of time.
Wells BL, Brown CC, Horm JW, Carleton RA, Lasater TM. Who participates in cardiovascular-disease risk factor screenings - experience with a religious organization based program. *American Journal of Public Health* 1994;84(1):113–5.	Non-UK corroborative – excluded due to lack of time.
Wiggers J, Considine R, Hazell T, Haile M, Rees M, Daly J. Increasing the practice of health promotion initiatives by licensed premises. *Health Education Behaviour* 2001;28:331–40.	Non-UK corroborative – excluded due to lack of time.
Yancey A, Miles O, Jordan A. Organizational characteristics facilitating initiation and institutionalization of physical activity programs in a multiethnic urban community. *Journal of Health Education* 1999;30(2):44–51.	Non-UK corroborative – excluded due to lack of time.

Other excluded papers

Paper	**Reason for exclusion**
Aaron JI, Evans RE, Mela DJ. Paradoxical effect of a nutrition labelling scheme in a student cafeteria. *Nutrition Research* 1995;15(9):1251–61.	Less than 3 months follow-up.
Achabal DD, McIntyre SH, Bell CH, Tucker N. The effect of nutrition P-O-P signs on consumer attitudes and behaviour. *Journal of Retail* 1987;63:9–24.	Country-wide intervention and not suitable for local implementation.
Albright CL, Flora JA, Fortmann SP. Restaurant menu labeling: Impact of nutrition information on entree sales and patron attitudes. *Health Education Quarterly* 1990;17(2):157–67.	Less than 3-months follow-up.
Allison DB, Weber MT. Treatment and prevention of obesity: what works, what doesn't work, and what might work*. Lipids* 2003;38(2):147–55.	Broad conceptual overview.
Ammerman AS, Lindquist CH, Lohr KN, Hersey J. The efficacy of behavioural interventions to modify dietary fat and fruit and vegetable intake: a review of the evidence. *Preventive Medicine* 2002;35:25–41.	No relevant papers.
Ammerman AS, Lindquist CH, Hersey J et al. *The efficacy of interventions*	Not possible to separate

to modify dietary behaviour related to cancer risk. AHRQ Evidence Report 25. Rockville: Agency for Healthcare Research and Quality, June 2001.	community from other interventions. Information in appendices does not match info in results chapters.
Andersen RE, Franckowiak SC, Snyder J, Bartlett SJ, Fontaine KR. Can inexpensive signs encourage the use of stairs? Results from a community intervention. *Annals of Internal Medicine* 1998;29(5):363–69.	Covered by systematic review 2000.
Anderson ES, Winett RA, Wojcik JR. Social-cognitive determinants of nutrition behavior among supermarket food shoppers: A structural equation analysis. *Health Psychology* 2000;19(5):479–86.	Behavioural/psychological analysis of healthy food-purchasing and methods of changing choices.
Anderson J, Haas MH. Impact of a nutrition education program on food sales in restaurants. *Journal of Nutrition Education* 1990;22:232–8.	No control group.
Anderson A, Cox D. Five a day – challenges and achievement. *Nutrition and Food Science* 2000;30(1):30–34.	– Quality corroboration study.
Anlinker JA, Winne M, Drake LT. An evaluation of the Connecticut farmers' market coupon program. *Journal of Nutrition Education* 1992;24(4):185–91.	Less than 3-months follow-up.
Anonymous. NHS can save billions by encouraging active travel. *SportEX Health* 2003;15:6.	Small news item about Sustrans leaflet launch.
Anonymous. Food issues: a partnership approach. *Community Health UK Action* 2004;63:14–5.	Discussion paper.
Aoun P, Brecht III CR, Gambert SR. Diabetes mellitus: Present and future preventive strategies – Part II. *Clinical Geriatrics* 2005;13(7):30–32.	All subjects with impaired glucose tolerance.
Balding J, Gimber P, Regis D, Wise A. A quarter of year 7 young men want to cycle to school. *Education and Health* 1997;15(4):49–52.	Survey of method of transport to school – no relevant information given.
Baranowski T, Anderson C, Carmack C. Mediating variable frame work in physical activity intervention. *American Journal of Preventive Medicine* 1998;15:266–97.	Behavioural science.
Baranowski T, Mendlein J, Resnicow K, Frank E, Cullen KW, Baranowski J. Physical activity and nutrition in children and youth: an overview of obesity prevention. *Preventive Medicine* 2000;31(2):S1–10.	Narrative overview – reference list checked.
Barnhart JM, Mossavar-Rahmani Y, Nelson M, Raiford Y, Wylie-Rosett J. Innovations in practice: an innovative, culturally sensitive dietary intervention to increase fruit and vegetable intake among African American women: a pilot study. *Topics in Clinical Nutrition* 1998;13:63–71.	Passed to Teesside.
Barton H, Baker J. Sustainability appraisal of plans. One day short course; 2004, Nov 5; Bristol, UK	Not relevant to review.
Batch JA, Baur LA. Management and prevention of obesity and its complications in children and adolescents. *Medical Journal of Australia* 2005;182(3):130–5.	Narrative overview.
Bedimo-Rung AL, Mowen AJ, Cohen DA. The significance of parks to physical activity and public health – A conceptual model. *American Journal of Preventive Medicine* 2005;28(2):159–68.	Discussion paper – relevant papers obtained.

Biddle SJH, Gorely T, Stensel DJ. Health-enhancing physical activity and sedentary behaviour in children and adolescents. *Journal of Sports Sciences* 2004;22(8):679–701.	Non-systematic review.
Blamey A, Mutrie N, Aitchison T. Health promotion by encouraged use of stairs. *British Medical Journal* 1995;311(7000):289–290.	Covered by systematic review evidence up to 2000.
Bonica JL. The effects of proximity and prompts on stair use. Microform Publications, University of Oregon Eugene, OR, 2002, 2. microfiche (142. fr 1911;): negative.	Not held at British Library – Unable to locate.
Booth KM, Pinkston MM, Poston WS. Obesity and the built environment. *Journal of the American Dietetic Association* 2005;105(5)(Suppl 1):S110–7.	Non-systematic literature review; non-UK corroborative.
Booth M, Bauman A, Oldenburg B, Marcus BH, Bauman A. Population prevalence and correlates of stages of change in physical activity. *Health Education Quarterly* 1993;20:431–40.	Population survey to determine who is most receptive to changing PA.
Booth M, Bauman A, Owen N, Gore C. Physical activity preferences, preferred sources of assistance, and perceived barriers to increased physical activity among physically inactive Australians. *Preventive Medicine* 1997;26:131–7.	Survey of PA barriers – none of stated barriers relevant to review. Non-UK corroborative.
Booth ML, Owen N, Bauman A, Clavisi O, Leslie E. Social-cognitive and perceived environment influences associated with physical activity in older Australians. *Preventive Medicine* 2000;31(1):15–22.	Causation – social–cognitive and environmental influences on PA.
Boutelle KN, Jeffery RW, Murray DM, Schmitz MK. Using signs, artwork, and music to promote stair use in a public building. *American Journal of Public Health* 2001;91(12):2004–6.	Included in Foster 2004 systematic review.
Boutelle KN, Jeffery RW, Murray DM, Schmitz MK. Using signs, artwork, and music to promote stair use in a public building. *American Journal of Public Health* 2001;91(12):2004–6.	Duplicate of above (Boutelle 2001).
Bowen DJ. Baseline data and design for a randomized intervention study of dietary change in religious organizations. *Preventive Medicine* 2004;39(3):602–11.	Trial protocol only.
Bozionelos G, Bennett P. The theory of planned behaviour as predictor of exercise: the moderating influence of beliefs and personality variables. *Journal of Health Psychology* 1999;4:517–29.	Theory of planned behaviour as predictor of exercise – no relevant evidence.
Brannstrom I, Weinehall L, Persson LA, Wester PO, Wall S. Changing social patterns of risk factors for cardiovascular disease in a Swedish community intervention programme. *International Journal of Epidemiology* 1993;22(5):1026–37.	Countrywide and not suitable for local implementation.
Brownell K, Stunkard AJ, Albaum JM. Evaluation and modification of exercise patterns in the natural environment. *American Journal of Psychiatry* 1980;137:1540–5.	Pre-1990 non-RCT.
Buller D, Morrill C, Taren D et al. Randomized trial testing the effect of peer education at increasing fruit and vegetable intake. *Journal of the National Cancer Institute* 1999;91:1491–1500.	Workplace-based.
Buttriss J, Stanner S, McKevith B et al. *A critical review of the psychosocial basis of food choice and identification of tools to effect positive food choice: a summary.* Report No. N09017. London: British Nutrition Foundation; 2004.	Non-systematic review – reference list checked.

Cairns S. Redirecting the school run. *Town and Country Planning*. 1999;68:300–1.	Insufficient detail.
CABE Space. *The value of public space: how high quality parks and public spaces create economic, social and environmental value*. London: CABE Space; 2004.	Little relevant evidence on interventions to do with obesity. Reference list checked.
CABE Space. *What would you do with this space? A good practice guide to involving children and young people in the design and care of urban spaces*. London: CABE Space; 2004.	Series of case studies – no relevant outcomes. NB: Suggested by GDG.
Campbell MK. Fruit and vegetable consumption and prevention of cancer: The Black Churches Unified for Better Health Project. *American Journal of Public Health* 1999;89(9):1390–6.	Government funded project.
Canning U, Bull J, Killoran A et al. *The evidence for 'what works' in community development and health improvement: talking health inequalities*. Health Development Agency; 2002.	Case series – reference list checked.
Caraher M, Dixon P, Felton M, South L, Tull A. *Making fruit and vegetables the easy choice: report of a Five-a-day pilot project in Hastings and St Leonards*. Brighton: Department of Health; 2002.	Countrywide government funded. Overall summary included as corroborative evidence in Department of Health 2003 .
Cavill N. Walking and health: making the links. *World Transport Policy and Practice* 2001;7(4):33–8.	Discussion paper – reference list checked.
Cervero R, Gorham R. Commuting in transit versus automobile neighbourhoods. *Journal of the American Planning Association* 1995;61:210–25.	Study of commuting in transit versus automobile neighbourhoods in California. No relevant evidence.
Cervero R, Duncan M. Walking, bicycling and urban landscapes: evidence from the San Francisco Bay area. *American Journal of Public Health* 2003;93(9):1478–83.	No intervention.
Chant S, Grant T, Andrews F. *Five-a-day keeps the doctor away: report of a Five-a-day pilot project in Somerset*. London: Department of Health; 2002.	Community-wide government funded. Overall summary included as corroborative evidence in Department of Health 2003.
Cheadle A. Evaluating community-based nutrition programs: comparing grocery store and individual-level survey measures of program impact. *Preventive Medicine* 1995;24(1):71–9.	Community-wide and not suitable for local implementation.
Cheadle A, Psaty BM, Curry S et al. Community-level comparisons between the grocery store environment and individual dietary practices. *Preventive Medicine* 1991;20:250–61.	Causation – link between reported healthy diet and availability of healthful food in local supermarkets.
Ciliska D. Interventions to improve nutritional intake in children and youth. In: Thomas H, Ciliska D, Micucci S, Wilson-Abra J, Dobbins M, Dwyer J, (eds), *Effectiveness of physical activity enhancement and obesity prevention programs in children and youth*. Hamilton, Ontario: Effective Public Health Practice Project; 2004.	All studies related to schoolchildren.
Ciliska D, Miles E, O'Brien MA et al. Effectiveness of community-based interventions to increase fruit and vegetable consumption. *Journal of*	No relevant studies.

Nutrition Education 2000;32(6):341–52.	
Cinciripini PM. Changing food selections in a public cafeteria. *Behaviour Modification* 1984;3:171–77.	Pre-1990 non-RCT.
Clarke G, Eyre H, Guy C. Deriving indicators of access to food retail provision in British cities: studies of Cardiff, Leeds and Bradford. *Urban Studies* 2002;39(11):2041–60.	Maps accessibility of food outlets but no corroborative evidence of people's eating habits and preferences.
Clemmens D, Hayman LL. Increasing activity to reduce obesity in adolescent girls: A research review. *Journal of Obstetric, Gynecologic, and Neonatal Nursing: Clinical Issues* 2004;33:801–8.	Relevant to schools review
Coady J, O'Hara E. *Five-a-day community project, County Durham and Darlington: Report of a Five-a-day pilot project*. London: Department of Health; 2002.	Community-wide government funded. Overall summary included as corroborative evidence in Department of Health 2003.
Cobb KF, Solera MK. 5-A-Day: a strategy for environmental change. *Topics in Clinical Nutrition* 2003;18(4):245–53.	Narrative overview – reference list checked.
Coday M, Klesages LM, Garrison RJ, Johnson KC, O'Toole M, Morris GS. Health opportunities with physical exercise (HOPE): social contextual interventions to reduce sedentary behaviour in urban settings. *Health Education Research* 2002;17(5):637–47.	Description of theoretical basis for trial only.
Colby JJ, Elder JP, Peterson G, Knisley PM, Carleton RA. Promoting the selection of healthy food through menu item description in a family-style restaurant. *American Journal of Preventive Medicine* 1987;3:171–7.	Pre-1990 non-RCT.
Coleman A. Utopia on trial: Vision and reality in planned housing. London: Hilary Shipman; 1985.	Pre-1990 non RCT.
Coleman A, Coleman D, Beresford P et al. Altered estates. London: Adam Smith Institute;1988.	Pre-1990 non-RCT.
Coleman KJ, Gonzalez EC. Promoting stair use in a US–Mexico border community. *American Journal of Public Health* 2001;91(12):2007–9.	Culturally relevant intervention to non-UK BMEG.
Connell D, Goldberg JP, Folta SC. An intervention to increase fruit and vegetable consumption using audio communications: in-store public service announcements and audiotapes. *Journal of Health Communication* 2001;6:31–43.	Less than 3-months follow-up.
Cordell HK, McDonald BL, Teasley RJ et al. Outdoor recreation participation trends. In: Cordell HK, ed. *Outdoor recreation in American life: a national assessment of demand and supply trends*. Champaign, IL: Sagamore Publishing; 1999:219–322.	Survey of participation trends – no relevant information.
Cox R, Gonzales-Vigilar C, Novascone M et al. Impact of a cancer intervention on diet-related cardiovascular disease risks of white and African-American EFNEP clients. *Journal of Nutrition Education* 1996;28:209–18.	US government-funded intervention.
Craig CL, Brownson RC, Cragg SE, Dunn AI. Exploring the effect of the environment on physical activity – A study examining walking to work. *American Journal of Preventive Medicine* 2002;23(2):36–43.	Causation – neighbourhood characteristics influencing physical activity.

Crane R, Crepeau R. *Does neighbourhood design influence travel? A behavioural analysis of travel diary and GIS data.* Working paper no. 374. Transportation Center, University of California, Berkeley; 1998.	No useful findings, USA.
Crane R. *The impacts of urban form on travel: a critical review.* Working paper no. WP99RC1. Lincoln Institute of Land Policy, Cambridge, MA: 1999.	Causation.
Cullen KW, Bartholomew LK, Parcel GS. Girl scouting: an effective channel for nutrition education. *Journal of Nutrition Education* 1997;29:86–91.	<3-months follow-up.
Cummins S, Macintyre S. The location of food stores in urban areas: a case study in Glasgow. *British Food Journal* 1999;101(7):545–53.	Analysis of location of food outlets to determine the existence of 'food deserts'.
Cummins S, Macintyre S. A systematic study of an urban foodscape: the price and availability of food in greater Glasgow. *Urban Studies* 2002;39(11):2115–30.	Looks at food availability – no evidence of corroboration for potential interventions.
Cummins SK, Jackson RJ. The built environment and children's health. *Paediatric Clinics of North America* 2001;48(5):1241.	Narrative overview, only obesity section relevant – reference list checked. NB: Suggested by GDG.
Cummins S, Petticrew M, Higgins C, Sparks L, Findlay A. Large scale food retailing as an intervention for diet and health: quasi-experimental evaluation of a natural experiment. Journal of Epidemiology and Community Health 2005; 59: 1035-1050	No control group. NB: Suggested by GDG.
Cummins S, Petticrew M, Sparks L, Findlay A. Large scale food retail interventions and diet. *British Medical Journal* 2005;330(7493):683–84.	Brief non-systematic review of large-scale food retail interventions – reference list checked.
Cunningham GO, Michael YL. Concepts guiding the study of the impact of the built environment on physical activity for older adults: a review of the literature. *American Journal of Health Promotion* 2004;18(6):435–43.	Causation – built environments/neighbourhoods and PA.
Curhan RC. The effects of merchandising and temporary promotional activities on the sales of fresh fruit and vegetables in supermarkets. *Journal of Market Research* 1997;11:286–94.	Pre-1990 non-RCT level evidence.
Curtin KA. *A needs assessment of the residents of Perry (Oklahoma) and evaluation of the city parks system*. Kinesiology Publications, University of Oregon Eugene, OR, 2003, 2. microfiche (178. fr 2001): negative.	Not held at British Library – Abstract only
Davis D, Bustamante A, Brown C et al. The urban church and cancer control: a source of social influence in minority communities. *Public Health Reports* 1994;109:500–6.	Cervical cancer only.
Davis DZ, Rogers T. Point-of-choice nutrition information for the modification of milk selection. *Journal of American College Health* 1982;30:275–8.	Pre-1990 non-RCT.
Davis-Chervin D, Rogers T, Clark M. Influencing food selections with point-of-choice nutrition information. *Journal of Nutrition Education* 1985;17:18–22.	Pre-1990 Non RCT

De Bourdeaudhuij I, Saelens BE, Sallis JF. Environmental correlates of physical activity in a sample of Belgian adults. *American Journal of Health Promotion* 2003;18(1):83–92.	Survey on causation.
Dearry A. Impacts of our built environment on public health. *Environmental Health Perspectives* 2004;112(11):A600–1.	Editorial.
DeHaven MJ, Hunter IB, Wilder L, Walton JW, Berry J. Health programs in faith-based organizations: Are they effective? *American Journal of Public Health* 2004;94(6):1030–6.	Little detail provided.
Demark-Wahnefried, W. McClelland, J W. Jackson, B. Campbell, M K. Cowan, A. Hoben, K. Rimer, B K. Partnering with African-American churches to achieve better health: lessons learned during the Black Churches United for Better Health 5. A Day project. *Journal of Cancer Education* 2000;15(3):164–7.	Discussion paper.
Demers A, Renaud L. Formative evaluation of a nutritional marketing project in city-center restaurants. *Evaluation Review* 1992;16(6):634–49.	No control group – better evidence available.
Department for Education and Skills, Department for Transport. *Travelling to school: an action plan*. Nottingham; Department for Education and Skills Publications, 2003.	Action plan, not a corroborative research study.
Department of Health. Choosing activity: a physical activity action plan. London: Department of Health; 2005.	Policy document without the supporting evidence – passed to NICE for background information.
Department of Health. *Five-a-day pilot initiatives: executive summary of the pilot initiatives evaluation study*. London: Department of Health; 2003.	Relevant to and included in community 1.
DePue JD, Wells BL, Lasater TM, Carleton RA. Volunteers as providers of heart health Programs in churches: a report on implementation. *American Journal of Health Promotion* 1990;4:361–86.	No relevant outcome data given.
Department for Environment, Transport and the Regions, CABE. *By design: urban design in the planning system: towards better practice.* London: DETR, CABE; 2000.	Guide with no evidence-based conclusions.
Keith Diaz Moore. Book review: Design for Assisted Living: Guidelines for Housing the Physically and Mentally Frail (Victor Regnier) *Journal of Architectural and Planning Research* 2005;22(1):86–88.	No indication of systematic approach to looking at intervention studies.
Dibb S. *Rating retailers for health: how supermarkets can affect your chances of a healthy diet.* London: National Consumer Council; 2004.	No corroborative information.
Dibsdall LA, Lambert N, Bobbin RF, Frewer LJ. Low-income consumers' attitudes and behaviour towards access, availability and motivation to eat fruit and vegetables. *Public Health Nutrition* 2003;6(2):159–68.	No relevant outcomes/qualitative results requested.
Dielman FM, Dijst M, Burghouwt G. Urban form and travel behaviour: micro-level household attributes and residential context. *Urban Studies* 2002;39(3):507–27.	Health aspects not mentioned.
Doherty M. Health promotion in places of worship. *Community Health Action* 1994;32:10–2.	No evaluations to provide corroborative evidence re outcomes.
Dolesh RJ. Follow the trail to improved health. *Parks and Recreation*	Un-referenced review article

(Ashburn) 2004;39(5):40–6.	discussing walking trails.
Dougherty MF, Wittsten AB, Guarino M. Promoting low-fat foods in the supermarket using various methods, including videocassettes. *Journal of the American Dietetic Association* 1990;90:1106–8.	Before and after study. No control group – better evidence available.
Dubbert PM, Johnson WG, Schlundt DG et al. The influence of calorific information on cafeteria food choices. *Journal of Applied Behavioural Analysis* 1984;17:85–92.	Pre-1990 non-RCT.
Dunn AL, Andersen RE, Jakicic JM. Lifestyle physical activity interventions. History, short- and long-term effects, and recommendations. *American Journal of Preventive Medicine* 1998;15(4):398–412.	– Quality systematic review – reference list checked.
Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HWI, Blair SN. Reduction in cardiovascular disease risk factors: six-month results from Project Active. *Preventive Medicine* 1997;26:883–92.	Relevant to Community 1 and 18-month results (Dunn 1999) already included.
Dunn AL, Garcia ME, Marcus BH, Kampert JB, Kohl III HW, Blair SN. Six-month physical activity and fitness changes in Project Active, a randomized trial. *Medicine and Science in Sports and Exercise* 1998;30(7):1076–83.	Relevant to Community 1 and 18-month results (Dunn 1999) already included.
Dunt D, Day N, Pirkis J. Evaluation of a community-based health promotion program supporting public policy initiatives for a healthy diet. *Health Promotion International* 1999;14(4):317–27.	Excluded on NICE advice at Community 1 Review.
Duquin M. A faith-based intergenerational health and wellness program. *Journal of Intergenerational Relationships* 2004;2(3/4):105–18.	No relevant outcomes given.
Durkin M, Hobbiss A, Robinson J. *Five-a-day in Airedale and Craven: Report of a Five-a-day pilot project*. London: Department of Health; 2002.	Community-wide government funded. Overall summary included as corroborative evidence in Department of Heath 2003
Eaton C, Reynes J, Assaf A, Feldman H, Lasater T, Carleton R. Predicting physical activity change in men and women in two New England communities. American Journal of Preventive Medicine 1993;9(4):209–19.	Survey of predictors of PA. No relevant evidence.
Ebbeling CB, Pawlak DB, Ludwig DS. Childhood obesity: public health crisis, common sense cure. *Lancet* 2002;360:473–852.	Systematic review of prevalence and determinants.
Eldridge A, Snyder M, Faus N et al. Development and evaluation of a labeling program for low-fat foods in a discount department store foodservice area. *Journal of Nutrition Education* 1997;29:159–161.	No control group.
Ellery S. Landlord’s food and fitness ideas help tenants fight the flab. *Inside Housing* 2004. No other details available	General discussion paper.
Elkins WL, Cohen DA, Koralewicz LM, Taylor SN. After school activities, overweight, and obesity among inner city youth. *Journal of Adolescence* 2004;27:181–89.	Discussion of risk.
Elvik R. Which are the relevant costs and benefits of road safety measures designed for pedestrians and cyclists? *Accident Analysis and Prevention* 2000;32(1):37–45.	Review of what is currently looked at in cost-benefit analyses of transport.
Eng E, Hatch JW. Networking between agencies and black churches: the lay health advisor model. *Prevention in Human Services* 1991;10(123):146.	Black churches – passed to Teesside.

Ernst ND, Wu M, Frommer P et al. Nutrition education at the point of purchase: the foods for health project evaluated. *Preventive Medicine* 1986;15:60–73.	Pre-1990 non-RCT.
Eves F. Impact of a new message format in getting people to use the stairs. *Active Living* 2002;11(4):2.	Not held by British Library. Unable to locate.
Ewing R. Can the physical environment determine physical activity levels. *Exercise and Sport Sciences Reviews* 2004;3302:69–75.	Non-systematic review.
Ewing R, Schmid T, Killingsworth R, Zlot A, Raudenbush S. Relationship between urban sprawl and physical activity, obesity and morbidity. *American Journal of Health Promotion* 2003;18(1):47–57.	Causation – built environment/environmental effects and obesity and physical activity. NB: Suggested by GDG.
Fitzgibbon ML, Stolley MR. Environmental changes may be needed for prevention of overweight in minority children*. Pediatric Annals* 2004;33(1):45–9.	Discussion paper.
Fitzpatrick MP, Chapman GE, Barr SI. Lower-fat menu items in restaurants satisfy customers. *Journal of the American Dietetic Association*. 1997;97:510–14.	No data point prior to intervention.
Foerster SB, Kizer KW, DiSogra LK, Bal DG, Krieg BF, Bunch KL. California's '5 a day – for better health!' campaign: an innovative population-based effort to effect large-scale dietary change. *American Journal of Preventive Medicine* 1995;11(2):124–31.	No control group.
Food Standards Agency, LACORS, Local Government Association. *Food: the local vision*. London: LACORS; 2002.	No relevant outcomes/no usable corroborative information.
Food Standards Agency. *Barriers to the development and uptake of reduced fat foods.* N09002. London: Food Standards Agency; 2005.	Duplicate of included paper: Know 2001
Fox KR. Childhood obesity and the role of physical activity. *Journal of the Royal Society of Health* 2004;124(1):34–9.	Non-systematic review.
Frank LD. Land use and transportation interaction – implications on public health and quality of life. *Journal of Planning Education and Research*. 2000;20(1):6–22.	Review article giving the author's personal viewpoint on land use and the effects on transportation/PA.
Frank LD, Engelke P, Hourigan D. *How land use and transportation systems impact public health: An annotated bibliography*. Working paper 2:1–63. City and Regional Planning Program College of Architecture (updated 26/12/2000)	No methodology to treat as non-systematic review. Mostly Non-UK corroborative.
Frank LD, Engelke P. How land use and transportation systems impact public health: A literature review of the relationship between physical activity and built form. *City and Regional Planning Program College of Architecture* 2005;8–12.	Non-systematic review.
Frank LD, Engelke PO. The built environment and human activity patterns: exploring the impacts of urban form on public health. *Journal of Planning Literature* 2001;16(2):202–28.	Narrative overview – reference list checked.
Frank LD, Andresen MA, Schmid TL. Obesity relationships with community design, physical activity and time spent in cars. *American Journal of*	Causation– reference list

Preventive Medicine 2004;27(2):87–96.	checked.
Frank LD. Economic determinants of urban form – resulting trade-offs between active and sedentary forms of travel. *American Journal of Preventive Medicine* 2004;27(3):146–53.	Discussion of economic forces and impacts on transportation and land use decisions.
French SA, Story M, Jeffery RW. Environmental influences on eating and physical activity. *Annual Review of Public Health* 2001;22:309–35.]	Literature review – reference list checked.
French SA, Story M, Neumark-Sztainer D, Fulkerson JA, Hannan P. Fast food restaurant use among adolescents: associations with nutrient intake, food choices and behavioural and psychosocial variables. *International Journal of Obesity and Related Metabolic Disorders* 2001;25(12):1823–33.	School-based/observational.
French SA, Jeffery RW, Story M, Hannan P, Snyder MP. A pricing strategy to promote low-fat snack choices through vending machines. *American Journal of Public Health* 1997;18(5):849–51.	No control group.
Frumkin H. Urban sprawl and public health. *Public Health Reports* 2002;117:201–17.	General discussion of air pollution and pedestrian accidents. NB: Suggested by GDG.
Gielen AC, Defrancesco S, Bishai D, Mahoney P, Ho S, Guyer B. Child pedestrians: the role of parental beliefs and practices in promoting safe walking in urban neighbourhoods. *Journal of Urban Health* 2004;81(4):545–55.	Injury risk/non-UK corroborative.
Gilbert K. Pedal cycling: positively healthy transport. *Health and Hygiene*. 1994;15(4):146–9.	Discussion paper.
Giles-Corti B, Macintyre S, Clarkson JP, Pikora T, Donovan RJ. Environmental and lifestyle factors associated with overweight and obesity in Perth, Australia*. American Journal of Health Promotion* 2003;18(1):93–102.	Causation – lifestyle/social and physical environmental factors and obesity/overweight.
Glanz K, Fallis JF, Saelens BE, Frank LD. Healthy nutrition environments: concepts and measures. *American Journal of Health Promotion* 2005;19(5):330–3.	Non-systematic literature review.
Glanz K, Hewitt A, Rudd J. Consumer behaviour and nutrition education: an integrative review. *Journal of Nutrition Education* 1992;24:267–77.	Pre-1995 systematic review.
Glanz K, Lankenau B, Foerster S, Temple S, Mullis R, Schmid T. Environmental and policy approaches to cardiovascular disease prevention through nutrition: opportunities for state and local action. *Health Education Quarterly* 1995;22:512–27.	Literature review – reference list checked.
Glanz K, Yaroch AL. Strategies for increasing fruit and vegetable intake in grocery stores and communities: policy, pricing and environmental change. *Preventive Medicine* 2004;39:S75–80.	– Quality systematic review.
Glanz K, Hoelscher D. Increasing fruit and vegetable intake by changing environments, policy and pricing: restaurant-based research, strategies and recommendations. *Preventive Medicine* 2004;39:S88–S93.	Narrative overview – reference list checked.
Goran MI, Treuth MS. Energy expenditure, physical activity, and obesity in children. *Paediatric Clinics of North America* 2001;48(4):931–53.	Narrative overview – reference list checked.
Gorbach S, Morrill-LaBrode A, Woods M et al. Changes in food patterns	Relevant to Community 1 and

during a low-fat dietary intervention in women. *Journal of the American Dietetic Association* 1990;90:802–9.	excluded from Community 1 – all subjects at elevated risk for breast cancer.
Greater London Authority. *Making London a walkable city*. London: Greater London Authority; 2004.	Discussion paper.
Green LW, Richard L, Potvin L. Ecological foundations of health promotion. *American Journal of Health Promotion* 1996;10:270–81.	General discussion paper.
Greiser E. Risk factor trends and cardiovascular mortality risk after 3.5 years of community-based intervention in the German Cardiovascular Prevention Study*. Annals of Epidemiology* 1993;3:S13–27.	Country-wide study and not suitable for local implementation.
Grilo CM, Pogue-Geile MF. The nature of environmental influences on weight and obesity: a behavior genetic analysis*. Psychological Bulletin* 1991;110(3):520–37.	Review of genetic vs. environmental influences on weight and obesity.
Guy CM. Corporate strategies in food retailing and their local impacts: a case study of Cardiff. *Environment and Planning A*1996;28:1575–602.	Not relevant to review topic.
Handy S. Urban form and pedestrian choices. Study of Austin neighborhoods. *Transportation Research Record* 1996;1552:135–44.	Causation.
Handy S. Health and community design: the impact of the built environment on physical activity. *Journal of the American Planning Association* 2004;70(3):375–6.	Book review only.
Hatch J, Jackson C. North Carolina Baptist church program. *Urban Health* 1981;10:70–1.	Pre-1990 non-RCT.
Hatch JW, Cunningham AC, Woods WW, Snipes FC. The fitness through churches project: description of a community-based cardiovascular health promotion intervention. *Hygiene* 1986;5:9–12.	Pre-1990 non-RCT.
Hayne CL, Moran PA, Ford MM. Regulating environments to reduce obesity. *Journal of Public Health Policy* 2004;25(3/4):391–407.	General discussion paper – reference list checked.
Health Development Agency. *Coronary heart disease: guidance for implementing the preventive aspects of the National Service Framework.* London: Department of Health; 2000.	Coronary heart disease guidance – reference list checked.
Health Education Authority. *The National Catering Initiative: promoting healthier choices.* London: Health Education Authority; 1998.	Workplace-based intervention.
Heath GW, Fuchs R, Croft JB, Temple S, Wheeler FC. Changes in blood cholesterol awareness: final results from the South Carolina cardiovascular disease prevention project. *American Journal of Preventive Medicine* 1995;11(3):190–6.	Blood cholesterol awareness outcome.
Heesch K, Brown D, Blanton C. Perceived barriers to exercise and stage of exercise adoption in older women of difference racial/ethnic groups. *Women and Health*2000;30(4):61–76.	US barriers to exercise adoption. Barriers not relevant to this review.
Hider PN. Environmental interventions to reduce energy intake or density: a critical appraisal of the literature. *NZHTA Report* 2001;4(2)	Duplicates information in other included reviews – reference list checked.
Hill JO. Environmental contributions to the obesity epidemic. *Science* 1998;280(5368):1374.	Discussion paper – reference list checked.

Hillsdon M, Thorogood M, Anstiss T, Morris J. Randomised controlled trials of physical activity promotion in free living populations: a review. *Journal of Epidemiology and Community Health* 1995;49:448–53.	No relevant papers identified from included studies.
Hoerr SM, Loudes VA. Can nutrition information increase sales of healthful vended snacks? *Journal of School Health* 1993;63:386–90.	No control group – better evidence available.
Holt NL, Bewick BM, Gateley PJ. Children's perceptions of attending a residential weight-loss camp in the UK. *Child: Care, Health and Development* 2005;31(2):223–31.	All subjects overweight/obese.
Horgen KB, Brownell KD. Comparison of price change and health message interventions in promoting healthy food choices*. Health Psychology* 2002;21(5):505–12.	No subject comparison group and less than 3-month follow-up. Before and after study.
Horgen KB. Promoting healthy food choices: A health message and economic incentive intervention. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2001; 62: 3-B	Not held at British Library – Abstract only
Humpel N, Owen N, Leslie E. Environmental factors associated with adults' participation in physical activity – a review. *American Journal of Preventive Medicine* 2002;22(3):188–99.	Causation – reference list checked.
Hunt MK, Lefebvre RC, Hixson ML, Banspach SW, Assaf AR, Carleton R. Pawtucket Heart Health Program: point-of-choice nutrition education program in supermarkets. *American Journal of Public Health* 1990;80:730–2.	No control group.
Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based research: assessing partnership approaches to improve pubic health. *Annual Review of Public Health* 1998;19:173–202.	Non-SR review of principles of community based research.
Jackson LE. The relationship of urban design to human health and condition. *Landscape and Urban Planning* 2003;64(4):191–200.	Narrative overview. Causation – impact of urban design on health and well being.
Jackson NW, Howes FS, Gupta S, Doyle JL, Waters E. Policy interventions implemented through sporting organisations for promoting healthy behaviour change Cochrane Database of Systematic Reviews 2005; 4(1)	No studies included in review.
Jackson RJ, Kochtitzky C. *Creating a healthy environment: the impact of the built environment on public health*. Washington DC: Sprawl Watch Clearing House; 2001.	Literature review – reference list checked. NB: Suggested by GDG.
Jago R, Baranowski T. Non-curricular approaches for increasing physical activity in youth: a review*. Preventive Medicine* 2004;39(1):157–63. [529]	Only one relevant study.
Jakicic JM, Wing RR, Butler BA, Robertson RJ. Prescribing exercise in multiple short bouts versus one continuous bout: effects on adherence, cardiorespiratory fitness, and weight loss in overweight women. *International Journal of Obesity* 1995;19:893–901.	All obese.
Jebb SA, Lambert J. Overweight and obesity in European children and adolescents. *European Journal of Pediatrics* 2000;159(Suppl 1):S2–4.	Summary of a panel discussion.
Jebb SA, Lang R, Penrose A. Improving communication to tackle obesity	Discussion/position paper.

in the UK. *Proceedings of the Nutrition Society* 2003;62:577–81.	
Jeffery RW, French SA, Raether C, Baxter JE. An environmental intervention to increase fruit and salad purchases in a cafeteria. *Preventive Medicine* 1994;23(6):788–92.	Before and after study. No control group – better evidence available.
Jeffery RW, Pirie PL, Rosenthal BS, Gerber WM, Murray DM. Nutrition education in supermarkets: an unsuccessful attempt to influence knowledge and product sales. *Journal of Behavioural Medicine*. 1982;5:189–200.	Pre-1990/no weight outcomes.
Jeffery RW, Utter J. The changing environment and population obesity in the United States. *Obesity Research* 2003;11:12S–22S	General discussion on the obesity epidemic in the USA.
Jones JL, Krummel DA, Wheeler K, Forbes B, Fitch C. The prevalence of heart-healthy menu items in west Virginia restaurants. *American Journal of Health Behaviour* 2004;28(4):328–34.	Survey to assess prevalence of low-fat menu items.
Jordan A. The role of media in children's development: an ecological perspective. *Development and Behavioural Pediatrics* 2004;25(3):196–206.	Not relevant to review question.
Kaduskar S, Boaz A, Dowler E, Meyrick J, Rayner M. Evaluating the work of a community cafe in a town in the south east of England: reflections of methods, process and results. *Health Education Journal* 1999;58:341–54.	Community café – objectives not relevant to obesity prevention.
Kane RL, Johnson PE, Town RJ, Butler M. A structured review of the effect of economic incentives on consumers' preventive behaviour. *American Journal of Preventive Medicine* 2004;27:327–52.	Relevant studies included in Community 1.
Kennedy L, Ubido J, Elhassan S et al. Dietetic helpers in the community: the Bolton community nutrition assistant's project. *Journal of Human Nutrition and Dietetics* 1999;12:501–12.	Relevant to Community 1 and included in update.
Kerr J, Eves F, Carroll D. Six-month observational study of prompted stair climbing. *Preventive Medicine* 2001;33(5):422–7.	Included in Foster 2004 systematic review.
Kerr J, Eves FF, Carroll D. The influence of poster prompts on stair use: The effects of setting, poster size and content. *British Journal of Health Psychology* 2001;6(4):397–405.	Included in Foster 2000 systematic review.
Kerr J, Eves FF, Carroll D. Getting more people on the stairs: the impact of a new message format. *Journal of Health Psychology* 2001;6(5):495–500.	Included in Foster 2000 systematic review.
Kerr J, Eves F, Carroll D. Encouraging stair use: stair-riser banners are better than posters. *American Journal of Public Health* 2001;91(8):1192–3.	Included in Foster 2004 systematic review.
Kerr J, Eves F, Carroll D. Can posters prompt stair use in a worksite environment? *Journal of Occupational Health*. 2001;43(4):205–7.	Workplace intervention.
Killingsworth R, Earp J, Moore R. Supporting health through design: challenges and opportunities. *American Journal of Health Promotion*. 2003;18(1):1–4.	Introduction to special issue of journal. Reference list checked.
Killingsworth RE, Schmid TL. Community design and transportation policies: new ways to promote physical activity. *Physician and Sports Medicine* 2001;29(2):31–2, 34.	General discussion paper.
King WC, Belle SH, Brach JS, Simkin-Silverman LR, Soska T, Kriska AM. Objective measures of neighbourhood environment and physical activity in	Causation.

older women. *American Journal of Preventive Medicine* 2005;28(5):461–9.	
King WC, Brach JS, Belle S, Killingsworth R, Fenton M, Kriska AM. The relationship between convenience of destinations and walking levels in older women. *American Journal of Health Promotion* 2003;18(1):74–82.	Causation – convenience walking to destination and PA levels.
King A. Co-ops in the food desert. Community Health 1999;49:10–2.	Not held in British Library – unobtainable.
Kohl HW, Hobbs KE. Development of physical activity behaviours among children and adolescents. *Pediatrics* 1998;101(3):549–54.	Narrative overview – reference list checked.
Korve MJ, Niemeier DA. Benefit–cost analysis of added bicycle phase at existing signalized intersection. *Journal of Transportation Engineering* 2002;128(1):40–8.	Not relevant to review topic.
Kumanyika SK, Charleston JB. Lose weight and win – a church-based weight-loss program for blood-pressure control among black-women. *Patient Education and Counselling* 1992;19(1):19–32.	Relevant to BMEG review.
Lang JE, Mercer N, Tran D, Mosca L. Use of a supermarket shelf-labeling program to educate a predominantly minority community about foods that promote heart health. *Journal of the American Dietetic Association*. 2000;100:804–9.	No relevant outcomes.
Lang T, Caraher M. Access to healthy foods: part II. Food poverty and shopping deserts: what are the implications for health promotion policy and practice? *Health Education Journal*. 1998;57(3):202–11.	Systematic review of prevalence and determinants – reference list checked.
Larkin M. Can cities be designed to fight obesity? Urban planners and health experts work to get people up and about. *Lancet* 2003;362(9389):1046–7.	Discussion paper.
Lasater T, Carleton R, Wells B. Religious organizations and large-scale health related lifestyle change programs. *Journal of Health Education* 1991;22(4):233–9.	Discussion paper.
Lasater TM, Wells BL, Carleton RA, Elder JP. The role of churches in disease prevention research studies. *Public Health Reports* 1986;101:125–31.	Pre-1990 non-RCT.
Lasater TM, Becker DM, Hill MN, Gans KM. Synthesis of findings and issues from religious-based cardiovascular disease prevention trials. *Annals of Epidemiology* 1997;7(7)(Suppl):S46–53.	Literature review – reference list checked.
Lasater TM, Dupue JD, Wells RP, Gans KM, Bellis J, Carleton RA. The effectiveness and feasibility of delivering nutrition education programs through religious organizations. *Health Promotion International* 1990;5(4):253–8.	Before-and-after study. No control group – better evidence available.
Laurendeau H, Battista RN, Potvin L. Impact of a nutrition information program on the content of grocery carts. *Canadian Journal of Public Health – Revue Canadienne de Sante Publique* 1993;84(6):376–81.	French only.
Lawlor DA, Ness AR, Cope AM, Davis A, Insall P, Riddoch C. The challenges of evaluating environmental interventions to increase population levels of physical activity: the case of the UK National Cycle Network. *Journal of Epidemiology and Community Health* 2003;57(2):96–101.	General discussion of how to evaluate the Sustrans network but no evaluation information included.
Lawrence RJ (ed). *Sustaining human settlement: a challenge for the new*	Series of discussion papers

millenium. North Shields, UK: Urban International Press; 2000.	and literature reviews about sustainable cities.
Lawrence RJ. Wanted: designs for health in the urban environment. *World Health Forum* 1996;17(4):363–6.	General discussion paper.
Lawrence SA. Behavioral interventions to increase physical activity. *Journal of Human Behavior in the Social Environment* 2002;6(1):2002–44.	Literature review – reference list checked.
Lawton CL, Delargy HJ, Smith FC, Hamilton V, Blundell JE. A medium-term intervention study on the impact of high- and low-fat snacks varying in sweetness and fat content: large shifts in daily fat intake but good compensation for daily energy intake. *British Journal of Nutrition* 1998;80:149–61.	Not community-based study
Leather S. Eating away the future: the unsustainable food economy. *Scotland's 21 Today*. 1997;13:5.	Discussion paper.
Leather S. Poverty and food: will the Food Standards Agency make a difference. *Poverty* 2000;107:11–13.	Flyer re Food Standards Agency.
Lenamond SG, Franckowiak S, Zuzak KB, Cummings ES, Crespo CJ, Andersen RE. A community intervention to promote stair use among African American commuters across the age spectrum. *Journal of the American Geriatrics Society* 2001;49(4):114.	Passed to Teesside; Meeting abstract only.
Levin JS. The role of the Black church in community medicine. *Journal of the National Medical Association* 1984;76:477–83.	Pre-1990 non-RCT.
Levy AS, Mathews O, Stephenon M, Tenney JE, Schucker RE. The impact of a nutrition information program on food purchases. *Journal of Public Policy Marketing* 1985;4:1–13.	Pre-1990 non-RCT.
Li F, Fisher KJ, Bauman A et al. Neighbourhood influences on physical activity in middle-aged and older adults: a multilevel perspective. *Journal of Aging and Physical Activity* 2005;13:87–114.	Research design.
Librett JJ, Yore MM, Schmid TL. Local ordinances that promote physical activity: a survey of municipal policies. *American Journal of Public Health* 2003;93(9):1399–403.	US survey of municipal ordinances – not relevant to review.
Lobstein T, Dibb S. Evidence of a possible link between obesogenic food advertising and child overweight. *Obesity Reviews* 2005 Aug;6(3):203–8.	Corroborative and includes UK data but excluded from December update – since RCTs and systematic reviews only included. Data are also old – from 1996.
Lusk A. Safewalks: Neighborhoods stroll to peaceful existence. *Parks and Recreation (Arlington)* 1995;30(8):44–9.	Overview.
Macaskill L, Dwyer JJM, Uetrecht C et al. An evaluability assessment to develop a restaurant health promotion program in Canada. *Health Promotion International* 2000;15(1):57–69.	Logic model.
Mackett RL. The health benefits of walking to school (Paper presented at the Sustrans National Conference on 'Championing safe routes to school: citizenship in action, September 2003). London: Centre for Transport Studies; 2003.	Duplicate of Anonymous. Food issues: a partnership approach. *Community Health UK Action* 2004;63:14–5..
Marcus BH, Owen N, Forsyth LA, Cavill NA, Fridinger F. Physical activity	– Quality systematic review.

interventions using mass media, print media and information technology. *American Journal of Preventive Medicine* 1998;15:362–78.	reference list checked.
Mayer JA, Heins JM, Vogel JM, Morrison DC, Lankester LD, Jacobs AL. Promoting low-fat entree choices in a public cafeteria. *Journal of Applied Behaviour Analysis* 1986;19(397):402.	Pre-1990 non-RCT.
Mayor of London. *Draft guide to preparing play strategies: towards the provision of safe and attractive play spaces in London's neighbourhoods.* London: Greater London Authority; 2004.	Preparing play strategies for London neighbourhoods as part of 2004 London Plan.
McClelland JW, Demark-Wahnefried W, Mustian RD, Cowan AT, Campbell MK. Fruit and vegetable consumption of rural African Americans: baseline survey results of the black churches united for better health 5. A Day project. *Nutrition and Cancer* 1998;30(2):148–57.	Baseline data but no outcomes reported.
McClintock H, Cleary J. English urban cycle route network experiments: the experience of the Greater Nottingham network. *Town Planning Review* 1993;64(2):169–92.	UK government funded and not suitable for local implementation.
McCormick J. *Healthy food policy: on Scotland's menu*? (Paper no 15). Edinburgh: Scottish Council Foundation; 2000.	Discussion of policy and no relevant evidence.
McDermott L, Stead M, Hastings G, Angus K. A systematic review of the effectiveness of social marketing nutrition and food safety interventions. University of Stirling: Institute for Social Marketing 2005;1–88 (plus appendices).	Studies included overweight participants or were not relevant to this review. Studies checked to confirm already included, if meet inclusion criteria.
McMillan TE. Urban form and a child's trip to school: The current literature an a framework for future research. *Journal of Planning Literature* 2005;19(4):440–56.	Non-systematic review.
McNabb W, Quinn M, Kerver J, Cook S, Karrison T. The PATHWAYS church-based weight loss program for urban African-American women at risk for diabetes *Diabetes Care*. 1997;20(10):1518–23.	All overweight and obese.
Meiselman HL, Hedderley D, Staddon SL, Pierson BJ, Symonds CR. Effect of effort on meal selection and meal acceptability in a student cafeteria. *Appetite* 1994;23:43–55.	Schools-based.
Metcalf B, Voss L, Jeffrey A, Perkins J, Wilkin T. Physical Activity cost of the school run: impact on schoolchildren of being driven to school (Early Bird 22) *British Medical Journal* 2004;329:832–3.	Already in Community 2, Metcalf 2004.
Micucci S. Environmental interventions to improve nutrition and increase physical activity in children and youth. In: Thomas H, Ciliska D, Micucci S, Wilson-Abra J, Dobbins M, Dwyer J, eds. *Effectiveness of physical activity enhancement and obesity prevention programs in children and youth*. Hamilton, Ontario: Effective Public Health Practice Project; 2004.	Schools-based.
Miles G, Eid S. The dietary habits of young people. *Nursing Times* 1997;93(50):46–8.	Schools-based.
Miles A. Using the mass-media to target obesity: An analysis of the characteristics and reported behaviour change of participants in the BBC's 'Fighting Fat, Fighting Fit' campaign. *Health Education Research* 2001;16(3):372.	Country-wide and not suitable for local implementation.

Mullis RM, Pirie P. Lean meats make the grade – a collaborative nutrition intervention program. *Perspectives in Practice* 1988;88(2):191–5.	Pre-1990 non RCT.
Mulvihill C, Rivers K, Aggleton P. A qualitative study investigating the views of primary-age children and parents on physical activity. *Health Education Journal*. 2000;59:166–79.	No intervention.
Murphy S, Powell C, Smith C. A formative evaluation of the Welsh heartbeat award scheme. *Nutrition and Health* 1994;9:317–27.	No relevant evidence.
Mutrie N, Blamey A. Encouraging stair walking. *British Journal of Sports Medicine* 2000;34(2):143–4.	Short report of before and after study with no methodological information and no outcomes – reference list checked.
Mutrie N, Blamey A, Mitchell J. *What stops people choosing the stairs?* Proceedings of the American College of Sports Medicine Physical Activity Interventions Conference, Dallas; 1997.	Unobtainable – not held at British Library.
Myers R, Roth DL. Perceived benefits of and barriers to exercise and stage of exercise adoption in young adults. *Health Psychology* 1997;16(3):277–83.	Transtheoretical reasoning.
National Institutes of Health NCI. *Five-a-day for better health program. Evaluation report*. Rockville, MD: National Cancer Institute; 2002.	Nationwide programme and not suitable for local implementation.
National Recreation and Park Association. *Hearts ’n Parks – report of 2003. Magnet Center performance data*. Bethesda Maryland: National Recreation and Park Association, 2003.	Nationwide and not suitable for local implementation. NB: Suggested by GDG.
NHS Health Scotland. *Routes to Health: case studies of two community-run mobile food shops*. Scotland, NHS Health Scotland, 2005.	Pamphlet on setting up mobile food shops – two case studies but little actual data
NHS Health Scotland. *Community food initiatives in Scotland: activities and issues.* Scotland: NHS Health Scotland, 2003.	General discussion of initiatives – no outcome or corroborative data.
Nies M, Vollman M, Cook T. Facilitators, barriers and strategies for exercise in European American women in the community. *Public Health Nursing* 1998;15(4):263–72.	Too general.
Northridge ME, Sclar ED, Biswas P. Sorting out the connections between the built environment and health: a conceptual framework for navigating pathways and planning healthy cities. *Journal of Urban Health*2003;80(4):556–68.	Not relevant.
Norton G, Suk M. America’s public lands and waters: the gateway to better health? *American Journal of Law, Medicine and Ethics* 2004;30:237–43.	Non-systematic literature review.
NSW Centre for Public Health Nutrition. *Best options for promoting healthy weight and preventing weight gain in NSW*. Sydney, Australia: NSW Centre for Public Health Nutrition; 2004.	Non-systematic review of reviews – reference lists examined. Passed to identification review.
O’Brien C. Planning transportation for and with children. *NCBW Forum Article* 2004;Oct 1:1–12.	General discussion paper on child friendly approaches to planning transport and roads.

	NB: Suggested by GDG.
O'Loughlin. Coeur en sante St-Henri: A heart health promotion programme in Montreal, Canada: Design and methods for evaluation. *Journal of Epidemiology and Community Health* 1995;49(5):495–502.	Later paper included O'Loughlin (1999).
Oexmann MJ, Ascanio R, Egan BM. Efficacy of a church-based intervention on cardiovascular risk reduction. *Ethnicity and Disease* 2001;11(4):817–22.	Before and after study. No control group – better evidence available.
Oexmann MJ, Thomas JC, Taylor KB et al. Short-term impact of a church-based approach to lifestyle change on cardiovascular risk in African Americans. *Ethnicity and Disease* 2000;10(1):17–23.	Church-based Afro-American.
Ogilvie D, Egan M, Hamilton V et al. Targeted health promotion activities encourage people to walk and cycle instead of using cars. *Evidence Based Healthcare and Public Health* 2005;9:139–40.	Abstract of Ogilvie 2004 already included.
Olson CM, Bisgoni CA, Thonney PF. Evaluation of a supermarket nutrition education program. *Journal of Nutrition Education*. 1982;14:141–5.	No data point before intervention.
Office of the Deputy Prime Minister, Home Office. *Safer places: the planning system and crime prevention.* London: Thomas Telford Ltd; 2004.	Not relevant to review – crime prevention case series. NB: Suggested by GDG.
Ostasiewicz L. *Evaluation of Tower Hamlets food co-ops.* London: Tower Hamlets Food Co-op; 1997.	Not held at British Library. Unable to locate.
Owen N, Bauman A, Booth M, Oldenburg B, Magnus P. Serial mass-media campaigns to promote physical activity: reinforcing or redundant? *American Journal of Public Health* 1995;85:244–8.	State-wide intervention and not suitable for local implementation.
Owens P. Neighborhood form and pedestrian life: Taking a close look. *Landscape and Urban Planning* 1993;26:115–35.	No relevant evidence.
Paine-Andrews A, Francisco VT, Fawcett SB, Johnston J, Coen S. Health marketing in the supermarket: using prompting, product sampling, and price reduction to increase customer purchases of low fat food. *Health Marketing Quarterly* 1996;14(2):85–99.	No control group.
Paradis G, O'Loughlin J, Elliott M et al. Coeur en Sante St-Henri – a heart health promotion program in a low-income, low education neighborhood in Montreal, Canada – theoretical-model and early field experience. *Journal of Epidemiology and Community Health* 1995;49(5):503–12.	Linked to paper O'Loughlin (1999) – already included.
Pate RR, Trost SG, Mullis R, Sallis JF, Wechsler H, Brown DR. Community interventions to promote proper nutrition and physical activity among youth. *Preventive Medicine* 2000;31:S138–49.	Literature review – reference list checked.
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Reilly JJ, McDowell ZC. Physical activity interventions in the prevention and treatment of paediatric obesity: systematic review and critical appraisal. *Proceedings of the Nutrition Society* 2003;62(611):665.	Looks at obesity treatments.
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Life trial. *Journal of Cancer Education*. 2000;15(3):156–63.	
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cycling: findings from the transportation, urban design, and planning literatures. *Annals of Behavioral Medicine* 2003;25(2):80–91.	environmental influences on PA.
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Scott D, Jackson EL. Factors that limit and strategies that might encourage people's use of public parks. *Journal of Park and Recreation Administration* 1996;14:1–17.	Theoretical, USA.
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Shaylor M, Fergusson M, Rowell A. *Costing the benefits: the value of cycling.* Cyclists' Touring Club: 1993.	Costings evidence not for relevant outcomes.

Silzer JS, Sheeska J, Tomasik HH, Woolcot DM. An evaluation of 'Supermarket Safari' nutrition education tours. *Journal of the Canadian Dietetic Association* 1994;55:179–83.	Less than 3-months follow-up.
Simon C, Wagner A, DiVita C et al. Intervention on adolescents' physical activity and sedentary behaviour (ICAPS): concept and 6-month results. *International Journal of Obesity* 2004;28: S9–S103.	Relevant to school review.
Sjolie AN, Thuen F. School journeys and leisure activities in rural and urban adolescents in Norway. *Health Promotion International*. 2002;17(1):21–30.	Causation study – predictors of PA based on existing facilities.
Sleap M, Warburton P. Are primary school children gaining heart health benefits from their journeys to school? *Child: Care, Health and Development* 1993;19:99–108.	No information on barriers or facilities. Just statistical information on methods of getting to school.
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Stanilov K. Health and community design: The impact of the built environment on physical activity. *Journal of Planning Education and Research* 2004;24(1):107–8.	Book review – reference list checked.
Staunton CE, Hubsmith D, Kallins W. Promoting safe walking and biking to school: the Marin County success story. *American Journal of Public Health* 2003;93(9):1431–4.	No control group. Methodology seriously flawed.
Steenhuis I, Van Assema P, Reubsaet A, Kok G. Process evaluation of two environmental nutrition programmes and an educational nutrition programme conducted at supermarkets and worksite cafeterias in the Netherlands. *Journal of Human Nutrition and Dietetics* 2004;17(2):107–15.	Process evaluation – reference list checked.
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Stokols D. Establishing and maintaining healthy environments: toward a social ecology of health promotion. *American Psychologist* 1992;47:6–22.	Psychological study.
Stroebele N, De Castro JM. Effect of ambience on food intake and food choice. *Nutrition* 2004;20(9):821–38.	Non-systematic review.
Strong WB, Malina RM, Blimkie CJR et al. Evidence based physical activity for school-age youth. *Journal of Pediatrics* 2005;146(6);732–7.	No relevant and interpretable data in review. Would need unpicking and essentially relevant to Schools and review of 2–5 year olds.
Strychar IM, Potvin L, Pineault R, Pineau R, Prevost D. A supermarket cardiovascular screening program: analysis of participants' solicitation of follow-up care. *American Journal of Preventive Medicine* 1994;10(5):283–89.	No relevant outcomes.
Strychar IM, Potvin L, Pineault R, Pineau R, Prevost D. Changes in knowledge and food behavior following a screening-program held in a supermarket. *Canadian Journal of Public Health – Revue Canadienne de Sante Publique* 1993;84(6):382–388.	Before and after study. No control group – better evidence available.
Sun WY, Sangweni B, Chen J, Cheung S. Effects of a community-based nutrition education program on the dietary behavior of Chinese-American	Relevant to BMEG review.

college students. *Health Promotion International* 1999;14(3):241–9.	
Sustrans. *The health benefits of safe routes to school*. Information Sheet FS15. Bristol: Sustrans Routes for People; 2000.	Non systematic literature review.
Sustrans. *Safe routes to school: three year review*. [Date unknown] [254]	Non systematic literature review..
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Tarry J. Class action. *Surveyor* 1999;186:16–8.	Very brief description of a project to increase walking to school.
Thomas H. Interventions to increase physical activity in children and youth. In: Thomas H, Ciliska D, Micucci S, Wilson-Abra J, Dobbins M, Dwyer J, eds. *Effectiveness of physical activity enhancement and obesity prevention programs in children and youth*. Hamilton, Ontario: Effective Public Health Practice Project; 2004.	All bar two studies related to schoolchildren.
Thomson H, Petticrew M, Morrison D. Housing improvement and health gain: a summary and systematic review. *British Medical Journal* 2001;323:187–90.	No relevant papers identified from included studies.
Tolley R, Bickerstaff K, Shaw S. Beyond public health: benefits of walking on children's social development. Staffordshire: The Centre for Alternative and Sustainable Transport; 1999.	– Quality study.
Trayer T. *Impact of environment based changes.* UKPHA; 2005.	Not available from British Library. Unable to locate.
Troped PJ, Saunders RP, Pate RR, Reininger B, Ureda JR, Thompson SJ. Associations between self-reported and objective physical environmental factors and use of a community rail-trail. *Preventive Medicine* 2001;32(2):191–200.	No control group – better evidence available.
Trost SG, Owen N, Bauman AE, Sallis JF, Brown W. Correlates of adults' participation in physical activity: review and update. *Medicine and Science in Sports and Exercise* 2002;34(12):1996–2001.	Causation – reference list checked.
Tudor-Locke C, Ainsworth BE, Adair LS, Popkin BM. Objective physical activity of Filipino youth stratified for commuting mode to school. *Medicine and Science in Sports and Exercise* 2003;35(3):465–71.	Survey of physical activity behaviour – no relevant evidence.
Turner LW. Cardiovascular health promotion in north Florida African-American churches. *Health Values* 1995;19(2):3–9.	Afro-American church-based. Sent to Teesside.
Unwin NC. Promoting the public health benefits of cycling. *Public Health* 1995;109(1):41–6.	Non-systematic review – causation.
Viner R. Predictors of change in body mass from childhood to adolescence. *Journal of Adolescent Health* 2004;34:121.	UK corroborative but only an abstract.
Vitetta-Miller R. Strategy 3: shop till you drop (pounds). *Shape* 2002;21(9):8.	Suggestions to consumers for a healthy shopping list.
Von Bernuth RD. 'The built environment and public health'. *Proceedings of the NSF Housing Research Agenda Workshop*, February 12–14, 2004, Orlando, Florida.. Syal M, Mullins M, Hastak M, eds. Vol. 2, Focus Group	Call for research into relationship between land use

4: 274–7.	and obesity.
Wagner EH, Wickizer TM, Cheadle A et al. The Kaiser Family Foundation Community Health Promotion Grants Program: findings from an outcome evaluation*. Health Service Research* 2000;35(3):561–89.	Multi-centre state/country-wide intervention and not suitable for local implementation.
Wagner J, Winett R. Promoting one low-fat, high-fiber selection in a fast food restaurant. *Journal of Applied Behavior Analysis* 1988;21:179–86.	Pre-1990 non-RCT.
Wagner JL, Winett RA, Walbert-Rankin J. Influences of a supermarket intervention on the food choices of parents and their children. *Journal of Nutrition Education* 1992;24(6):306–11.	Family study.
Wakefield J. Fighting obesity through the built environment. *Environmental Health Perspectives* 2004;112(11):A616–8.	Discussion paper.
Walden K. Back to school. *Green Places* 2004;3:25–7.	Discussion paper – no relevant outcomes. NB: Suggested by GDG.
Wang G, Macera CA, Scudder-Soucie B, Schmid T, Pratt M, Buchner D. A cost-benefit analysis of physical activity using bike/pedestrian trails. *Health Promotion Practice* 2005;6(2):174–9.	Pass information to Paul Trueman at York University.
Wang G, Macera CA, Scudder-Soucie B et al. Cost analysis of the built environment: the case of bike and pedestrian trials in Lincoln, Neb*. American Journal of Public Health* 2004;94(4):549–53.	Already excluded from Community 2 review, Wang 2004 [173].
Wansink B, Linder LR. Interactions between forms of fat consumption and restaurant bread consumption. *International Journal of Obesity* 2003;27(7):866–868.	No baseline measures.
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Wardle J, Rapoport L, Miles A, Afuape T, Duman M. Mass education for obesity prevention: the penetration of the BBC's 'Fighting Fat, Fighting Fit' campaign. *Health Education Research* 2001;16(3):343–55.	Relevant to awareness review.
Webb K, Hawe P, Noort M. Collaborative intersectoral approaches to nutrition in a community on the urban fringe*. Health Education and Behavior* 2001;28(3):306–19.	Descriptive evaluation – no evidence provided.
Webster J. Tackling food poverty: the options for local authorities. *Benefits* 1999;(24):7–10.	Discussion paper.
Weinehall L, Westman G, Hellsten G et al. Shifting the distribution of risk: results of a community intervention in a Swedish programme for the prevention of cardiovascular disease. *Journal of Epidemiology and Community Health* 1999;53(243):250.	In Community 1 review.
Westerterp-Plantenga MS, Wijckmans-Duijsens NEG, Verboeket-van de Venne WPG, de Graaf K, van het Hof KH, Weststrate JA. Energy intake and body weight effects of six months reduced or full fat diets, as a function of dietary restraint*. International Journal of Obesity and Related Metabolic Disorders* 1998;22(1):14–22.	Intervention to determine whether reduced-fat foods aid weight loss.
Weststrate JA, van het Hof KH, van den Berg H et al. A comparison of the effect of free access to reduced fat products or their full fat equivalents on	Intervention not relevant.

food intake, body weight, blood lipids and fat-soluble antioxidants levels and haemostasis variables. *European Journal of Clinical Nutrition*. 1998;52(6):389–95.	
White RR. Health and community design: The impact of the built environment on physical activity. *Ecological Economics* 2005;52(2):258–9.	Book review.
Wilson L. Implementation and evaluation of church-based health fairs. *Journal of Community Health Nursing* 2000;17(1):39–48.	Evaluation of success of a program planning model – no relevant evidence.
Winett RA, Anderson ES, Whiteley JA et al. Church-based health behavior programs: Using social cognitive theory to formulate interventions for at-risk populations. *Applied and Preventive Psychology* 1999;8(2):129–42.	Overview and protocol.
Winett RA, Anderson ES, Bickley PG et al. Nutrition for a Lifetime System: A multimedia study for altering food supermarket shoppers' purchases to meet nutritional guidelines. *Computers in Human Behaviour* 1997;13(3):371–92.	Excluded at critical appraisal stage as RCT – but data extraction completed.
Winett RA, Wagner JL, Moore JF et al. An experimental evaluation of a prototype public access nutrition information system for supermarkets. *Health Psychology* 1991;10(1):75–8.	Less than 3-months follow-up.
Wing RR, Jeffery RW. Food provision as a strategy to promote weight loss. *Obesity Research* 2001;9(Suppl 4):S271–5.	All obese or overweight.
Wong F, Huhman M, Heitzler C et al. VERB – A social marketing campaign to increase physical activity among youth. *Preventing Chronic Disease: Public Health Research, Practice and Policy* 2004;Jul;1(3):1–7.	Description of components of a physical activity campaign for 9–13-year-olds in USA. NB: Suggested by GDG.
Wrieden WL, Anderson AS, Longbottom PJ et al. *Assisting dietary change in low-income communities: assessing the impact of a community-based practical food skills intervention (CookWell).* N09011. London: Food Standards Agency; 2002.	Included in Community 1 review.
Wrigley N. 'Food deserts' in British cities: policy context and research priorities. *Urban Studies* 2002;39(11):2029–2040.	Introduction and overview of 'food deserts' theme – reference list checked.
Wrigley N, Warm D, Margetts B, Whelan A. Assessing the impact of improved retail access on diet in a 'food desert': a preliminary report. *Urban Studies* 2002;39(11):2061–2082.	Covered by included paper Wrigley (2003).
Wrigley N, Warm D, Margetts B. *Deprivation, diet and food retail access: findings from the Leeds 'Food Deserts' study*. Southampton: University of Southampton; 2002.	Covered by included paper Wrigley (2003).
Yancey AK. Building capacity to prevent and control chronic disease in underserved communities: expanding the wisdom of wisewoman in intervening at the environmental level. *Journal of Women's Health* 2004;13(5):644–9.	General discussion of research with no outcome data.
Yanek LR, Becker DM, Moy TF, Gittelsohn J, Koffman DM. Project Joy: faith based cardiovascular health promotion for African American women. *Public Health Reports* 2001;116(Suppl 1):68–81.	Afro-American church-based. Sent to Teesside.
Zaccari V, Dirkis H. Walking to school in inner Sydney. *Health Promotion*	Schools-based.

Journal of Australia 2003;14:137–40.	
Zifferblatt S, Wilbur CS, Pinksy JL. Changing cafeteria eating habits. *Journal of the American Dietetic Association* 1980;76:15–20.	Pre-1990 non-RCT/workplace-based.
Zimring C, Joseph A, Nicoll GL, Tsepas S. Influences of building design and site design on physical activity: research and intervention opportunities. *American Journal of Preventive Medicine* 2005;28(2)(Suppl 2):186–93.	Non-systematic review.
Zunft HJF, Friebe D, Seppelt B et al. Perceived benefits of healthy eating among a nationally representative sample of adults in the European Union. *European Journal of Clinical Nutrition* 1997;51(Suppl 2):S41–6.	Europe-wide survey to determine main perceived benefits of healthy eating.

Appendix 11

THE EFFECTIVENESS OF INTERVENTIONS TO PREVENT WEIGHT GAIN TARGETED AT BLACK AND MINORITY ETHNIC GROUPS, AT VULNERABLE GROUPS AND AT INDIVIDUALS AT VULNERABLE LIFE-STAGES

EVIDENCE SUMMARY TABLES

EVIDENCE SUMMARY TABLE 1: INTERVENTIONS TO PREVENT WEIGHT GAIN, OR IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT (DIET AND ACTIVITY), IN BLACK AND MINORITY ETHNIC GROUPS

SUMMARY

Sixteen randomised controlled trials (RCTs) were included overall within Black and minority ethnic groups (BMEGs). Ten RCTs in adult African American or Black American populations were identified (four included only females), six RCTs in 8–10-year-old African American girls (Baranowski 1990; Stolley 1997; Baranowski 2003; Beech 2003; Robinson 2003; Story 2003) (one study included both mothers and their daughters and reported outcomes for both [Stolley 1997], another study included both adults and their children [Baranowski 1990]), one RCT in 11–15-year-old African American adolescents [Wilson 2002], and one study in Black preschool children (Fitzgibbon 2005). All the studies were published between 1997 and 2005, with the exception of Baranowski, which was published in 1990. All were conducted in America and five of the RCTs in adults were set in churches. Seven adult RCTs had follow-up between 5 and 30 months duration, seven RCTs that included children had 12- to 14-week follow-ups and one RCT in preschool children had a 2-year follow-up.

Regarding the adult RCTs, mean age ranged from 37 to 60 years; mean age in the two family interventions was 31–32 years (Baranowski 1990; Stolley 1997). 73–80% of the study populations consisted of females, with a mean BMI ranging from 29 to 33 kg/m^2 and dropout rate ranging from 0 to 44% and sample size varying from 52 (Newton & Perri 2004) to 1325 (Hall 2003). Although the study by Hall and colleagues (2003) was targeted at minorities and assessed outcomes according to race, only 28% of the population were classified as ‘Black’. All the other included studies in this section were virtually exclusively in African American or Black American populations.

Four RCTs concentrated on a dietary intervention in adult Black/African American populations (three studies specifically focussing on increasing fruit and vegetables and one study of a low-fat diet). Two RCTs concentrated on an exercise only intervention (walking) in adults and another ten studies had a diet and exercise intervention. Two of the ten adult RCTs reported weight, eight reported dietary intake (five studies focussing solely on fruit and vegetable intake). Two studies that conducted physical activity (PA) interventions (walking) reported PA outcomes only and two diet and exercise studies reported energy expenditure (Baranowski 1990; Yanek 2001). The four GEMS pilot studies and the study in preschool children reported weight, dietary intake and PA, two other studies that included children reported dietary intake only (Stolley 1997; Wilson 2002) and another study including children reported PA outcomes only (Baranowski 1990).

Evidence of efficacy for weight management/reduction

Two RCTs were identified which reported weight outcomes out of nine studies that included adults (Yanek 2001; Hall 2003). The study by Hall and colleagues (2003) showed modest but statistically significant decreases in weight (–1.4 kg), BMI (–0.6 kg/m^2), waist (–1.9 cm) and hip (–0.9 cm) circumference in Black American women following a low-fat diet for 6 months. Yanek and colleagues (2001) showed a significant reduction in BMI (–1.1 kg/m^2) and waist (–0.66 inches [1.7 cm]) circumference but not weight or % body fat at 1 year in African American female churchgoers following a diet and moderate aerobic activity intervention.

Eight RCTs were identified in African American/Black American children with four studies conducted as pilots for one trial (GEMS). All eight studies included diet and PA components and all the GEMS pilots included an active control. Two studies randomised either a mother and child dyad (Stolley 997) or a family unit, which included one or two adults and varying number of children living in the same household (Baranowski 1990). Mothers were actively involved in on of the GEMS pilot studies (Beech 2003). All four GEMS pilot studies reported no change in BMI at 12-weeks follow-up, two studies did not report weight outcome data at 12 weeks for the children, but one of these studies reported 'no weight change' between intervention and control group mothers (Stolley 1997) and the other study reported 'no significant differences' between groups for anthropometric measures (Baranowski 1990). Seven of the studies were not adequately powered to detect weight changes at 12–14 weeks. Ethnic minority children from Head Start programmes in Chicago that received a 14-week diet and PA intervention (Hip Hop to Health Jr) had significantly smaller increases in BMI compared with control children at 1-year follow-up (0.06 vs. 0.59 kg/m^2; difference –0.53 kg/m^2 (95% confidence interval [CI] –0.91, –0.14), $p = 0.01$; and at 2-year follow-up, 0.54 vs. 1.08 kg/m^2; difference –0.54 kg/m^2 (95% CI –0.98, –0.10), $p = 0.02$, with adjustment for baseline age and BMI. This study was adequately powered.

Evidence of efficacy for diet/physical activity outcomes

Diet

Seven adult RCTs reported dietary intake with four studies aimed at increasing fruit and vegetable intake amongst African American churchgoers (Campbell 1999; Resnicow 2001, 2004, 2005). Two of the fruit and vegetable interventions (Campbell 1999; Resnicow 2001) acted as parent studies for the third fruit and vegetable study (Resnicow 2004). In all four studies, fruit and vegetable intake was significantly increased in the intervention church populations up to 2 years, and one study reported significant difference in % energy intake from fat (Resnicow 2004). A culturally tailored diet and PA intervention significantly increased fruit and vegetable intake at 1 year compared with controls, who received education materials only; motivational telephone counselling had an additive effect (Resnicow 2005). A low-fat dietary intervention produced significant decreases in % energy intake from fat (–10.98%) and total energy intake (–379 kcal [–1.59 MJ]) at 6 months in postmenopausal Black American women (Hall 2003). A diet and moderate aerobic activity intervention produced significant decreases in total energy intake (–117 vs. –7 kcal [–490 vs. –29 kJ]) and total fat intake (–8.1 vs. 2.3 g/d) but not % energy from fat (Yanek 2001) at 1 year. Saturated fat intake (–2.1 oz [59 g]) and % energy from fat (–7.9%) was significantly reduced at 12 weeks in African American mothers following a diet and PA intervention (Stolley 1997).

Physical activity

Two adult RCTs promoted walking and included a home-based element, among sedentary ethnic minority populations. Both studies significantly increased the amount of walking in all participants from baseline to follow-up, but brief education was just as effective as adding mail and telephone counselling (Chen 1998) and a culturally tailored programme was no more effective than the standard programme (Newton 2004). One study including diet and moderate aerobic activity failed to show a significant difference in energy expenditure between intervention and control at 1 year (Yanek 2001). A culturally specific low-fat diet and aerobic exercise intervention in Black American families did not produce significantly increased metabolic equivalent tasks (METs) or energy expenditure at 14 weeks compared with control; both significantly increased energy expenditure from baseline (Baranowski 1990). A culturally tailored diet and PA intervention significantly increased PA at 1 year compared with controls, who received education materials only; however, motivational telephone counselling did not increase effectiveness of the culturally tailored diet and PA intervention (both active interventions increased PA compared with controls).

Within the RCTs in girls, all four GEMS pilots failed to show significant difference between study groups with regard to dietary intake or PA at 12 weeks (NB: controls were active controls in GEMS). There were a few exceptions: the parent and child intervention groups combined significantly reduced intake of sweetened drinks compared with non-active control in the Memphis GEMS study (Beech 2003). The Stanford GEMS pilot showed significant reduction in television (TV) viewing in the intervention group (Robinson 2003). The GEMS Minnesota pilot (Story 2003) and the study by Stolley (1997) both showed significant reduction in % energy from fat in the intervention girls. The Hip Hop to Health Jr study demonstrated only one significant difference between intervention and control preschool children regarding diet/activity outcomes and this was a difference in % energy from saturated fat at 1-year follow-up (11.6 vs. 12.8%, $p = 0.002$).

Amongst African American adolescents, social cognitive theory (SCT) and SCT plus motivational interviewing to increase fruit and vegetable intake, were equally effective compared with control at 12 weeks (Wilson 2002). The children of a family diet and exercise intervention actually decreased activity (METs) compared with the control children who increased activity (METs) and energy expenditure (Baranowski 1990).

Evidence of corroboration in the UK

Six population surveys, two reviews and two intervention studies of diet and PA in BMEG populations in Britain were identified for corroborative evidence. The majority focused on South Asian women and one focused on White Irish adults. Another two non-UK surveys including African Americans were also included.

EVIDENCE TABLE 1: INTERVENTIONS TO PREVENT WEIGHT GAIN, OR IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT (DIET AND ACTIVITY), IN BLACK AND MINORITY ETHNIC GROUPS

(A) ADULTS

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
Hall et al. 2003 Women's health trial: feasibility study in minority populations RCT 1++ **Aim:** To examine the effect of a low-fat diet on anthropometric and biochemical variables in postmenopausal women of diverse ethnic backgrounds.	**Eligibility criteria:** Postmenopausal women 50–79 years, consuming diet with at least 36% total energy derived from fat. Women were 165% above ideal body weight, special minority focussed recruitment. Women taking medications to lower blood lipids or insulin were excluded. This study was included in the review because not only was it in minority ethnic groups but it met all our inclusion criteria, i.e. the subjects were not all obese at baseline. **Setting:** Atlanta, Alabama and Miami, USA, multi-site. Intervention *n* = 1325 Control *n* = 883 56% non-Hispanic White, 28% Black, 16% Hispanic; mean age 60 years.	**Intervention:** Reduce total fat intake to 20% or less of total energy, also reduce saturated fatty acids and cholesterol, increase fruits, vegetables and wholegrain, no emphasis on reduced energy intake, weight loss or exercise; groups of 8–15 led by research nutritionist, weekly sessions for initial 6 weeks, then monthly for 9 months, then quarterly. **Control**: Control group received pamphlet on general dietary guidelines. **Follow-up:** Minimum 6 months and maximum 18 months. The duration of follow-up varied because the end of the study was the same for all participants, regardless of the date when they joined the study.	**Lost to follow-up**: Intervention: 649 of 1720 Control: 234 of 649 (see confounders/comments) **Weight (kg):** Mean difference between baseline and 6 month follow-up measurements. Negative values indicate positive health changes with intervention compared with control. White –1.4 (–1.9 to –0.99) Black –1.7 (–2.27 to –1.02) Hispanic –1.2 (–2.31 to 0.00) **BMI (kg/m^2):** White –0.6 (–0.72 to –0.38) Black –0.6 (–0.88 to –0.41) Hispanic –0.5 (–0.90 to –0.03) **Waist (cm):** White –1.7 (–2.27 to –1.08) Black –1.9 (–2.71 to –1.08)	Funded by National Cancer Institute and the National Heart, Lung and Blood Institute Women were randomised over 18-month period and the duration of follow-up varied because the stop date was same for all participants, regardless of their entry date. Many women were recruited relatively late in the study with administrative censoring prior to their schedules 12 or 18 month visit. A large number of women (*n* = 1720) completed the 6-month visit and this represented 81% of the women randomised to the intervention group and 74% of the women

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Baseline BMI (kg/m^2) (mean) Intervention White 27.8 (SD 4.6) Black 30.1 (SD 4.3) Hispanic 29.2 (SD 4.4) Control White 28.1 (SD 4.5) Black 30.5 (SD 4.3) Hispanic 29.8 (SD 5.5)		Hispanic –0.9 (–2.44 to 0.59) **Hips (cm):** White -1.7 (–2.22 to –1.12) Black –0.9 (–1.67 to –0.17) Hispanic –0.9 (–2.44 to 0.59) **Diet:** Fat (% energy) White –11.9 (–12.97 to –10.8) Black –10.98 (–12.28 to –9.29) Hispanic –5.7 (–8.52 to –2.78) Energy (kcal/d) White –306 (–402 to –210) (–1.28 [–1.68 to –0.88] MJ) Black –379 (–510 to –247) (–1.56 [–2.13 to –1.03] MJ) Hispanic –695 (–948 to –442) (–2.91 [–3.97 to –1.85] MJ) **Authors' conclusion**: In older White, Black and Hispanic women, a long-term low-fat dietary intervention in the absence of any particular focus on reducing energy intake was accompanied by modest but generally statistically significant	randomised to the control group. The change in total number of participants at baseline and 6-month interval primarily reflects follow-up time available from randomisation rather than dropout. Some degree of under-reporting of dietary intakes likely as degree of weight loss was less than would be expected by reported decreased energy intake – occurred in both intervention and control groups. Power calculations were not reported so it is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control.

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
			decreases in weight and anthropometric indices. **Physical activity:** Not reported.	
Yanek et al. 2001 Project Joy RCT 1+ **Aim:** To test nutrition and PA interventions in the church environment to reduce cardiovascular risk in urban communities where most African American women are regular churchgoers.	**Eligibility criteria:** African American women aged ≥40 years regularly attending Inner city churches in Baltimore with known level of high interest and participation in local activities, 80% African American congregation, average Sunday attendance at least 150 individuals, no currently active programme in weight control, exercise or smoking cessation for women aged ≥40 years, churches stratified by denominations. Pregnancy, myocardial or stroke, renal dialysis or undergoing treatment for cancer were exclusions. **Setting:** Baltimore, MD, USA. SP *n* = 267 SI *n* = 188 SH *n* = 74 529 women in total from 16 churches.	**SI intervention:** Behavioural model based on standard group methods with weekly sessions including weigh-in and group discussion then 30–45 min nutrition education module that included taste test or cooking demonstration (standardised for initial 20 weeks and taught by study staff who were female African American health educators), 30 min moderate intensity aerobic activity (could include brisk walking, water aerobics, Tae Bo and varied between churches), goals behaviours included 30 min or more exercise 5 to 7 days per week, five servings fruits and vegetables every day, 25 g fibre/day, fat consumption ≤40 g/day, 1200–1800 kcal [5.02–7.53 MJ] per day, sodium intake ≤2400 mg/day , smoking cessation. **SP intervention:** Same as above supplemented with spiritual and church cultural component which included group prayers and health messages enriched with scripture and	**Lost to follow-up**: 44% (235 of 529) Intention to treat (ITT) analysis carried out (i.e. on the 529) Results combined for SP and SI groups (see confounders/comments). **Weight:** Mean change intervention vs. control at 1 year: Weight (lb): –1.1 (SE 0.42) vs. 0.83 (SE 0.52) (–0.50 [SE 0.19] vs. 0.37 [SE 0.24] kg) BMI (kg/m^2): –1.1 (SE 0.42) vs. 0.14 (SE 0.09)* Waist (inches): –0.66 (SE 0.11) vs. –0.007 (SE 0.20)* (–2.79 [SE 0.28]	Intensive community involvement in design and pilot of study to encourage cultural relevance and ownership; intervention based on community action and social marketing model. Most women from churches randomised to self-help group were not interested in the intervention and so recruitment was lower. SP and SI significantly more likely to return for follow-up; completers significantly older, lower income, less likely to be employed and attended more sessions.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Mean age 52–54 years, most had completed high school, three out of four were employed, slightly more than half had hypertension, more than two out of five had arthritis. **Baseline BMI (kg/m^2):** SP+SI: 32.6 (SD 7), *n* = 455 SH: 31.7 (SD 8), *n* = 74	PA conducted with gospel music or praise or worship dance. **SH intervention:** Control group of non spiritual, self-help interventions, received all Project Joy educational materials plus American Heart Association guidelines and no further help except a hotline number for consultation from professional Project Joy health educators. **All groups:** Separate retreats held for each church following baseline assessment to kick-start the programme. **Follow-up:** 1 year.	vs. –0.02 [SE 0.51] cm) Body fat (%): –0.37 (SE 0.11) vs. –0.11 (SE 0.10) **Diet:** Mean change intervention vs. control at 1 year: Energy intake (kcal/d): –117 (SE 16) vs. –7 (SE 32)* (–489 [SE 67] vs. –29 [SE 134] kJ/d) Total fat (g/d): –8.1 (SE 0.99) vs. –2.3 (SE 2.0)* % Energy from fat: –1.7 (SE 0.27) vs. –1.2 (SE 0.47) Energy expenditure (kcal/d): 38 (SE 21) vs. 28.2 (SE 45) (159 [SE 88] vs. 118 [SE 188] kJ/day) ***Significant** **Physical activity:** Not reported.	SI and SP became very similar as women in SI women initiated prayer and scripture of their own accord. Power calculations were not reported so it is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
			Authors' conclusions: Intervention participants achieved clinically important improvements in cardiovascular disease risk profiles after 1 year that did not occur in the self-help groups; church-based interventions can significantly benefit cardiovascular health of African American women.	
Stolley 1997 Cluster RCT 1+ **Aim:** To examine the effectiveness of a culturally specific obesity prevention programme for preadolescent girls and their mothers. Mothers were included in the study for numerous	**Eligibility criteria:** African American girls (7–12 years old) and their mothers living in Chicago's inner city and attending a local Cabrini-Green tutoring programme (to address educational needs of children living at the poverty level). Chicago, USA **Intervention:** *n* = 32 mother–daughter pairs **Control:** *n* = 30 mother–daughter pairs **Mean age:** Mothers:	**Intervention:** Culturally specific low fat, low-energy diet and increased PA (including meal planning, tasting, music and dance, one session low-impact aerobics delivered by qualified staff from the tutoring programme). Two forms of incentives were offered; in return for participating in each of the health screenings, mothers received US$25.00 and daughters received US$10.00. As well as this each mother-daughter pair received US$5.00 gift certificate for a local grocery store chain at the end of each week's session. **Control:** General health programme. This programme was run similar to the	**Lost to follow-up:** At the end of the intervention 22% (*n* = 11) of mothers and 17% (*n* = 11) of daughters had dropped out the study. **Weight:** Weight of women remained unchanged from baseline in both intervention and control group. No data on weight change in daughters reported. **Diet:** Significant reductions in intervention mother's daily saturated fat intake (–2.1 oz [59 g], $p < 0.05$) and %	Thinner mothers were more likely to drop out The drop out mothers had a mean weight of 158 lb (71.7 kg), whereas the finishers had a mean weight of 179 lb (81.2 kg) ($p < 0.05$). 62% of the mothers and 19% of the daughters were obese and analyses of baseline values on all dependent variables showed no differences across treatment and control groups. It is not clear if the study

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
reasons: 1) they are the primary people who shop and cook for their families; 2) girls would more likely to attend regularly if their mothers also attended; 3) girls are more likely to make and maintain positive eating behaviour changes if they received support and role modelling from their mothers; 4) mothers are more likely to support changes in their daughters behaviours if they played a role in the change.	Intervention = 31.5 years Control = 33.7 years Daughters: Intervention = 9.9 years Control = 10.0 years **Intervention mothers:** 56% unemployed, 72% single, mean years education 11.4. **Control mothers:** 60% unemployed, 70% single, mean years education 11.3. **Baseline BMI (kg/m^2):** Mothers, intervention: 29.1 (6.7) Mothers, control: 30.8 (8.7) Daughters, intervention: 18.4 (4.0)(Daughters, control: 20.1(6.4) **% Overweight:** Mothers: Intervention group: 31.4% Control group: 38.7% Daughters: Intervention group: 7.9% Control group: 16.3% Not reported if the differences	treatment group, with control subjects meeting in small groups (*n* = 7–10) with group leaders. The focus of each session was on general health topics such as communicable disease control, relaxation techniques and stress reduction (i.e. not a culture-specific curriculum). The groups attended separate programs for 1 hour per week for 11 weeks. **Follow-up:** Post-test at 12 weeks.	energy from fat (–7.9%, $p < 0.001$) compared with controls. For daughters, authors found a significant effect of group on saturated fat, dietary cholesterol intake and percentage daily fat. Percentage of energy as fat in the treatment group diet was 39.1 at baseline and 35.2 at post-test ($p < 0.05$). To assess changes in eating behaviour during over the course of the intervention 2 × 2 (Group × Time) repeated measures multivariate analysis of variance (MANOVA). For daughters there was a Group × Time interaction for percentage of energy from fat, i.e. daughters reduced their percentage of energy from fat over the 12 weeks. **Authors' conclusions:** Intervention mothers exhibited significant decrease in intake of saturated fat and	was sufficiently powered to detect a significant effect of intervention compared with control. Randomisation was by cluster and analysis was by individual, which may limit reliability of the results.

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
	between groups was significant at baseline.		dietary fat. Results of the study were stronger for treatment mothers than for treatment daughters. Daughters in the treatment group reported only minor changes in their percentage of energy from fat as post treatment. Mothers appeared to be more concerned about their health and weight status than the daughters, the majority of whom were normal weight. **Physical activity:** Not reported.	
Baranowski et al. 1990 Cluster RCT 1– **Aim:** To improve diet and increase PA among a sample of predominantly low-income,	**Eligibility criteria:** Inclusion: Families (people living in the same household) of self-identified Black American ethnicity with a child in the 5th, 6th or 7th grades, healthy and willing to participate. Exclusion: Diagnosed chronic illness that would impose dietary or exercise restrictions.	**Intervention:** Culturally specific, one 90-min evening education session followed by two fitness sessions per week which were followed by fruit juice and low-fat low-salt snack for 14 weeks. Educational sessions included individual counselling (10–20 min each session with each family), small group education (20 min) and minimised lecturing/maximised participation.	**Lost to follow-up:** Not reported. **Weight:** Data not reported but authors report no significant differences between groups regarding anthropometric measures. **Diet:** Reported in another	Study participants were not self-selected – families were vigorously recruited from Black American students enrolled in 5th, 6th or 7th grade private and public schools (included home visits to recruit). There were significant

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
Black American families	**Setting:** Galveston, TX, USA. Intervention: *n* = 50 families (63 adults, 64 children) Control: *n* = 44 families (51 adults and 56 children) **Mean age (years):** Adults Intervention: 31.8 Control: 32.9 Children Intervention: 10.6 Control: 10.9 **Gender:** Intervention: 21% male, 79% female Control: 12% male, 88% female **Socio-economic data** Unemployed: 22% of subjects in both the intervention and control group were unemployed. Family income no more than US$15000 (this value is not corrected for the 2004 inflation value): Intervention: 91%	Included testimonials, aerobic activity and snack components; located in a convenient building within the community (formerly a Black high school). Aerobic activity sessions in a fitness centre (gym was refitted as modern fitness facility). Incentives included free transport and babysitting, weekly raffle, family fitness album containing picture of family taken each time attended evening session, sun visors, jump ropes, exercise shorts, etc; reminders and monetary rewards for accurately completing food and activity records; low fat, low-energy diet and increased PA (including meal planning, tasting, music and dance, one session low-impact aerobics). This occurred for first 7 weeks then in response to low participation and comments from participants – small group education component was dropped and didactic information included in the individual family component, participants no longer required to attend education session before the fitness session nor required to complete daily food and activity record; Black professionals hired for key staff positions. Providers of the intervention were University staff, exercise physiologists and qualified fitness centre staff.	publication, which has been ordered for appraisal. **Physical activity:** Energy expenditure in METs (a validated way of measuring energy expenditure. It is a way of expressing the rate of energy expenditure from a given PA) Adults (pre–post) Intervention: 241.4 (SD 22.8) – 247.8 (SD 46.6), *n* = 50 Control: 235.5 (SD 16.1) – 248.0 (SD 29.4), *n* = 48. Pre to post changes were detected in METS for both intervention and control group adults. Post values for energy expenditure were higher than pre values in both the intervention and control group ($p < 0.01$). In children an interaction effect in METs indicated a decrease in activity for the intervention group and an increase in activity for the control group ($p < 0.01$).	problems with lack of adherence to the intervention. Only eight out of 60 adults and ten of 64 children attended more than half the fitness sessions. The average participation across all education/fitness sessions was 28%. The authors suggest that factors such as a bomb scare, hurricane alert, centennial celebration and start of school year may have affected attendance. It is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control. Randomisation was by cluster and analysis was by individual, which may limit reliability of the

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Control: 83% NB. The federal poverty level for a family of four (2004) is US$18.850. Less than high school education: Intervention: 13% Control: 27%, ($p < 0.05$) In both groups subjects were Predominantly blue collar and clerical. **Baseline BMI:** Not reported.	**Control:** No contact. **Follow-up:** 14 weeks.	No differences were detected between the intervention group and control groups on indicators of cardiovascular fitness (pulse or blood pressure). **Energy expenditure in kcal per week (7-day exercise recall):** Adults (pre–post) Intervention: 19,073 (SD 6152) – 19,592 (SD 6630) (79.80 [SD 25.73] – 81.97 [SD 27.74] MJ per week), *n* = 50 Control: 17,483 (SD 4941) – 18,544 (SD 4958) (17.15 [SD 20.67] – 77.59 [SD 20.74] MJ per week), *n* = 48 Adult METs were significantly increased ($p < 0.01$) in both intervention and control from pre to post 14 weeks; post values were higher than pre values in both intervention and control for energy expenditure, and the intervention adults had consistently higher values	results.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
			than control. A significant interaction effect ($p < 0.05$) was detected on weight and body surface area. However, this was probably due to two males in the intervention group who lost a significant amount of weight **Authors' conclusions:** The intervention programme did not increase the aerobic activity/PA in intervention group families. Although adults reported moderate energy expenditures (2499 kcal/day [10.46 MJ/day] in the control group and 2724 kcal/day [11.40 MJ/day] in the intervention group), there was little aerobic activity after our programme, except among children. The frequency of PA at the end of the intervention was highest ($p < 0.05$) among children in the intervention group who attended more than half of the fitness sessions (5.4 times per week)	

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
			and was identifiable between those attending none (2.5 times per week) or less than half the sessions (2.8 times per week). No differences were detected among adult subjects. Programme ineffectiveness was not due to the subjects already being fit or engaging in exercise outside of the intervention but could have been due to the fact of low final participation rates in the intervention programme.	
Physical activity				
Newton & Perri 2004 RCT 1+ **Aim:** To compare the effects of three home-based exercise promotion programmes for improving	**Eligibility criteria:** African American, 30–69 years, sedentary lifestyle (<1 hour per week leisure time PA over previous 12 months), free from significant medical illnesses. **Setting:** Florida, USA PA (physician advice control): *n* = 10 SB (standard behavioural counselling): *n* = 22 CS (culturally sensitive counselling):	This study was part of a larger study which had a physician advice group and four groups that varied in frequency and intensity of exercise, (walk 3–4 or 5–7 days per week, at 45–55% or 65–75% of their heart rate reserve (no further details reported); participants within each active intervention group had different frequency and intensity of exercise prescribed but this was similar across groups. Participants could be prescribed to walk 3 or 4 (M) days or 5 to 7 days per week (H). In addition they received an intensity prescription of 45–55% or 65–	**Lost to follow-up:** PA: zero SB: 5 (23%) CS: 4 (15%) **Weight:** Not reported. **Diet:** Not reported. **Physical activity:** Number of days of exercise completion (derived from PA)	CS and SB produced significant improvements in cardiorespiratory fitness (VO_{2max}) that was superior to PA. It is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control groups.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
cardiorespiratory fitness in sedentary African American adults.	*n* = 20 **Age (mean) (years):** PA: 47.3 SB: 44.0 CS: 45.0 Majority were female (81%) married (59%) had some college education or greater (92%) were working full-time (86%) and had personal income of at least US$25,000 per year (75%). **Baseline BMI (kg/m^2):** PA: 30.18 (SD 8.58), *n* = 10 SB: 32.02 (SD 4.94), *n* = 22 CS: 31.65 (SD 7.17), *n* = 20 Not all subjects were obese; no significant difference.	75% of their heart rate reserves (no further details reported) This meant the four intervention groups were made up of the four intensity frequency combinations: LM, LH, HM, HH. The duration of exercise for intervention subjects was set at 30 min. **Physical activity:** Minimal treatment, met with physician who gave general advice on exercise based on national guidelines and American Heart Association booklet ‘Exercise and Your Heart’, followed by monthly (× six) physician-led meetings of various health topics. All subjects in this group were African Americans. **SB:** Ten × group sessions over 6 months (weekly month 1, biweekly months 2–3, monthly months 4–6); led by counsellors with graduate training in exercise and/or behavioural science held in university hospital, attended groups as part of larger study (see above) The subjects in the SB condition attended groups with predominantly White group members and White group leaders (70% of the participants recruited into the larger walking study were White); written	showed that there was no significant difference between SB, CS and PA groups at 6 months ($p = 0.679$). However, within group analyses showed that participants in the CS and SB groups significantly increased their frequency/days per week of walking (only walking was assessed in the study from baseline to 6 months ($p < 0.05$). Note: subjects in the CS and SB groups were the only groups to significantly increase their days walking from baseline to 6 months ($p < 0.05$). **Authors conclusion:** The study showed that CS produced significant improvements in cardiorespiratory fitness that was superior to PA. Subjects in the CS groups showed significantly greater improvements in cardiorespiratory fitness compared with those in the	

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
		materials and key behavioural components were goal setting, self-monitoring, problem solving, relapse prevention. **CS**: Identical to SB with exception that all group participants were African American, led by African American counsellors, conducted at suite located in African American community, materials designed to address socio-cultural concerns regarding exercise. **Follow-up:** 6 months	PA group. Subjects in the CS group also were more satisfied with various aspects of their treatment than were members of the other two groups. Although all three groups led to increases in self-reported PA but only the CS treatment demonstrated significant improvements ($p < 0.05$) in cardiorespiratory fitness. The results also showed that the culturally sensitive group produced additional positive changes in social support and participant satisfaction.	
Chen et al. 1998 RCT 1+ **Aim:** To evaluate a minimal intervention programme designed to promote walking among	**Eligibility criteria:** Women not currently exercising more than once per week or walking more than 90 min per week, able to speak comprehend and read English, free of any heart disease, at least 6th grade education. **Setting:** San Diego, USA Mean age 37 years, 58% married or living with partner, 63% employed	**Intervention:** Subjects received two pamphlets published by the American Heart Association (AHA). The first was ' Exercise and Your Heart' (a 32-page pamphlet with guidelines for beginning and maintaining an exercise program). The second, 'Silent Epidemic: the truth about women and heart disease' is a 27-page booklet on heart disease and risk factors in women. Subjects also received the Stanford walking kit and one-page tip sheet salient to ethnic minority women	**Lost to follow-up**: Significantly more women were lost to follow-up at 5 months in the intervention group, compared with control: (19 of 62 [30%] in intervention vs. 4 of 63 [6%] in control; $p < 0.05$). **Weight:** Not reported. **Diet:**	It is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control.

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
sedentary ethnic minority women.	outside home; 57 Latinas, 51 African Americans, 9 Asian or Pacific Islanders, 8 other/mixed ethnic origin. Behavioural intervention *n* = 62 Educational control *n* = 63 **Baseline weight:** Intervention: 163.7 (SD 41.8) lb (74.25 [SD 18.96] kg) Control: 166.6 (SD 44.0) lb (77.57 [SD 19.96] kg) Rational for including this study was that it met all the criteria. Although it is likely that the subjects are overweight (based on average height), the subjects are not obese so can it is included.	regarding barriers to exercise, and telephone counselling (based on SCT, six × 20–30 min, by graduate and advanced undergraduate student counsellors who received training) over 8 weeks in individually tailored home-based programme. Participants (from each group) paid US$5 at 2-month and again at 5-month follow-up plus pair of exercise shoes at 2-month follow-up. **Control:** Received same AHA written materials and 5 min telephone call. **Follow-up:** Five months and subset at 30 months.	Not reported. **Physical activity:** Both groups reported significantly increased walking at 5-month follow-up (mean change from baseline = 40 min in intervention vs. 52 min in control group, no significant difference); both groups continued to report more walking than baseline at 30-month follow-up of 50 participants (53 min intervention vs. 57 min control, no significant difference between groups). However, there was no significant difference in increase of PA levels between groups at either 5 months or 30 months follow-up **Authors conclusions:** Home-based behavioural intervention using mail and telephone counselling was not more effective than brief education – both increased walking among sedentary	

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
			ethnic minority women;	
Diet				
Resnicow 2005 Healthy Body Healthy Spirit trial RCT (cluster) 1+ **Aim:** To test effectiveness of culturally targeted self-help intervention compared with standard education materials.	**Setting:** Sixteen Black churches in Atlanta metropolitan area, USA **Mean age:** Intervention 2: 46.6 years Intervention 1: 45.9 years Control: 46.3 years **Female (%):** Intervention 2: 78% Intervention 1: 76.1% Control: 74.2% More than 60% had income >US$40,000 **Completed college or higher:** Intervention 2: 44.9% Intervention 1: 50.0% Control: 41.2% Majority middle to upper socio-economic status (SES) African Americans. Intervention 2: *n* = 304 Intervention 1: *n* = 335	**Intervention 2:** Culturally targeted self-help nutrition and PA materials plus 4 telephone counselling calls based on motivational interviewing. **Intervention 1:** Culturally targeted self-help nutrition and PA materials. **Control:** Standard nutrition and PA materials Nutrition intervention focused on increasing fruit and vegetable consumption. Intervention and follow-up = 1 year.	1056 adults recruited and 906 followed up at 1 year (86%). **Mean change in fruit and vegetable intake at 1 year:** Intervention 2: 1.13 servings Intervention 1: 0.44 servings Control: 0.17 servings (mean of 2-, 19- and 36-item FFQs). Total time of PA increased significantly more in interventions 1 and 2 compared with group 1 for ‘all activity’, over 3 METs, and ‘exercise items’ (using CHAMPS instrument). Authors conclude there was a clear additive effect for motivational interviewing (intervention 2) on fruit and vegetable intake, whereas motivational interviewing did not enhance intervention 1 for PA measures.	Churches received financial incentives to participate.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Control: n = 267			
Resnicow et al. 2004 Body and Soul Cluster RCT 1++ **Aim:** To test the impact of the intervention when delivered by volunteer members of African American churches with less training, monitoring and support (real-world conditions).	**Eligibility criteria:** African American adults attending church. **Setting:** California, south-east and north-east. 1022 individuals across 15 churches. Intervention group n = 8 churches. Comparison group n = 7 churches. Number of participants in the study n = 854. All subjects were African American, 73–76% female, mean age 51 years, 60% married or living with partner, 50% had household income >US$50,000 and almost 70% reported at least some college education. **Baseline BMI:** Not reported.	**Intervention:** Churches agreed to implement several core church wide activities including a kick-off event, forming a project coordination committee, conducting at least three church-wide nutrition events plus one additional event involving the pastor and making at least one policy change; The American Cancer Society (ACS) provided churches with implementation manual and trained a volunteer liaison within each church; all individuals received *Eat For Life* cookbook which contained recipes submitted by church members from Eat for Life Trial and contained at least one-quarter serving fruit or vegetable per serving and low in fat; each church received a video developed for the study targeting fruit and vegetable intake using spiritual and secular motivational messages and lasting 18 min for public screening; motivational interviewing provided to individuals for voluntarily enrolled (unlike church-wide activities) provided by lay members (mainly with degree and background in a helping profession) who received training by ACS staff. The intervention lasted for 6 months and individuals which did not	**Lost to follow-up**: 15% intervention, 17% comparison (no significant difference). 854 of 1022 assessed in total at 6 months **Weight:** Not reported. **Diet:** At 6 months, participants in intervention group reported significantly greater consumption of fruits and vegetables than those in comparison group, adjusted post-test difference was 0.7 servings per day based on a two-item measure and 1.4 servings for the 17-item measure change in fruits was 0.4 servings (2-item) and 0.9 servings (17-item, 0.15 attributable to increase in fruit juice); change in vegetables was 0.2 (2-item) servings and 0.5 servings (17-item).	Constructed from two independent interventions to increase fruit and vegetable intake among African Americans in African American churches in southern USA 'Black Churches United for Better Health' and 'Eat for Life'. (Both parent trials included in this review.) Funded by ACS. Primary costs for the motivational interviewing training (trainer fees US$750 per day). Churches received US$5 incentive per completed baseline interview and again at 6-month follow-up plus US$500 if obtained completed questionnaires for at least 90% of their baseline participants.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
		respond to the 6-month post-test questionnaire were contacted by telephone by trained staff from the University of North Carolina and offered to receive a second questionnaire by mail or to complete it over the phone. **Control:** No details reported. **Follow-up:** 6 months. Two measures of fruit and vegetable intake were obtained at baseline and the 6-month follow-up. One was the National Cancer Institute (NCI) 19-item fruit and vegetable FFQ that assessed dietary intake over the past 4 weeks. Two items assessing French fry intake were excluded from the questionnaire, which left 17 items. The second measure was composed of two items used to assess usual fruit and vegetable intake that had a separate item for total fruits and total vegetables consumed each day.	There was a small but significant difference between groups in % energy from fat (32.8 [SE 0.27] in intervention vs. 33.7 [SE 0.31]; *p* < 0.05) in control. **Authors' conclusion:** Positive effects on behaviour change can be achieved in real-world conditions. Effect sizes were smaller but significant compared with parent efficacy trials **Physical activity:** Not reported.	Self-report. It is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control. Authors report that all 15 churches 'reached the baseline quota of 60 participants'. Randomisation was by cluster and analysis was by individual, which may limit reliability of the results.
Resnicow et al. 2001 Eat For Life Trial	**Eligibility criteria:** African American adults attending Baptist and Methodist churches. **Setting:**	**Intervention**: Culturally sensitive multi-component self-help intervention: 23 min video, cookbook with recipes submitted by members that contained at least one-	**Lost to follow-up**: 150 of 1011 dropped out. (15%) Control attrition: 33%	This study was used in the development of Resnicow 2004, not same participants.

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
Cluster RCT 1++ **Aim:** To increase fruit and vegetable intake in African Americans delivered through Black churches.	Atlanta, USA. **Churches:** *n* = 14 Control group: *n* = 4 Self-help intervention with one telephone cue call: *n* = 6 Self-help group with one cue call and three counselling calls: *n* = 4 Total number of subjects in the study: *n* = 1011 The number of participants per church averaged 72 (range 53–130) Mean age 44 years, 73% female, 54% married or living together, 45% income >US$39,999, 9.3% less than high school education. **Baseline BMI:** Not reported.	quarter serving fruit or vegetable per serving and low in fat; other education materials and quarterly newsletter. **Intervention 1:** Above plus one telephone call 2 weeks after baseline health fair to cue participants to use materials. **Intervention 2:** Above plus one telephone call 2 weeks after baseline health fair to cue participants to use materials plus three counselling calls based on motivational interviewing at 3, 6 and 10 months from baseline. Providers of the intervention included University researchers, national non-governmental health agency and the National Institutes of Health. To encourage participation, churches were provided with a US$10 donation for each adult subject (up to 60 per church) that completed baseline assessment. Churches received incentives ranging from US$250 to US$2000 (from the NCI depending on the proportion of baseline participants that attended the post-test health fair.	Culturally sensitive multi-component self-help intervention with one telephone cue call, attrition: 6% Culturally sensitive multi-component self-help intervention with one cue call and three counselling calls, attrition: 18% Dropouts were significantly younger, less likely to be married, to attend church more times per week and more likely to report alcohol use in the past 30 days. **Weight:** Not reported. **Diet:** At 1 year, the increase from baseline in fruit and vegetable intake was largest in Intervention 2; net difference between intervention 2 and control: 1.38, 1.03, 1.21 daily servings of fruits and vegetables (2-, 7- and 36-item FFQs respectively). Net	Dropouts were significantly younger, less likely to be married, less likely to attend church more times per week and more likely to report alcohol use in last 30 days. This study had power to detect a difference of one half serving of fruits and vegetables between intervention group 2 and control, with a power of 0.80 and alpha 0.05 Randomisation was by cluster and analysis was by individual, which may limit reliability of the results.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
		Control: Received standard nutrition education materials initially and culturally sensitive intervention materials 1 year post-test i.e. they received their intervention materials 1 year after the post-test. **Follow-up:** 1 year. **Diet**: Multiple measures of dietary intake were obtained to provide a converging estimate of actual intake. All subjects completed a seven-item FFQ, based on the behavioural Risk Factor Surveillance System that assessed fruit and vegetable intake in the past month. A two-item measure was used to assess usual fruit and vegetable intake. The third instrument was a 36-item fruit and vegetable FFQ, based on the Health Habits and History Questionnaire that was developed for this particular study.	difference between intervention 2 and intervention 1 was 1.14, 1.10 and 0.97 servings (2-, 7- and 36-item FFQs respectively) ($p < 0.05$). NB. Fruit and vegetable intake increased in both interventions compared with the control group. **Authors' conclusions:** Motivational interviewing when given in conjunction with a culturally appropriate multi-component self-help intervention appears to be a promising strategy for modifying dietary behaviour. **Physical activity:** Not reported.	
Campbell et al. 1999 The Black Churches United For Better Health Project	**Eligibility criteria:** African American church members. **Setting:** Fifty Black churches in ten rural counties in eastern North Carolina, USA.	**Intervention:** Based on a holistic approach that focussed on numerous factors to help improve fruit and vegetable consumption. This included targeting activities at individual, social network and community levels; used PRECED-	Response rate was 77.3% **Weight:** Not reported. **Diet:** Mean difference (portion	Funded by NCI. Survey was pilot tested and validated with a 3-day food record obtained form 146 members of the

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
Cluster RCT 1++ **Aim:** To increase fruit and vegetable consumption by at least 0.5 daily servings among rural African American church members (for cancer prevention).	Intervention: *n* = 1198 Control: *n* = 1321 73% female, 98% African-American, average age 53.8 years, 55% married, 67% at least a high school education, 59% household income below $20,000 per year. **Baseline BMI**: Not reported. **Knowledge that five or more daily servings needed for health (baseline):** Intervention: 11.4% Delayed intervention/ control: 10.0% **Baseline fruit and vegetable consumption (number):** Intervention Fruits and vegetables: 3.84 Fruits: 2.14 Vegetables: 1.69 Delayed intervention: Fruits and vegetables: 3.65 Fruits: 2.04 Vegetables: 1.61	PROCEED model incorporating stages-of-change transtheoretical model, SCT and social support models. Intervention included planting gardens, 5-a-day educational sessions (at least two in each church), cookbook and recipe tasting, serving more fruits and vegetables at church functions, church members attended bimonthly training sessions to help other church members, coalitions were formed between church members and received training to plan community events, pastor support from the pulpit, grocer-vendor involvement and church initiated activities such as 5-a-day Sundays. The intervention was provided by Research staff, participating churches and local agencies, lay advisors (church members identified as natural helpers) and pastors. Intervention churches received funds to implement programme US$2500 per year, all churches received discretionary funds US$1000 per year. **Control:** Delayed intervention (received no advice). **Follow-up:** 20 months	serving) at 2 years adjusted for demographic and baseline intakes: Total fruits and vegetables: 0.85 (SE 0.12), *p* = 0.0001. Fruits: 0.66 (SE 0.09), *p* = 0.0001. Vegetables: 0.19 (SE 0.04), *p* = 0.003. Largest increases in fruit and vegetable consumption were observed among people aged 66 years or older (1 serving), those with education beyond high school (0.92 servings), widowed or divorced (0.96 servings), attending church frequently (1.3 servings); least improvement occurred amongst those aged 18–37 years and those who were single. **Authors' conclusions:** Study was successful in achieving dietary change among rural African Americans.	same subsample that completed the 1-year interim survey. Income level significantly higher in control group compared with intervention. It is not clear if the study was sufficiently powered to detect a significant effect of intervention compared with control.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/comments
			Physical activity: Not reported.	

(B) CHILDREN

Weight				
Fitzgibbon 2005 Hip Hop to Health Jr RCT 1+	African American and Latino minority children (3–5 years old) in 24 Head Start sites in Chicago. **Mean age (months):** Intervention: 48.6 (SD 7.6) Control: 50.8 (SD 6.4) **% Female:** Intervention: 49.7% Control: 50.5% **% Black:** Intervention: 99% Control: 80.7% **Baseline BMI (kg/m^2):** Intervention: 16.5 (SD 1.5) Control: 16.7 (SD 2.0)	Reduction in fat, increase in fibre, increase in PA and inclusion of family are main elements of intervention. Theoretical base is combination of social learning theory and transtheoretical model of stages of change. Children had 45 min, three times per week for 14 weeks, hands-on learning about go and grow foods (' foods that will help you go and grow') vs. slow foods (' will make you slow'), using puppets of characters from each of the food groups. Parents had weekly newsletter, homework (compensated US$5 if completed), and twice weekly 30-min low-impact aerobic classes at children's Head Start sites. Control had 20-min class once per week for 14 weeks, spent on general health	14-week active intervention plus 2 years follow-up. Intervention *n* = 179 Control *n* = 183 Intervention children had significantly smaller increases in BMI compared with control children at 1-year follow-up (0.06 vs. 0.59 kg/m^2; difference –0.53 (95% CI –0.91, –0.14) kg/m^2, *p* = 0.01; and at 2-year follow-up, 0.54 vs. 1.08 kg/m^2; difference –0.54 (95% CI –0.98, –0.10) kg/m^2, *p* = 0.02, with adjustment for baseline age and BMI. Demonstrated only one significant difference between intervention and control children regarding diet/activity	Trial was piloted for 3 weeks where elements were changed. Curriculum materials translated and taught in both English and Spanish. Twelve of the sites were randomly assigned to receive the intensive intervention and 12 were assigned to the general health intervention.

		activity. Parents had weekly newsletter,	outcomes and this was a difference in % energy from saturated fat at 1-year follow-up (11.6 vs. 12.8%, *p* = 0.002).	
Baranowski 2003 GEMS – Baylor RCT 1+ **Aim:** To prevent obesity in African American girls.	**Eligibility criteria:** Eight-year-old African American girls, at least 50th percentile for age and gender BMI, with a parent willing to be involved, children needed access to internet, aimed at middle-income families, Texas, USA Intervention: *n* = 16 Control: *n* = 19 **Mean age:** Intervention: 8.3 (SD 0.3) years Control: 8.4 (SD 0.3) **Sex:** Girls only.	**Intervention:** All participants received below plus self-esteem enhancement and cultural awareness programme. **Control:** Set in a day summer camp (4 weeks) then in homes (8-week internet intervention), the intervention was delivered by trained personnel in camp and researchers via a website, aimed at increasing fruit and vegetable and water consumption and enhance PA. **Follow-up**: 12 weeks.	ITT analysis. **Weight, diet and physical activity:** No significant difference between groups for BMI, waist circumference, PA (accelerometer, checklist and questionnaire), or dietary intake at 12 weeks. There were diet differences in lower total energy (–231 kcal [–966 kJ]) and the total % of energy from fat, greater consumption of water and fruit juice and lesser consumption of sweetened beverages. It was also shown that the treatment group girls heavier at baseline showed a trend (*p* < 0.08) toward lower BMI compared with the heavier girls in the control group. Only subjects in the intervention group improved.	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to detect a significant intervention effect. Fully powered studies of two of the GEMS pilots are currently underway.
Beech 2003 GEMS-Memphis RCT	**Eligibility criteria:** African American girls, 8–10 years old, at least 25th percentile for age and gender BMI, able to participate in physical education (PE) classes at	School- and home-based intervention delivered by a trained researcher and a community lay health educator. **Intervention 1:**	ITT analysis, 100% follow-up. **Weight, diet and physical activity:** No significant difference	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to

1+ **Aim:** To prevent obesity in African American girls.	school, with a parent willing to be involved. Set in low-income areas, Tennessee, USA **Sample size** Intervention 1: *n* = 21 Intervention 2: *n* = 21 Control: *n* = 18 **Mean age:** Intervention (child): 8.7 (SD 0.8) years. Intervention (parent): 9.1 (SD 0.7) years . Control: 8.9 (SD 0.8) years. Mean age of parents varied from 34 to 39 years and was significantly different between groups (older mothers in control group). **Socio-economic data:** 35% total household income less than US$20,000 per year (i.e. low income, as earlier definition), 50% of girls lived in female-headed households. **Baseline BMI (kg/m^2) of the children:** Intervention 1: 25.5 (SD 7.4). Intervention 2**:** 23.0 (SD 5.6). Control: 22.6 (SD 5.6). Therefore, the baseline measurements show that the	Child-targeted intervention with girls only, 30 min hip-hop aerobics (also promote enjoyment) and 30 min healthy eating (decrease high-fat foods, increase water/reduce sweetened beverages, increase fruit and vegetable intake, promote healthy nutrition-related behaviours; take home element and gift incentives; 12 × weekly 90 min sessions. **Intervention 2:** Parent-targeted intervention with parents only, 25 min dance segment and 25 min interactive and didactic nutrition components 12 × weekly 90 min sessions. **Control:** Three × monthly 90 min sessions to improve self-esteem (nutrition and PA not addressed). **Follow-up:** 12 weeks.	between groups for BMI, waist circumference, PA (accelerometer and questionnaire), or dietary intake at 12 weeks with the exception of: parent and child intervention groups combined were consuming significantly fewer sweetened drinks (34% less, $p = 0.03$) compared with the control group at 12 weeks. **Authors' conclusion:** Study demonstrates feasibility, acceptability and efficacy of culturally relevant obesity prevention intervention in preadolescent African American girls and their parents/caregivers.	detect a significant intervention effect. Fully powered studies of two of the GEMS pilots are currently underway. Based on SCT Twelve-week non-randomised feasibility study conducted before this intervention. The control received less contact than intervention groups, which may have contributed to difference in effect between groups.

	subjects are not obese and although the mean BMI of intervention group 1 shows they are slightly overweight. Significance of these differences are not reported. **Baseline BMI of parents:** Not reported.			
Robinson 2003 GEMS-Stanford RCT 1+ **Aim:** To prevent obesity in African American girls.	**Eligibility criteria:** African American girls (8–10 years old), at least 50th percentile for age and gender BMI, with a parent having a BMI >25 kg/m^2, willing to be involved. Set in Oakland and Palo Alto, CA, USA. Intervention: *n* = 28 Control: *n* = 33 **Mean age:** Intervention: 9.5 (SD 0.8) years. Control: 9.5 (SD 0.9) years.	**Intervention:** After-school dance classes set in community centres designed to improve PA, reduce sedentary behaviours and enhance diet. The intervention called START (Sisters Taking Action to Reduce Television) was delivered by trained university-based dance instructors and a female African American intervention specialist. The programme consisted of daily dance classes during school weeks and reducing TV viewing time was covered in five home-based lessons. Four community lectures were also provided. **Control:** The control intervention was implemented to be an up-to-date information-based health education programme to promote healthful diet and activity patterns. It included presenting monthly community health lectures, delivered by volunteers from the African American task forces of the local chapters of the AHA and the American Diabetes Association. The content of the newsletter focussed on reducing risks for	ITT analysis. **Weight, diet and physical activity:** No significant difference between groups for BMI, waist circumference, PA (accelerometer and checklist), or dietary intake at 12 weeks. Significantly less TV viewing in the intervention group at 12 weeks (*p* = 0.007). At follow-up, the treatment group reported 23% less media use, relative to controls (–4.96/21.33) and a significant decrease in total household TV use relative to controls.	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to detect a significant intervention effect. Fully powered studies of two of the GEMS pilots are currently underway.

		obesity, heart disease, stroke, hypertension and diabetes and included age-related and culturally targeted educational materials. **Follow-up:** 12 weeks.		
Story 2003 GEMS-Minnesota RCT 1+ **Aim:** To prevent obesity in African American girls.	**Eligibility criteria:** 8–10-year-old African American girls, at least 25th percentile for age and gender BMI, with a parent willing to be involved. Set in low-income areas, Minnesota, USA Intervention: *n* = 26 Control: *n* = 28 **Mean age:** Intervention: 9.3 (SD 0.9) years. Control: 9.4 (SD 0.9) years. **Sex:** Girls only.	**Intervention:** Lunchtime clubs in school designed to improve nutrition, PA and self-esteem through a range of activities. The intervention which was conducted twice per week, focused on increasing healthy eating and PA. Intervention meetings, designed in a 'club meeting' format, were held twice per week for 1 hour after school at each of the schools used in the study. The intervention was based on SCT (Bandura) and targeted key points from three domains: 1) environmental factors such as peer support; 2) personal factors such as knowledge and values; and 3) behavioural factors such as goal setting and social reinforcement. Providers of the intervention included University Staff, Trained African American GEMS staff and school staff. **Control:** The control group served as an 'active placebo', non-nutrition/PA condition and focussed on promoting positive self-esteem and cultural enrichment. Participants attended monthly Saturday morning meetings (three meetings over	ITT analysis. **Weight, diet and physical activity:** No significant difference between groups for BMI, waist circumference, PA (accelerometer and questionnaire), or dietary intake at 12 weeks. % Energy from fat (parental reported) and low-fat food practices (parental reported) were significantly better in intervention group compared with control.	This study was a pilot study to assess feasibility and was not intended to be sufficiently powered to detect a significant intervention effect. Fully powered studies of two of the GEMS pilots are currently underway.

		12 weeks). This included arts and crafts; self-esteem activities, creating memory books and a workshop on African percussion instruments. **Follow-up:** 12 weeks.		
Baranowski et al. 1990 Cluster RCT 1– **Aim:** To improve diet and increase PA among a sample of Black American families.	**Eligibility criteria:** Inclusion: Families (people living in the same household) of self-identified Black-American ethnicity with a child in the 5th, 6th or 7th grades, healthy and willing to participate. Exclusion: Diagnosed chronic illness that would impose dietary or exercise restrictions. **Setting:** Galveston, TX, USA. Intervention: *n* = 50 families (63 adults, 64 children) Control: *n* = 44 families (51 adults and 56 children) **Mean age (years):** Adults Intervention: 31.8 Control: 32.9 **Gender:** Intervention: 21% male, 79% female Control: 12% male, 88% female **Unemployed:**	**Intervention:** Culturally specific, one 90-min evening education session followed by two fitness sessions per week which were followed by fruit juice and low-fat low-salt snack. Fourteen weeks, educational sessions included individual counselling (10–20 min each session with each family), small group education (20 min) and minimised lecturing/maximised participation and included testimonials, aerobic activity and snack components. Located in a convenient building cherished by the community (formerly a Black high school). Aerobic activity sessions in a fitness centre (gym was refitted as modern fitness facility). Incentives included free transport and babysitting, weekly raffle, family fitness album containing picture of family taken each time attended evening session, sun visors, jump ropes, exercise shorts, etc; reminders and monetary rewards for accurately completing food and activity records; low fat, low-energy diet and increased PA (including meal planning, tasting, music and dance, 1 session low-impact aerobics); this occurred for first 7 weeks then in response to low	**Lost to follow-up:** Not reported, average 28% participation. **Weight:** Data not reported but states that no significant differences between groups regarding anthropometric measures. **Physical activity:** 1) Energy expenditure in METs per week (7-day exercise recall): Children (pre – post) Intervention: 238.1 (SD 22.3) – 231.2 (SD 14.3), *n* = 59 Control: 231.2 (SD 12.0) – 237.2 (SD 21.8), *n* = 52 2) Energy expenditure in kcal per week (7-day exercise recall): Children (pre – post) Intervention: 9559 – 9684 (40.00–40.52 MJ/week),	*Not* self-presenting volunteers, families were vigorously recruited from Black American students enrolled in 5th, 6th or 7th grade private and public schools in Galveston, TX, USA (included home visits to recruit). Only 8 out of 60 adults and 10 of 64 children attended more than half the fitness sessions, average participation = 28%. Bomb scare, hurricane alert, centennial celebration and start of school year may have affected attendance. Diet outcomes reported in another publication but not relevant

	22% both groups. **Family income less than US$15,000:** Intervention: 91% Control: 83% **Less than high school education:** Intervention: 13% Control: 27%, $p < 0.05$ **Mean age children (years):** Intervention: 10.6 Control: 10.9 Predominantly blue collar and clerical. **Baseline BMI:** Not reported.	participation and comments from participants – small group education component was dropped and didactic information included in the individual family component, participants no longer required to attend education session before the fitness session nor required to complete daily food and activity record; Black professionals hired for key staff positions. **Control:** No contact. **Follow-up:** 14 weeks	*n* = 59 Control: 10,226 – 11,031 (42.77–46.15 MJ/week), *n* = 52 For the children an interaction effect in METs indicated a decrease in activity in the intervention group and an increase in activity in the control; control children increased energy expenditure more than the intervention children. **Authors' conclusions:** Programme did not achieve goal of increased habitual aerobic activity for the intervention group families, final participation was low therefore it is not surprising there was no differential effect of the programme on activity or fitness.	outcomes for this report (sodium only). It is not clear if the study was sufficiently powered to detect a significant effect of intervention compared with control.
Diet and /or physical activity				
Wilson et al. 2002 Cluster RCT 1+ **Aim:** To assess the effects of SCT plus	**Eligibility criteria:** Inclusion: Healthy 11–15-year-old African Americans from three middle schools, normotensive, no pre-existing cardiovascular disease or chronic disease, not currently taking medications, within 30% ideal weight for height.	**SCT:** SCT principles which include education, behavioural skills training, feedback and reinforcement; increase fruit and vegetable intake to six to eight servings per day and increase aerobic activity to 30–60 min/day for 7 days per week by the end of the programme; all	**Lost to follow-up:** SCT + MI = 17% SCT only = 30% Control = 31% **Weight:** Not reported.	Control group all male and SCT + MI had significantly greater number of married parents. Significantly more

motivational interviewing to increase fruit and vegetable intake in African American adolescents.	**Setting:** Richmond, Virginia, inner-city area, USA. SCT + MI (Social Cognitive Theory and Motivational Interviewing): *n* = 17 SCT only: *n* = 20 Control: *n* = 16 **Mean age:** 11–15 years. **Gender (male/female):** SCT + MI: 8/9 SCT only: 7/13 Control: 16/0 **Weight:** SCT + MI: 52 (SD 9) kg SCT only: 57(SD 22) kg Control: 53 (SD 19) kg	participants recruited from and took part in after-school intramural sports programme Team Up, 3 × per week and a fruit and vegetable cooking class 1 day per week. **SCT + MI:** As above with additional 30 min of self-presentation videotapes where participates given interview questions prior to interview and asked to generate several coping strategies to increase fruit and vegetable intake and PA that they had used as effective coping strategies, then videoed and allowed to view videos. **Control:** Twelve weekly sessions to maintain usual diet and exercise, general health related issues provided in education materials. **Follow-up:** 12 weeks. Providers of the intervention were the research team and school staff.	**Diet:** Pre – post fruit and vegetable servings/per day: SCT + MI: 2.6 (SD 1.4) – 5.7 (SD 2.2), $p < 0.05$ SCT: 2.5 (SD 1.2) – 4.8 (SD 2.4), $p < 0.05$ Control: 2.3 (SD 1.0) – 3.3 (SD 2.1), $p>0.05$) Correlation analyses revealed that only the SCT + MI group showed that dietary self-concept and dietary self-efficacy were both significantly ($p < 0.05$) correlated with post treatment fruit and vegetable intake and change in fruit and vegetable intake, respectively. **Physical activity:** 'No significant time or group effects for any of the physical activity measures.' **Authors' conclusion:** These findings suggest that the change in fruit and vegetable intake in the SCT + MI group resulted from strategic self-presentation, which induced positive shifts in self-concept and self-efficacy. It appears that SCT + MI and SCT alone were both effective	people were lost to follow-up in the SCT + MI group, compared with SCT alone and control groups. The study lacked sufficient power to detect a significant difference in fruit and vegetable intake between groups.

			at increasing fruit and vegetable intake compared with control. (Study reports in relation to fruit and vegetable intake and PA that no interaction or main effects were significant). The two active treatments changed significantly from baseline to follow-up on intake of fruit and vegetable but the control group did not.)	
Stolley 1997 Cluster RCT 1+ **Aim:** To examine the effectiveness of a culturally specific obesity prevention programme for preadolescent girls and their mothers.	**Eligibility criteria:** 7–12-year-old African American girls and their mothers living in Chicago's inner city and attending a local Cabrini–Green tutoring programme (to address educational needs of children living at the poverty level). Chicago, USA. Intervention: *n* = 32 mother–daughter pairs. Control: *n* = 30 mother–daughter pairs. **Mean age (years):** Intervention: 9.9 Control: 10.0 **Baseline BMI (kg/m^2)** Daughters, intervention: 18.4 (4.0) Daughters, control: 20.1 (6.4)	**Intervention:** Culturally specific low-fat, low-energy diet and increased PA (including meal planning, tasting, music and dance, one session low-impact aerobics). Providers of the intervention included researchers and staff from the Cabrini Green tutoring programme. Financial incentives were also given. In return for taking part in each of the health screenings, mothers received US$25.00 and daughters received US$10.00. Additionally, each mother daughter pair in attendance got a US$5.00 gift certificate for a local grocery store chain at the end of each week's session. **Control:** General health programme. Twelve weekly 1-hour meetings then every 3 months for 15 months.	**Lost to follow-up**: At the end of the intervention 22% (*n* = 11) of mothers and 17% (*n* = 11) of daughters had dropped out the study. **Weight:** Not reported. **Diet:** Intervention girls had significant reductions in % energy from fat (–3.9%, $p < 0.05$) compared with controls. **Weight:** Weight of women remained unchanged from baseline in both intervention and control group. No data on weight change in daughters reported.	This study had a number of limitations which will affect reliability of the results: There were very few participants, a large proportion of which dropped out of the study. Analyses were not by ITT. Outcomes were only reported for 12 weeks follow-up. Weight outcomes were not reported for daughters. Finally, it is not clear if

	19% of daughters were obese at baseline.	**Follow-up:** 18 months.	**Diet:** Significant reductions in mother's daily saturated fat intakes (–2.1 oz [59 g], $p < 0.05$) and % of energy from fat (–7.9%, $p < 0.001$) with intervention when compared with controls. Intervention daughters reported only minor changes in % energy from fat. **Authors' conclusions:** Intervention mothers exhibited significant decrease in intake of saturated fat and dietary fat. Results of the study were stronger for treatment mothers than for treatment daughters. Daughters in the treatment group reported only minor changes in their % energy from fat as post-treatment. Mothers appeared to be more concerned about their health and weight status than the daughters, the majority of whom were normal weight.	the study was sufficiently powered to detect a significant effect of intervention compared with control.

Evidence of corroboration (external validity)

Evidence of salience from studies conducted in the UK

First author	Study population	Research question	Length of follow-up	Main results	Confounders/comments

Evidence of implementation					
First author	**Study design**	**Study population**	**Research question**	**Length of follow-up**	**Main results**
Fox 2004	Case studies	South Asians (mainly at risk for heart disease).	Best practice guide to support delivery of heart disease services to South Asian communities in UK.	N/a	**Coventry 5-a-day scheme:** Provides people with money-off vouchers to spend on fruit and vegetables (£2 per week for 4 weeks, participants required to spend £4 of their own money at same time), valid in two stores in each area plus city centre and market, linked with delivery scheme that charges 50p to deliver, which can come off the voucher; free recipe cards, community nutrition scheme can give one-on-one help on preparing and cooking food in people's homes; there is evidence of groups of people shopping together. **The Coriander Club, Spitalfields City Farm:** Group of Bangladeshi women who get together and grow vegetables, two weekly gardening days and one weekly healthy cookery class, take home the vegetables in return for labour on the farm, growing vegetables is culturally acceptable hobby and opportunity to be physically active; Coriander Club is member of Taste of a Better Future project which is a national network of ethnic minority women's food growing groups (40-plus groups) set up in 1999, 40-plus group using spaces on housing estates and disused inner city plots to grow organic fruit and vegetables; as well as nutritious foods they enjoy making friends, sharing skills and bolstering communities. **Birmingham Food Net:** Cook and taste sessions run by community food workers, evaluation at end of five-session course shows participants (high South Asian population) include more fruit and vegetables, fish, cereals and starchy foods, use less oil and change to unsaturated fats; some report being more physically active and have learnt about healthy eating; some have had little exposure to education sessions, some women need convincing they have more to learn about cooking, some have low-level of knowledge about healthy eating, but all link diet with health.

					Bradford Trident Healthy Living Project weight management programme: Twelve-week group programme, emphasis on food and diet, discuss recipes, cooking methods, food labels, encouraged to keep food diaries, many have lost weight, learn recipes from all over world, low-budget recipes, active participation and ownership and empowerment are vital principles, subsidised health and fitness club membership given as incentive at end of programme. **Dietary intervention in high risk families with coronary heart disease in Ealing:** Family-based programme in cardiology department at Ealing hospital, cardio-protective diet emphasising low glycaemic index approach, shopper and cook attend as well as the patient, hold classes in evenings to ensure high attendance, lowers cholesterol by 18%, systolic blood pressure by 3 mmHg, body weight by 3.7 kg compared with a conventional care group, and persist beyond 1 year beyond completion of intervention programme and has impact on children (low intensity, easy to put into practice in primary care with modest extra resources. **Walking for Health in Wolverhampton:** Asian Community Walking Developer promotes walking within the community, she leads five different weekly group walks and trains volunteers, important to build trust and friendship into the meetings, gift voucher incentive of £1 for each five led-walks a person does, can collect up to £20 in vouchers to use in shops and leisure facilities in Wolverhampton. **Sitara:** Women-only project in West Yorkshire (75% South Asian), activities include exercise to music, swimming, aquafit, weights room, circuits and sauna; entailed hard work, co-operation and commitment to overcome problems around cultural issues, self-financing, prices kept low, holds four sessions per week and attracts up to 300 visits per week, couldn't have worked without commitment of all organisations involved (Primary Care Trusts [PCTs], council, local leisure). **Hamara Healthy Living Centre, Leeds:** Includes men's walking group, father-and-son swimming sessions and circuit training, participants encouraged to train as volunteers; sister organisation,

					Leeds Health Focus runs women's aerobic classes and women-only swimming, activities are designed around needs of participants, outreach work includes encouraging taxi drivers to incorporate PA into everyday lives (cleaning taxis), Hamara trainers offer after school aerobics and circuit training, basketball, football and cricket to four local schools (there is now a waiting list). **Al-Badr Health and Fitness:** New fitness centre in East London serving entire Muslim community; encourages and enables Muslim men and women to participate in physical fitness and health awareness programmes, state of the art equipment, separate male and female sessions (no male staff during female sessions) advertised on website.
Women's Health Initiative Study Group, Women's Health Initiative Dietary Modification Trial	FFQ as part of RCT	Postmenopausal women (USA).	To assess adherence to a low-fat diet.	5 years	This paper describes adherence to a low-fat dietary pattern (<20% energy from fat, five or more fruit/vegetable and six or more grain servings daily) in years 1 and 5 of the Women's Health Initiative Dietary Modification Trial, which was designed to examine the effects of a low-fat dietary pattern on risk of breast and colorectal cancers and other chronic diseases in postmenopausal women. Participants were randomly assigned to a low-fat dietary intervention arm (40%, *n* = 19,542) or a usual diet control arm (60%, *n* = 29,294). Women in the intervention arm completed 18 group sessions during the first year, followed by quarterly annual maintenance sessions. Adherence was assessed as control minus intervention (C – I) group differences in % total energy from fat as estimated by a FFQ. Based on these self-reported dietary data, mean C – I was 10.9 % points of energy from fat at year 1, decreasing to 9.0 at year 5. Factors associated with poorer adherence were being older, being African American or Hispanic (compared with White), having low income, and being obese. Group session attendance was strongly associated with better dietary adherence.
French 2000	Survey	Women aged 25–45 years, enrolled in Pound of Prevention Study	To examine demographic, behavioural and dietary correlates of frequency of fast food restaurant	3 years	Twenty-one percent of the sample reported eating three or more fast food meals per week. Frequency of fast food restaurant use was higher among younger women, those with lower income, non-White ethnicity, greater body weight, lower dietary restraint, fewer low-fat eating behaviours, and greater TV viewing. Intake of several other foods, including fruits and vegetables, did not differ by frequency of fast food restaurant use.

		(USA).	use.		
Williams 1999	Uncontrolled 6-week study.	Fifteen overweight or obese Asian women in Old Trafford, Manchester.	Examine perceptions of and change in weight from a healthy eating and exercise intervention.	17-month follow-up after 14-week programme.	45-min low-impact stretch and tone exercises to music led by fitness instructor each week for 14 weeks; home exercise advice; dietitian then gave advice regarding increasing fruit and vegetable intake, reducing amount of fat and oil in cooking, reducing intake of fatty and sugary foods; link worker available to interpret. Ten of 13 women lost weight, median weight loss after 14 week: –2.6 kg (range –0.7 to –10.7); from 14 weeks to 17 months eight of the women lost weight with median of –2.4 kg (range –0.4 to –7.5). Formal methods of recruiting had very little impact, verbal recommendation of the group by link worker and participants was more effective, intervention fulfilled social and weight loss functions and both functions were interrelated and affected weight, difficulty getting to venue and needs of family coming first were cited as reasons for none attendance; women who said they would definitely re-attend were generally those with a higher BMI.
White 1998	Review of interventions.	Papers published in English language 1985–96 in minority ethnic groups.	To review the effectiveness of health promotion in minority ethnic groups.	Various.	Dearth of relevant research on nutritional health promotion among minority ethnic groups in UK; 29 studies, 19 studies in African American population, two in UK that were supplementation studies in infant and toddlers (not relevant here); 13 of 29 studies demonstrated some degree of effectiveness, though only seven judged effective for their main nutritional aims in minority ethnic groups; educational approaches (one-to-one, group or community-wide in homes, schools or community settings); policy measures (school food policies); and technological measures (food supplements) demonstrated some degree of effectiveness; behavioural modification was more likely to be effective in European origin groups than minority ethnic groups (when compared), few studies can be directly applicable to UK, most were experimental or demonstration studies; many community-based projects to promote healthy eating in ethnic minorities in UK were identified in 'grey' literature, lacked formal evaluation and any sound evidence of effectiveness.
Bush 1998	Review	South Asians,	To evaluate opportunities fro	Various.	**South Asians:** GP clinic in Leeds for screening for coronary heart disease risk factors; high

		African Caribbeans, White Irish in UK.	and barriers against good nutritional health in minority ethnic groups.		attendance thought due to interpreter, increase in number of families reducing fat in cooking and changing to vegetable oil, several patients lost weight and a lot of women wanted to lose weight but had difficulty reconciling with family eating patters, failure to take up advice explained by family commitments, habit, health beliefs, environment and finances. Primary care initiative in Tower Hamlets, The Healthy Eastender project; dietary advice and materials appropriate to minority ethnic groups including Bangladeshi and African Caribbean– no evaluation. Dietary survey of Bengali women in Tower Hamlets concluded that unfamiliar food objects without verbal explanations are not likely to be recognised and pictures alone may not convey messages – implications for dietary surveys in this population. **African Caribbean:** Primary care initiative in Tower Hamlets, The Healthy Eastender project; dietary advice and materials appropriate to minority ethnic groups including Bangladeshi and African Caribbean – no evaluation. Studies in Manchester and Birmingham showed that African Caribbeans purchased more expensive imported Caribbean foods and because of lower incomes they spent a larger proportion on food. **White Irish:** Lack of intervention with Irish migrants in Britain. Lifestyle intervention in workplace in Galway aimed specifically at women concluded key to promoting healthy eating is in providing access to healthy options in canteen and reinforcing availability of these options through clear, simple and specific messages.
Carroll 2002	Literature review, survey, case studies and uncontrolled trial pilot	South Asian Muslim women in UK.	How effective is ‘exercise on prescription’ in promoting PA in South Asian women in UK?	6 weeks for pilot study.	**Case studies:** West Pennine Health Authority: ‘A prescription for exercise’ Bradford Health Authority: ‘Bradford encouraging exercising people’ Leicestershire Health Authority: ‘Activity for life’ Birmingham Health Authority: ‘Exercise for prescription’ Blackburn with Darwen: ‘Fitness for life’

	intervention with interviews.				Women expressed positive effect of exercise on health and well-being, increased energy levels and motivation, social aspects, but many significant barriers: access, cost, childcare, cultural codes of conduct, language, racism and religious discrimination. Exercise on Prescription schemes suffer following shortcomings: 1) some areas have special provision for Asian Muslim women but many areas do not; issues with promoting the scheme in general and specifically for South Asian women; 2) dependent upon commitment of staff vital especially when lack of continuous funding, programmes are short-term and oversubscribed, and difficult for women to finance continuing exercise; 3) dependent upon good communications between multi-agencies that are not used to working together; 4) lack of clarity regarding roles and functions; 5) no direct links between community and the agencies to encourage participation (poor awareness and access to schemes); 6) lack of evaluation/monitoring of schemes; 7) difficulties with location of facilities (need to use local community facilities), inadequate public transport, fears of safety of walking; 8) need for more Asian members of staff at leisure facilities to communicate and understand needs of Asian women and availability of written materials in appropriate languages; 9) difficult to provide women-only sessions, female instructors; 10) need to consider childcare facilities; 11) GPs and leisure centre staff and instructors need to be supportive and receive appropriate training. The pilot programme ‘Exercise to Health’ in Beeston, Leeds, was seen as being successful by both providers and women who participated (14 women interviewed at 6-week follow-up), good attendance and far more demand for the service than could be met. Women were willing to pay if had to, but only if classes were kept local, expectations were fulfilled, energy levels increased and more motivated, happier

					and healthier with positive attitude towards continuing exercising.
Health Education Authority, 1999	Survey	England	To evaluate health and lifestyle in BMEGs.	N/a	Indian, Pakistani and Bangladeshi people reported lower levels of familiarity with terms such as ‘starchy foods’, ‘dietary fibre’ and ‘fat’, and knowledge of foods high in these terms was poor; Indian women most likely not to have time to exercise; good understanding amongst all ethnic groups that exercise was important to maintain health; some reasons for not exercising appear specific to ethnic minority groups such as modesty, fear of mixed sex activity and of going out alone (not confined to Muslims); language and culture were otherwise rarely mentioned as perceived barriers; low levels of knowledge of recommended levels of physical exercise were reported, unemployment and patterns of employment had significant impact on levels of PA.
Rai, 1997	Survey	UK-wide	To evaluate PA.	N/a (cross-sectional)	Barriers to exercise are not culturally specific (barriers similar in White adult population and South Asian and Black communities; differences faced by South Asian Muslim women were related to importance of Islam and being Muslim. Mainly enjoyment but also habit, appearance, health, being a role model to children and social benefits were factors that motivated physically active people. Similar to rest of UK, South Asian people said low participation in PA due to low motivation (could be due to high level of stress in this population which could be caused by poverty and racism). No fundamental cultural or religious reasons for prohibition of PA amongst South Asian population. Lack of time, burden of domestic duties and family responsibilities cited as main barriers to participation. South Asians give low priority to PA; part of normal everyday life and concept of paying for it was strange; self-conscious about body size or shape. Lack of privacy, dress-codes, separate sex provision, actual or potential experiences of racism all acted as barriers to exercise, also ‘not fitting in’, high costs, personal safety, transport, opening hours, childcare facilities.
Asian Arts & Leisure	Survey	South Asian	To evaluate use of local leisure	N/a	South Asian women emerged as particular cause for concern; barriers included poor knowledge of English language, nervousness about dress, acceptance by

Planners, 1996		population in Hounslow	facilities.	(Cross-sectional)	other service users and possible injury.
Shelley 1995	Population survey	White Irish	To evaluate cardiovascular risk changes following 5-year health promotion community programme.	Five years – population survey (cross-sectional) before and after programme in Kilkenny and reference country (Offaly).	Kilkenny Health Project for cardiovascular disease prevention; BMI increased in men and women in intervention and reference counties; resources should be targeted at those with least education and those at increased risk of coronary heart disease (CHD) fish, chicken, fruit and vegetables eaten more frequently post-intervention.
Majmudar 1995	Survey	South Asian women in Bristol	To evaluate PA.	N/a (cross-sectional)	South Asian women most likely not to exercise were those >24 years old who were less fluent in written and spoken English. Fear of racial harassment discourages women from walking or jogging alone and using public transport to get to leisure facilities.
Verma 1994	Survey	Six non-European (with national distribution) ethnic groups in Manchester, UK	To evaluate PA.	N/a (cross-sectional)	Women of all ethnic groups who would like to take part in exercise have many common barriers. South Asian women, particularly Pakistanis and Bangladeshis, suffer additional barriers to exercise related to culture and custom (expected approval of other members of community, including religious teachers, parents, siblings and friends). Religion powerfully reinforced the authority and behaviour patterns which appeared to reduce participation; racism acted as constraint.

EVIDENCE SUMMARY TABLE 2: INTERVENTIONS TO PREVENT WEIGHT GAIN, OR IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT, IMPROVE DIET AND INCREASE ACTIVITY LEVELS, IN VULNERABLE GROUPS (LOW-INCOME, LOW-LITERACY, SPASTIC CEREBRAL PALSY, DOWN'S SYNDROME AND LEARNING DIFFICULTIES)

SUMMARY

Six of the 14 RCTs of BMEGs were of low-income subjects. Both of the pregnancy studies were in low-income women. None of the seven smoking studies or the study during menopause was in low-income populations. Three further studies were identified here in low-income populations, one which separately recruited low-income women and analysed results by income for the women only (Jeffery 1997, Pound of Prevention study), one study in Mexican American mainly women with low-income and low-literacy (Howard-Pitney 1997) and one study in low-income Mexican American 10-year-old schoolchildren (Trevino 2004, 2005). The results of these three studies and three further studies, one study in children with spastic cerebral palsy, one study in adults with learning difficulties and one study in adults with Down's syndrome, are reported here.

Two of the studies included in the BMEGs were in low-come populations; one in a church-setting that significantly increased fruit and vegetable consumption (Campbell 1999) and one partially home-based study that showed brief education was just as effective as adding counselling to increase amount of walking (Chen 1998). Two of the GEMS pilots recruited African American mothers and girls from low-income areas (Beech 2003; Story 2003). One family-based intervention targeted single mums with children living at the poverty level (Stolley 1997) and another family intervention included 83–91% with less than US$15,000 annual income (Baranowski 1990).

One of the studies that aimed to prevent excessive weight gain during pregnancy was set in an obesity clinic for low-income women (Polley 2002) and the other study in pregnancy included 40% women who had household incomes below 185% federal poverty line and analysed weight outcome by income.

Evidence of efficacy for weight management/reduction

Low-income women who received the intervention to prevent excessive weight gain during pregnancy had a significantly reduced risk of excessive gestational weight gain (OR 0.41, 95% CI 0.20, 0.81); overweight women within this subgroup were at significantly reduced risk of retaining more than 2.27 kg at 1 year postpartum (OR 0.24, 95% CI 0.07, 0.89). The RCT of diet and exercise using a stepped care approach to prevent excessive weight gain in pregnancy was effective in reducing the frequency of excessive weight gain in normal weight women (58 vs. 33% gained above recommended weight, intervention vs. control), but had no significant effect among overweight women, with a trend in the opposite direction.

The low-intensity diet and exercise intervention 'The Pound of Prevention Study' showed no significant difference by treatment group (education, education plus lottery incentive and control) at 1 year regarding weight (education plus lottery incentives: 3.23 [SE 0.98] lb [1.47 {SE 0.45} kg]; education only: 2.11 [SE 0.99] lb [0.96 {SE 0.45} kg; control: 1.30 [SE 0.72] lb [0.59 {SE 0.33} kg]). The authors suggest intervention may be having a greater impact on high- than low-income women. A culturally specific low-fat dietary intervention in Mexican American women of low-literacy and low-income, set in California (both included 6-weeks intervention vs. standard nutrition, with intervention having further 12 weeks maintenance) failed to increase the effect of a stand nutritional education course without maintenance period, and there was no weight change in either group at 18 weeks but the study was not powered to detect any changes in weight. Mexican-American children from economically disadvantaged households who received a diet and exercise intervention to prevent diabetes (none had diabetes at baseline) did not improve % body fat compared with control at 1 year.

A 9-month aerobic exercise programme (45 min, four times per week) in 9-year-old children (*n* = 20) with spastic cerebral palsy, set in Germany reported ‘no changes’ in fat mass compared with an average 1.1 kg increase in the control group. A 12-month intervention to reduce obesity using health practitioner input with adults with learning difficulties in Manchester, UK, showed that in the control group obesity levels deteriorated in 10.2%, remained the same in 81.6% and improved in 8.2%. In the intervention group 10.5% deteriorated, 63.2% remained the same and 26.3% improved. Mean BMI did not appear to significantly differ from baseline or between groups at 1 year. (The mean BMI in the intervention group was significantly higher than in the control at baseline, BMI 34 vs. BMI 28 at baseline.) A 12-week cardiovascular and strength exercise programme in adults with Down’s syndrome showed a significant difference between groups ($p < 0.01$) with a slight reduction in weight at 12 weeks whereas control group weight increased. BMI was not significantly different between groups at 12-weeks.

It is important to note that in both the two adult studies (in adults with learning difficulties and Down’s syndrome) the majority of participants were obese (69% in total in adults with Down’s syndrome).

Evidence of efficacy for diet/physical activity outcomes

One study significantly increased the amount of walking in all participants from baseline to follow-up, but brief education was just as effective as adding mail and telephone counselling in low-income previously sedentary ethnic minority women (Chen 1998). One church-based intervention significantly increased fruit and vegetable intake amongst low-income African Americans (Campbell 1999).

Saturated fat intake (–2.1 oz [59 g]) and % energy from fat (–7.9%) was significantly reduced at 12 weeks in African American mothers following a diet and PA intervention (Stolley 1997). A culturally-specific low-fat diet and aerobic exercise intervention in low-income Black American families did not produce significantly increased METs or energy expenditure at 14 weeks compared with control; both significantly increased energy expenditure from baseline (Baranowski 1990).

The parent and child intervention groups combined significantly reduced intake of sweetened drinks compared with non-active control in the Memphis GEMS study (Beech 2003). The GEMS Minnesota pilot (Story 2003) and the study by Stolley (1997) both showed significant reduction in % energy from fat in the intervention girls. The children of a family diet and exercise intervention actually decreased activity (METs) compared with the control children who increased activity (METs) and energy expenditure (Baranowski 1990).

The RCT to prevent excessive weight gain during pregnancy in low-income women reported a lack of significant effect of the intervention on changes in intake of high fat foods and changes in exercise level from recruitment to 30 weeks were not related to treatment condition or BMI (Polley 2002).

The low-intensity diet and exercise intervention ‘The Pound of Prevention Study’ showed no significant difference by treatment group (education, education plus lottery incentive and control) at 1 year regarding dietary intake or PA. The authors suggest intervention may be having a greater impact on high than low-income women.

Within the low-literacy, low-income population, both the intervention and the standard nutrition education group significantly reduced % energy from fat. Within the cerebral palsy children, PA ratio (24-hour energy expenditure/resting energy expenditure) did not differ between intervention group and control group but both significantly increased from baseline. Mexican American children from economically disadvantaged households who received a diet and exercise intervention to prevent diabetes (non had diabetes at baseline) dietary fat intake did not differ between groups ($p = 0.52$). Using a modified Harvard step test the change in physical fitness score between pre-intervention and post-intervention was significantly different between intervention and control children after adjusting for age and pre-intervention BMI ($p < 0.003$). It is important to note that the PA outcomes are based on a smaller sample of the original cohort (Trevino 2005) and the dietary outcomes are based on the larger cohort sample (Trevino 2004).

Evidence of corroboration in the UK
No corroborative evidence was identified regarding PA and low-income populations. The health practitioner intervention to reduce obesity in adults with learning difficulties was conducted in Manchester, UK, and so has direct relevance to this population within the UK.

EVIDENCE TABLE 2: INTERVENTIONS TO PREVENT WEIGHT GAIN, IMPROVE DIET AND INCREASE ACTIVITY LEVEL IN VULNERABLE GROUPS (LOW-INCOME, LOW-LITERACY, SPASTIC CEREBRAL PALSY, DOWN'S SYNDROME AND LEARNING DIFFICULTIES)

<table>
<tr><th>First author, study design, research type, quality, weight</th><th>Study population</th><th>Intervention details and length of follow-up</th><th>Results</th><th>Confounders/ comments</th></tr>
<tr>
<td>Jeffery & French 'Pound of Prevention' study, 1997

RCT
1+

Aim:
To examine whether weight gain can be prevented using low-intensity intervention.</td>
<td>Eligibility criteria:
Age 20–45 years, not currently pregnant or having given birth within 12 months, not currently in treatment for serious medical or psychological disorder, willingness to participate for 3 years.

Setting:
Four local health departments in the Minneapolis/St Paul, Minnesota metropolitan areas.

Sample size (numbers analysed, numbers randomised by treatment group not reported, 404 in total):
Education plus lottery incentives: <i>n</i> = 82
Education only: <i>n</i> = 82
Control: <i>n</i> = 150

60% of high-income and 20% of low-income women were</td>
<td>Education only:
Behavioural and educational messages: pay attention to weight by weighing yourself at least once per week, eat two servings of fruit each day, eat three servings of vegetables each day, reduce intake of high-fat foods, walk three times per week for at least 20 min; monthly newsletter to deliver above messages; postcard sent with newsletter to be returned by participants with questions about whether participant has completed the above messages and opportunity to write any questions of which a selection will be answered in next month's newsletter; face-to-face education to individuals twice in first year held by health department nutritionist covering basic nutrition and exercise principles.

Education plus lottery incentives:</td>
<td>Lost to follow-up:
14% did not differ between groups but differed significantly within low-income women across treatment groups compared with high-income women and men across treatment groups; see table below for the proportion completing 1-year follow-up by treatment group and participant type.
<table>
<tr><th></th><th>Education only</th><th>Education and lottery</th><th>Total</th></tr>
<tr><td>Men</td><td>74</td><td>66</td><td>70</td></tr>
<tr><td>High-income women</td><td>78</td><td>81</td><td>80</td></tr>
<tr><td>Low-income women</td><td>57</td><td>67</td><td>62</td></tr>
<tr><td>Total</td><td>70</td><td>73</td><td>72</td></tr>
</table>
Weight:
No significant difference by treatment group in any of the participant subgroups at 1 year.

Education plus lottery incentives: +3.23 (SE 0.98) lb (1.47 [SE 0.44] kg).
Education only: +2.11 (SE 0.99) lb (0.96 [SE 0.45] kg).
Control: +1.30 (SE 0.72) lb (0.59 [SE 0.33] kg)</td>
<td>Additional recruiting for low SES women; low-income defined as self-report of US$25,000 per year or less, low-income women paid US$20 for completing initial 1.5-hour assessment.

Because of the different ways participants were recruited and differed regarding risk of weight gain, participants were subgrouped and analysed</td>
</tr>
</table>

<table>
<tr><th>First author, study design, research type, quality, weight</th><th>Study population</th><th>Intervention details and length of follow-up</th><th>Results</th><th>Confounders/ comments</th></tr>
<tr>
<td></td>
<td>married, high-income participants were well-educated compared with low-income women, majority of population were White; high-income women were less likely to smoke and low-income women were more likely to smoke. No differences between treatment groups were statistically significant. Three differences approached significance: BMI, which was about one unit higher in the education only group than in the education plus lottery group; PA, which was slightly higher in the control group than the other groups; and prior participation in a formal weight loss programme, which was higher in the education only condition than in the other two conditions. (These three variables were adjusted for statistically.)

Baseline BMI (kg/m^2):
Not reported by treatment group, mean 28.2 for low-income women, mean 26.1 for high-income women.</td>
<td>Received same as above plus opportunity to have name entered into US$100 lottery draw each month if they mail back their monthly postcard.

Providers of the intervention included researchers from the School of Public Health, University of Minnesota.

Control:
No details.

Follow-up:
3 years; this paper reports 1 year results by low-income.</td>
<td>Results showed there was less weight gain among intervention subjects versus control subjects in men and high-income women, but more weight gain was shown by low-income women in the intervention vs. control groups.
<table>
<tr><th>All mean (SE)</th><th>Low-income women</th><th>High-income women</th></tr>
<tr><td>Energy intake (kcal/day):</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>–208 (104)</td><td>–27 (42)</td></tr>
<tr><td>Education only</td><td>–336 (108)</td><td>–66 (44)</td></tr>
<tr><td>Control</td><td>–218 (79)</td><td>–62 (29)</td></tr>
<tr><td>Energy intake (MJ/day):</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>–0.87 (0.44)</td><td>–0.11 (0.16)</td></tr>
<tr><td>Education only</td><td>–1.40 (0.45)</td><td>–0.28 (0.18)</td></tr>
<tr><td>Control</td><td>–0.91 (0.33)</td><td>–0.26 (0.12)</td></tr>
<tr><td>Energy from fat (%)</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>–1.76 (0.79)</td><td>–1.96 (0.56)</td></tr>
<tr><td>Education only</td><td>–2.49 (0.81)</td><td>–1.98 (0.59)</td></tr>
<tr><td>Control</td><td>–1.04 (0.60)</td><td>–0.87 (0.39)</td></tr>
<tr><td>Vegetables (servings per day:</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>0.02 (0.13)</td><td>0.02 (0.09)</td></tr>
<tr><td>Education only</td><td>0.07 (0.13)</td><td>–0.05 (0.09)</td></tr>
<tr><td>Control</td><td>–0.12 (0.10)</td><td>0.13 (0.06)</td></tr>
<tr><td>Fruits (servings</td><td></td><td></td></tr>
</table>
</td>
<td>separately; men, high-income women and low-income women; only outcomes for women by treatment group are reported here.

Less than 10% participated in face-to-face sessions.

It is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control.</td>
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<table>
<tr><th>First author, study design, research type, quality, weight</th><th>Study population</th><th>Intervention details and length of follow-up</th><th>Results</th><th>Confounders/ comments</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>per day):</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>–0.02 (0.08)</td><td>0.10 (0.07)</td></tr>
<tr><td>Education only</td><td>–0.05 (0.09)</td><td>–0.001 (0.07)</td></tr>
<tr><td>Control</td><td>–0.14 (0.06)</td><td>–0.01 (0.05)</td></tr>
<tr><td>Physical activity score*</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>2.00 (3.30)</td><td>1.80 (2.10)</td></tr>
<tr><td>Education only</td><td>–0.30 (3.50)</td><td>0.40 (2.20)</td></tr>
<tr><td>Control</td><td>–4.40 (2.60)</td><td>0.50 (1.50)</td></tr>
<tr><td>Walks per week:</td><td></td><td></td></tr>
<tr><td>Education + lottery</td><td>0.38 (0.27)</td><td>0.19 (0.79)</td></tr>
<tr><td>Education only</td><td>–0.02 (0.28)</td><td>–0.21 (0.20)</td></tr>
<tr><td>Control</td><td>–0.22 (0.21)</td><td>–0.05 (0.13)</td></tr>
</table>

Frequency per week of each activity multiplied by estimated intensity score in METs
Increased walking was associated with less weight gain in women ($p < 0.01$), in high-income women ($p < 0.06$) and low-income women.

Authors’ conclusion:
These results suggest the intervention may be having a greater impact on high than low-income women. The only significant treatment effect was observed at one year was an increase in the frequency of reported weighing amongst subjects in the intervention group.

Among men and high-income women, early results relating to weight gain were encouraging and if
</td><td></td></tr>
</table>

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/ comments
			sustained for 3 years would produce a positive outcome. Oppositely, trends in low-income group were negative at 1 year. This was a discouraging finding given their high risk for weight gain and obesity.	
Howard-Pitney et al. 1997 SNAP Cluster RCT 1+ **Aim:** To test the effectiveness of the Stanford Nutrition Action Program (classroom-based nutrition curriculum), an experimental trial to reduce dietary fat intake among low-literacy, low-income adults.	**Eligibility criteria:** Not reported. **Setting:** Twenty-four vocational training and general education degree classes (six community sites), San Jose, CA, USA. **Sample size:** Intervention: *n* = 183 Control: *n* = 168 Average grade level reading ability across two group = 7.4, 66% at 8th grade or below, majority were young women, Hispanic, born in USA, most spoke English at home, lived in poverty, had children <18 years old living with them, 82% of the Hispanic participants identified themselves as Mexican American. **Mean age:**	**Intervention group ('SNAP')**: 6-week classroom-based; six × 90 min sessions taught by professional nutrition health educators, organised into lessons covering sources of dietary fat, food guide pyramid, food label reading and low-fat eating when away from home; interactive learning with few written materials; culturally appropriate to majority of Hispanic women; low-fat recipes, food tasting and demonstrations, behavioural goal setting. Followed by 12 weeks maintenance: telephone (15 min scripted calls made by SNAP teachers and research assistants) or mail contact every 2 weeks to provide support and encourage regarding low-fat eating. **Control:** General nutrition classes taught by paraprofessional nutrition	**Lost to follow-up:** 31% did not differ between groups. Subjects lost from the study were most often from vocational training sites and had gained employment during the study. Missing data for cases were imputed from the subjects most recent measurement and assumed no change in outcome measures. A Cochran–Mantel–Haenszel statistical test indicated that there was no difference in attrition between the SNAP and the general nutrition classes. **Weight:** Net change, SNAP vs. control at 6 weeks: BMI: 0.0 (SD 0.1) kg/m^2, *p* = 0.87 Net change, SNAP vs. control from 6 weeks to 18 weeks: BMI: 0.0 (SD 0.2) kg/m^2, *p* = 0.94 **Diet:** Net change, SNAP vs. control at 6 weeks: Total dietary fat, g/d: 7.6 (SD 19.2), *p* = 0.20 Total saturated fat, g/d: –2.9 (SD 7.5), *p* = 0.21 Energy from total fat, %: –2.3 (SD 2.6), *p* = 0.01	In about half of the six sites the nutrition course was mandatory. Low-literacy was defined as eighth grade or lower reading ability. BMI was not a direct focus of the intervention. A large proportion of subjects was lost to follow-up. This may limit the reliability of the

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/ comments**
	Intervention: 31 years Control: 31 years **Education, % 12 years or less:** Intervention: 78% Control: 76% **Hispanic:** Intervention: 58% Control: 59% **Family income <US$10,000 per year, %:** Intervention: 63% Control: 66% **Baseline BMI:** Not reported.	educator, to improve knowledge and nutrition choices of low-income families from different ethnic backgrounds, five lessons on food guide pyramid, one on food safety and meal-planning; didactic presentation with handouts and recipes; received no maintenance intervention. **Follow-up:** 18 weeks	Energy from saturated fat, %: –0.9 (SD 1.2), *p* = 0.02 Net change, SNAP vs. control from 6 weeks to 18 weeks: Total dietary fat, g/d: +4.5 (SD 17.4), *p* = 0.39 Total saturated fat, g/d: +1.5 (SD 6.7), *p* = 0.44 Energy from total fat, %: –0.4 (SD 2.4), *p* = 0.56 Energy from saturated fat, %: –0.3 (SD 1.0), *p* = 0.45 **Authors' conclusion:** Results of the study indicate that SNAP's nutrition education curriculum for low income, low literacy was significantly ($p < 0.05$) more effective in achieving fat-related nutritional changes than a strong alternative general nutritional curriculum. The general nutrition curriculum showed equal or better improvements on components (which was not evaluated in this study, e.g. daily nutrition requirements and food safety) the results showed significant gains ($p < 0.05$) for SNAP participants in fat-related nutrition knowledge, attitudes, self efficacy and percentage of energy from total and saturated fat (which was reduced over 5 months 37.1 to 33.2% and 13.3 to 11.9%, respectively. Although both groups reduced their total daily energy intake by more than 300 kcal (1.26 MJ), it was shown that SNAP classes made better choices than the general nutrition group about energy levels in	results. Randomisation was by cluster and analysis was by individual, which may limit reliability of the results. It is not clear if the study was sufficiently powered to detect a significant effect of intervention compared with control.

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/ comments
			their diet by selecting lower fat foods. Although the curriculum showed significant ($p < 0.05$) results for dietary reductions in fat intake, BMI showed no change. This is probably due to the fact that SNAP emphasised eating less fat but not necessarily less energy, did not mention exercise and only touched upon the potential weight benefits that dietary fat reduction might achieve.	
Trevino 2004, 2005 Cluster RCT 1+	**Eligibility criteria:** Not clearly described. **Participants:** Fourth-grade students. **Setting:** Elementary schools located in low-income inner city neighbourhoods of the San Antonio Independent School District, TX, USA. Intervention (five schools): *n* = 200 Control (four schools): *n* = 187 **Age (mean):** Intervention: 9.8 years Control: 9.7 years 97% of students were Mexican	To evaluate the effect of the Bienestar Health Program (programme designed to reduce risk factors associated with the onset of type 2 diabetes) on physical fitness in low-income Mexican American children. The Bienestar Health Program was based on SCT and designed to decrease dietary fat and increase dietary fibre consumption and to promote participation in moderate to vigorous PAs. Programme activities were bilingual and included a parent education and involvement programme, a classroom health and PE curriculum, a student after-school health club and a	**Lost to follow-up:** All fourth grade students were invited to participate. 88% returned parental consent forms. Complete data was collected from 387 students (78%). Of 189 students in control group at baseline, complete data collected from 187. All 200 students in the intervention group at baseline returned complete data. **Weight at follow-up:** Not reported in Trevino 2005. In Trevino 2004 (larger sample of same study): % body fat, adjusted difference intervention ($n = 619$) vs. control ($n = 602$) +0.18 (95% CI, –1.75 to 2.11), $p = 0.56$ **Dietary intake:** Not reported in Trevino 2005; in Trevino 2004 dietary fat intake did not differ between groups ($p = 0.52$). **Physical activity (from Trevino 2005):** Outcome reported is physical fitness measured using a modified Harvard step test. Change in physical	All except body fat data are from Trevino 2005 paper. Parents and students who participated in the programme received coupons denoted in dollar amounts as an incentive and reinforcement, which could be exchanged for merchandise. These papers report interim

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/ comments
	American, more than 95% were in US Department of Agriculture food assistance programmes, 53% female, an average of 3.5 people occupied each household, mean household incomes US$10,337 in the intervention group and US$11,691 in the control schools. **Baseline BMI (kg/m^2):** No difference in baseline BMI between intervention and control groups. Control boys: 19.18 (SD 4.14) Intervention boys: 19.23 (SD 4.78) Control girls: 19.90 (SD 5.42) Intervention girls: 18.92 (SD 4.87)	school cafeteria programme. **Length of intervention:** 8 months. **Follow-up:** No further follow-up after 8-month intervention.	fitness score (PFS) between pre-intervention and post- intervention was significantly different between intervention and control groups after adjusting for age and pre-intervention BMI, *F*(1,381) = 8.69, $p < 0.003$. **Mean change in physical fitness score:** Control boys: –0.52 (SD 1.08) Control girls: 0.13 (SD 1.08) Intervention boys: 3.37 (SD 1.08) Intervention girls: 2.52 (SD 1.01) **Authors' conclusion:** It is possible to improve the physical fitness of low-income Mexican American preadolescent children through a comprehensive school-based programme.	results as this is ongoing 4-year study. Independent consultants performed randomisation using random numbers table. Significantly more Mexican American children in intervention group which may potentially bias in favour of intervention (which is tailored to Mexican American children)
Van Den Berg-Emons et al. 1998	**Eligibility criteria:** Age 7–13 years, day students with spastic cerebral palsy (normal intelligence and mild	**Intervention:** 45-min exercise sessions four times per week above the normal school and therapy programme;	**Lost to follow-up:** Zero. **Weight:**	Aerobic power, anaerobic power and muscle

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/ comments**
RCT 1+ **Aim:** To assess whether 9-month predominantly aerobic sports programmes (four or two sessions per week) are effective in increasing the level of daily PA in school children with spastic cerebral palsy.	mental retardation). **Setting:** Children's Rehabilitation Centre Franciscusoord in Valkenberg, Germany. Half the children were ambulant and half were wheelchair-bound, 16 were diplegic and four were tetraplegic. **Sample size:** Intervention: *n* = 10 Control: *n* = 10 **Gender, male/female:** Intervention: 4/6 Control: 7/3 **Age (years):** Intervention: 9.5 (1.6) Control: 8.8 (1.1) **BMI (kg/m^2):** Intervention: 19.0 (4.3) Control: 18.1 (2.6)	predominantly aerobic: cycling, wheelchair driving, running, swimming, training on a 'flying saucer', mat exercise; **Control:** No extra physical training. Providers of the intervention were staff from the Children's Rehabilitation Centre Franciscusoord in Valkenberg. **Follow-up:** 9 months.	Change in fat mass at 9 months: Intervention: 'no changes' Control: +1.1 (SD 1.6) kg **Physical activity:** PA ratio (24-hour energy expenditure/sleeping (resting) energy expenditure), pre – post: Intervention: 1.34 (SD 0.25) – 1.55 (SD 0.18) Control: 1.24 (SD 0.21) – 1.34 (SD 0.20) Average increase from baseline to 9 months was significant in intervention group at *p* = 0.07, control did not significantly differ from pre to post and no significant difference between intervention and control at 9 months. **Authors' conclusion:** Although aerobic training has a limited effect on PA in children with cerebral palsy, it may prevent deterioration in body composition and improve muscle strength.	strength also reported. Only results for initial 9 months reported here because same participants used as historical control in second 9-month programme. Generalisability of this study would be limited. The study lacked sufficient power to detect a significant difference in fruit and vegetable

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/ comments
				intake between groups.
Rimmer 2004 RCT (individual) 1+ **Aim:** To evaluate the effects of combined programme of strength and cardiovascular conditioning in adults with Downs Syndrome;	**Participants:** Sedentary adults with Down's syndrome who lived with family members or resided in group homes and other supported-living facilities. **Setting:** University of Illinois, Chicago, USA **Mean age:** 39.4 years, 56% female, 54% White Intervention: *n* = 30 Control: *n* = 22 69% were obese (BMI >30 kg/m^2), another 17% were overweight (BMI >25 kg/m^2).	**Intervention:** 30 min cardiovascular exercise and 15 min of strength exercise, 3 days per week for 12 weeks, supervised by one registered clinical exercise physiologist and two assistants. Participants had three or four initial familiarisation sessions. Study adequately powered to detect 5 to 10% mean difference in effect between intervention and control.	**Change in weight pre – post (kg):** Intervention: 80.5 (SD 20) vs. 79.5 (SD 19.9) Control: 76.8 (SD 18.1) vs. 78.5 (SD 17.9), $p < 0.01$ **Change in BMI pre – post (kg/m^2):** Intervention: 35.2 (SD 8.7) vs. 34.7 (SD 9.2) Control: 33.9 (SD 7.6) vs. 34.4 (SD 7.1), non-significant Authors concluded significant difference between groups for weight but not BMI or skinfold thickness. Intervention weight slightly reduced at 12 weeks whereas control group weight increased.	Four participants had potential structural heart disease.
Chapman et al 2005 CBA 2– Prospective pre-/post-	**Eligibility criteria:** Adults with learning disabilities referred to Healthy Living Coordinator (HLC). **Setting:** Not clear, Manchester, UK.	To evaluate health practitioner input to reduce obesity for adults with learning disabilities. The intervention involved a physiotherapist employed to act as an HLC. The HLC provided input to individuals referred for	**Lost to follow-up**: Not clear between baseline and follow-up. Thirty-eight assessed in intervention and 49 in control. **Weight:** The authors report that differences in weight change between the two groups reached statistical significance with a greater weight reduction in the	Significant differences between groups at baseline, comparison group were from 3-day

First author, study design, research type, quality, weight	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/ comments**
intervention design with a comparison group. **Aim:** To evaluate health practitioner input to improve healthy living and reduce obesity for adults with learning difficulties.	Intervention: *n* = 38 Control: *n* = 50 **Age (mean):** Intervention: 37.12 (SD 8.75) years Control: 43.32 (SD 10.97) years 43% of total group were women, 57 % men. No significant differences in gender between intervention and control groups. People in the intervention group were significantly less likely to be in adult placement or family homes and more likely to be in dispersed housing. **Baseline BMI (kg/m^2):** 97% of the intervention group and 64% of the control group were initially classified as overweight or obese. Statistically significant differences between the intervention and control groups for initial weight and BMI. The control group had a lower initial weight (mean 70.4 [SD 17.22] kg) than the input	support to improve their lifestyle. The intervention incorporated home visits, advice, design of activity programmes in conjunction with support staff and relatives, providing health promotion information. The assessment addressed issues such as: current PA levels; previous activities enjoyed; likes and motivations; support available; current dietary strategies in place; barriers to a healthy lifestyle; provision of resources. **Length of intervention:** 12 months. **Follow-up:** No further follow-up after 12-month intervention.	intervention group but this is not entirely clear from the data presented. **Body mass index (kg/m^2):** Control: Baseline BMI: 28.35 (SD 6.45); 6 months BMI 28.70 (SD 6.39); 1 year BMI 28.76 (SD 6.4). Intervention: Baseline BMI 34.89 (SD 5.72); 6 months BMI 34.57 (SD 5.49); 1 year BMI 34.28 (SD 5.58). In the control group obesity levels deteriorated in 10.2%, remained the same in 81.6% and improved in 8.2%. In the intervention group 10.5% deteriorated, 63.2% remained the same and 26.3% improved. **Diet:** Not reported. **Physical activity:** Not reported. **Authors' conclusions:** There was greater weight reduction in the intervention group (see above)	resource centres who did not receive HLC and outcome measures were measured by day centre and physiotherapist (HLC measured outcomes in intervention group).

First author, study design, research type, quality, weight	Study population	Intervention details and length of follow-up	Results	Confounders/ comments
	group (mean 86.48 [SD 15.02] kg). The control group had a lower initial BMI than the input group (mean 28.35 [SD 6.45] kg/m^2) than the input group (mean 34.89 [SD 5.72] kg/m^2).			

Evidence of corroboration (external validity)

Evidence of salience from studies conducted in the UK

First author	Study population	Research question	Length of follow-up	Main results	Confounders/comments
Chapman 2005	As above.	Adults with learning difficulties in Manchester, UK.	As above.	As above.	As above.

Evidence for implementation – Will it work in the UK?

First author	Study design	Study population	Research question	Length of follow-up	Main results
Chapman 2005	As above.	Adults with learning difficulties in Manchester, UK	As above.	As above.	The intervention involved a physiotherapist employed to act as an HLC. The HLC provided input to individuals referred for support to improve their lifestyle.
Food Standards Agency (FSA) 2003	Review.	Low-income, UK	To review food and low-income initiatives in UK.	Various,	Great deal of existing work to tackle food poverty by local sector health workers running statutory initiatives focussing on individual behaviour change. Very low numbers of projects are reporting actual changes in behaviour or attitudes. Structural factors on not being addressed. Consultation with the community is not being done. Other agencies as well as health sector need to get involved.

Tingay 2003	Questionnaire	Subjects attending ten general medical practices in inner-city London.	To evaluate experiences of food insecurity in relation to income.	N/a	Responses were obtained from 431/495 (87%) subjects. Overall 87 (20%) of subjects were classified as food insecure. Food insecurity was negatively associated with household income (*p* = 0.004). University-educated subjects (8%) were less often food insecure than all others (26%). Subjects who were food insecure were less likely to report eating fruit daily (food secure 48%, food insecure 33%, *p* = 0.017) or vegetables or salads daily (food secure 56%, food insecure 34%, *p* = 0.002). Experiences of food insecurity may be common in households with incomes at the level of the UK national minimum wage or lower.
Dibsdall 2003	Questionnaire survey	Participants were 680 low-income men and women, aged 17–100 years. Homes owned by a large UK housing association.	To determine low-income consumers' attitudes and behaviour towards fruit and vegetables, in particular issues of access to, affordability of and motivation to eat fruit and vegetables.	N/a	Age, employment, gender, smoking and marital status all affected attitudes towards access, affordability and motivation to eat fruit and vegetables. Few (7%) participants experienced difficulty in visiting a supermarket at least once a week, despite nearly half having no access to a car for shopping. Fruit and vegetables were affordable to this low-income group in the amounts they habitually bought; purchasing additional fruits and vegetables was seen as prohibitively expensive. Less than 5% felt they had a problem with eating healthily and yet only 18% claimed to eat the recommended five or more portions of fruit and vegetables every day. Findings from this particular group suggest that, of the three potential barriers, access and affordability were only a small part of the 'problem' surrounding low fruit and vegetable consumption.
Kennedy 2001	Review of SUPER project	Low-income adults in Liverpool.	To identify the various benefits and obstacles involved and to identify links with progress at the local level.		The European Food and Shopping Research Project (SUPER project) was established under the World Health Organization (WHO) European network of Healthy Cities to help local projects implement the principles of health promotion (World Health Organization, 1986). This paper describes the SUPER project and its implementation in Liverpool (1989–97), where levels of unemployment, deprivation and ill health are amongst the highest in the UK. Research consistently demonstrates that low-income households find it difficult to adopt healthy eating guidelines. Contrary to popular belief, this is due to economic and circumstantial barriers such as lack of income, access to shops, or inadequate storage and cooking facilities, not lack of

					nutrition knowledge (Dobson et al. 1994) More recent attempts involve tailoring nutrition education to the socio-cultural needs of poorer groups and the development of local food initiatives such as ‘cook and taste’. Here, participants are shown how to implement guidelines under difficult financial circumstances. However, critics argue this fails to address the real issue of food poverty: lack of money. Moreover, previous work demonstrates that this type of approach is labour intensive and is unable to reach a sufficiently large proportion of those in need to be cost-effective (Kennedy et al. 1998). More recent work suggests that although worthy, most projects reach a small population and are rarely sustained beyond initial funding (McGlone et al. 1999). The emphasis is on changing the physical and social environment to facilitate lifestyle changes by individuals (Vaandrager et al. 1992). The stated aims of SUPER are: • to describe the food patterns, nutritional problems and food policy issues in five European cities; • to describe the processes relating to health promotion activities in communities and to identify the optimum conditions for best practice; • to achieve a positive change in dietary behaviour, and attitudes to food and health; • to decrease differences in nutritional status between higher and lower socio-economic groups within the Study population; and • to develop more sustainable nutrition promotion in communities by incorporating activities initiated by local projects into organisational structures. According to project reports, in the period 1989–95, the approach remained focussed on nutrition education and disseminating information. Since the introduction of the lay food workers, the approach in Liverpool

					has become much broader, focusing more on health promotion and less on nutrition education. A major strength, and possibly the most important outcome, of the project in Liverpool was the process of reorientation experienced by participating health professionals and organizations. Experience demonstrated, however, that community involvement or community participation was much more difficult to achieve in practice. Local people were involved in the data collection process, but because they were excluded from planning what questions to ask they were provided with no real sense of ownership. It is essential that communities share responsibility for the rapid appraisal and help identify local needs in order to develop a sustainable programme of activities. Vaandrager describes the key elements of the approach used to promote healthy eating in Liverpool (Vaandrager, 1989): • participation in the Health Education Authority's (HEA) ‘Look after your heart’ programme – nutrition education campaign; • the main activity in 1988 was the ‘lifestyle fair’ – a 3-day health fair; • Liverpool Health Authority signed up to the HEA ‘Look after your heart’ Workplace Charter – incorporating activities to promote healthier eating amongst employees; • establishment of a Local Authority Food Policy Network. Illing (1992) describes three activities developed for the Croxteth area for the 14-month intervention period • school recipe competition; • nutrition open days in health clinic – information stalls, posters, leaflets; • a Nutrition in Action Group established (1991) to help develop nutrition strategy for Liverpool and to examine issues re: school meals (Illing, 1992). In 1993 more comprehensive but similar activities were organised over 4–14 months. Supermarkets: • monthly promotional activities and healthy eating themes:

					– ‘enjoy your food with less fat’ (poster) – ‘the importance of fruit and vegetables’ – ‘enjoy your food with less sugar’ – ‘a varied diet a healthy diet’; • a dietitian held a stall in the foyer of local supermarket offering promotional literature, such as information leaflets, posters or display boards, and to answer customer questions. Schools: • dietitian gives talks on healthy eating themes; • competition – pupils to design healthy eating leaflet; • posters and leaflets distributed; • school meals– healthier menu items highlighted for a limited period (every fourth week); • parent support group – practical demonstration sessions: healthier cooking. Community group: • healthy eating talks and practical demonstrations with mums and toddler groups (Smit & Rolling, 1993); • activities for the period 1995–97: – increased involvement in the work of the West Everton Community Health Forum; – Liverpool Food and Health Strategy Development Group established to represent wider agenda (1999); – introduction of lay nutrition workers – community food workers (1996); – food workers use an outreach work approach and consult communities to develop responses to help local people address barriers to healthy eating; – practical advice on ‘how-to’ implement healthy eating messages is provided for small community groups; – represent community members on health forums or committees to place local food issues (e.g. lack of shops) on the agenda; – offer referrals to people requiring help with non-nutrition problems (e.g. debt). (Sources: Judd & Jones, 1995; Heeson, 1996.)

French, 2000	Survey	Women aged 25–45 years, enrolled in Pound of Prevention Study (USA)	To examine demographic, behavioural and dietary correlates of frequency of fast food restaurant use in a community-based sample of 891 adult women.	3 years	Twenty-one percent of the sample reported eating three or more fast food meals per week. Frequency of fast food restaurant use was higher among younger women, those with lower income, non-White ethnicity, greater body weight, lower dietary restraint, fewer low-fat eating behaviours, and greater television viewing. Intake of several other foods, including fruits and vegetables, did not differ by frequency of fast food restaurant use.
Women's Health Initiative Study Group, 2004 Women's Health Initiative Dietary Modification Trial	FFQ as part of RCT	Postmenopausal women (USA)	To assess adherence to a low-fat diet.	5 years	This paper describes adherence to a low-fat dietary pattern (less than 20% energy from fat, five or more fruit/vegetable and six or more grain servings daily) in years 1 and 5 of the Women's Health Initiative Dietary Modification Trial, which was designed to examine the effects of a low-fat dietary pattern on risk of breast and colorectal cancers and other chronic diseases in postmenopausal women. Participants were randomly assigned to a low-fat dietary intervention arm (40%, *n* = 19,542) or a usual-diet control arm (60%, *n* = 29,294). Women in the intervention arm completed 18 group sessions during the first year, followed by quarterly annual maintenance sessions. Adherence was assessed as control minus intervention (C – I) group differences in percent total energy from fat as estimated by a food frequency questionnaire. Based on these self-reported dietary data, mean C – I was 10.9 percentage points of energy from fat at year 1, decreasing to 9.0 at year 5. Factors associated with poorer adherence were being older, being African American or Hispanic (compared with White), having low income, and being obese. Group session attendance was strongly associated with better dietary adherence.

EVIDENCE SUMMARY TABLE 3a: INTERVENTIONS TO PREVENT WEIGHT GAIN, IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT, IMPROVE DIET AND INCREASE ACTIVITY LEVELS IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (MENOPAUSE)

SUMMARY

One systematic review of 18 RCTs assessed the effect of exercise (walking, other aerobic training, resistance training, strength training with weights machines or combinations) in postmenopausal women. One RCT was included that aimed to prevent excessive weight gain during the menopause, with the full anthropometric results at 54 months published in 2003. The study was conducted in Pittsburgh and followed women from pre-menopause for 54 months when 35% of the women had become postmenopausal. The aim of the intervention was to provide modest weight loss to keep the women at their baseline weight by the end of the study. The study reported changes in weight, BMI, % body fat, % fat-free mass, PA and energy intake. The intervention included 1300 kcal (5.44 MJ)/day (25% of energy from total fat, 7% of energy from saturated fat and 100 mg cholesterol), PA expenditure of 1000–1500 kcal (4.19–6.28 MJ)/week (mainly through increasing walking and lifestyle activities) other lipid-lowering dietary strategies, i.e. increasing soya protein, fruits and vegetables and fibre if necessary; provided in a cognitive-behavioural programme and compared with an assessment-only control.

In the study, women were predominantly White, college-educated and employed full-time. 53.6% were of normal weight at baseline and all women were healthy with average risk factor levels. Mean age was 47 years and mean BMI was 25 kg/m^2. Women (*n* = 535) were randomised and the study was adequately powered to detect statistically significant differences in outcomes, with only 5% dropout and an ITT analysis.

Evidence of efficacy for weight management/reduction

In the systematic review, weight and body fat were studied in 18 studies with 1804 subjects. Body composition was improved in nine studies and most studies showed a small loss of body weight and fat. The effect seemed to be optimal when combining exercise with a weight-reducing diet. The most effective results were accomplished in three studies with overweight participants who used weight-reducing diets in combination with exercise training. The mean weight loss ranged was 2–10 kg in 12 weeks to 1 year.

At 54 months 55% of the intervention women were at or below their baseline weight compared with 26% in the control.

Mean weight change (kg) at 54 months was also significant between groups (–0.1 [SD 5.2] intervention vs. +2.4 [SD 4.9] control. There was a significant reduction in waist circumference (cm) at 54 months compared with control (–2.9 [SD 5.3] vs. –0.5 [SD 5.6], $p < 0.001$). There was a significant reduction in BMI (kg/m^2) in intervention women compared with control at 54 months (0.05 [SD 2.0] vs. 0.96 [SD 1.8], $p < 0.001$). Change in % body fat was also significantly reduced in the intervention group compared with control at 54 months (–0.5 [SD 4.1] vs. 1.1 [SD 3.9], $p < 0.01$). Fat-free mass (kg) was also significantly reduced in the intervention group compared with control at 54 months (0.0 [SD 1.9] vs. 0.5 [SD 2.1], $p < 0.05$).

Evidence of efficacy for diet/physical activity outcomes

In the systematic review the most effective exercise prescription for losing body fat was 30–60 min of walking or other aerobic training at 45–75% VO_{2max} on 3–5 days per week for 15 weeks to 1 year, or strength training with weight machines, five exercises with 80% of one repetition maximum with eight repetitions and three sets twice a week for 1 year.

Energy intake (kcal/day) was significantly reduced in the intervention group compared with control at 54 months (–160 [SD 465] vs. –25 [SD 560] [–0.67 {SD 1.95} vs. –0.10 {SD 2.34} MJ/day], $p < 0.01$). The intervention group reported eating significantly less dietary fat and cholesterol than controls.

There was a significant increase in the amount of energy expended through physical exercise (kcal/day) in the intervention group compared with controls at 54 months (275 [SD 1173] vs. –113 [SD 1261] [1.15 {SD 4.91} vs. –0.447 {SD 5.28} MJ/day], $p < 0.001$) (blocks walked (***no further details reported)*** (kcal/ 188 [SD 615] vs. –83 [SD 611] kcal/day [0.79 {SD 2.57} vs. –0.35 {SD 2.56} MJ/day], $p < 0.001$). There was no significant difference between the groups in terms of energy expended through sport and recreational activity (kcal/day) (intervention vs. control): 57 (SD 1023) vs. –47 (SD 1104) (0.24 [SD 4.28] vs. –0.20 [SD 4.62] MJ/day). There was a significant increase in the intervention group (counts/hour of activity) when measured with the activity monitor at 54 months compared with control (2.3 [SD 9.1] vs. –0.26 [SD 7.8], $p < 0.01$).

Evidence of corroboration in the UK
Evidence of corroboration was limited. Although none of the identified RCTs focussing on pregnancy, menopause or smoking cessation were UK-based, it is likely that the findings are applicable to the UK population.

Cost-effectiveness data
No cost-effectiveness data were reported.

EVIDENCE TABLE 3a: INTERVENTIONS TO PREVENT WEIGHT GAIN IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (MENOPAUSE)

First author, study design, research type, quality	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/ Comments**
Asikainen et al. (2004) Systematic Review (RCTs with >25 subjects and <35% attrition) 1++	All the subjects used in the studies were postmenopausal women aged 50–65 years. If a study had younger or older women then it was accepted providing the mean age was in the range of 50–65 years. Subjects had either been selected either on a voluntary basis or from a population-based sample. All subjects were sedentary at baseline or had some leisure PA that was kept constant during the study. Healthy women were accepted as well as subjects with diseases or risk factors such as dyslipidaemia, hypertension, obesity or osteoporosis. Hormone replacement therapy (HRT) and other medications were allowed.	To evaluate data from RCTs on exercise training studies with special reference to improving health in early postmenopausal women. Walking, other aerobic training, resistance training, strength training with weights machines or combinations of these were used. Exercise could be in addition to diet. Minimum 8 weeks. No further details on length of follow-up	Weight and body fat were studied in 18 studies with 1804 subjects. Body composition was improved in nine studies. Most studies showed a small loss of body weight and fat. The effect seems to be optimal when combining exercise with a weight reducing diet. The most effective results were accomplished in three studies with overweight participants who used weight-reducing diets in combination with exercise training. The mean weight loss ranged from 2 to 10 kg in 12 weeks to 1 year. The most effective exercise prescription for losing body fat was 30–60 min of walking or other aerobic training at 45–75% VO_{2max} on 3–5 days per week for 15 weeks to 1 year, or strength training with weight machines, five exercises with 80% of one repetition maximum with eight repetitions and three sets twice per week for 1 year.	Training programmes were relatively short in duration. VO_{2max} and muscular strength also reported in paper but not extracted for this review.
Simkin-Silverman et al.	**Eligibility criteria:** **Inclusion:**	**Intervention:** **Phase 1:** Cognitive-	**Lost to follow-up:** Intervention: *n* = 14	Some activity self-reported as

First author, study design, research type, quality	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/ Comments**
2003 RCT 1++ **Aim:** To test whether an intensive behavioural lifestyle intervention aimed at dietary and PA behaviour could prevent: 1) menopausal-related increases in LDL-cholesterol: and 2) weight gain NB. This is the only one RCT that met the criteria for inclusion.	Women aged 44–50 years who by self-report were pre-menopausal and not taking HRT, BMI 20–34 kg/m^2, fasting total cholesterol 140–260 mg/dl, fasting LDL-cholesterol 80–160 mg/dl, fasting glucose levels >140 mg/dl, diastolic blood pressure >95 mmHg **Exclusion:** Women taking lipid-lowering medication, antihypertensive medication, thyroid medication, psychotropic medication. **Setting:** Health Studies Clinic, University of Pittsburgh, USA. **Sample size:** Intervention: *n* = 260 Control: *n* = 275 Predominantly White, married, college educated, employed full-time. **Baseline BMI (kg/m^2):** Normal weight (BMI ≤24.9):	behavioural approach to weight control with strong emphasis on increasing PA and cholesterol lowering. Weeks 1–20 included 15 group meetings (20 women per group), given homework assignments and handouts, given weight loss goal in order to prevent any weight gain above baseline by end of the trial (BMI [kg/m^2] ≤24 asked to lose 2.3 kg, BMI 25–26 asked to lose 4.5 kg, BMI 27–34 asked to lose 6.8 kg). For first month followed daily diet of 1300 kcal (5.44 MJ], 25% energy from fat, 7% energy from saturated fat, 100 mg cholesterol, then could modify to suit their taste preferences; sessions on recipe modification, food labelling, social support, assertiveness training, restaurant eating; calcium supplement plus vitamin D (1200 mg/day) recommended, asked to increase PA expenditure to	Control: *n* = 12 **Weight outcomes:** Weight change from baseline (mean kg, intervention vs. control): 6 months: –4.9 vs. –0.4 18 months: –3.0 vs. +0.3 54 month: –0.1 (SD 5.2) vs. +2.4 (SD 4.9) At or below baseline weight at 54 months (intervention vs. control): 55 (136/246) vs. 26% (68/261); $p < 0.05$ Waist circumference (cm) at 54 months (intervention vs. control): –2.9 (SD 5.3) vs. –0.5 (SD 5.6), $p < 0.001$ Change in BMI (kg/m^2) (intervention vs. control): 0.05 (SD 2.0) vs. 0.96 (SD 1.8), $p < 0.001$ Change in % body fat (intervention vs. control): –0.5 (SD 4.1) vs. 1.1 (SD 3.9), $p < 0.01$ Fat-free mass (measured with a Hologic QDR 2000 dual-energy X-ray absorptiometer [DEXA]) (kg) (intervention vs. control):	was dietary intake, activity monitor actually measured PA. This study had power to detect an effect size of intervention of 90% or greater for weight and LDL-Cholesterol compared with control, at a significance level of 0.05 (two-tailed comparisons with an alpha level of 0.05)

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/ Comments
	53.6% Overweight (BMI 25–29.9): 35.5% Obese (BMI ≥30.0): 10.8% Mean BMI: 25	1000–1500 kcal [4.19–6.28 MJ)/week (e.g. brisk walking 10–15 miles [16–24 km]) combining moderate aerobic activity with lifestyle activity, women monitored intake and activity and received feedback. **Phase 2:** Months 6–54, group meetings: months 6, 7, 8, 10, 12 and 14 provided women with additional behavioural skills, support and motivation, and offered 6-week refresher programmes (cooking demonstrations, low-fat taste panels, group walks, dance classes, exercise classes, mail and telephone follow-up continued, incentives and group competitions also, energy intake gradually increased as women met their weight goal, received individual small group consultation if experienced weight gain (two to three times	0 (SD 1.9) vs. 0.5 (SD 2.1), *p* < 0.05 **Dietary outcomes:** Change in energy intake (kcal/day) from baseline (intervention vs. control): –160 (SD 465) vs. –25 (SD 560) (–1.09 [SD 1.95] vs. –0.10 [SD 0.01] MJ/day), *p* < 0.01 Intervention group reported eating significantly less dietary fat and cholesterol than controls. **Physical activity outcomes (change from baseline):** Physical activity (kcal/day) (intervention vs. control): 275 (SD 1173) vs. –113 (SD 1261) (1.15 [SD 4.91] vs. –0.47 [SD 5.27] MJ/day), *p* < 0.001 Blocks walked [no further details reported***]*** (kcal/day) (intervention vs. control): 188 (SD 615) vs. –83 (SD 611) (0.79 [SD 2.57] vs. –0.35 [SD 2.56] MJ/day), *p* < 0.001 Change in sport and recreational activity from baseline (kcal/day) (intervention vs. control): 57 (SD 1023) vs. –47 (SD 1104) (0.24	

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/ Comments
		per year), cholesterol rise (three to six individual consultations and cholesterol monitoring, emphasising soy protein, fruit and vegetable and fibre to lower cholesterol) or exercise relapse. The research team from the University of Pittsburgh and nurses from the Health Studies Clinic provided the intervention. **Control:** Assessment only control group. **Follow-up:** 54 months (follow-up assessment done at 6, 18, 30, 42 and 54 months).	[SD 4.28] vs. –0.20 [SD 4.62] MJ/day), $p < 0.0001$ Changes in activity monitor from baseline (counts/hour) (intervention vs. control): 2.3 (SD 9.1) vs. –0.26 (SD 7.8), $p < 0.01$ **Authors' conclusion:** In healthy women, weight gain and increased waist circumference during the peri- to postmenopause can be prevented with a long-term lifestyle dietary and PA intervention.	

Evidence of corroboration (external validity)

Evidence of salience from studies conducted in the UK

First author	Study population	Research question	Length of follow-up	Main results	Confounders/comments

Evidence for implementation – Will it work in the UK?

EVIDENCE SUMMARY TABLE 3b: INTERVENTIONS TO PREVENT WEIGHT GAIN, IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT, IMPROVE DIET AND INCREASE ACTIVITY LEVELS IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (PREGNANCY)

SUMMARY

Two studies (one RCT and one CBA) were included that aimed to prevent excessive weight gain during pregnancy and were published in 2001 and 2002. One further CCT was included that aimed to test the hypothesis that continuing a regular regimen of recreational exercise alters the time specific rate of maternal weight gain and subcutaneous fat deposition during pregnancy. The CBA study was conducted in New York and followed women from early pregnancy to 1-year postpartum (Olson 2004). The RCT was conducted in Pittsburgh and followed women from prior to 20-weeks gestation to 8-weeks postpartum (Polley 2002). The CCT was conducted in Cleveland and followed women from pre-pregnancy to 37-weeks gestation (Clapp 1995). All of the studies reported weight change; one reported dietary and PA outcomes (Polley 2002). The CBA study included an intervention group that had their gestational weights monitored and received education about appropriate weight gain during pregnancy and healthy eating and exercise advice, compared with a historical control group. The RCT included an intervention group that received advice about weight gain during pregnancy and a diet substituting high-fat ‘fast foods’ with fruit and vegetables and increasing moderate exercise (walking). This intervention was a stepped care approach where women received additional sessions and behavioural goals were increasingly structured should she exceed recommended levels of weight gain at any time during the pregnancy, compared with standard nutritional counselling. The CCT compared participants who continued with the same regular exercise as before pregnancy to those who voluntarily stopped regular exercise. Most of the intervention participants continued to exercise at least three times per week for 30 min or more at an intensity >50% VO_{2max} throughout pregnancy to 37th week.

A Cochrane systematic review of diet in pregnancy reports that the limited evidence available suggests that protein/energy restriction of pregnant women who are overweight or exhibit high weight gain is unlikely to be beneficial and may be harmful to the developing fetus. Only three studies were included, two in Scotland that were both published prior to 1990, one in obese women and the other in women with high gestational weight gain between weeks 20–30.

In the CBA study, 94% were aged between 20–40 years, 75% were of normal pre-pregnancy BMI, 41% were having first baby and 40% had household incomes below 185% federal poverty line. In the RCT, mean age was 25.5 years, 47% were first pregnancies, 57% were unemployed (setting was an obesity clinic for low-income women) just under half of both the control and intervention group women were classed as overweight (BMI 31–34 kg/m^2). One hundred and twenty women were randomised in the RCT and 179 participants in the intervention group of the CBA study were compared with 381 women in the historical control group. In the CCT participants mean age was 31 years, parity ranged from 0 to 2; participants were well educated with family incomes at or above 75th percentile for their state of origin, they were non-smoking White females. There were significantly more homemakers and/or part-time workers in intervention group (31 vs. 14%, $p < 0.05$) and the percentage of women with jobs known to require moderate PA was significantly higher in the control group (39 vs. 23%. $p < 0.05$). Forty-four women in the exercise intervention group and 35 women were in the control group. Baseline body mass (before pregnancy) was 58.1 kg in the intervention group and 60.2 kg in the control group. Mean weekly duration of exercise was 172 min and mean exercise intensity was 66% VO_{2max} for all participants at baseline.

Evidence of efficacy for weight management/reduction
All three studies reported weight change. The CBA study demonstrated that the diet and exercise intervention reduced the risk of excessive gestational weight gain in the low-income subgroup only. Low-income women who received the intervention had a significantly reduced risk of excessive gestational weight gain (OR 0.41, 95% CI 0.20, 0.81); overweight women within this subgroup were at significantly reduced risk of retaining more than 2.27 kg at 1-year postpartum (OR 0.24, 95% CI 0.07, 0.89).

The RCT of diet and exercise using a stepped care approach was effective in reducing the frequency of excessive weight gain in normal weight women (33% intervention vs. 58% control), with the intervention having no significant effect among overweight women but a trend in the opposite direction. The CCT demonstrated that continuing a regular exercise regimen throughout pregnancy resulted in significantly less total weight gain (13.0 [SD 0.5] vs. 16.3 [SD 0.7] kg, $p < 0.0001$). Increases in the sum of skinfold thicknesses were 22 ± 2 and 31 ± 2 mm intervention vs. control at 37 weeks. The intervention did not influence the rate of early pregnancy weight gain or subcutaneous fat deposition but decreases both in late pregnancy. However, overall pregnancy weight gain remains well within the normal range.

Within the Cochrane systematic review (Kramer 2003) of diet during pregnancy, three trials involving 384 women were included. Both Campbell trials (UK) reported that energy/protein restriction was associated with a significant reduction in weekly maternal weight gain, although the magnitude of the reduction was much larger in the 1975 trial (random effects weighted mean difference [WMD] –254.81 [95% CI –436.56, –73.06] g/week). The two trials reporting on birth weight (Campbell 1983; Badrwai 1993) yielded highly (and statistically significantly) heterogeneous results, with Campbell 1983 reporting virtually no effect of the intervention (WMD 6.00 [95% CI –121.55, +133.55] g) but Badrwai (1993) finding a large significant adverse effect (WMD –450.00 [95% CI –624.72, 275.28] g). Postpartum weight retention was not reported.

Evidence of efficacy for diet/physical activity outcomes
The RCT reported a lack of significant effect of the intervention on changes in intake of high-fat foods and changes in exercise level from recruitment to 30 weeks were not related to treatment condition or BMI.

Evidence of corroboration in the UK
Although none of the individual studies was conducted with the UK, the interventions could be implemented in the UK. Two studies published in 1975 and 1983 and included in the review of diet in pregnancy (Kramer 2003) were conducted in Scotland.

EVIDENCE TABLE 3b. INTERVENTIONS TO PREVENT WEIGHT GAIN IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (PREGNANCY)

First author, study design, research type, quality	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
Kramer 2003 Cochrane systematic review 1+	Pregnant women	Energy and protein intake in pregnancy. Review of the effects of advice to increase or reduce energy or protein intake, or of actual energy or protein supplementation or restriction during pregnancy on energy and protein intakes, gestational weight gain and the outcome of pregnancy. Various follow-up Campbell 1975 intervention included 1200 kcal (5.02 MJ)/day low-carbohydrate diet from 30 weeks gestation compared with normal diet. Campbell 1983 intervention involved 1250 kcal (5.23 MJ)/day diet in obese women compared with control. Badrwai intervention involved 1500–2000 kcal	Three trials involving 384 women were included. Both Campbell trials reported that energy/protein restriction was associated with a significant reduction in weekly maternal weight gain, although the magnitude of the reduction was much larger in the 1975 trial (random effects WMD –254.81 [95% CI –436.56, –73.06] g/week). Energy/protein restriction had no effect on either (proteinuric) pre-eclampsia or pregnancy-induced hypertension (with or without proteinuria), although the small number of trials and participants provides inadequate statistical power to exclude a small effect. The two trials reporting on birth weight (Campbell 1983; Badrwai 1993) yielded highly (and statistically significantly) heterogeneous results, with Campbell 1983 reporting virtually no effect of the intervention (WMD 6.00 [95% CI –121.55, +133.55] g) but Badrwai (1993) finding a large significant adverse effect (WMD –450.00 [95% CI –624.72, –275.28] g).	This review just focuses on one element of the Cochrane review: evaluation of low-energy diets in pregnant women who are obese or have high gestational weight gain. Two Campbell studies were conducted in Scotland, one in obese women and the other in women with high gestational weight gain between weeks 20–30. Both were conducted prior to 1990.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
		(6.28–8.37 MJ)/day diet in obese Egyptian women compared with normal WHO-recommended diet;	These large differences in results could reflect either differences in study samples (Scotland vs. Egypt) or differences in the degree of energy/protein restriction achieved. Only Campbell (1983) reported results bearing on gestational duration; the results appear to exclude an important adverse effect of dietary restriction (WMD in mean gestational age +0.25 (95% CI –0.17 to +0.67) weeks). Other outcomes, including fetal/infant mortality and other measures of maternal morbidity (e.g. Caesarean section) or postpartum weight retention, have not been reported. The limited evidence available suggests that protein/energy restriction of pregnant women who are overweight or have high weight gain is unlikely to be beneficial and may be harmful to the developing fetus.	
Olson et al. 2004 CBA (historical control) 2++ **Aim:**	**Eligibility criteria:** Women with normal (19.8–26.0 kg/m^2) and high (26.1–29.0 kg/m^2) BMI entered prenatal care before third trimester, ≥18 years old at delivery, no medical condition	**Intervention:** Graphic design of the Institute of Medicine gestational weight gain grid, separate colour-coded grid was developed for of the four pre-pregnancy BMI	**Lost to follow-up:** Not reported; 21 excluded from intervention group and 22 excluded from control group. Details of the historical control group and recruitment details are described elsewhere in studies by Kendall et al. (2001) and Hinton & Olson	Twelve women who participated in historical control group also participated in prospective intervention group. Bias was detected in the historical control self-reported pre-pregnancy

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
To evaluate the efficacy of an intervention to prevent excessive gestational weight gain.	that might impact body weight, mentally competent, planned to deliver locally and keep the infant, gave birth to live, singleton, term infant. 20% single, 41% having first baby. 96% White **Setting:** Bassett Healthcare (hospital and primary care clinic system serving ten-county area in upstate New York). **Sample size:** Intervention: $n = 179$ Historical control: $n = 381$ **Age:** 94% between 20 to 40 years in both groups. **185% or less below the Federal poverty line:** Intervention: 37.4% Control: 43.3% **Baseline BMI (kg/m^2):** Normal BMI (median, range):	groups, used to determine pre-pregnancy BMI, plotting gestational weight gain (2-hour orientation programme given for interested providers, attendance voluntary with continuing education credits given; patient education component included health check book that contained weight gain and self-monitoring tools; also food guide pyramids and tips for healthy eating and exercise in pregnancy; five × 1-page newsletters (pre-tested in focus groups that included low-income women); postcards sent with newsletters encouraging active participations, asking questions that were answered in next newsletter and prize incentives for sending back postcard. Providers of the intervention included Bassett Healthcare staff and the researchers	(2001). **Gestational weight gain (mean, kg):** Intervention: 14.10 (SD 4.51) Control: 14.80 (SD 4.68), $p = 0.09$ **Proportion of women gaining more than recommended weight:** Intervention: 41% Control: 45%, $p = 0.3$ Low-income women in intervention: 33% Low-income women in control: 52%, $p < 0.01$ Significant difference in excess weight gain within low-income women also seen in overweight and normal BMI groups. **Normal BMI:** Low-income women in intervention: 29% Low-income women in control: 45%, $p = 0.05$ **Overweight:** Low-income women in intervention: 44% Low-income women in control: 72%, $p = 0.04$ No significant effect of intervention detected in high-income women.	weight so weight in both groups was calculated from last prenatal visit where weight was measured. This study had power to detect an effect size of intervention of 90% statistical power to detect a 50% reduction from the observed 71% gaining above the weight range in the historical group, with a 5% false-positive rate using a two-sided test of significance. Within low-income women, there was a 96% statistical power to detect 50% reduction from the observed 52% gaining above the weight range in the historical group with a two-sided 5% false-positive rate.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Intervention: 22.6 (19.8–26.0), *n* = 290 Control: 23.1 (20.0–26.0), *n* = 131 Overweight (BMI median, range): Intervention: 27.2 (26.1–29.0), *n* = 91 Control (historical control group): 27.2 (26.0–29.0), *n* = 48	**Control:** Not reported. **Follow-up:** 12-months postpartum.	**Weight retention at 1-year postpartum (kg):** Intervention: 0.59 (4.74) Control: 1.31 (5.60) **Women retaining 2.27 kg or more at 1-year postpartum:** Intervention: 31% Control: 38%, *p* = 0.14 Low-income and overweight women: Intervention: 25% Control: 55%, *p* = 0.04 High-income and normal BMI: Intervention: 24% Control: 36%, *p* = 0.07 **Diet:** Not reported. **Physical activity:** Not reported. **Author's conclusion:** The intervention reduced the risk of excessive gestational weight gain in the low-income subgroup only. Low-income women who received the intervention had a significantly reduced risk of excessive gestational weight gain (OR 0.41, 95% CI 0.20, 0.81).	

First author, study design, research type, quality	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
			Overweight women within this subgroup were at significantly reduced risk of retaining more than 2.27 (OR 0.24, 95% CI 0.07, 0.89) kg.	
Polley et al. 2002 RCT 1+ **Aim:** To determine whether a stepped care behavioural intervention will decrease the percentage of women who gain more than the Institute of Medicine recommendation for gestational weight gain.	**Eligibility criteria:** Low-income women before 20 weeks gestation **Exclusion:** Women underweight (BMI <19.8 kg/m^2), <18 years old, first prenatal visit was above 12 weeks gestation, those with high-risk pregnancy **Setting:** Obstetric clinic for low-income women at a hospital in Pittsburgh, PA, USA. Age 25.5 (SD 4.8) years, 39% Black, 45% high school or less, 57% unemployed, 47% first pregnancy. **Sample size:** Intervention: *n* = 61 (32 normal weight and 29 overweight) Control: *n* = 59 (33 normal weight and 26 overweight)	**Intervention:** Delivered by masters and doctoral level staff with training in nutrition or clinical psychology, participants given information on appropriate weight gain during pregnancy, exercise and healthful eating, newsletters mailed biweekly, sent personalised graph of weight gain after each clinic visit, women exceeding weight gain given additional individualised nutrition and behavioural counselling (stepped care approach with increasingly structured behavioural goals if weight continued to exceed recommended levels). Focus on decreasing high fat foods such as 'fast food' items, substituting with fruit and vegetables, increasing walking and developing a	**Lost to follow-up:** Intervention: *n* = 27 Control: *n* = 19 **Proportion of women gaining more than recommended weight and mean weight gain:** Intervention Normal weight: 33.3%, *n* = 10, 23.6 kg Control Normal weight: 58.1%, $p < 0.05$ *n* = 18, 19.1 kg Intervention Overweight: 59.3%, *n* = 16, 17.7 kg Control Overweight: 31.8%, $p = 0.07$, *n* = 7, 17.3 kg Although intervention significantly reduced percent normal weight women who exceed weight gain goal, intervention had no significant effects on average weight gain from pre-pregnancy to delivery and weight gains were	Randomisation was stratified by BMI category and race. Pre-pregnancy weight was self-reported. Women whose weight exceeded guidelines were given additional sessions No significant effects of race on percentage of women with excessive weight gain ($p > 0.3$). Weight gained before recruitment was strongly related to excessive weight gain ($p < 0.0001$). It is not clear if the study was sufficiently powered to detect a significant effect on weight outcomes with intervention compared with control.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Baseline BMI (kg/m^2): Normal weight Intervention: 22.8 (1.9), *n* = 30 Control: 22.5 (2.0), *n* = 31 Overweight Intervention: 31.4 (6.0), *n* = 27 Control: 34.1 (7.2), *n* = 22	more active lifestyle. Contacted by telephone between clinic visits **Control:** Standard nutritional counselling provided by physicians, nurses, nutritionists and Women, Infants and Children (WIC) counsellors emphasising well balanced diet and multivitamin/iron supplement. **Follow-up:** 8-weeks postpartum (from prior to 20 weeks gestation).	comparable between Black and White women. **Weight retention at mean 8-weeks postpartum:** Intervention Normal weight: 4.4 (SD 5.4) kg Control Normal weight: 6.2 (SD 4.5) kg Intervention Overweight: 3.6 (SD 5.6) kg Control Overweight: 0.3 (SD 7.0) kg Weight retention was strongly correlated with weight gain during pregnancy ($r = 0.89$, $p < 0.001$). **Diet:** No effect of intervention on changes in intake of high-fat foods. **Physical activity:** Changes in exercise level from recruitment to 30 weeks were not related to treatment condition or BMI. **Authors' conclusion:** The intervention was effective in	

First author, study design, research type, quality	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
			reducing the frequency of excessive weight gain in normal weight women, the intervention had no significant effect among overweight women but the trend was in the opposite direction; the more intensive stepped care element that occurred subsequent to excessive weight regain may have been a less effective component than the prevention component (fewer women in the intervention group exceeded recommended weight gain at any point during their pregnancy (63 vs. 94%);	
Clapp 1995 CBA 2– **Aim:** To test the hypothesis that continuing a regular regimen of recreational exercise alters the time specific rate of maternal weight gain and subcutaneous fat deposition during pregnancy.	**Eligibility criteria:** Normal women with generally active lifestyles who also engaged in regular exercise at or above a basic conditioning level for the primary purpose of health and recreation for at least 6 months and who conceived and experienced a normal pregnancy. Participants were unselected and consecutively enrolled. **Exclusion:** Women with infertility or pregnancy complications. **Setting:**	**Intervention:** Participants continued with same regular exercise as before pregnancy; exercise levels varied widely between but not within participants during pregnancy. Most continued to exercise at least three times per week for 30 min or more at an intensity greater than 50% VO_{2max} throughout pregnancy to 37th week. **Control:** Participants who voluntarily stopped their regular	**Lost to follow-up:** Intervention: *n* = 27 Control: *n* = 19 When covaried for the minor differences in preconceptional weight the rate of weight gain was similar in the control (0.3 kg/week) and intervention groups (0.25 kg/week) through to the 15th week. Between 15th–23rd week and 23rd–30th weeks the rate of weight gain was significantly ($p < 0.05$ and $p < 0.002$) less in the intervention group. Averaging 0.47 vs. 0.57 kg/week in the control group. Although the rate of weight gain decreased between 30 and 37 weeks in both groups, the women in the intervention group continued to gain	Randomisation was stratified by BMI category and race. Not aimed at preventing excessive weight gain in pregnancy. Intervention and control groups were self-selecting Significant important differences at baseline which may confound results.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Obstetric clinic, Cleveland, OH, USA. Age 31 (SD 0.3) years, parity ranged from 0 to 2; well educated (mean 17.3 years), family incomes at or above 75th percentile for their state of origin, non-smoking White; significantly more homemakers and/or part-time workers in intervention group (31 vs. 14%, $p < 0.05$); percentage of women with jobs known to require moderate PA was significantly higher in control group (39 vs. 23%, $p < 0.05$); **Sample size:** Intervention: $n = 44$ Control: $n = 35$ **Baseline body mass: (prior to pregnancy):** Intervention: 58.1 (SD 1.0) kg Control: 60.2 (SD 1.2) kg Mean height for all participants 166.7 (SD 0.6) cm **Mean weekly duration of exercise:** All participants: 172 ± 6 min **Mean exercise intensity:**	exercise regimen because of concern that it would have negative effects on pregnancy, $n = 31$ or reduced it below baseline fitness levels in very early pregnancy, $n = 4$). All participants consumed a balanced diet, reported energy intake rose consistently during pregnancy with no significant differences between the two groups; however, 12 aerobics instructors who were intervention participants had significantly greater energy intake. **Follow-up:** 37 weeks	significantly ($p < 0.001$) less than the controls (0.31 vs. 0.47 kg/week). As a result total weight gain was significantly ($p < 0.0001$) less in the intervention group (13.0 [SD 0.5] vs. 16.3 [SD 0.7] kg). Increases in the sum of skinfold thicknesses were 22 ± 2 mm and 31 ± 2 mm intervention vs. control at 37 weeks. Authors conclude that continuing a regular exercise regimen throughout pregnancy does not influence the rate of early pregnancy weight gain or subcutaneous fat deposition but decreases both in late pregnancy. However, overall pregnancy weight gain remains well within the normal range.	

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	All participants: 66 ± 1% VO_{2max}. **Significant differences at baseline:** Sum of five skinfold thicknesses greater in control group, also subjects who continued to exercise (intervention group) spent 44% ($p < 0.01$) exercising each week than those subjects who stopped (control group) representing average difference in energy expenditure of 600 kcal (2.51 MJ)/week.			

Evidence of corroboration (external validity)

Evidence of salience from studies conducted in the UK

First author	Study population	Research question	Length of follow-up	Main results	Confounders/comments

Evidence for implementation – Will it work in the UK?

Pregnancy Anderson 1995	CCT	Maternity hospital in Aberdeen.	To assess the effect of dietary advice education intervention on nutrient intake during pregnancy.	From booking to 26 weeks gestation.	Intervention participants received information packs on nutrition at time of booking and at 26-weeks gestation, all participants received general pregnancy health guide. Results showed that knowledge about nutrition was significantly higher in the intervention group (magnitude unlikely to make difference in practice), but no significant differences were noted on attitude variables or nutrient intake (fat, energy).

EVIDENCE SUMMARY TABLE 3c: INTERVENTIONS TO PREVENT WEIGHT GAIN, OR IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT, IMPROVED DIET AND INCREASED ACTIVITY LEVELS, IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (SMOKING CESSATION)

(METHODOLOGY: Report continuous abstinence [no smoking since quitting] rather than point prevalence abstinence [no smoking in past 7 days], report weight gain by quitters in each treatment group only, report latest follow-up point only.)

SUMMARY

Seven smoking cessation studies (six RCTs and one CBA) were included that aimed to prevent excessive weight gain when stopping smoking. Five of the RCTs only included women. Five of the studies were published between 1999 and 2004 and two studies were published in 1992 (Hall 1992; Pirie 1992). Five studies were conducted in North America, one in Sweden (Danielsson, 1999) and one in Iceland (Jonsdottir, 2001). All studies had at least 12-months follow-up from when participants quit smoking. All of the studies reported % rates of continuous abstinence and weight change; none reported dietary or PA outcomes. All the studies included a smoking cessation intervention, three RCTs focussed on dietary interventions including energy reduction, food replacements, and early and late introduction of diet. Two RCTs focussed on diet and exercise intervention (Hall 1992; Pirie 1992; both arms had identical exercise) and two studies focussed on an exercise only intervention (Marcus 1999; Jonsdottir 2001).

Participants mean age within the studies ranged from 39 to 47 years, BMI ranged from 24 to 28 kg/m^2 at baseline. Numbers of cigarettes smoked per day ranged from 19 to 32 cigarettes and where reported years of smoking ranged from 22 (Marcus 1999) to 30 years (Hall 1992; Danielsson 1999). Numbers of participants in each arm ranged from 33 (Jonsdottir 2001) to 150 (Danielsson 1999). The majority of studies only included women who wanted to stop smoking and control their weight and were therefore a motivated population.

Evidence of efficacy for weight management/reduction

All seven studies reported weight change; only weight change in women who remained continuously abstinent is reported here.

One RCT (Spring 2004) compared a low-energy (150 kcal [630 kJ]/day deficit) diet given in the initial 8 weeks alongside exercise and smoking cessation programme with diet given in the later 8 weeks of the 16-week treatment period, with both compared with a control which consisted of the smoking cessation programme only. Nine-month abstinence did not differ between the groups (weight control did not undermine smoking cessation) with 18.2% in the control, 21.4% early diet and 19.5% in the late diet group. Nine-month weight change also did not differ between the groups (6.20 kg in control, 7.57 kg in early diet, 4.88 kg in late diet).

In one CBA study (Jonsdottir 2001) of an exercise intervention in a convenience sample of self-referred participants, the addition of exercise in a gym did not significantly improve abstinence rates (20.6 vs. 39.4%, $p = 0.16$) or prevent weight gain (3.0 vs. 5.0 kg, $p = 0.37$) compared with control in a healthcare centre, despite the exercise group having paid more money to take part (all participants received option of nicotine replacement therapy [NRT] and received health education and both individual and group behavioural modification).

One study (Perkins 2001) demonstrated that cognitive behavioural therapy (CBT) for weight concerns (to promote acceptance of and reduce concerns about modest weight gain when stopping smoking) significantly attenuated weight gain (2.5 vs. 7.7 kg) and significantly increased rates of abstinence (21 vs. 9%), compared with standard smoking cessation counselling in weight concerned women (13% abstinence in weight control group, no significant weight control vs. CBT for weight concerns). The third arm of the intervention included a 500 kcal (2.10 MJ)/day deficit, but there was no significant difference in weight change between this weight control arm and the standard intervention arm (5.4 vs. 7.7 kg).

One exercise intervention (Marcus 1999) in sedentary women significantly improved smoking abstinence compared with control (11.9 vs. 5.4% $p = 0.05$), but there was no significant difference in weight gain (8.92 vs. 5.76 kg respectively) at 60 weeks post-quit.

One intervention (Danielsson 1999) included a very-low-energy (6.7 MJ/day) food replacement supplied to female participants for three 2-week periods; this was in addition to nicotine gum, which all participants could use. At 12 months the food replacement group had 28% abstinence compared with 16% abstinence within the control group ($p = 0.02$). There was, however, no significant difference between the groups regarding weight gain (2.5 kg in intervention vs. 3.8 kg in control, $p = 0.61$).

One study (Hall 1992) included a low energy, low-fat diet if participants gained 2 lb (0.90 kg) or more, plus aerobic exercise, this intervention had three arms: specific (individualised diet and exercise plan); non-specific (not individualised) diet and exercise; and a standard control group. At 12 months both active interventions (specific and non-specific diet and aerobic exercise) had a greater risk of smoking than the control group (specific intervention 21%, non-specific intervention 22%, control 35% continuous abstinence). The authors reported no significant difference between the three groups regarding weight change (0.86 kg specific intervention, 3.35 kg non-specific intervention, 3.61 kg control).

One RCT (Pirie 1992) included four arms all including smoking cessation treatment with weight control added in one arm, nicotine gum in another arm and both nicotine gum plus weight control in another arm. The two arms that included weight control element also included a walking element. At 12-months post-treatment, the arm that included smoking cessation plus nicotine gum and the highest rate of abstinence and there was no significant difference between the intervention arms regarding weight change (ranged from 9.77 to 14.15 lb [4.43 to 6.42 kg]).

Evidence of efficacy for diet/physical activity outcomes
None of the studies reported diet or PA outcomes relevant to this review.

Evidence of corroboration in the UK
Although none of the studies were conducted with the UK, many of the interventions cited within the included studies could be implemented in the UK.

EVIDENCE TABLE 3C. INTERVENTIONS TO PREVENT WEIGHT GAIN IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (SMOKING CESSATION)

First author, study design, research type, quality	**Study population**	**Intervention details and length of follow-up**	**Results**	**Confounders/comments**
Perkins et al. 2001 Cluster RCT 1+ **Aim:** To identify most effective approach to addressing weight gain concerns in women quitting smoking.	**Eligibility criteria:** Women, 18–65 years old, smoking at least ten cigarettes per day, free of any major health problem or illicit drug use, significantly interested in quitting smoking, endorsing concerns about weight gain after quitting. **Exclusion:** Women trying to become pregnant or following medically prescribed diet were excluded. **Setting:** Allegheny County, Pennsylvania. **Sample size:** Total *n* = 219 Weight control group:	**All:** CBT smoking cessation counselling (ACS Fresh Start program). Therapists were women with master's degrees in clinical or counselling psychology that received intensive didactic training and weekly supervision. Participants received ten × 90 min group sessions (ten to twelve participants) over 7 weeks, two sessions per week during first 3 weeks and one session per week in last 4 weeks. Participants instructed to quit smoking after group's fourth session and before fifth session, follow-up at 3, 6 and 12 months post-quit; asked not to use NRT **Weight control intervention:** Subjects were given daily energy goals (typically less than 500 kcal [2.09 MJ] less than would be required to maintain baseline weight if still smoking) and were instructed to self-monitor daily food intake in a	**Lost to follow-up:** By the end of the 7 weeks of treatment (4 weeks post-quit) was 19% for CBT group, 10% for the weight control group and 21% for the control/standard group. Also the difference between weight control and standard was significant ($p < 0.05$). Mean attendance at the three follow-up sessions was 62% and did not differ between the three groups. **12-month continuous abstinence: (assumed dropouts resumed smoking):** Weight control: 13% CBT for weight concerns: 21% Standard: 9% (Not significant between weight control vs. CBT for weight concerns, but significant between CBT for weight concerns vs. standard.) **Weight gain (only in abstinent women):**	Significantly more participants in CBT for weight concerns vs. weight control had dieted in last 12 months at baseline Outcome results not changed when analyses were repeated excluding participants who used nicotine replacement therapy. Pre-quit BMI predicted cessation outcome at 1 year Self-reported abstinence verified by exposed air carbon monoxide readings Randomisation was by cluster and

	n = 72, mean BMI 25.6 kg/m^2 CBT: *n* = 72, mean BMI 25.8 kg/m^2 Standard: *n* = 75, mean BMI 25.5 kg/m^2 **Age:** Weight control: 45.7 (SD 10.4) CBT: 44.3 (SD 9.5) Standard: 43.6 (SD 10.0) **College graduate:** Weight control: 51.4% CBT: 43.0% Standard: 46.7% **Smoking rate (years):** Weight control: 27.4 (SD 10.4) CBT: 24.7 (SD 10.9) Standard: 24.9 (SD 10.1) **Baseline BMI (kg/m^2):** Weight control: 25.6 (SD 5.4) CBT: 25.8 (SD 4.7) Standard: 25.5 (SD 4.7)	diary, which was reviewed weekly by the group therapist. Subjects also graphed their weight on a chart containing a solid horizontal line across time at their pre-quit baseline weight. Participants encouraged to practice self-monitoring and stimulus control particularly to reduce between-meal snacking. **Cognitive beviourial therapy for weight concerns:** Promote acceptance of and reduce concerns about modest weight gain, self-monitor negative thoughts, promote health benefits of quitting smoking superseding health risks of weight gain, reducing dietary restraint, improving body image, discourage dieting and encourage moderate consumption of healthy foods during between-meal snacking. **Control (standard advice):** Non-specific social support, discussed other aspects of quitting, discussion of weight gain concerns was discouraged. **Follow-up:** 12-months post-quit.	Weight control: 5.4 (SD 3.3) kg CBT for weight concerns: 2.5 (SD 4.2) kg Standard: 7.7 (SD 4.7) (Significant between CBT for weight concerns vs. standard but not significant between weight control vs. standard or CBT vs. weight control.) **Diet:** Not reported. **Physical activity:** Not reported. **Author's conclusion:** CBT to reduce weight concerns but not weight control, improved smoking abstinence in weight concerned women beyond that produced by standard cessation counselling; weight control group attenuated post-cessation weight gain, unexpectedly, weight gain in the CBT group was also less than weight gain in the standard group but not different from that in the weight control group.	analysis was by individual, which may limit reliability of the results. It is not clear if the study was sufficiently powered to detect a significant effect with intervention when compared with control.

Marcus et al. 1999 Commit to quit RCT 1+ **Aim:** To determine if regular, vigorous exercise, a healthful alternative to smoking, enhances the achievement and maintenance of smoking cessation and reduces weight gain among sedentary female smokers.	**Eligibility criteria:** Inclusion: Healthy sedentary women aged 18–65 years, regularly smoked ten or more cigarettes per day for at least 3 years, exercised less than twice per week for at least 6 months. Exclusion: Current or planned use of NRT, medical problems or use of medications that would make compliance difficult, current psychiatric illness, alcohol or substance abuse, were excluded. **Setting:** The Miriam Hospital, Providence, RI, USA. **Sample size:** Exercise: *n* = 134 Control: *n* = 147 **Age (years):** Exercise: 40.7 (SD 9.1) Control: 39.7 (SD 8.8)	**All:** 12-week group- (approximately 15 participants) based smoking cessation programme, quit at week 4, then 8-week treatment programme. **Exercise intervention:** Resting heart rate plus 60–85% heart rate reserve, started 3 weeks before quit date, three exericse sessions per week for 12 weeks, 5-min warm up, 30–40 min aerobic activity, 5-min cool-down with stretching, supervised by exercise specialist. Providers of the intervention included an exercise specialist and staff from the Miriam Hospital and Brown University School of Medicine in Providence, Rhode Island. **Control:** 12-week wellness programme started 3 weeks before quit date, three × 45–60 min supervised sessions per week, advised not to adopt exercise. **Follow-up:** 60 weeks post quit.	**Lost to follow-up:** At 12 months: Exercise 44% Control 49.7% (not significant). ITT analysis on all 281 participants (lost to follow-up assumed to have relapsed). **60-weeks continuous abstinence:** Exercise: 11.9% (*n* = 16) Control: 5.4% (*n* = 8) *p* = 0.05 **Weight:** Only in abstinent women –among quitters, exercise participants gained significantly less weight at 8 weeks but difference was not significant at 20 and at 60 weeks. **60 weeks weight:** Exercise: 8.92 (SD 8.9) kg, *n* = 15 Control: 5.76 (SD 12.6) kg, *n* = 6 **Diet:** Not reported. **Physical activity:** Not reported (only VO_{2max}). **Authors' conclusion:** Vigorous exercise as part of CBT for smoking cessation leads to improved rates of continuous abstinence in young to middle-aged	Significantly higher BMI and body weight in exercise group at baseline compared with control. Exercise participants exercised at 83% maximum heart rate. Self-reported abstinence verified by exposed air carbon monoxide readings A total sample size of 150 at 12-months was projected to provide a power of 80% (alpha=0.05) and to detect a 21% net difference in smoking rates between intervention and control.

	Education (years): Exercise: 13.8 (SD 2.1) Control: 13.8 (SD 2.1) **Smoking rate, cigarettes per day:** More than 20. Exercise: 22.9 (SD 9.7) Control: 21.8 (SD 9.0) **Smoking (years):** Exercise: 22.6 (SD 8.8) Control: 22.2 (SD 9.0) **Baseline BMI (kg/m^2):** Exercise: 26.1 (SD 5.2) Control: 24.8 (SD 4.7)		female smokers who averaged more than one pack of cigarettes per day for more than 20 years, maintained at 12 months, CBT to attenuate weight gain was only effective during treatment period (when participated in exercise).	
Danielsson et al. 1999 RCT 1++ **Aim:** To determine whether intermittent use of very-low-energy diet	**Eligibility criteria:** Inclusion: Female smokers aged 30–60 years who wanted to stop smoking and maintain their body weight, BMI 23–31 kg/m^2, smoke at least ten cigarettes per day for at least 3 years, have made at least one serious	**All:** Eleven sessions over 16 weeks including three group sessions with a dietitian and standardised written information, each session 45 min in groups of 10–15 women, follow-up at 21, 26,3 9 and 52 weeks. 2 mg nicotine gum (Nicorette) (could switch to 4 mg if consumed more than 20 pieces per day), free gum for 3 months then advised to	**Lost to follow-up:** At 12 months Intervention: *n* = 35 women Control: *n* = 51 women ITT analysis. **52 weeks complete and continuous abstinence:** Intervention: 28% (*n* = 38) Control: 16% (*n* = 24) *p* = 0.02	96 of 201 women at 12 month follow-up were still using NRT Significantly more women reported headaches in VLED compared with control. Self-reported abstinence verified by

(VLED) to improve weight control affected the success of a smoking cessation programme.	attempt to stop and restarted because of weight gain. Exclusions: Cardiovascular disease, participation in another clinical study in previous 6 months, clinical important renal or hepatic disease, pregnancy or lactation, lactose intolerance, alcohol or drug abuse, use of smokeless tobacco or NRT, gout, acute porphyria, insulin-dependent diabetes mellitus, vegetarian diet, any serious metabolic or malignant disease likely to interfere with compliance. **Setting:** Obesity Unit, University Hospital, Sweden. **Sample size:** Intervention *n* = 137 Control *n* = 150	taper consumption, on request gum supplied up to 12 months; standardised balanced diet of 6.7 MJ/day, behaviour modification sessions for stopping smoking and providing support for weight control. **Intervention:** Nutrilett 1.76 MJ/day (420 kcal total food replacement given free of charge for three × 2-week periods (weeks 1 and 2, 7 and 8, 13 and 14). Compliance with the VLED was based on self-reported adherence and verified through ketone body analysis in urine, sampled by the women at home. Women with missing samples were asked to provide a urine sample after the VLED period. **Follow-up:** 52 weeks	**Weight (abstainers):** 52 weeks weight loss: Intervention: 2.5 (95% CI 0.78–4.3) kg Control: 3.8 (95% CI 2.5–5.1) kg, *p* = 0.61 **Diet:** Not reported- not known reported if the subjects actually used the meal replacement product. **Physical activity:** Not reported. **Authors' conclusion:** Smoking can be stopped for up to 1 year with acceptable weight control in women selected for their previous weight control problems when attempting to quit. (Significant difference in quitting in favour of VLED but no differences in weight gain at 12 months.)	exposed air carbon monoxide readings. This study had power to detect an effect size of intervention of 80% compared with control, at a significance level of alpha 0.05.

	Age (years): Intervention: 46.9 (SD 7.0) Control: 46.8 (SD 6.9) **Mean number of cigarettes smoked per day:** Intervention: 20.0 (SD 6.3) Control: 19.1 (SD 6.2) **Smoking (years):** Intervention: 29.6 (SD 6.9) Control: 28.1 (SD 7.4) 210 of 287 women had used NRT before. **Baseline BMI (mean, kg/m^2):** Intervention: 26.7 (SD 2.2) Control: 26.9 (SD 2.3)			
Hall et al. 1992 RCT 1+ **Aim:** To evaluate an innovative weight gain prevention programme to reduce smoking	**Eligibility criteria:** Inclusion: Smoke at least ten cigarettes per day in past week or be at least 10% above ideal weight. Exclusions: Cardiovascular or pulmonary disease,	**All:** Smoking treatment programme of Seven × 90 min group sessions (five to eight participants) of aversive smoking and relapse prevention skill training in initial two weeks, assessed at weeks 2, 6, 12, 26 and 52; four female therapists (one master's level social worker and one doctoral level	**Lost to follow-up:** Not reported, participants with missing data were coded as smoking. **52 weeks abstinence:** Tailored intervention: 21% (*n* = 11) Non-tailored intervention: 22% (*n* = 11) Standard control: 35% (*n* = 19) Two active interventions had	Standard intervention smoked significantly more cigarettes per day pre-treatment, innovative intervention had significantly greater variance in cigarettes smoked and pre-treatment body weight.

relapse risk.	diabetes, hospitalisation for major mental illness in previous year, any chronic condition that would influence eating or activity levels. **Setting:** San Francisco. **Sample size:** Intervention, *n* = 53 Control, *n* = 51 Standard treatment control, *n* = 54 **Age (years):** Tailored intervention, 40.68 (SD 8.71) Control, 41.22 (SD 8.96) Standard treatment control, 39.24 (SD 8.92) **Female:** Tailored intervention: 77% Control: 67% Standard treatment control: 74% **Smoking rate, cigarettes per day:** Innovative	psychologist treated 88% of participants), two female dietitians and a male exercise consultant also participated. **Tailored intervention:** Weight-gain prevention sessions weeks 3–6, daily monitoring. Eat what liked unless gained 2 lb (0.91 kg) or more then encouraged to use low calorie low fat diet designed to lose 2 lb (0.91 kg) per week individualized exercise plan of aerobic exercise three or more times per week, behavioural self-management of eating. **Non-tailored intervention**: Weight gain prevention sessions weeks 3–6, no attempt to individualize diet or exercise or behavioural components **Control:** Standard (?) assessment at week 6 only, information pack on good nutrition and exercise at last smoking treatment session not targeted at smoking-cessation induced weight gain. **Follow-up:** 52 weeks. Providers of the intervention	greater risk of smoking compared with control. **Weight (non smokers):** 52 weeks weight: Tailored intervention: 0.86 (3.95) kg, *n* = 10 Non-tailored intervention: 3.35 (2.38) kg, *n* = 7 Standard control: 3.61 (3.99) kg, *n* = 14 **Diet:** Only reported on subgroup of 68 (75%) of the original sub-sample that completed dietary recalls at every assessment. These subjects did not differ from either the whole sample or the sample of 91 on whom the researchers attempted to collect data on cigarettes smoked or body weight. **Physical activity:** Only reported on subgroup. **Authors' conclusion:** Because there was no significant difference between abstinent and smoking subjects in the tailored intervention condition suggests that the condition prevented weight gain, particularly when this lack of difference is compared with the significant differences found between abstinent and smoking	Self-reported abstinence verified by exposed air carbon monoxide readings. It is not clear if the study was sufficiently powered to detect a significant effect of intervention when compared with control.

	intervention: 25.65 (SD 12.56) Control: 24.91 (SD 10.80) Standard treatment control: 31.59 (SD 11.74) **Baseline mean body weight (kg):** Innovative intervention: 72.68 (SD 17.72) kg Non-specific control: 69.23 (SD 12.38) kg Standard treatment control: 67.65 (SD 12.51) kg	included four female therapists, two female registered dietitians and a male exercise consultant.	subjects in the non-specific intervention. Differences in the control group also failed to reach significance, which meant interpretation of results was difficult. In the tailored intervention there was evidence of early compliance with dietary instruction, especially among women and abstinent subjects. Higher smoking rates in two active interventions is troubling, complicated interventions may have detracted from non-smoking	
Pirie et al. 1992 RCT 1++ **Aim:** To evaluate a weight control programme in addition to nicotine gum to enhance smoking cessation	**Eligibility criteria:** Inclusion: Women aged 20–64 years who wanted to quit smoking and maintain weight. Exclusions: Women who wanted to gain weight, pregnancy, history of gastric ulcer, substance abuse previous 6 months, cardiovascular disease including hypertension, temporal mandibular	**All:** 8-week programme (orientation session plus seven treatment sessions) with follow-up 6- and 12-months post-treatment, social support, cognitive behavioural skills, quit night occurs in week 4; facilitators were female ex-smokers trained by American Lung Association to be group leaders for the Freedom From Smoking (FFS) standard advice/control programme also given extra training regarding specific additional treatments for this study. Standard advice/control + behavioural weight control and	**Lost to follow-up:** 8% at 12 months but were contacted by telephone resulting in 100% follow-up **12-months post-treatment continuous abstinence (%):** Freedom from Smoking (FFS/ standard advice/control): 14.6 (95% CI 7.8, 21.4) Standard advice/control + behavioural weight control: 23.1 (95% CI 15.2, 31.0) Standard advice/control + nicotine gum: 31.5 (95% CI 22.7, 40.3)	US$100 deposit returned to participant at 12-months follow-up Self-reported abstinence verified by exposed air carbon monoxide readings Lack of success in producing differential weight changes among groups meant could not test hypothesis that females who gain more weight following

	joint syndrome, active cancer treatment. **Setting:** Minneapolis, USA **Sample size** Smoking/standard advice/control (FFS): *n* = 103 Standard advice/control + behavioural weight control: *n* = 108 Standard advice/control + nicotine gum: *n* = 108 Standard advice/control + nicotine gum + behavioural weight control: *n* = 98 **Age (years):** FFS: 42.3 Standard advice/control + behavioural weight control: 44.0 Standard advice/control + nicotine gum: 42.9 Standard	Standard advice/control + nicotine gum + behavioural weight control: weight control counselling accompanied each of the seven standard advice/control sessions and included decreasing energy intake by 100 to 300 kcal (420 to 1260 kJ)/day and gradually increasing exercise to 1 hour of walking or its equivalent three times per week. Standard advice/control **+ nicotine gum and** Standard advice/control **+ nicotine gum + behavioural weight control:** 2 mg nicotine polacrilex chewing gum issued free for 8 weeks and 3-months follow-up, encouraged to chew at least three pieces per day. Providers of the intervention included researchers and Health care centre/clinic staff **Follow-up:** 14 months (12 months post-quit).	Standard advice/control + nicotine gum + behavioural weight control: 14.3 (95% CI 7.4, 21.1) Standard advice/control + nicotine gum had highest abstinence **Weight change abstainers:** 12-months post-treatment weight (mean lbs): Control (*n* = 15): 10.08 (95% CI 4.57, 15.59),lb *n* = 15 + Behavioural weight control (*n* = 25): 9.77 (95% CI 5.50, 14.04) lb + Nicotine gum (*n* = 34): 9.97 (95% CI 6.30,13.64) lb + Nicotine gum + behavioural weight control (*n* = 14): 14.15 (95% CI 8.45, 19.85) lb No significant difference in weight gain among abstainers within each treatment group at 12 months follow-up. **Diet:** Not reported. **Physical activity:** Not reported.	smoking cessation would demonstrate higher levels of relapse. Power not reported. Study reports: 'in order to yield a sufficient sample' ... 'goal of recruiting and randomising 360 individuals was surpassed by 57'.

	advice/control + nicotine gum + behavioural weight control: 43.4 **College graduates (%):** FFS: 31.3 Standard advice/control + behavioural weight control: 27.8 FFS + nicotine gum: 24.1 Standard advice/control + nicotine gum + behavioural weight control: 20.6 **Mean number cigarettes per day**: FFS: 25.6 Standard advice/control + behavioural weight control: 26.9 Standard advice/control + nicotine gum: 24.9		**Author's conclusion:** Behavioural weight control programme did not reduce smoking cessation but did not attenuate weight gain.	

	Standard advice/control + nicotine gum + behavioural weight control: 25.1 **Baseline BMI (mean, kg/m^2):** FFS: 23.7 (95% CI 23.1, 24.3) Standard advice/control + behavioural weight control: 24.5 (95% CI 23.7, 25.3) Standard advice/control + nicotine gum: 24.2 (95% CI 23.4, 25.0) Standard advice/control + nicotine gum + behavioural weight control: 24.0 (95% CI 23.4, 24.6)			
Spring et al. 2004 RCT 1+ **Aim:** To re-examine	**Eligibility criteria:** Inclusion: Women aged 20–75 years who smoked ten or more cigarettes per day for last year, willing and able to participate, follow a	**All:** 16 weeks behavioural smoking cessation treatment, quit smoking at week 5, followed up 9 months after quit date; led by licensed clinical psychologist and psychology graduate student, group sessions and additional telephone support,	**Lost to follow-up:** At 16 weeks: Early diet *n* = 29 (27%), late diet *n* = 18(17%), control *n* = 32 (30%) At 9 months: Early diet *n* = 59, late diet *n* = 59, control *n* = 67 (72 in first cohort not	Self-reported abstinence verified by exposed air carbon monoxide readings – 58.1% reported smoking that escaped detection by the ecolyser on at

whether adding behavioural weight control to cessation treatment suppresses weight gain but undermines abstinence and to determine whether outcomes differ depending on whether weight control intervention begins concurrently or after smoking cessation treatment.	pre-packaged meal plan and PA programme, be willing to accept random assignment. Exclusions: Current substance abusers, pregnant, lactating, current using of NRT, appetitive suppressants, beta-blockers, history of diabetes, hypoglycaemia, eating disorder, psychosis, surgery for obesity, currently dieting, strong biases against or prior experience with Nutri/System meal plan. **Setting:** Three centres: University of Illinois, Chicago; Finch University of Health Sciences-Chicago Medical School; and the Hines Veterans Affairs Medical Center.	traditional behavioural techniques taught including contract for quit date. **Early diet intervention:** Diet and exercise during first 8 weeks cessation treatment; 150 kcal (630 kJ) per day decrease, pre-packaged three meals per day plus two high-carbohydrate low-fat snacks per day to be consumed late afternoon/evening, received meals each week during 16 weeks, supplemented by fresh fruits and vegetables, final transition week with 4 days low-fat grocery store meals plus 3 days meal plans; encouraged to do 30 min moderate intensity activity at least 5 days per week, trained in self-monitoring heart rate and led on 30 min group walks at end of initial 8 weeks treatment. **Late diet intervention:** Received identical exercise at same time as early diet group and received identical diet during final 8 weeks cessation treatment. **Control:** Focused on smoking cessation and received weight loss counselling at week 16 **Follow-up:**	asked to attend follow-up). ITT analysis. **9-months post-treatment continuous abstinence** (measured from week 7 which was 2 weeks after quit date, missing data coded as smoking): Early diet: 21.4% Late diet: 19.5% Control: 18.2% No significant difference between early diet versus control and late diet vs. control on smoking cessation at 12 months. **Weight change** (continuous abstainers, measured change from week 7): 9 months post-quit weight change (mean): Early diet: 7.57 (SD 8.24) lb (3.43 [SD 3.74] kg) Late diet: 4.88 (SD 7.06) lb (2.21 [SD 3.20] kg) Control: 6.20 (SD 6.65) lb (2.81 [SD 3.02] kg No significant difference in weight gain between late diet and control at 9 months. **Diet:** Not reported.	least 1 occasion Statistical power was low for weight change outcome because 9-month data were available for only 37% of the sample. This study was not sufficiently powered to detect a significant effect of intervention compared with control.

	Sample size: Early diet: *n* = 104 Late diet: *n* = 104 Control: *n* = 107 66% White, 31% African American, 3% other; middle-aged, mildly depressed, moderately overweight, mildly weight concerned women who were moderately heavy smokers and mildly to moderately nicotine dependent. **Mean age (years):** Early diet: 41.45 (SD 9.80) Late diet: 43.20 (SD 9.81) Control: 43.39 (SD 11.28) **Smoking rate, cigarettes per day:** Early diet: 20.24 (SD 8.64) Late diet: 21.02 (SD 510.90) Control: 19.75 (SD 8.88) **Baseline BMI**	9 months post-quit.	**Physical activity:** Not reported. **Authors' conclusion:** For post-cessation weight control, the findings suggest superiority for a sequential approach that addresses smoking cessation before initiating weight control treatment.	

	(mean, kg/m^2): Early diet: 27.23 (SD 4.99) Late diet: 28.26 (SD 5.95) Control: 26.80 (SD 5.44)			
Jonsdottir & Jonsdottir, 2001 CBA 2++ **Aim:** To examine whether adding exercise to a multi-component smoking cessation programme will increase smoking cessation and suppress weight gain.	**Eligibility criteria:** Participants self-referred. **Setting:** One health centre and one health club in Reykjavik, Iceland **Sample size:** Intervention 1: *n* = 34 Intervention 2: *n* = 33 **Female:** Intervention 1: 61.8%, *n* = 21 Intervention 2: 36.4%, *n* = 12 **Mean age (years):** Intervention 1: 43.5 (SD 11.9) Intervention 2: 39.3 (SD 9.0) Participants had smoked 1 to 40 years. Not significant between groups	**Intervention 1 (usual intervention/control):** NRT (nicotine medication, gum and spray adjusted to individual needs), health education, behavioural modification and individual and group counselling all provided by one nurse (author of study). Group counselling for 1 month with five sessions and individual counselling for 1 year, contacted four times by telephone 3 weeks after last group session, 6 weeks, 3 months and 6 months later (12 months after first smoke-free day); second day after the first group session was defined as the quitting day**.** **Intervention 2:** Same as intervention 1 except the group counselling lasted for 2 months with seven meetings and the four telephone contacts started one month after last session with 3-month intervals until 12 months after first smoke-free day; in addition an exercise specialist supervised physical exercise	**Lost to follow-up:** Zero (NB: convenience sample) **12 months lapse-free abstinence (%):** Intervention 1: 20.6% (*n* = 7) Intervention 2: 39.4% (*n* = 13), *p* = 0.16 **Weight (abstainers):** 12 months post-quit weight gain (mean, kg): Intervention 1: 3.0 (SD 3.9) (*n* = 5) Intervention 2: 5.0 (SD 3.8) (*n* = 11), *p* = 0.37 **Diet:** Not reported. **Physical activity:** Not reported. **Author's conclusion:** A non-significant difference in abstinence at one year and weight gain was demonstrated between the two interventions, further studies with a larger sample size are needed.	Participants self-referred and paid for the intervention. Intervention 2 was more expensive as subjects paid more for their intervention and they had more often attempted to quit smoking, which may indicate that they were more motivated to quit than the participants in intervention 1/control. Self-reported abstinence verified by exposed air carbon monoxide readings. Weight measured at baseline and mainly self-reported at 1 year, 20 participants in intervention 1 and seven participants in

	on years smoked or smoked cigarettes per day. Baseline BMI not reported.	programme three times per week (increasing from 40 to 80 min) during 2 months of group counselling and the following 4 months participants continued without exercise specialist and at their own time schedule; aerobic training, 40% consisting of treadmills and stationary biking, weight lifting (40%) and stretching exercises (20%). Providers of the intervention were one nurse from the health care centre, plus staff from the University of Iceland. **Follow-up:** 265 days (8 months) post-quit.		intervention 2 were not willing to be weighed at follow-up. Difference in frequency and timing of contacts varied between groups. Intervention 2 participants had more often attempted to quit (may have therefore been more motivated) Convenience sample. Only 15.8% (*n* = 8) participants used nicotine medication by end of intervention, no statistical difference between smokers and abstainers regarding use of NRT. This study was not sufficiently powered to detect a significant effect of intervention compared with control.

Evidence of corroboration (external validity)

Evidence of salience from studies conducted in the UK

Evidence of salience

First author	Study population	Research question	Length of follow-up	Main results	Confounders/comments

Evidence for implementation – Will it work in the UK?

First author	Study design	Study population	Research Question	Length of follow-up	Main results
Perkins 1997	Review	Weight concerned women who want to stop smoking (USA).	To assess rationales for three different treatment approaches.	Various.	Three approaches: more effective weight control; direct reduction in weight concerns by CBT; and smoking cessation only. Although weight concern is a serious obstacle to quitting smoking, particularly for women, it is not clear how best to address these concerns in the context of smoking cessation. The authors conclude that a more logical approach may be to assist weight-concerned smoker in attitudes to weight in relation to health risks of continuing smoking.
Ussher 2003 Smoking cessation	RCT	UK adults	To examine whether exercise counselling increases smoking abstinence and reduces tobacco withdrawal and gains in weight and body fat.	6 weeks	Male and female smokers (*n* = 299) were assigned randomly to a 7-week smoking cessation programme, including nicotine replacement therapy plus either: (1) exercise counselling; or (2) health education advice with equal contact time as for the exercise counselling condition. There was no significant difference in smoking abstinence between the exercise group (*n* = 154) and the controls (*n* = 145) at 6 weeks (39.6 vs. 38.6%), nor was there any difference in gains in weight or body fat, although those in the exercise group increased their exercise levels. Exercise participants reported less tension, anxiety and stress than the controls during the first week of smoking abstinence (p = 0.03, 0.01 and 0.04, respectively), less irritability throughout 2 weeks of abstinence (p = 0.03) and less

					restlessness throughout 3 weeks of abstinence (*p* = 0.04). Adding brief exercise counselling to a smoking cessation programme did not increase smoking abstinence or reduce gains in weight or body fat significantly, although exercise levels were raised and there were some beneficial effects on psychological symptoms.

SEARCH STRATEGY

1. exp OBESITY/
2. exp Weight Gain/
3. exp Weight Loss/
4. obes$.af.
5. (weight gain or weight loss).af.
6. (overweight or over weight or overeat$ or over eat$).af.
7. weight change$.af.
8. ((bmi or body mass index) adj2 (gain or loss or change)).af.
9. body mass.ti,ab.
10. or/1-9
11. exp Behavior Therapy/
12. exp Social Support/
13. exp Family Therapy/
14. exp Psychotherapy, Group/
15. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).af.
16. (group therapy or family therapy or cognitive therapy).af.
17. ((lifestyle or life style) adj (chang$ or intervention$)).af.
18. counsel?ing.af.
19. social support.af.
20. (peer adj2 support).ti,ab.
21. (children adj3 parent$ adj therapy).af.
22. or/11-21
23. exp OBESITY/dh [Diet Therapy]
24. exp Diet, Fat-Restricted/
25. exp Diet, Reducing/
26. exp Diet Therapy/
27. exp FASTING/
28. diet$.af.
29. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).af.
30. (low calorie or calorie control$ or healthy eating).af.
31. (fasting or modified fast$).af.
32. exp Dietary Fats/
33. (fruit or vegetable$).af.
34. (high fat$ or low fat$ or fatty food$).af.
35. formula diet$.af.
36. or/23-35
37. exp EXERCISE/
38. exp Exercise Therapy/
39. exercis$.af.
40. (aerobics or physical therapy or physical activity or physical inactivity).af.
41. (fitness adj (class$ or regime$ or program$)).af.
42. (aerobics or physical therapy or physical training or physical education).af.
43. dance therapy.af.
44. sedentary behavio?r.af.
45. or/37-44
46. exp Complementary Therapies/
47. (alternative medicine or complementary therap$ or complementary medicine).af.
48. (hypnotism or hypnosis or hypnotherapy).af.
49. (acupuncture or homeopathy or homoeopathy).af.
50. (chinese medicine or indian medicine or herbal medicine or ayurvedic).af.

51. or/46-50
52. ((diet or dieting or slim$) adj (club$ or organi?ation)).af.
53. (weightwatcher$ or weight watcher$).af.
54. (correspondence adj (course$ or program$)).af.
55. (fat camp$ or diet$ camp$).af.
56. or/52-55
57. exp Health Promotion/
58. exp Health Education/
59. mass media/
60. (health promotion or health education).af.
61. (media intervention$ or community intervention$).af.
62. (community adj2 program$).af.
63. (family intervention$ or parent$ intervention$).af.
64. or/57-63
65. exp Health Policy/
66. exp Nutrition Policy/
67. (health polic$ or food polic$ or nutrition polic$).af.
68. or/65-67
69. exp OBESITY/pc [Prevention & Control]
70. exp Primary Prevention/
71. (primary prevention or secondary prevention).af.
72. (preventive measure$ or preventative measure$).af.
73. (preventive care or preventative care).af.
74. (obesity adj2 (prevent$ or treat$)).af.
75. or/69-74
76. exp Controlled Clinical Trials/
77. exp Random Allocation/
78. exp Double-Blind Method/
79. exp Single-Blind Method/
80. exp PLACEBOS/
81. exp Research Design/
82. exp Intervention Studies/
83. exp Evaluation Studies/
84. exp Cost Benefit Analysis/
85. (time adj series).tw.
86. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).af.
87. controlled clinical trial.pt.
88. placebo$.af.
89. (matched communities or matched populations).af.
90. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).af.
91. (comparison group$ or control group$).af.
92. matched pairs.af.
93. (outcome study or outcome studies).af.
94. (quasiexperimental or quasi experimental or pseudo experimental).af.
95. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).af.
96. randomi?ed.hw.
97. (cohort or survey: or qualitative).ti,ab.
98. or/76-97
99. exp Meta-Analysis/
100. meta-analys$.ti,ab.
101. metaanalys$.ab,ti.
102. meta analys$.ab,ti.

103. Cochrane.ab,sh,ti.
104. (review$ or overview$).ti.
105. review$.pt.
106. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
107. pooled analys$.ab,ti.
108. ((data adj2 pool$) and studies).mp.
109. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
110. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
111. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
112. or/99–111
113. (retrospective$ adj2 review$).ab,sh,ti.
114. (case$ adj2 review$).ab,sh,ti.
115. (record$ adj2 review$).ab,sh,ti.
116. (patient$ adj2 review$).ab,sh,ti.
117. (patient$ adj2 chart$).ab,sh,ti.
118. (peer adj2 review$).ab,sh,ti.
119. (chart$ adj2 review$).ab,sh,ti.
120. (case$ adj2 report$).ab,sh,ti.
121. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
122. or/113-121
123. 122 not (122 and 112)
124. 112 not 123
125. 22 or 36 or 45 or 51 or 56 or 64 or 68 or 75
126. 10 and 98 and 125
127. 10 and 124 and 125
128. 126 or 127
129. Residence characteristics/
130. Delivery of health care/
131. Community Networks/
132. Social Change/
133. Social Support/
134. Community Health Aides/
135. Community Health Nursing/
136. Community Health Planning/
137. Community Health Services/
138. Community-Institutional Relations/
139. Community Medicine/
140. Community Pharmacy Services/
141. Rural Health Services/
142. Public Health/
143. Public Health Practice/
144. Public Health Nursing/
145. Preventive Health Services/
146. Primary Prevention/
147. (primary prevention or secondary prevention).af.
148. (preventive care or preventative care).af.
149. Physician's role/
150. Peer Group/
151. Self-Help Groups/
152. Health Personnel/

153. Allied Health Personnel/
154. mass media/
155. ((gp$ or general practitioner$ or physician$) adj5 (intervention$ or refer$ or advi$ or train$ or run$)).af.
156. ((nurse$ or health visitor$ or pharmacist$ or pharmacy) adj5 (intervention$ or refer$ or led or support$ or advi$ or train$ or run$)).af.
157. ((health professional$ or nutritionist$ or dietician$) adj5 (intervention$ or refer$ or led$ or support$ or advi$ or train$ or run$)).af.
158. ((peer$1 or lay or professional$1 or community or agenc$) adj5 support).af.
159. ((peer$1 or lay or community) adj5 (group$1 or network$1 or program$ or clinic$)).af.
160. health promotion/mt
161. (exercise$ prescri$ or exercise$ refer$).af.
162. ((nutrition or diet) adj2 advi$).af.
163. community wide.af.
164. social support.af.
165. social network$.af.
166. ((lifestyle$ or life style$) adj2 (change$ or advi$)).af.
167. or/129–166
168. 128 and 167
169. animal/
170. human/
171. 169 not (169 and 170)
172. 168 not 171
173. limit 172 to yr=1990-2005
174. exp OBESITY/
175. exp Weight Gain/
176. exp Weight Loss/
177. obes$.ti,ab.
178. (weight gain or weight loss).ti,ab.
179. (overweight or over weight or overeat$ or over eat$).ti,ab.
180. weight change$.ti,ab.
181. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
182. body mass.ti,ab.
183. or/174-182
184. exp Behavior Therapy/
185. exp Social Support/
186. exp Family Therapy/
187. exp Psychotherapy, Group/
188. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
189. (group therapy or family therapy or cognitive therapy).ti,ab.
190. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.
191. counsel?ing.ti,ab.
192. social support.ti,ab.
193. (peer adj2 support).ti,ab.
194. (children adj3 parent$ adj therapy).ti,ab.
195. or/184-194
196. exp OBESITY/dh [Diet Therapy]
197. exp Diet, Fat-Restricted/
198. exp Diet, Reducing/
199. exp Diet Therapy/
200. exp FASTING/

201. diet$.ti,ab.
202. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).ti,ab.
203. (low calorie or calorie control$ or healthy eating).ti,ab.
204. (fasting or modified fast$).ti,ab.
205. exp Dietary Fats/
206. (fruit or vegetable$).ti,ab.
207. (high fat$ or low fat$ or fatty food$).ti,ab.
208. formula diet$.ti,ab.
209. or/196-208
210. exp EXERCISE/
211. exp Exercise Therapy/
212. exercis$.ti,ab.
213. (aerobics or physical therapy or physical activity or physical inactivity).ti,ab.
214. (fitness adj (class$ or regime$ or program$)).ti,ab.
215. (aerobics or physical therapy or physical training or physical education).ti,ab.
216. dance therapy.ti,ab.
217. sedentary behavio?r.ti,ab.
218. or/210-217
219. exp Complementary Therapies/
220. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
221. (hypnotism or hypnosis or hypnotherapy).ti,ab.
222. (acupuncture or homeopathy or homoeopathy).ti,ab.
223. (chinese medicine or indian medicine or herbal medicine or ayurvedic).ti,ab.
224. or/219–223
225. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
226. (weightwatcher$ or weight watcher$).ti,ab.
227. (correspondence adj (course$ or program$)).ti,ab.
228. (fat camp$ or diet$ camp$).ti,ab.
229. or/225-228
230. exp Health Promotion/
231. exp Health Education/
232. mass media/
233. (health promotion or health education).ti,ab.
234. (media intervention$ or community intervention$).ti,ab.
235. (community adj2 program$).ti,ab.
236. (family intervention$ or parent$ intervention$).ti,ab.
237. or/230-236
238. exp Health Policy/
239. exp Nutrition Policy/
240. (health polic$ or food polic$ or nutrition polic$).ti,ab.
241. or/238–240
242. exp OBESITY/pc [Prevention & Control]
243. exp Primary Prevention/
244. (primary prevention or secondary prevention).ti,ab.
245. (preventive measure$ or preventative measure$).ti,ab.
246. (preventive care or preventative care).ti,ab.
247. (obesity adj2 (prevent$ or treat$)).ti,ab.
248. or/242-247
249. exp Controlled Clinical Trials/
250. exp Random Allocation/
251. exp Double-Blind Method/
252. exp Single-Blind Method/

253. exp PLACEBOS/
254. exp Research Design/
255. exp Intervention Studies/
256. exp Evaluation Studies/
257. exp Cost Benefit Analysis/
258. (time adj series).tw.
259. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
260. controlled clinical trial.pt.
261. placebo$.ti,ab.
262. (matched communities or matched populations).ti,ab.
263. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
264. (comparison group$ or control group$).ti,ab.
265. matched pairs.ti,ab.
266. (outcome study or outcome studies).ti,ab.
267. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
268. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
269. randomi?ed.hw.
270. (cohort or survey: or qualitative).ti,ab.
271. or/249-270
272. exp Meta-Analysis/
273. meta-analys$.ti,ab.
274. metaanalys$.ab,ti.
275. meta analys$.ab,ti.
276. Cochrane.ab,sh,ti.
277. (review$ or overview$).ti.
278. review$.pt.
279. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
280. pooled analys$.ab,ti.
281. ((data adj2 pool$) and studies).mp.
282. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
283. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
284. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
285. or/272-284
286. (retrospective$ adj2 review$).ab,sh,ti.
287. (case$ adj2 review$).ab,sh,ti.
288. (record$ adj2 review$).ab,sh,ti.
289. (patient$ adj2 review$).ab,sh,ti.
290. (patient$ adj2 chart$).ab,sh,ti.
291. (peer adj2 review$).ab,sh,ti.
292. (chart$ adj2 review$).ab,sh,ti.
293. (case$ adj2 report$).ab,sh,ti.
294. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
295. or/286–294
296. 295 not (295 and 285)
297. 285 not 296
298. 195 or 209 or 218 or 224 or 229 or 237 or 241 or 248
299. 183 and 271 and 298
300. 183 and 297 and 298
301. 299 or 300
302. Residence characteristics/

303. Community Health Planning/
304. Community Health Services/
305. Community-Institutional Relations/
306. Public Health/
307. Environment Design/
308. City planning/
309. Social Environment/
310. Housing/
311. Restaurants/
312. restaurant$.ti,ab.
313. neighbo?rhood$.ti,ab.
314. community wide.af.
315. built environment$.ti,ab.
316. shop$.ti,ab.
317. supermarket$.ti,ab.
318. vending machine$.ti,ab.
319. food desert$.ti,ab.
320. church$.ti,ab.
321. urban environment$.ti,ab.
322. (barriers adj10 food).ti,ab.
323. guide to community preventive services.ti,ab.
324. (youth club$ or gym$ or leisure cent$ or leisure service$).ti,ab.
325. or/302-324
326. 301 and 325
327. animal/
328. human/
329. 327 not (327 and 328)
330. 326 not 329
331. limit 330 to yr=1990-2005
332. exp OBESITY/
333. exp Weight Gain/
334. exp Weight Loss/
335. obes$.ti,ab.
336. (weight gain or weight loss).ti,ab.
337. (overweight or over weight or overeat$ or over eat$).ti,ab.
338. weight change$.ti,ab.
339. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
340. body mass.ti,ab.
341. exp Diet, Fat-Restricted/
342. exp Diet, Reducing/
343. (fruit or vegetable$ or healthy eating or diet$).ti,ab.
344. (high fat$ or low fat$ or fatty food$).ti,ab.
345. exp EXERCISE/
346. (physical activity or physical inactivity or physical fitness).ti,ab.
347. or/332-346
348. exp Behavior Therapy/
349. exp Social Support/
350. exp Psychotherapy, Group/
351. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
352. (group therapy or cognitive therapy).ti,ab.
353. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.

354. counsel?ing.ti,ab.
355. social support.ti,ab.
356. (peer adj2 support).ti,ab.
357. or/348-356
358. exp OBESITY/dh [Diet Therapy]
359. exp Diet, Fat-Restricted/
360. exp Diet, Reducing/
361. exp Diet Therapy/
362. exp FASTING/
363. diet$.ti,ab.
364. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).ti,ab.
365. (low calorie or calorie control$ or healthy eating).ti,ab.
366. (fasting or modified fast$).ti,ab.
367. exp Dietary Fats/
368. (fruit or vegetable$).ti,ab.
369. (high fat$ or low fat$ or fatty food$).ti,ab.
370. formula diet$.ti,ab.
371. or/358–370
372. exp EXERCISE/
373. exp Exercise Therapy/
374. exercis$.ti,ab.
375. (aerobics or physical therapy or physical activity or physical inactivity).ti,ab.
376. (fitness adj (class$ or regime$ or program$)).ti,ab.
377. (aerobics or physical therapy or physical training or physical education).ti,ab.
378. dance therapy.ti,ab.
379. sedentary behavio?r.ti,ab.
380. or/372-379
381. exp Complementary Therapies/
382. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
383. (hypnotism or hypnosis or hypnotherapy).ti,ab.
384. (acupuncture or homeopathy or homoeopathy).ti,ab.
385. (chinese medicine or indian medicine or herbal medicine or ayurvedic).ti,ab.
386. or/381-385
387. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
388. (weightwatcher$ or weight watcher$).ti,ab.
389. (correspondence adj (course$ or program$)).ti,ab.
390. (fat camp$ or diet$ camp$).ti,ab.
391. or/387-390
392. exp Health Promotion/
393. exp Health Education/
394. (health promotion or health education).ti,ab.
395. media intervention$.ti,ab.
396. or/392–395
397. exp Health Policy/
398. exp Nutrition Policy/
399. (health polic$ or food polic$ or nutrition polic$).ti,ab.
400. or/397-399
401. exp OBESITY/pc [Prevention & Control]
402. exp Primary Prevention/
403. (primary prevention or secondary prevention).ti,ab.
404. (preventive measure$ or preventative measure$).ti,ab.
405. (preventive care or preventative care).ti,ab.

406. (obesity adj2 (prevent$ or treat$)).ti,ab.
407. or/401-406
408. exp Controlled Clinical Trials/
409. exp Random Allocation/
410. exp Double-Blind Method/
411. exp Single-Blind Method/
412. exp PLACEBOS/
413. exp Research Design/
414. exp Intervention Studies/
415. exp Evaluation Studies/
416. exp Cost Benefit Analysis/
417. (time adj series).tw.
418. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
419. controlled clinical trial.pt.
420. placebo$.ti,ab.
421. (matched communities or matched populations).ti,ab.
422. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
423. (comparison group$ or control group$).ti,ab.
424. matched pairs.ti,ab.
425. (outcome study or outcome studies).ti,ab.
426. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
427. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
428. randomi?ed.hw.
429. (cohort or survey: or qualitative).ti,ab.
430. or/408-429
431. exp Meta-Analysis/
432. meta-analys$.ti,ab.
433. metaanalys$.ab,ti.
434. meta analys$.ab,ti.
435. Cochrane.ab,sh,ti.
436. (review$ or overview$).ti.
437. review$.pt.
438. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
439. pooled analys$.ab,ti.
440. ((data adj2 pool$) and studies).ti,ab.
441. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
442. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
443. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
444. or/431-443
445. (retrospective$ adj2 review$).ab,sh,ti.
446. (case$ adj2 review$).ab,sh,ti.
447. (record$ adj2 review$).ab,sh,ti.
448. (patient$ adj2 review$).ab,sh,ti.
449. (patient$ adj2 chart$).ab,sh,ti.
450. (peer adj2 review$).ab,sh,ti.
451. (chart$ adj2 review$).ab,sh,ti.
452. (case$ adj2 report$).ab,sh,ti.
453. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
454. or/445-453
455. 454 not (454 and 444)

456. 444 not 455
457. 357 or 371 or 380 or 386 or 391 or 396 or 400 or 407
458. 347 and 457 and 430
459. 347 and 457 and 456
460. 458 or 459
461. animal/
462. human/
463. 461 not (461 and 462)
464. 460 not 463
465. exp workplace/
466. exp working conditions/
467. exp occupations/
468. exp occupation/
469. exp business/
470. exp staff development/
471. exp employee incentive plans/
472. exp incentives/
473. exp management/
474. exp personnel management/
475. exp office management/
476. exp work/
477. exp occupational health/
478. exp occupational health services/
479. exp employer/
480. exp employer-employee relations/
481. exp employer health costs/
482. exp employee assistance programs/
483. exp named groups by occupation/
484. exp ‘occupational health and safety’/
485. employment:.ti,ab.
486. occupation:.ti,ab.
487. (worker: or employe: or staff: or personnel: or workforce).ti,ab.
488. (employ: adj2 (place: or site: or locat: or set: or environ:)).ti,ab.
489. (work: adj2 (place: or site: or locat: or set: or environ: or condition:)).ti,ab.
490. (work?place: or work?site: or work?locat: or work?set: or work?environ:).ti,ab.
491. (job: adj2 (place: or site: or locat: or set: or environ:)).ti,ab.
492. (job?place: or job?site: or job?locat: or job?set: or job?environ:).ti,ab.
493. (corporat: or business: or public sector: or private sector:).ti,ab.
494. office:.ti,ab.
495. vocation:.ti,ab.
496. trade:.ti,ab.
497. or/465–496
498. and/464,497
499. limit 498 to yr=1990-2004
500. exp OBESITY/
501. exp Weight Gain/
502. exp Weight Loss/
503. obes$.ti,ab.
504. (weight gain or weight loss).ti,ab.
505. (overweight or over weight or overeat$ or over eat$).ti,ab.
506. weight change$.ti,ab.
507. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.

508. body mass.ti,ab.
509. or/500-508
510. exp Behavior Therapy/
511. exp Social Support/
512. exp Family Therapy/
513. exp Psychotherapy, Group/
514. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).ti,ab.
515. (group therapy or family therapy or cognitive therapy).ti,ab.
516. ((lifestyle or life style) adj (chang$ or intervention$)).ti,ab.
517. counsel?ing.ti,ab.
518. social support.ti,ab.
519. (peer adj2 support).ti,ab.
520. (children adj3 parent$ adj therapy).ti,ab.
521. or/510–520
522. exp OBESITY/dh [Diet Therapy]
523. exp Diet, Fat-Restricted/
524. exp Diet, Reducing/
525. exp Diet Therapy/
526. exp FASTING/
527. diet$.ti,ab.
528. (low calorie or calorie control$ or healthy eating).ti,ab.
529. (fasting or modified fast$).ti,ab.
530. exp Dietary Fats/
531. (fruit or vegetable$).ti,ab.
532. (high fat$ or low fat$ or fatty food$).ti,ab.
533. formula diet$.ti,ab.
534. or/522–533
535. exp EXERCISE/
536. exp Exercise Therapy/
537. exercis$.ti,ab.
538. (aerobics or physical therapy or physical activity or physical inactivity).ti,ab.
539. (fitness adj (class$ or regime$ or program$)).ti,ab.
540. (aerobics or physical therapy or physical training or physical education).ti,ab.
541. dance therapy.ti,ab.
542. sedentary behavio?r.ti,ab.
543. or/535-542
544. exp Complementary Therapies/
545. (alternative medicine or complementary therap$ or complementary medicine).ti,ab.
546. (hypnotism or hypnosis or hypnotherapy).ti,ab.
547. (acupuncture or homeopathy or homoeopathy).ti,ab.
548. (chinese medicine or indian medicine or herbal medicine or ayurvedic).ti,ab.
549. or/544–548
550. ((diet or dieting or slim$) adj (club$ or organi?ation)).ti,ab.
551. (weightwatcher$ or weight watcher$).ti,ab.
552. (correspondence adj (course$ or program$)).ti,ab.
553. (fat camp$ or diet$ camp$).ti,ab.
554. or/550-553
555. exp Health Promotion/
556. exp Health Education/
557. mass media/
558. (health promotion or health education).ti,ab.

559. (media intervention$ or community intervention$).ti,ab.
560. health promoting school$.ti,ab.
561. ((school or community) adj2 program$).ti,ab.
562. (family intervention$ or parent$ intervention$).ti,ab.
563. (parent$ adj2 (behavio?r or involv$ or control$ or attitude$ or educat$)).ti,ab.
564. or/555-563
565. exp Health Policy/
566. exp Nutrition Policy/
567. (health polic$ or food polic$ or nutrition polic$).ti,ab.
568. or/565–567
569. exp OBESITY/pc [Prevention & Control]
570. exp Primary Prevention/
571. (primary prevention or secondary prevention).ti,ab.
572. (preventive measure$ or preventative measure$).ti,ab.
573. (preventive care or preventative care).ti,ab.
574. (obesity adj2 (prevent$ or treat$)).ti,ab.
575. or/569-574
576. exp Controlled Clinical Trials/
577. exp Random Allocation/
578. exp Double-Blind Method/
579. exp Single-Blind Method/
580. exp PLACEBOS/
581. exp Research Design/
582. exp Intervention Studies/
583. exp Evaluation Studies/
584. exp Cost Benefit Analysis/
585. (time adj series).tw.
586. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).ti,ab.
587. controlled clinical trial.pt.
588. placebo$.ti,ab.
589. (matched communities or matched schools or matched populations).ti,ab.
590. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
591. (comparison group$ or control group$).ti,ab.
592. matched pairs.ti,ab.
593. (outcome study or outcome studies).ti,ab.
594. (quasiexperimental or quasi experimental or pseudo experimental).ti,ab.
595. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
596. randomi?ed.hw.
597. (cohort or survey: or qualitative).ti,ab.
598. or/576-597
599. exp Meta-Analysis/
600. meta-analys$.ti,ab.
601. metaanalys$.ab,ti.
602. meta analys$.ab,ti.
603. Cochrane.ab,sh,ti.
604. (review$ or overview$).ti.
605. review$.pt.
606. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
607. pooled analys$.ab,ti.
608. ((data adj2 pool$) and studies).mp.
609. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
610. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.

611. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
612. or/599-611
613. (retrospective$ adj2 review$).ab,sh,ti.
614. (case$ adj2 review$).ab,sh,ti.
615. (record$ adj2 review$).ab,sh,ti.
616. (patient$ adj2 review$).ab,sh,ti.
617. (patient$ adj2 chart$).ab,sh,ti.
618. (peer adj2 review$).ab,sh,ti.
619. (chart$ adj2 review$).ab,sh,ti.
620. (case$ adj2 report$).ab,sh,ti.
621. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
622. or/613-621
623. 622 not (622 and 612)
624. 612 not 623
625. 521 or 534 or 543 or 549 or 554 or 564 or 568 or 575
626. 509 and 598 and 625
627. 509 and 624 and 625
628. 626 or 627
629. animal/
630. human/
631. 629 not (629 and 630)
632. 628 not 631
633. limit 632 to yr = 1990–2004
634. exp child/
635. exp adolescent/
636. exp infant/
637. (child$ or adolescent$ or infant$).af.
638. (teenage$ or young people or young person or young adult$).af.
639. (schoolchildren or school children).af.
640. (pediatr$ or paediatr$).af.
641. (boys or girls or youth or youths).af.
642. or/634-641
643. 642 and 633
644. exp OBESITY/
645. exp Weight Gain/
646. exp Weight Loss/
647. obes$.af.
648. (weight gain or weight loss).af.
649. (overweight or over weight or overeat$ or over eat$).af.
650. weight change$.af.
651. ((bmi or body mass index) adj2 (gain or loss or change)).af.
652. body mass.ti,ab.
653. or/644-652
654. exp Behavior Therapy/
655. exp Social Support/
656. exp Family Therapy/
657. exp Psychotherapy, Group/
658. ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).af.
659. (group therapy or family therapy or cognitive therapy).af.
660. ((lifestyle or life style) adj (chang$ or intervention$)).af.

661. counsel?ing.af.
662. social support.af.
663. (peer adj2 support).ti,ab.
664. (children adj3 parent$ adj therapy).af.
665. or/654-664
666. exp OBESITY/dh [Diet Therapy]
667. exp Diet, Fat-Restricted/
668. exp Diet, Reducing/
669. exp Diet Therapy/
670. exp FASTING/
671. diet$.af.
672. (diet$ adj (modif$ or therapy or intervention$ or strateg$)).af.
673. (low calorie or calorie control$ or healthy eating).af.
674. (fasting or modified fast$).af.
675. exp Dietary Fats/
676. (fruit or vegetable$).af.
677. (high fat$ or low fat$ or fatty food$).af.
678. formula diet$.af.
679. or/666–678
680. exp EXERCISE/
681. exp Exercise Therapy/
682. exercis$.af.
683. (aerobics or physical therapy or physical activity or physical inactivity).af.
684. (fitness adj (class$ or regime$ or program$)).af.
685. (aerobics or physical therapy or physical training or physical education).af.
686. dance therapy.af.
687. sedentary behavio?r.af.
688. or/680–687
689. exp Complementary Therapies/
690. (alternative medicine or complementary therap$ or complementary medicine).af.
691. (hypnotism or hypnosis or hypnotherapy).af.
692. (acupuncture or homeopathy or homoeopathy).af.
693. (chinese medicine or indian medicine or herbal medicine or ayurvedic).af.
694. or/689–693
695. ((diet or dieting or slim$) adj (club$ or organi?ation)).af.
696. (weightwatcher$ or weight watcher$).af.
697. (correspondence adj (course$ or program$)).af.
698. (fat camp$ or diet$ camp$).af.
699. or/695-698
700. exp Health Promotion/
701. exp Health Education/
702. mass media/
703. (health promotion or health education).af.
704. (media intervention$ or community intervention$).af.
705. (community adj2 program$).af.
706. (family intervention$ or parent$ intervention$).af.
707. or/700-706
708. exp Health Policy/
709. exp Nutrition Policy/
710. (health polic$ or food polic$ or nutrition polic$).af.
711. or/708-710
712. exp OBESITY/pc [Prevention & Control]

713. exp Primary Prevention/
714. (primary prevention or secondary prevention).af.
715. (preventive measure$ or preventative measure$).af.
716. (preventive care or preventative care).af.
717. (obesity adj2 (prevent$ or treat$)).af.
718. or/712-717
719. exp Controlled Clinical Trials/
720. exp Random Allocation/
721. exp Double-Blind Method/
722. exp Single-Blind Method/
723. exp PLACEBOS/
724. exp Research Design/
725. exp Intervention Studies/
726. exp Evaluation Studies/
727. exp Cost Benefit Analysis/
728. (time adj series).tw.
729. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask)).af.
730. controlled clinical trial.pt.
731. placebo$.af.
732. (matched communities or matched populations).af.
733. (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).af.
734. (comparison group$ or control group$).af.
735. matched pairs.af.
736. (outcome study or outcome studies).af.
737. (quasiexperimental or quasi experimental or pseudo experimental).af.
738. (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).af.
739. randomi?ed.hw.
740. (cohort or survey: or qualitative).ti,ab.
741. or/719-740
742. exp Meta-Analysis/
743. meta-analys$.ti,ab.
744. metaanalys$.ab,ti.
745. meta analys$.ab,ti.
746. Cochrane.ab,sh,ti.
747. (review$ or overview$).ti.
748. review$.pt.
749. (synthes$ adj3 (literature$ or research or studies or data)).ab,ti.
750. pooled analys$.ab,ti.
751. ((data adj2 pool$) and studies).mp.
752. ((hand or manual or database$ or computer$) adj2 search$).ab,ti.
753. ((electronic or bibliographic$) adj2 (database$ or data base$)).ab,ti.
754. ((review$ or overview$) adj10 (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$)).ab.
755. or/742-754
756. (retrospective$ adj2 review$).ab,sh,ti.
757. (case$ adj2 review$).ab,sh,ti.
758. (record$ adj2 review$).ab,sh,ti.
759. (patient$ adj2 review$).ab,sh,ti.
760. (patient$ adj2 chart$).ab,sh,ti.
761. (peer adj2 review$).ab,sh,ti.
762. (chart$ adj2 review$).ab,sh,ti.
763. (case$ adj2 report$).ab,sh,ti.

764. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ab,sh,ti.
765. or/756-764
766. 765 not (765 and 755)
767. 755 not 766
768. 665 or 679 or 688 or 694 or 699 or 707 or 711 or 718
769. 653 and 741 and 768
770. 653 and 767 and 768
771. 769 or 770
772. animal/
773. human/
774. 772 not (772 and 773)
775. 771 not 774
776. limit 775 to yr=1990-2005
777. (vulnerable adj group).ti,ab.
778. inequalit$.ti,ab.
779. (deprivation or deprived).ti,ab.
780. (health adj inequalit$).ti,ab.
781. (social adj inequalit$).ti,ab.
782. (urban adj renewal$).ti,ab.
783. (inner adj cit$).ti,ab.
784. (social adj class).ti,ab.
785. unemploy$.ti,ab.
786. (low adj income).ti,ab.
787. ((single or lone or sole) adj (parent$ or mother)).ti,ab.
788. homeless$.ti,ab.
789. jobless$.ti,ab.
790. exclusion.ti,ab.
791. (inequity or inequitable$).ti,ab.
792. (social adj exclusion).ti,ab.
793. (socially adj excluded).ti,ab.
794. (social adj disadvantage$).ti,ab.
795. (social adj isolation).ti,ab.
796. (social adj gradients).ti,ab.
797. ((deprived or disadvantaged) adj communit$).ti,ab.
798. underprivileged.ti,ab.
799. ((low or lower or less or poor or poorer or level) adj (socioeconomic or education or income)).ti,ab.
800. (income adj differentials).ti,ab.
801. (income adj gap).ti,ab.
802. (income adj distribution).ti,ab.
803. ((assist$ or support$ or improv$) adj ((single adj (parent$ or mother)) or homeless$ or jobless$ or unemploy$ or refugee$ or (socially adj excluded) or disadvantaged or underprivileged)).ti,ab.
804. stigma.ti,ab.
805. socioeconomic factors.ti,ab.
806. (child$ adj (abandoned or neglected or abused or hospital$ or disadvantaged or disabled)).ti,ab.
807. (special adj (school$ or education or need$)).ti,ab.
808. (exclusion adj (education or school$)).ti,ab.
809. (child$ adj (special adj need$)).ti,ab.
810. (child$ adj care).ti,ab.

811. (learning adj (disorder$ or difficult$ or disabilit$)).ti,ab. [mp = title, original title, abstract, name of substance word, subject heading word]
812. institution$.ti,ab.
813. (secure adj housing).ti,ab.
814. (care adj home).ti,ab.
815. (nursing adj home).ti,ab.
816. or/777-815
817. *Menopause/ph [Physiology]
818. menopaus$.ti,ab.
819. *Smoking/pc [Prevention & Control]
820. smok$.ti,ab.
821. *postpartum period/ or *pregnancy/
822. pregnan$.ti,ab.
823. or/817–822
824. exp continental population groups/
825. exp ethnic groups/
826. vulnerable populations/
827. minority groups/
828. (minority adj group).ti,ab.
829. (black or blacks or ethnic$ or refugee$).ti,ab.
830. or/824-829
831. 816 or 823 or 830
832. 776 and 831
833. 173 or 331 or 499 or 643
834. 832 not 833
835. 833 and 832
836. (cohort or survey: or qualitative).ti,ab.
837. 834 and 836
838. 834 not 837

DATA SOURCES

The following information sources were initially searched. No references were identified which had not already been identified through searches for other rapid reviews.

AMED
ASSIA
British Nursing Index
CAB Abstracts
CENTRAL (Cochrane Controlled Trials Register)
CINAHL
Clinical Evidence - http://www.clinicalevidence.org
Cochrane Database of Systematic Reviews
CRD (EED database) http://www.york.ac.uk/inst/crd
DARE
Embase
EPPI-Centre - http://eppi.ioe.ac.uk/
ERIC
Food Standards Agency - http://www.food.gov.uk/science/research/
HDA Evidence Base - http://www.hda-online.org.uk/html/research/effectiveness.html
Health Evidence Bulletins – Wales - http://hebw.cf.ac.uk
HealthPromis
IUHPE (International Union for Health Promotion and Education) - http://www.iuhpe.nyu.edu/pubs/index.html
Medline
NCCHTA - http://www.ncchta.org
NICE – www.nice.org.uk
Public Health Effectiveness (Hamilton, Ontario) - http://www.health.hamilton-went.on.ca/CSCARB/EPHPP/ephpp.htm
PsycINFO
SIGN – http://www.sign.ac.uk
Social Science Citation Index (equiv. to Current Contents)
Sociological Abstracts
Sport Discus

A second search was then developed with CPHE to ensure that no potentially relevant references had been overlooked. This search was run in Medline only and did not produce any additional references to those identified in previous rapid reviews. Search terms included terms for Black and minority ethnic groups, vulnerable groups and vulnerable life-stages.

The Cochrane database was also double checked for relevant RCTs – as the agreed review parameters. Bibliographies of included studies were also searched, as were key reports and systematic reviews with these topic areas (Bush 1997, Ciliska 2004, Fox 2004, Hunter 2004, Thomas 2004, Summerbell 2005) and a database of references identified for the ongoing systematic review funded by the World Cancer Research Fund at Teesside.

EXCLUDED REFERENCES

1. Agurs-Collins TD, Kumanyika SK, Ten Have TR et al. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. *Diabetes Care* 1997;20:1503–11.	Participants with non-insulin-dependent diabetes mellitus.
2. Aiello EJ, Yasui Y, Tworoger SS et al. Effect of a yearlong, moderate-intensity exercise intervention on the occurrence and severity of menopause symptoms in postmenopausal women. *Menopause* 2004;11:382–8.	One-year RCT to reduce menopausal symptoms in obese postmenopausal women (does report weight but not main aim).
3. Allison DB, Kanders BS, Osage GD et al. Weight-related attitudes and beliefs of obese African-American women. *Journal of Nutrition Education* 1995;27:18–23.	Questionnaire of obese African American women's attitudes to weight.
4. Anderson JV. Bybee DI, Brown RM et al. 5 A day fruit and vegetable intervention improves cosumption in a low-income population. *Journal of the American Dietetic Association* 2001;101**:**195-202.	Controlled study only 2 months duration in low-income population.
6. Austin SB, Field AE, Wiecha J et al. The impact of a school-based obesity prevention trial on disordered weight-control behaviors in early adolescent girls. *Archives of Pediatriatric and Adolescent Medicine* 2005;159:225–30.	Report published March 2005 on use of diet pills in Planet Health (study included in schools review and this publication to be included in update of school review).
7. Balcazar H, Castro FG, Krull JL, Balcazar H, Castro FG, Krull JL. Cancer risk reduction in Mexican American women: the role of acculturation, education, and health risk factors. *Health Education Quarterly* 1995;22:61–84.	Not intervention (Mexican American women).
8. Bayot A, Capafons A, Cardena E, Bayot A, Capafons A, Cardena E. Emotional self-regulation therapy: a new and efficacious treatment for smoking. *American Journal of Clinical Hypnosis* 1997;40:146–56.	Not aimed at preventing weight gain during smoking cessation.
9. Beckmann CR, Beckmann CA. Effect of a structured antepartum exercise program on pregnancy and labor outcome in primiparas. *Journal of Reproductive Medicine* 1990;35:704–9.	Pregnancy but not aimed at preventing weight gain (main aim pregnancy and labour outcome).
10. Bhargava A, Guthrie JF, Bhargava A, Guthrie JF. Unhealthy eating habits, physical exercise and macronutrient intakes are predictors of anthropometric indicators in the Women's Health Trial: Feasibility Study	Women's Health Trial: feasibility study in minority populations- reports predictors of anthropometric

in minority Populations. *British Journal of Nutrition* 2002;88:719–28.	indicators but not results of actual intervention (main trial paper included in report).
11. Blocker DE, Freudenberg N, Blocker DE, Freudenberg N. Developing comprehensive approaches to prevention and control of obesity among low-income, urban, African-American women. *Journal of American Medical Women's Association* 2001;56:59–64.	Literature review only, US-based.
12. Boraz MA, Simkin-Silverman LR, Wing RR et al. Hormone replacement therapy use and menopausal symptoms among women participating in a behavioral lifestyle intervention. *Preventive Medicine* 2001;33:108–14.	Only reports menopausal symptoms: Women' Healthy Lifestyle Project.
13. Boury JM, Debra A. Factors related to postpartum depressive symptoms in low-income women. *Women Health* 2004;39:2004–34.	Only baseline data.
14. Bronner Y, Boyington JEA. Developing weight loss interventions for African-American women: Elements of successful models. *Journal of the National Medical Association* 2002;94(4):224–235.	Review of weight loss interventions for African American women (may be relevant for 'public health management of obesity review').
16. Chiechi LM, Secreto G, Vimercati A et al. The effects of a soy rich diet on serum lipids: the Menfis randomized trial. *Maturitas* 2002;41:97–104.	Soya-rich diet for postmenopausal women to reduce cardiovascular disease risk.
18. Coday M. Health Opportunities with Physical Exercise (HOPE): social contextual interventions to reduce sedentary behavior in urban settings. (Project among disadvantaged overweight adults in the inner city. 56 refs). *Health Education Research* 2002;637(Oct): 17.	Ongoing – no outcome results reported.
19. Covington C. Cybulski MJ, Davis TL et al. Kids on the move: preventing obesity among urban children. *American Journal of Nursing* 2001; 101(3):73-77,79,81-2.	Not aimed at preventing obesity – literature review of treatments and recommendations.
20. Covington DL, Peoples-Sheps MD, Buescher PA, Bennett TA, Paul MV. An evaluation of an adolescent prenatal education program. *American Journal of Health Behavior* 1998;22:323–33.	Review of an uncontrolled programme not aimed at preventing weight gain.

21. Crawford V, Scheckenbach R, Preuss HG, Crawford V, Scheckenbach R, Preuss HG. Effects of niacin-bound chromium supplementation on body composition in overweight African-American women. *Diabetes Obesity and Metabolism* 1999;1:331–7.	Eight-week crossover study of chromium for weight loss in African-American women.
22. Cullen KW, Karen W. Validity and reliability of a behavior-based food coding system for measuring fruit, 100% fruit juice, vegetable, and sweetened beverage consumption: Results from the Girls health Enrichment Multisite Studies. *Preventive Medicine* 2004;38 (suppl):s33-s42.	Baseline data for GEMS only.
23. DeBate RD & Davis TA, Program: LEAP: Lifestyle Enhancement for African American Women Population. *Health Education and Behavior* 2004;31(6):662-667.	Overview of 10-week intervention, diet and exercise in African American women within churches – no outcomes reported.
24. Demark W. Partnering with African American churches to achieve better health: Lessons learned during the Black Churches United for Better Health 5 A Day project. *Journal of Cancer Education* 2000;15:164–7.	Literature review only, US-based.
25. Dennis KE, Tomoyasu N, McCrone S. Self-efficacy targeted treatments for weight loss in postmenopausal women. *Scholarly Inquiry for Nursing Practice* 2001;15(3): 259-276.	Behavioural intervention for weight loss in obese postmenopausal women with 6-month follow-up
26. Douchi T, Matsuo T, Uto H et al. Lean body mass and bone mineral density in physically exercising postmenopausal women. *Maturitas* 2003;45:185–90.	Cross-sectional study.
27. Drayton-Brooks S, White N. Health promoting behaviors among African American women with faith-based support. *ABNF Journal* 2004;15:84–90.	Literature review only, US-based.
28. Dwyer JJM, Hansen B, Barrera M et al. Maximising children's physical activity: an evaluability assessment to plan a community-based, multi-strategy approach in an ethno-racially and socio-economically diverse city. *Health Promotion International* 2005*;*18(3):199-208.	Not intervention.

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33. Fitzgibbon ML. Quantitative assessment of recruitment efforts for prevention trials in two diverse Black populations. *Preventive Medicine* 1998; 27(6): 838-845.	Review of recruitment efforts for prevention trials in minority children, US-based.
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35. Fulton JE, McGuire MT, Caspersen CJ, Dietz WH. Interventions for weight loss and weight gain prevention among youth: current issues. *Sports Medicine* 2001;31:153–65.	Literature review only.
36. Gans KM, Kumanyika SK, Lovell HJ et al. The development of SisterTalk: a cable TV-delivered weight control program for black women. *Preventive Medicine* 2003;37:654–67.	Ongoing study, no outcome results reported.
37. Gris JC, Schved JF, Feugeas O et al. Impact of smoking, physical training and weight reduction on FVII, PAI-1 and hemostatic markers in sedentary men. *Thrombosis and Haemostasis* 1990;64:516–20.	Aim to assess effect of physical training and smoking cessation on plasma levels (not to prevent

	weight gain).
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42. Jeffery RW, Gray CW, French SA et al. Evaluation of weight reduction in a community intervention for cardiovascular disease risk: changes in body mass index in the Minnesota Heart Health Program. *International Journal of Obesity and Related Metabolic Disorders* 1995;19:30–9.	Minnesota Heart Health Programme (not aimed specifically at BMEG, vulnerable groups or lifestages).
43. Kanders BS, Ullman-Joy P, Foreyt JP et al. The Black American Lifestyle Internvetion (BALI): a weight loss program for working class African American women. *Journal of the American Dietetic Association* 1994;94:310–2.	10-week pilot study- not controlled, obese, weight loss not prevention.
44. Klem ML, Viteri JE, Wing RR. Primary prevention of weight gain for women aged 25–34: the acceptability	Not vulnerable life-stage (women are not pregnant

of treatment formats. *International Journal of Obesity and Related Metabolic Disorders* 2000;24:219–25.	and cannot generalise these results to pregnant women), also US-based.
45. Kuller LH, Simkin-Silverman LR, Wing RR, Meilahn EN, Ives DG. Women's Healthy Lifestyle Project: A randomized clinical trial: results at 54 months. *Circulation* 2001;103:32–7.	Although this meets all parameters – another report of 5-year results is already included in the review.
46. Kumanyika SK, Charleston JB. Lose weight and win – A church-based weight-loss program for blood-pressure control among Black-women. *Patient Education and Counseling* 1992;19:19–32.	Weight loss intervention in obese Black women (church-based) with 6-month follow-up, for blood pressure control, 47% taking antihypertensive medication not clear why excluded as other church-based also obese.
47. Lenamond SG, Franckowiak S, Zuzak KB, Cummings ES, Crespo CJ, Andersen RE. A community intervention to promote stair use among African American communters across the age spectrum. *Journal of the American Geriatrics Society* 2001;49:114.	Abstract only, 1 month intervention of culturally appropriate sign to encourage walking in African-American commuters.
48. Lloyd C, Sullivan D. NEW solutions: an Australian health promotion programme for people with mental illness. *International Journal of Therapy and Rehabilitation* 2003 May;10(5):204–10.	Uncontrolled intervention re mainly drug-induced weight gain.
49. Luke B, Luke B. Improving multiple pregnancy outcomes with nutritional interventions. *Clinical Obstetrics and Gynecology* 2004;47:146–62.	Review and intervention to improve twin pregnancy interventions (not specifically aimed at preventing excessive weight gain).
50. Marcus BH, King TK, Albrecht AE et al. Rationale, design, and baseline data for Commit to Quit: an exercise efficacy trial for smoking cessation among women. *Preventive Medicine* 1997;26:586–97.	Ongoing – no outcome results reported.
51. Marshall D. Obesity in people with intellectual disabilities: the impact of nurse-led health screenings and health promotion activities. *Journal of Advanced Nursing* 2003; 41.(2):147-153.	Not controlled, 8 weeks duration, in obese adults and aimed at weight reduction, with learning difficulties in Northern Ireland.
52. Matvienko O, Lewis DS, Schafer E. A college nutrition science course as an intervention to prevent weight gain in female college freshmen. *Journal of Nutrition Education* 2001;33:95–101.	Not included BMEG, vulnerable group or life-stage.

53. McCarran MS, Andrasik F. Behavioral weight-loss for multiplie-handicapped adults: Assessing caretaker involvement and measures of behavior change. *Addictive Behavior* 1990;15:1990–20.	Controlled study of eight adults with cerebral palsy, 19-week intervention with 12-month follow-up, weight and BMI outcomes reported, obese at baseline.
54. McClelland JW, Demark-Wahnefried W, Mustian RD, Cowan AT, Campbell MK. Fruit and vegetable consumption of rural African Americans: baseline survey results of the black churches united for better health 5 A Day project. *Nutrition and Cancer* 1998;30:148–57.	Baseline data only for ongoing Black Churches United for Better Health project.
55. McMahon A. Kelleher CC. Helly G. Duffy E. Evaluation of a workplace cardiovascular health promotion programme in the Republic of Ireland. *Health Promotion International* 2002;17(4):297–308.	Uncontrolled study in White Irish workers, no useable outcomes.
56. Melnyk mg, Weinstein E. Preventing obesity in black women by targeting adolescents: a literature review. *Journal of the American Dietetic Association* 1994;94:536–40.	Literature review only – US based.
57. Oexmann MJ, Thomas JC, Taylor KB et al. Short-term impact of a church-based approach to lifestyle change on cardiovascular risk in African Americans. *Ethnicity and Disease* 2000;10:17–23.	Uncontrolled study of eight educational sessions in African-American churches to improve cardiovascular risk factors, with follow-up at 10 weeks reported with follow-up at 1 year planned. All obese at baseline.
58. Perkins KA, Levine MD, Marcus MD et al. Addressing women's concerns about weight gain due to smoking cessation. *Journal of Substance Abuse Treatment* 1997;14:173–82.	Not an intervention, US-based.
59. Peterson KE. Design of an intervention addressing multiple levels of influence on dietary and activity patterns of low-income, postpartum women. *Health Education Research* 2002;17(5):531-540.	Ongoing – no outcome results reported.
60. Poston WS 2nd, Haddock K, Olvera NE et al. Evaluation of a culturally appropriate intervention to increase physical activity. *American Journal of Health Behavior* 2001;25(4): 396-406.	Mexican American (not included in BMEG review).

61. Prentice R, Thompson D, Clifford C et al. Dietary fat reduction and plasma estradiol concentration in healthy postmenopausal women. The Women's Health Trial Study Group. *Journal of the National Cancer Institute* 1990;82:129–34.	Plasma hormone concentrations only in intervention arm of Women's Health Trial (postmenopausal women).
62. Quinn RD, Quinn Rothacker D. Five-year self-management of weight using meal replacements: comparison with matched controls in rural Wisconsin *Nutrition* 2000;16:344–8.	Baseline only data for ongoing Eat for Life Trial to increase fruit and vegetable consumption in African-American churches, 1-year follow-up to be reported.
63. Resnicow K, Wallace DC, Jackson A et al. Dietary change through African American churches: Baseline results and program description of the Eat for Life trial. *Journal of Cancer Education* 2000;15:156–63.	Review.
64. Reusser ME, DiRienzo DB, Miller GD et al. Adequate nutrient intake can reduce cardiovascular disease risk in African Americans. *Journal of the National Medical Association* 2003;95:188–95.	Review.
65. Rossner S. Physical activity and prevention and treatment of weight gain associated with pregnancy: current evidence and research issues. *Medicine and Science in Sports and Exercise* 1999;31:S560–3 .	Five-year weight control study in rural Wisconsin, no further details reported, not BMEG, vulnerable group or life-stage.
66. Sachdeva R, Mann SK, Sachdeva R, Mann SK. Impact of nutrition education and medical supervision on pregnancy outcome. *Indian Pediatrics* 1993;30:1309–14.	Controlled study of nutritional intervention to increase weight gain in pregnancy in Indian women.
67. Sanderson B, Littleton MA, Pulley LV. Environmental, policy, and cultural factors related to physical activity among rural, African American women. *Women Health* 2002;36:75–90.	Focus groups of barriers, enablers and suggestions for physical activity interventions in rural African American women.
68. Schmitz K, Jensen M, Kugler K et al. Strength training for obesity prevention in midlife women. *International Journal of Obesity and Related Metabolic Disorders* 2003;27(3):326-333.	Not included BMEG, vulnerable group or life-(women are not experiencing menopause and cannot generalise these results to menopausal women), also US-based.
69. Shapses SA, Heshka S, Heymsfield SB, Shapses SA, Heshka S, Heymsfield SB. Effect of calcium supplementation on weight and fat loss in women.	All obese premenopausal and postmenopausal women in three separate RCTs –

Journal of Clinical Endocrinology and Metabolism 2004; 89:632–7.	aim of interventions was weight loss.
70. Simkin-Silverman LR, Wing RR, Simkin-Silverman LR, Wing RR. Weight gain during menopause. Is it inevitable or can it be prevented? *Postgraduate Medicine* 1953;108:47–50.	One-year results of Women's Healthy Lifestyle Project- 5 year results included in report.
71. Simmons D Fleming C. Cameron M. Leakehe L. A pilot diabetes awareness and exercise programme in a multiethnic workforce. *New Zealand Medical Journal* 1996;109(1031):373–6.	Obese Maori and Pacific Islanders.
72. Simpson M, Earles J, Folen R et al. The Tripler Army Medical Center's LE3AN program: a six-month retrospective analysis of program effectiveness for African-American and European-American females. *Journal of the National Medical Association* 2004;96:1332–6.	Retrospective weight loss study and obese at baseline.
73. Steegers EA, Van Lakwijk HP et al. (Patho)physiological implications of chronic dietary sodium restriction during pregnancy; a longitudinal prospective randomized study. *British Journal of Obstetrics and Gynaecology* 1991;98:980–7.	Six-month RCT to assess effects of low sodium intervention in pregnancy (reports weight change but aim is not to prevent excessive weight gain).
74. Stolley MR, Melinda R. Addressing multiple breast cancer risk factors in African-American women. *Journal of the National Medical Association* 2004;96(1):76-86.	One-year pilot study in obese women targeting multiple breast cancer risk (diet and exercise and breast health).
75. Talcott GW, Fiedler ER, Pascale RW, Klesges RC, Peterson AL, Johnson RS. Is weight gain after smoking cessation inevitable? *Journal of Consulting and Clinical Psychology* 1995; 63(2):313-316.	Six-week intervention, US-based.
76. Turner. Cardiovascular health promotion in north Florida African-American churches. *Health Values* 1995;19:3–9.	CBA study in African American churches to increase awareness of cardiovascular disease, improve blood pressure, nutrition behaviour and PA. No weight outcomes but are diet intake and physical activity outcomes. Excluded as better quality study

	included in review for this population.
77. Van der Maten GD, van Raaij JM, Visman L et al. Low-sodium diet in pregnancy: effects on blood pressure and maternal nutritional status. *British Journal of Nutrition* 1997;77:703–20.	Low sodium vs. ad libitum diet to assess effects on blood pressure and nutritional status in pregnancy (women in both groups did not receive dietary advice, main aim was not to prevent excessive weight gain).
78. Wadden TA, Stunkard AJ. Obesity in black adolescent girls: a controlled clinical trial of treatment by diet, behavior modification, and parental support. *Pediatrics* 1990;85:345–52.	All obese at baseline.
79. Weinsier RL, Hunter GR, Gower BA et al. Body fat distribution in white and black women: different patterns of intraabdominal and subcutaneous abdominal adipose tissue utilization with weight loss. *American Journal of Clinical Nutrition* 2001;74:631–6.	Aim – to compare racial differences in fat patterns following weight loss. Compared Black and White women overweight at baseline who then received weight loss >10 kg over 22–25 weeks then anthropometric data compared with control group of never overweight Black and White women.
80. White J. Minority patients: clinical strategies to promote exercise. *Physician and Sportsmedicine* 1993;21:136–44.	Overview of strategies, not relevant to British ethnic minorities.
83. Wing RR, Hamman RF, Bray GA et al. Achieving weight and activity goals among diabetes prevention program lifestyle participants. *Obesity Research* 2004;12:1426–34.	Diabetes Prevention Programme, designed to prevent diabetes in obese women, 3-year RCT, weight loss, 18.9% African-American.
84. Wing RR. Changing diet and exercise behaviors in individuals at risk for weight gain. *Obesity Research* 1995;3(Suppl 2):s277–82.	Unobtainable from British Library.
85. Wolfe WA. A review: maximizing social support--a neglected strategy for improving weight management with African-American women. *Ethnicity and Disease* 2004;14:212–8.	Literature review, US-based.

86. Yancey AK, Miles OL, McCarthy WJ et al. Differential response to targeted recruitment strategies to fitness promotion research by African-American women of varying body mass index. *Ethnicity and Disease* 2001:11(1):115–23.	Ongoing, no outcomes reported.

Appendix 12

TREATMENT OF OVERWEIGHT AND OBESITY IN NON-CLINICAL SETTINGS

EVIDENCE SUMMARY TABLES

CONTENTS

EVIDENCE TABLE 1a: EVIDENCE OF EFFICACY (INTERNAL VALIDITY) FOR THE MANAGEMENT OF OVERWEIGHT AND OBESITY IN ADULTS

All summary data are mean values unless otherwise stated.
Studies are grouped by intervention.
Within each intervention category, studies are listed by study type in the following order: systematic review; randomised trial (RCT); controlled non-randomised trial (CCT), controlled before and after study (CBA), interrupted time series (ITS); other study type.
Within each study type, studies are listed in alphabetical order.

First author, country, study design, research type, quality	**Study population**	**Research aim/question**	**Intervention details, length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for the management of overweight and obesity in adults					
Commercial weight-loss programmes					
Ahrens 2003 [3037] USA RCT Individual 1–	**Setting:** A pharmacy in Iowa, USA. **Meal replacement (MR):** *n* = 45 BMI (kg/m^2): 29.5 (SD 2.2) Weight (kg): 81.9 (SD 11.1) Waist circumference (cm): 89.1 (SD 8.5) Age (years): 47.6 (SD 7.9) **Conventional reduced-energy diet (RED):** *n* = 43 BMI (kg/m^2): 29.0 (SD 2.6) Weight (kg): 78.3 (SD 10.1) Waist circumference (cm): 87.0 (SD 8.2)	To compare a meal replacement programme with a conventional RED for weight management using the pharmacy as the setting and the pharmacist as the point of contact for dietary advice.	**MR:** Participants received free liquid meal replacement shakes (Slim-Fast) and were instructed to use these to replace two main meals per day for the first 12 weeks, and one main meal a day for the following 10 weeks. They were also given dietary advice involving instruction on healthy eating, the prescription of a daily energy intake in the first 12 weeks and assistance in self-selecting the rest of their diet. Participants were given physical activity (PA) advice at their initial visit. They returned to the pharmacy every 2 weeks	**Loss to follow-up**: 12-week intervention: *n* = 27/95 (28%) Weight maintenance: *n* = 40/95 (42%) Not reported for individual groups. **Weight (kg):** Over the 12-week intervention period, weight decreased significantly ($p < 0.001$) in both MR (–4.9 [SE 0.3]) and RED (–4.3 [SE 0.3]) groups. There was no significant difference between the two groups. During the weight maintenance phase, from week 12 to week 22, there was a significant ($p = 0.02$) further loss in the RCD group (–0.9 [SE 0.4]). The change in the MR group (–0.7 [SE 0.4]) was not	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. No ITT. Funded by Slim-Fast Nutrition Institute.

	Age (years): 47.8 (SD 9.5) **Other relevant information:** Ninety-five participants (12.6% male) were randomised but data are only provided for participants who remained in the programme at week 2. Participants were required to be free of specific medical conditions and have a BMI of 25–32 kg/m^2.		for a 15 min review to discuss progress and to collect their shakes. **Delivered by:** A registered dietitian reviewed diet plans and was consulted as needed. Two pharmacists provided all other support. The pharmacists received no special training. **RED:** Participants were given dietary advice involving instruction on healthy eating, the prescription of a daily energy intake and assistance in self-selecting their diet using diabetic exchange lists. After 12 weeks they were instructed to return to a healthy diet of their choice. Participants were given the same PA advice and support as the intervention group. **Delivered by:** As intervention group. **Length of follow-up:** 12 and 22 weeks. **Other agencies involved:** None reported. **Other information related to**	statistically significant. There was no significant difference between the two groups. **Waist circumference (% change):** Significant reductions were reported in the intervention group at 12 weeks (–5.31%) and 22 weeks (–8.08%) and in the control group at 12 weeks (–6.10%) and 22 weeks (–7.82%). There was no significant difference between the groups.	

			delivery: None.		
Heshka 2003 [36] USA Individual RCT 1++	**Setting:** Home based. **Self-help:** *n* = 212 BMI (kg/m^2): 33.6 (SD 3.7) Weight (kg): 93.1 (SD 14.4) Waist (cm): 99 (SD 12) Age (years): 44.0 (SD 10) Gender: 13% male **Weight Watchers programme:** *n* = 211 BMI (kg/m^2): 33.8 (SD 3.4) Weight (kg):94.2 (SD 13.1) Waist (cm): 101 (SD 12) Age (years): 45 (SD 10) Gender: 18% male **Other relevant information:** Participants were recruited from clinic records or advertisement. Individuals with a BMI of 27–40, aged 18–65, including persons with health problems for which weight reduction is a medically accepted therapy, were eligible. Potential participants were excluded if already involved	To compare weight loss and health benefits achieved and maintained through self-help weight loss vs. weight loss with a structured commercial programme.	**Self-help:** Participants received a 20 min consultation with a dietitian at baseline and week 12 visits. Participants were given publicly available printed material encouraging dietary principles and exercise guidelines for safe weight loss. Other information resources were brought to their attention (e.g. websites). Two-year intervention. **Delivered by:** Dietitian. **Weight Watchers:** Participants were given vouchers for free attendance at sessions of Weight Watchers. The locations of this programme were reviewed with participants. The programme consists of a food plan, an activity plan, and a behaviour modification plan. There were weekly 1-hour group meetings led by successful programme graduates. They conduct the weekly weigh-in, act as role models, and provide written educational materials and social support.	**Loss to follow-up (at 2 years):** Self-help: *n* = 53 (25%) Weight Watchers: *n* = 61 (28.9%) **BMI (kg/m^2):** Self-help: –0.5 (SD 0.2), Year 1 –0.2 (SD 0.2), Year 2 (from baseline) Weight Watchers: –1.6 (SD 0.2), Year 1 –1.1 (SD 0.2), Year 2 (from baseline) A greater reduction in BMI from baseline was shown in the commercial programme than the self-help programme at year 1 ($p < 0.001$), and at year 2 ($p < 0.001$). The Weight Watchers group demonstrated significant mean change from baseline to follow-up at year 1 ($p < 0.001$), and at year 2 ($p < 0.001$). The self-help group demonstrated significant mean change from baseline to year 1 follow-up ($p < 0.01$), but not at year 2. **Weight (kg)** Self-help: –1.3 (SD 0.4), Year 1 –0.2 (SD 0.4), Year 2 (from baseline)	Randomisation well covered. Adequate allocation concealment. No mention of blinding. Loss to follow-up >20%. ITT analysis performed. Missing values were imputed by last-observation-carried-forward or linear interpolation and participants who made no follow-up visits were assumed to remain at baseline value. Results from ITT, modified ITT and completers only were similar. In the self-help group, 20 participants reported using weight loss medication (including herbal products); ten reported enrolling in some form of structured weight loss programme (including Weight Watchers);

	in a weight loss programme or if they had taken prescription weight loss medications in the previous 90 days.		2-year intervention. **Delivered by:** Weight Watchers programme graduates. **Length of follow-up:** 2 years. **Other agencies involved:** None reported. **Other information related to delivery:** None.	Weight Watchers: –4.3 (SD 0.4), Year 1 –2.9 (SD 0.5), Year 2 (from baseline) Weight loss of participants from baseline in the Weight Watchers programme was significantly greater than that in the self-help programme at year 1 (*p* < 0.001) and at year 2 (*p* < 0.001). The Weight Watchers group demonstrated a significant change from baseline (*p* < 0.001) at year 1 and at year 2. The self-help group demonstrated a significant change from baseline at year 1 (*p* < 0.01), but not at year 2. There was no significant difference between Weight Watchers and self-help groups in the percentage of participants who had lost between 5 and 10% of their original weight at year 1 (17 vs. 11%) or year 2 (18 vs. 15%). Significantly more Weight Watchers participants than self-help participants had lost more than 10% of their original weight at year 1 (21 vs. 9%; *p* = 0.002) and year 2 (16 vs. 6%; *p* = 0.005). **Waist circumference (cm):** Self-help: –1.6 (SD 0.6), Year 1 –0.6 (SD 0.6), Year 2	and nine reported following an alternative diet plan (e.g. Atkins, The Zone) at some point during the 2-year study. Funded by Weight Watchers International.

				Weight Watchers: –4.1 (SD 0.6), Year 1 –2.4 (SD 0.6), Year 2 A greater reduction in waist circumference from baseline was found in the Weight Watchers programme compared with the self-help programme at year 1 ($p = 0.003$) and at year 2 ($p = 0.02$). The Weight Watchers programme demonstrated a significant change from baseline at year 1 ($p < 0.01$) and at year 2 ($p < 0.04$). The self-help programme demonstrated a significant change from baseline at year 1 ($p < 0.02$) but not at year 2. **Other outcomes:** Participants who dropped out of the study were younger, had higher BMI, greater percentage body fat, were more likely to be smokers and reported lower income than completers ($p < 0.05$ for all comparisons). Dropout characteristics did not differ by treatment group. There was no statistically significant difference between men and women in weight loss. There were no statistically significant differences between the groups in the amount of improvement on quality of life	

				scales (Short-Form 36 Health Survey, Impact of Weight on Quality of Life Questionnaire)	
Rippe 1998 [12522] USA RCT Individual 1–	**Setting**: Weight Watchers, Jericho, New York, USA **Intervention:** *n* = 40 Baseline data reported for completers only (*n* = 30) Weight (kg): 81.2 (SD 7.6) % Body fat: 36.8 (SD 2.6) Height (cm): 161.6 (SD 6.7) Age (years): 37.4 (SD 7.9) Gender: 0% male **Control:** *n* = 40 Baseline data reported for completers only (*n* = 14): Weight (kg): 82.1 (SD 5.3) % Body fat: 36.2 (SD 2.7) Height (cm): 167.6 (SD 5.4) Age (years): 35.6 (SD 5.9) Gender: 0% male **Other relevant information:** Women aged 20–49 years who were 20–50% over desirable weight for height (Metropolitan Life Insurance Table 1983) were eligible provided they had not participated in a weight loss/exercise programme in	**Aim:** To assess the effects of a 12-week weight loss strategy in moderately overweight women.	**Intervention:** Subjects were enrolled in a 12-week nationally available weight loss programme (Weight Watchers International). **Nutrition:** Self-selected, hypoenergetic diet with an energy range of 33,258 to 41,462 kJ. **Exercise:** Self-selected exercise plan expending ≥6279 kJ/week by fourth week. **Behaviour:** Education regarding behaviour modification techniques, as well as problem solving and coping skills for weight loss challenges. **Group support:** Weekly meetings. **Delivered by:** Facilitated by a trained lay leader who has lost weight on the programme. **Control**: Subjects were asked to maintain their baseline	**Loss to follow-up:** Intervention: *n* = 10 (25%) Control: *n* = 26 (65%) **Weight (kg):** The intervention group lost significantly more weight than the control group (–6.07 [SD 4.01] and +1.31 [SD 1.28] respectively; $p < 0.001$). **% Body fat:** The intervention group lost significantly more body fat than the controls (–4.3%, and –0.2% respectively; $p < 0.001$). **Other outcomes:** Quality of Life was assessed using SF-36 Health Survey. Intervention group participants achieved significant improvements ($p < 0.006$) in their perception of their physical function, vitality and mental health after the 12-week period. Changes in control group participants were not statistically significant.	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. No ITT. Controls were taller and more physically active at baseline ($p < 0.05$). Funding from Weight Watchers International.

	the previous 3 months.		nutritional and PA practices for 12 weeks. **Delivered by:** N/a **Length of follow-up:** 12 weeks. **Other agencies involved:** None reported. **Other information related to delivery:** Unclear whether enrolment to the Weight Watchers programme was free.		
Rothacker 2000 [3952] USA CBA 2–	**Setting**: Intervention: Two rural neighbouring villages, Wisconsin. Control: Residency within a 50-mile (80-km) radius of the study centre. **Intervention:** *n* = 158 Although 158 participants were recruited to the weight loss programme, data for 134 participants (50 men and 84 women) were presented at baseline. **BMI (kg/m^2):** Men 32.5 (SD 4.4)	**Aim**: To assess 5-year weight changes after a self-managed meal-replacement weight loss programme.	**Intervention**: A self-managed meal replacement weight control programme. Participants were instructed to follow the label instructions of a 200–220 kcal (840–920 kJ), fortified, milk-based meal replacement diet (shake). This product replaced two meals each day for the first 3 months, and then 1–2 meals each day thereafter until their ideal weight was achieved. For maintenance participants replaced one meal each day with a shake or monitored their	**Loss to follow-up:** Intervention: *n* = 24 (16%) Control: *n* = ? (unclear) **BMI (kg/m^2):** Intervention: A significant decrease in BMI was found for both males (–1.8, SD 1.8) and females (–1.6, SD 2.6). Control: BMI increased significantly for both males (2.2, SD 3.5) and females (2.5, SD 4.1) The authors do not present *p* values. **Weight (kg):** Intervention:	The authors did not state process for selecting controls. The authors investigated change within groups. They did not assess whether there was a between group difference in the extent of change. Funded by Slim-Fast Nutrition Institute

	Women 30.7 (SD 5.6) **Weight (kg):** Men 102.9 (SD 15.3) Women 81.2 (14.7) **Age (years):** Men 40.3 (SD 10.3) Women 41.4 (SD 10.6) **Gender:** 37.3% Male **Control:** From an unclear number of initial participants, data were provided for *n* = 389 (142 men and 247 women) **BMI (kg/m^2):** Men 31.7 (SD 4.9) Women 30.2 (SD 5.6) **Weight (kg):** Men 96.3 (SD 15.2) Women 80.6 (SD 15.8) **Age (years):** Men 40.3 (SD 10.0) Women 42.0 (SD 10.5) **Gender:** 37% Male		weight daily. If participants gained more than 1–2 kg, they were instructed to return to regular use of the meal replacement product. No medical intervention was provided. Participants were asked to weigh-in each week at the local village centre during the first 3 months, and then twice per year. Meal replacement products were provided free of charge from the local grocers. **Delivered by:** Unclear. **Control:** Control weight data were obtained from three medical clinics within 50 miles (80 km) of the study centre. Self-report weight data was used for baseline for 28% of the participants. Controls were weighed at follow-up. Three controls were selected for each participant and were matched for gender, BMI (within 2 kg/m^2), and age (within 5 years).	A significant decrease in weight was found in both male (–5.8, SD 5.4; $p < 0.001$) and female (–4.2, SD 6.9; $p < 0.001$) participants. Control: A significant increase in weight was shown for both male (6.7, SD 10.2; $p < 0.001$)) and female (6.5, SD 10.7; $p < 0.001$) subjects.	

			Length of follow-up: 5 years **Other agencies involved:** None stated. **Other information related to delivery:** **None.**		
Interventions using computers					
Agras 1990 [11342] USA RCT Individual 1+	**Setting:** Hand-held computer-assisted therapy, California. **Computer alone:** *n* = 30 Weight (kg): 76.9 **Computer plus support:** *n* = 30 Weight (kg): 78.7 **Behaviour therapy:** *n* = 30 Weight (kg): 78.5 **Other relevant information:** Ninety mild to moderately overweight women (BMI 25–35 kg/m^2) were admitted to the study. Age (years): 45.2 (SD 12.4) BMI (kg/m^2): 29.7 (SD 4.3)	To compare the efficacy of hand-held computer therapy alone, computer therapy with support, and therapist-conducted weight loss programmes.	12-week weight loss programme. All three groups aimed to reduce energy intake (not >1200 kcal [5.02 MJ]) so that weight loss occurred and participants exercised 20–45 min, at least three times per week. **Computer alone:** At a 90-min introductory group session participants were given a hand-held computer to use for the duration of the programme. Participants received an oral presentation, and an operational manual, describing the computer and weight loss programme, in addition to a book of energy values. Participants were requested to set daily energy intake and exercise goals and enter these on the computer. Energy intake	**Loss to follow-up (12 months):** Computer alone: *n* = 1 (3.3%) Computer plus support: *n* = 1 (3.3%) Behaviour therapy: *n* = 0 (0%) **Weight (kg):** Computer alone: Post-treatment: 74.6 6 months: 75.5 12 months: 76.6 Computer plus support: Post-treatment: 76.1 6 months: 76.6 12 months: 76.8 Behaviour therapy: Post-treatment: 76.7 6 months: 75.8 12 months: 77.5 Weight loss, from pre- to post-treatment, for all participants combined was 2.19 kg ($p < 0.001$). The authors report that no significant differences	Randomisation well covered. No mention of allocation concealment or blinding. Loss to follow-up <20%. Unclear if ITT used. Supported by National Institute of Arthritis, Diabetes, and Digestive Kidney Diseases.

	% Overweight: 125.3 (SD 21.1) Marital status: 15% single, 64% married, 21% divorced/separated. Of the participants in the two computer-based groups, 69% had experience with computers at work, 46% had access to a home computer and 33% used a home computer on a weekly basis. Individuals meeting DSM-IV criteria for bulimia, major depression, alcohol or drug dependence, or psychosis were excluded.		information was added to the computer throughout the course of the day. Meals could be planned on the computer; other options included a trainer to promote slow eating, and messages aimed at motivating or reminding the participant of distorted cognitions related to eating. Reinforcing statements depending on individual progress were also provided Longer-term feedback on energy intake, exercise and weight (based on a 14-day period) could be examined, from which participants were encouraged to set new goals and change behaviour. **Delivered by:** Unclear. **Computer plus support:** In addition to the programme described above, participants attended four group sessions in weeks 2, 4, 6 and 8. Sessions were therapist led. Brief education on weight loss, including diet and exercise, discussed by the group. Any problems regarding the use of the computer were also discussed at these sessions.	between groups were shown at any point from post-treatment to 1-year follow-up (data not presented). **Eating behaviour:** (Assessed using Eating Patterns Questionnaire) Significant changes were seen in eating patterns at both 12 weeks and 12 months, but there were no between-group differences. **Cost-effectiveness** (kg lost/US$100): Computer alone: Post-treatment: 4.12 6 months: 3.02 12 months: 0.52 Computer plus support: Post-treatment: 1.57 6 months: 1.29 12 months: 1.1 Behaviour therapy: Post-treatment: 0.68 6 months: 1.11 12 months: 0.43 A significant post-treatment difference between groups was shown ($p < 0.01$), with the computer alone group demonstrating greater cost-effectiveness than either computer with support ($p < 0.05$) or behaviour therapy (BT) ($p < 0.05$) groups.	

			Delivered by: Therapist. **Behaviour therapy:** Ten sessions over a 12-week period. A treatment manual from the Stanford Eating Disorders Clinic was followed. The programme included education on the problem and treatment of overweight, principles of behaviour change, and enhancement of self-control. Participants were requested to monitor their food intake and the circumstances surrounding that intake as well as activity levels during treatment. **Delivered by:** Psychologist. **Length of follow-up:** 1 year. **Other agencies involved:** None reported. **Other information related to delivery:** Participants were asked to deposit US$75 at the start; US$25 was returned at each of three post-treatment assessments.	**Programme adherence:** (During last week of treatment) Computer alone: 29% Computer plus support: 70% BT: 29% The authors report that this difference was not significant (data not presented). **Other outcomes:** All three groups were equally confident in the treatment group to which they had been assigned, felt that treatment made sense and would recommend their treatment to friend. There was a significant decrease from baseline in the Beck Depression Inventory score in all three groups at both 12 weeks and 12 months, with no between group differences. There were decreases in the number of participants engaging in binge eating and increases in participant satisfaction with weight in all three groups at 12 months, with no between group differences.	

Jones 2002 [3986] USA RCT Individual 1–	**Setting:** University classroom or home, Mesa, AZ, USA**.** **Classroom:** *n* = 24 BMI (kg/m^2): 28.8 (SD 4.3) Weight (lb): 172.9 (SD 28.4) (78.4 [SD 12.9] kg) Waist-to-hip ratio: 0.77 (SD 0.06) **Computer:** *n* = 25 BMI (kg/m^2): 29.4 (SD 5.6) Weight (lb): 171.9 (SD 32.3) (78.0 [SD 14.6] kg Waist-to-hip ratio: 0.77 (SD 0.08) **Textbook:** *n* = 25 BMI (kg/m^2): 29.8 (SD 4.4) Weight (lb): 173.0 (SD 28.9) (78.5 [SD 13.1] kg) Waist/hip ratio: 0.76 (SD 0.05) **Other relevant information:** All participants were female, with an average age of 42 years (range 22–	To compare the effectiveness of three methods for delivering a weight loss education programme for women.	Three active interventions, all based on the textbook, The LEARN Program for Weight Control by Kelly Brownell (1994). All groups had identical weekly written assignments on which feedback was provided. **Classroom:** 1-hour weekly classes consisting of lectures, group activities, discussion, and assessment, for an unstated number of weeks. **Delivered by:** Not stated. **Computer:** Participants collected a new program disk containing a single lesson each week for an unstated number of weeks. Lessons contained knowledge, tests and feedback on results. Participants were encouraged to communicate with the instructor by phone or email with any questions or problems. **Delivered by:** Not stated. **Textbook:** Participants collected a new reading assignment each week	**Loss to follow-up**: *n* = 19 (26%). Not reported for each group separately. **BMI (kg/m^2):** (At 12-week follow-up) Classroom: 28.2 (SD 4.2) Computer: 28.7 (SD 5.5) Textbook: 29.2 (SD 4.8) All groups: Baseline 29.4 (SD 4.8), 6 weeks 28.6 (SD 4.5), 12 weeks 28.7 (SD 4.8) There was a statistically significant reduction in BMI from baseline to follow-up across all groups ($p < 0.001$). There was no statistically significant difference between groups in the extent of change. **Weight (lb):** At 12 week follow-up: Classroom: 170.5 (SD 28.7) (77.3 [SD 13.0] kg) Computer: 166.6 (SD 30.4) (75.6 [SD 13.8 kg) Textbook: 169.1 (SD 31.1) (76.7 [SD 14.1 kg) All groups: Baseline 172.6 (SD 29.5) (78.3 [SD 13.4] kg) 6 weeks 168.0 (SD 26.8) (76.2 [SD 12.2] kg) 12 weeks 168.9 (SD 29.5) (76.7 [SD 13.4] kg)	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. Although there were statistically significant decreases in weight outcomes, the actual changes were small. There were two follow-up points but the authors do not report when the significant change occurred.

	76). Fifty-eight participants were university staff members, five were students, two were faculty members and eight were recruited from the surrounding area. 82% were White. Participants were required to be at least 10 lb (4.5 kg) over ideal weight based on Metropolitan Life tables, be able to attend a class once per week, and have computer access.		for an unstated number of weeks. They were encouraged to communicate with the instructor by phone or email with any questions or problems. **Delivered by:** Not stated. **Length of follow-up:** 12 weeks. **Other agencies involved:** None reported. **Other information related to delivery:** Participants paid US$25 deposit, which was returned along with an additional US$25 upon completion of the course.	There was a statistically significant reduction in weight from baseline to follow-up across all groups (*p* < 0.01). There was no statistically significant difference between groups in the extent of change. **Waist-to-hip ratio:** At 12 week follow-up: Classroom: 0.75 (SD 0.05) Computer: 0.72 (SD 0.05) Textbook: 0.76 (SD 0.08) All groups: Baseline 0.77 (SD 0.06) 6 weeks 0.75 (SD 0.06) 12 weeks 0.75 (SD 0.07) There was a statistically significant reduction in BMI from baseline to follow-up across all groups (*p* < 0.05). There was no statistically significant difference between groups in the extent of change. **Other:** There were no significant differences between groups on weekly attendance.	
Tate 2003 [12537] USA RCT Individual	**Setting:** Rhode Island; setting was wherever participants had computer access. **Internet only:** *n* = 46 BMI (kg/m^2): 33.7 (SD 3.7)	To compare the effects of an Internet weight loss programme alone vs. with the addition of behavioural counselling via	**Internet only:** At an introductory 1-hour group session, participants received instruction on diet, exercise and behaviour change including recommendations on energy intake (1200–1500 kcal [5.02–6.28 MJ]) and PA, and were	**Loss to follow-up:** Internet only: *n* = 7 (15%) Internet + e-counselling: *n* = 8 (17%) **BMI (kg/m^2):** There was a significant difference (*p* = 0.03) at 12 months between BMI change (kg/m^2) in the behavioural e-	Randomisation adequately addressed. No mention of allocation concealment or blinding. Loss to follow-up <20%.

1+	Weight (kg): 89.4 (SD 12.6) Waist circumference (cm): 111 (SD 11.7) Age (years): 47.3 (SD 9.5) Gender: 11% male Ethnicity: 89% White Education: 48% college degree or higher Web/email experience (months): 80 (SD 58) Weekly Internet use (hours): 3.8 (SD 4.9) **Internet + behavioural e-counselling:** *n* = 46 BMI (kg/m^2): 32.5 (SD 3.8) Weight (kg): 86.2 (SD 14.3) Waist circumference (cm): 108 (SD 12.4) Age (years): 49.8 (SD 9.3) Gender: 9% male Ethnicity: 89% White Education: 52% college degree or higher Web/email experience (months): 87 (SD 71) Weekly Internet use (hours): 5.1 (SD 5.5) **Other relevant information:** Participants were required to have computer access and to have one or more other risk factors for type 2	email provided for 1 year to individuals at risk of type 2 diabetes.	encouraged to self-monitor these daily. They were also given access to a secure study website and a demonstration of its use. The website provided a tutorial on weight loss, a new tip and link each week, a directory of weight loss resources and a message board. Participants were required to submit their weight weekly for which they received email reminders. The total duration of the intervention was 12 months. **Delivered by:** Unclear who gave introductory meeting. **+ Behavioural e-counselling:** Participants attended the same introductory meeting with the Internet-only group and were given access to the same website but a different message board. They were also able to communicate via email with a counsellor. During the first month, the counsellor emailed participants five times per week, providing feedback, recommendations for change, answers to questions and general support. For the remaining 11 months emails were sent weekly. The total	counselling group (–1.6 [SD 2.2]) and the Internet only group (–0.8 [SD 2.1]). **Weight (kg):** There was a significant difference ($p = 0.04$) at 12 months between change in the behavioural e-counselling group (–4.4 [SD 6.2]) and the Internet only group (–2.0 [SD 5.7]). There was also a significant difference ($p = 0.03$) in the percentage of initial body weight lost by the behavioural e-counselling group (4.8%) and the Internet-only group (2.2%) at 12 months. **Waist circumference (cm):** There was a significant difference ($p = 0.05$) at 12 months between change in the behavioural e-counselling group (–7.2 [SD 7.5]) and the Internet-only group (–4.4 [SD 5.7]). **Log-in frequency:** There were significantly ($p < 0.05$) more log-ins to the website by the behavioural e-counselling group than the Internet-only group at all timepoints.	Weight outcomes were analysed using ITT. For those with missing data, change from baseline was assumed to be zero. Funded by American Diabetes Association.

	diabetes as well as being overweight (BMI 27–40 kg/m^2). Individuals with major health problems or recent weight loss ≥4.5 kg were excluded.		duration of the intervention was 12 months. **Delivered by:** Unclear who gave introductory meeting. Counsellors had masters or doctoral degrees in education, nutrition or psychology. **Length of follow-up:** 12 months. **Other agencies involved:** None reported. **Other information related to delivery:** Participants were seen at baseline, 3, 6 and 12 months for measurements, and were paid US$10–25 for attendance.		
Tate 2001 [3942] USA RCT Individual 1+	**Setting:** Participants were employees of a large network of hospitals. The study website was accessible on the organisation's Intranet. **Internet behaviour therapy:** *n* = 46 BMI (kg/m^2): 29.1 (SD 3.0) Weight (kg): 77.4 (SD 9.4) Waist circumference (cm):	To determine whether a structured Internet behavioural weight loss programme produces greater initial weight loss and changes in waist circumference than a weight loss education	**Internet behaviour therapy:** Participants were treated as the comparison group (described below) but they were also instructed to use an electronic diary on the website to record weekly self-monitoring information and to contact a therapist if required. They also received weekly behavioural weight loss lessons and personalised feedback via email, and they had access to a group electronic bulletin board.	**Loss to follow-up**: Behaviour therapy: *n* = 13 (28%) for weight and waist circumference, *n* = 14 (30%) for diet and activity. Education: *n* = 13 (29%) for weight and waist circumference, *n* = 15 (33%) for diet. *n* = 17 (38%) for activity. **Weight (kg):** There was a significant change over time ($p < 0.001$) in both groups. The	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. ITT for weight and waist circumference outcomes (using baseline data carried forward) but not for diet and activity

	98.5 (SD 9.4) Age (years): 41.1 (SD 11.6) Gender: 11% male Ethnicity: 89% White Education: 63% college degree or higher Web or email experience (months): 60.9 (SD 47.4) **Internet education:** *n* = 45 BMI (kg/m^2): 28.9 (SD 3.1) Weight (kg): 78.8 (SD 11.6) Waist circumference (cm): 98.4 (SD 10.2) Age (years): 40.6 (SD 9.7) Gender: 11% male Ethnicity: 78% White Education: 55% college degree or higher Web or email experience (months): 60.8 (SD 43.7) **Other relevant information:** Participants were recruited via email and a worksite webpage advertisement. Participants were required to be healthy with a BMI of 25–36 kg/m^2 and to agree not to seek additional weight loss treatment for 1 year.	website.	Participants who did not send a log in were contacted by email. **Delivered by:** A doctoral-level clinical psychologist gave introductory and follow-up meetings. A doctoral-level therapist provided individualised emailed feedback. **Internet education:** Participants were given access to a website providing basic information related to weight loss and a directory of resources about diet, exercise, self-monitoring, and behavioural topics for 24 weeks. They received an introductory 1-hour group lesson on behavioural weight control where they were advised on energy and fat intake and PA and were encouraged to use the self-monitoring web resources. They attended 15 min individual meetings with a clinical psychologist at 3 and 6 months. **Delivered by:** A doctoral-level clinical psychologist gave introductory and follow-up meetings.	weight change from baseline in the BT group was –3.2 (SD 2.9) at 3 months and –2.9 (SD 4.4) at 6 months. In the education group the change from baseline was –1.0 (SD 2.4) at 3 months and –1.3 (SD 3.0) at 6 months. Weight loss was significantly greater in the BT group than the education group at both 3 months ($p < 0.001$) and 6 months ($p = 0.04$). The goal of 5% weight loss was achieved by significantly ($p = 0.07$) more participants in the BT group (35%) than in the education group (18%). **Waist circumference (cm):** There was a significant change over time in both groups ($p = 0.004$). The waist change from baseline in the BT group was –5.3 (SD 4.9) at 3 months and –4.6 (SD 5.5) at 6 months. In the education group the change from baseline was –2.1 (SD 3.9) at 3 months and –2.3 (SD 3.9) at 6 months. The decrease in waist circumference was significantly greater in the BT group than the education group at both 3 months ($p = 0.001$) and 6 months ($p = 0.02$). **Website log-in frequency:** Participants in the BT group logged-on more often than those in the education group. Log-in frequency decreased in	outcomes. Diet and PA were self-reported. Funding was provided by a research division of Knoll Pharmaceutical.

			Length of follow-up: 6 months. **Other agencies involved:** None reported. **Other information related to delivery:** All participants received instruction on login procedures and website navigation. Participants were paid US$10 and US$25 for attending the 3- and 6-month follow-up appointments respectively.	both groups over time.	
Taylor 1991 [11346] USA RCT Individual 1–	**Setting:** Hand-held computer-based. **Computer-assisted therapy (CAT):** *n* = 28 Weight (kg): 78.8 Gender: 0% male **Frozen Foods First (FFF) + CAT:** *n* = 27 Weight (kg): 74.5 Gender: 0% male **Other relevant information:** Female participants with BMI between 25 and 35 were recruited via newspaper advertisements.	To investigate factors that might produce greater weight loss using CAT.	**CAT:** For a 12-week period participants were given a hand-held computer onto which they were encouraged to enter details of their diet on a daily basis, as well as exercise after every episode and their weight each week. They were encouraged to enter targets for weight loss and energy intake. The computer provided feedback on progress and a 12-week exercise programme. Participants who were not attaining their weight loss goals were encouraged to use a guided weight loss programme. This programme prescribed frozen meals to provide 1200 kcal (5.02 MJ) per day.	**Loss to follow-up:** At 12 weeks: CAT: *n* = 4 (14%) FFF + CAT: *n* = 1 (4%) At 38 weeks: CAT: *n* = 7 (25%) FFF + CAT: *n* = 2 (7%) **Weight (kg):** At 12 weeks there was a significant difference ($p < 0.001$) between weight change in the CAT group (–3.1 [SD 2.2]) and the FFF + CAT group (–5.3 [SD 2.2]). At 38 weeks the weight loss from baseline was still significantly different ($p < 0.0001$) between the two groups; CAT group –0.9 (SD 3.6), FFF + CAT group –3.8 (SD 2.7). **Adherence:**	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20% in one arm. No intention to treat (ITT) analysis. Analysis of those participants lost to follow-up found them to be significantly heavier and less confident of success than subjects remaining in the study.

	The mean age of all participants was 43.7 (SD 1.1) years.		Participants also attended four 1.5-hour group meetings to introduce them to the computer and then to discuss problems with the programme. **Delivered by:** Not stated. **FFF + CAT:** For a 12-week period participants were given a hand-held computer but were instructed to follow the guided weight loss programme (described above) and only use the computer to record weight and exercise. After they had lost 8–10 lb (3.6–4.5 kg) or after the fifth week of the programme, they proceeded as the CAT group. **Delivered by:** Not stated. **Length of follow-up:** 38 weeks. **Other agencies involved:** None reported. **Other information related to delivery:** All participants were required to give a deposit of US$100,	At week 12, the average number of computer entries per week was not significantly different between the two groups, 3.2 in the FFF + CAT group and 3.6 in the CAT group. This was about 50% of the recommended entries. **Other outcomes:** Participants had positive attitudes about computer-use, which did not change over the course of treatment. The FFF + CAT group found the computer less interesting than the CAT group at the end of the programme. Assuming that dropouts lost no weight, the mean weight loss for participants with BMI (kg/m^2) <31 (*n* = 43) was 4.3 kg compared with 2.7 kg for those with BMI >31 (*n* = 14). The difference between the groups was significant ($p < 0.05$).	Baseline weight was taken into consideration in the analysis of weight outcomes.

			which was returned after completion of follow-up assessments.		
Womble 2004 [57] USA RCT Individual 1+	**Setting:** Recruited by University of Pennsylvania. Setting was wherever participants accessed the Internet. **eDiets:** *n* = 23 BMI (kg/m^2): 33.9 (SD 3.2) Weight (kg): 93.4 (SD 12.6) Age (years): 44.2 (SD 9.3) Gender: 0% male **Weight loss manual:** *n* = 24 BMI (kg/m^2): 33.0 (SD 3.0) Weight (kg): 87.9 (SD 10.8) Age (years): 43.3 (SD 11.1) Gender: 0% male **Other relevant information:** Participants were required to have daily access to the Internet. Participants had to be free of specific physical conditions (reported in paper).	To assess the efficacy of eDiets.com (a commercial weight loss programme) in improving weight, cardiovascular health, and quality of life.	**eDiets:** Participants were given free 1-year membership of eDiets.com. They were encouraged to log-on to the programme daily, and met with a psychologist at weeks 8, 16, 26 and 52 for 20 min to review progress. There were also brief assessment visits every 4 weeks to obtain weight and blood pressure. The eDiets.com programme includes a virtual visit with a dietitian, individualised diet prescription and grocery lists, an animated fitness instructor and PA recommendations tailored to participants' self-reported fitness, access to online meetings and bulletin board support groups, a 24-hour helpdesk, email reminders and bi-weekly newsletters. **Delivered by:** Baseline and follow-up meetings were with a psychologist (one of the researchers). Research assistants conducted the assessment visits.	**Loss to follow-up**: eDiets: *n* = 8 (35%) Weight loss manual: *n* = 8 (33%) (One lost participant in the weight loss manual group developed diabetes and was excluded from all analyses.) **Weight (kg):** At week 16, the eDiets group had lost 0.7 (SD 2.7) and the weight loss manual group 3.0 (SD 3.1) and at week 52 the losses were 0.8 (SD 3.6) and 4.0 (5.1) respectively. There was a significant (p = 0.02) weight loss over time for both groups, and the weight loss manual group showed greater weight loss than the eDiets group at both week 16 (p = 0.01) and week 52 (p = 0.04). **Eating-related behaviour:** (Assessed by Eating Inventory; included treatment completers only) There were no statistically significant differences between the groups in self-reported eating restraint, disinhibition and hunger. **Attendance:** Attendance at scheduled visits did not differ significantly between groups. **Other outcomes:** Mood was assessed using the Beck	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. Analysis of weight outcomes was performed using last observation carried forward. Analysis using baseline carried forward or completers only gave similar results but differences between groups did not reach statistical significance. Analysis of eating-related behaviour and other outcomes included treatment completers only. Funded by North American Association for the Study of Obesity and National Intitutes of Health.

			Weight loss manual: Participants were given a copy of the weight loss manual 'LEARN Program for Weight Management 2000' and after 16 weeks were given a maintenance guide. They received the same schedule of progress meetings with the psychologist and assessment visits as the intervention group. **Delivered by:** Same as the intervention group. **Length of follow-up:** 1 year (outcomes reported at weeks 16 and 52). **Other agencies involved:** None reported **Other information related to delivery:** Participants were paid US$50 for completing the 52-week assessment.	Depression Inventory-II. At week 52 treatment completers reported significantly ($p < 0.004$) fewer symptoms of depression than at baseline. There were differences between the groups. Quality of Life was evaluated using the Short Form-36 Health Survey. At week 52 treatment completers reported significant improvements in physical functioning ($p < 0.05$) and vitality ($p < 0.003$) compared with baseline. There were no differences between the groups.	
Dennison 1996 [11287] USA CBA 2–	**Setting:** Two sites of a large car-manufacturing firm, New York. **Intervention:** Ninety-three participants enrolled, but data are for completers only.	To determine whether a computer-assisted instruction nutrition program would assist employees in maintaining	**Computer instruction program:** Eight weekly classes of 'Weigh To Go' computer-based program, consisting of nutrition information and computerised food intake and activity analysis, delivered in a worksite computer laboratory.	**Loss to follow-up**: Weight outcome: Intervention (both groups): $n = 71$ (76%) Control: $n = 32$ (80%) Diet outcomes: Intervention (both groups): $n = 76$ (82%) Control: $n = 33$ (83%)	Data reported for completers only.

	Computer instruction program: *n* = 11 Weight (lb): 238.8 (108.3 kg) **Non-computer instruction programme:** *n* = 11 Weight (lb): 203.6 (92.4 kg) **Control:** Forty participants enrolled from the second factory site, but data are for completers only (*n* = 8). Weight (lb): 233.5 (105.9 kg) **Other relevant information:** The 30 completers (all groups combined) had the following characteristics: Mean age (years): 47 Gender: 90% male Ethnicity: 90% White They were described as being mainly blue collar workers. Participants were required to be between 20–35% above their desirable	weight loss and dietary intake improvements for a 1-year period.	Additionally, activities such as power walking and cycling were conducted (no details provided). **Non-computer instruction programme:** Eight weekly classes with the same content as the computer instruction intervention but participants had no computer interaction. Additionally, activities such as power walking and cycling were conducted (no details provided). **Delivered by:** The intervention team consisted of a certified health educator, a registered dietitian and an exercise technician. **Control:** No intervention. **Delivered by:** N/a **Length of follow-up:** 1 year **Other agencies involved:** None reported. **Other information related to delivery:**	**Weight (lb):** Change at follow-up: Computer instruction program: –20.2 (–9.2 kg) Non-computer instruction programme:–2.7 (–1.2 kg) Control: +2.0 (+0.9 kg) There was no statistically significant difference between the three groups, nor between intervention groups combined and control.	

	weight using standard weight tables.		The Activated Health Education model was used as the basis of the intervention.		
Interventions in a work-based setting					
Dennis 1999 [4011] USA RCT Individual 1–	**Setting:** Onboard a US Navy aircraft carrier, the participants' place of work for a 6-month period. **Intervention:** Twenty-seven were randomised to the group, but data are for completers only (*n* = 21). BMI (kg/m^2): 33.9 (SD 2.7) Weight (kg): 108.1 (SD 10.2) Waist circumference (cm): 111.5 (SD 4.8) Age (years): 31.9 (SD 7.1) Gender: 100% male Previous weight loss attempts (*n*): 5.4 (SD 6.0) **Control:** Twenty were randomised to the group but data are for completers only (*n* = 18). BMI (kg/m^2): 33.0 (SD 2.9) Weight (kg): 106.7 (SD 12.0) Waist circumference (cm): 111.3 (SD 6.8) Age (years): 30.4 (SD 5.7)	To determine whether a multi-faceted approach to weight loss and physical readiness could be implemented onboard a deployed US Navy ship.	**Intervention:** Participants attended weekly 1-hour lecture and discussion sessions in small groups (7–12 individuals) for 16 weeks. They were given food exchange lists from which to make dietary choices falling within NCEP Step I (Heart Healthy) guidelines and they were taught behaviour modification techniques. They also took part in the standard Navy exercise programme consisting of 1 hour of exercise 4 days per week. **Delivered by:** Weekly sessions were conducted by a Navy dietitian. **Control:** Participants were provided with nutrition fact sheets and brochures if requested, but no other assistance for weight management. They also took part in the same standard Navy exercise programme as the intervention group. **Delivered by:**	**Loss to follow-up**: Intervention: *n* = 6/27 (22%) Control: *n* = 2/20 (10%) **BMI (kg/m^2):** Intervention: 31.3 (SD 3.3) Control: 31.2 (SD 3.0) There was a significant ($p < 0.001$) reduction in BMI in both groups over time and the reduction was significantly greater ($p < 0.05$) in the intervention group than control. **Weight (kg):** Intervention: 99.6 (SD 9.7) Control: 101.1 (SD 12.5) There was a significant ($p < 0.001$) reduction in weight in both groups over time and the reduction was significantly greater ($p < 0.05$) in the intervention group than control. **Waist circumference (cm):** Intervention: 100.1 (SD 5.6) Control: 102.7 (SD 7.8) There was a significant ($p < 0.001$) reduction in waist circumference in both groups over time, but no statistically	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20% in one arm. No ITT. The authors state that the publication of articles about the treatment programme in onboard newspapers may have contaminated the control group and led to competition between the two groups.

	Gender: 100% male Previous weight loss attempts (*n*): 2.1 (SD 2.4) **Other relevant information:** All service members stationed on the ship who were classified as not meeting body composition standards (*n* = 47) were invited to take part in the study. All consented and were randomised. However data are only presented for those who completed the study (*n* = 39).		N/a **Length of follow-up:** 16 weeks **Other agencies involved:** None reported. **Other information related to delivery:** **None.**	significant difference between the groups. **Other outcomes:** There were no significant differences between the groups in self-esteem (The Cooper Self-Esteem Inventory) and mood (Profile of Mood State). There was an improvement in depression (Center of Epidemiologic Studies Depression Scale) for the treated group versus the controls. There were significant differences between the groups at baseline on the eating behaviour measures (Binge Eating Scale, Eating Behaviour Inventory and Eating Self-Efficacy Scale) with the intervention group scoring more poorly. The intervention group improved on these measures so that following the intervention they were similar to the control group.	
Follick 1984 [11709] USA RCT Individual 1–	**Setting:** The participants' worksite, a general hospital. **Incentive:** *n* = 24 % Overweight: 31.6 **Control:** *n* = 24 % Overweight: 28.9% **Other relevant**	To examine the effects of an incentive procedure designed to decrease attrition in a behavioural worksite weight-loss intervention.	**Incentive:** Participants attended 14 30-min group behavioural weight-loss sessions. The first ten sessions were held weekly and focussed on losing weight, and the final four sessions were held fortnightly and focussed on the maintenance of weight loss. Before the programme started participants were required to give a US$5 deposit for each session. One US$5 deposit was	**Loss to follow-up:** Non-completers were defined as those attending fewer than 11 sessions and/or not completing all required assignments: Incentive: *n* = 10 (42%) Control: *n* = 19 (79%) **% Overweight:** (completers only) Repeated measures analysis of variance (ANOVA) showed that both groups lost weight over the course of	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. No ITT. Outcome data was only reported for participants defined as completers.

	information: All participants (*n* = 48): Age (years): range 20 to 69 Gender: 15% male % Overweight: range 10–113		returned at each session provided the subject attended (three 'excused absences' were allowed provided all other requirements were fulfilled), submitted completed daily food and energy intake records, and weighed in. At the end of the programme forfeited deposit money was divided between participants who attended at least 11 sessions and met all other requirements. **Delivered by:** Two psychologists led the sessions. **Control:** Participants followed the same behavioural weight-loss programme as the incentive group, and were required to give the same pre-programme deposits. The deposits were returned to the participants at the first session. **Delivered by:** Two psychologists led the sessions. **Length of follow-up:** 6 months. **Other agencies involved:**	the intervention but there was no significant difference between the groups. The incentive group were 23.60 (SD 12.00)% overweight at baseline, 17.57 (SD 12.97)% overweight after the 18 week programme and 22.30 (SD 16.91)% overweight at 6 month follow-up. The control group were 27.64 (SD 13.12)% overweight at baseline, 22.70 (SD 10.32)% overweight after the 18 week programme and 28.20 (SD 14.96)% overweight at 6 month follow-up. **Attendance:** There was a significant difference ($p < 0.01$) in the number of sessions attended by the incentive group (9.42 [SD 4.04]) and the control group (6.04 [SD 2.68]).	

			None reported. **Other information related to delivery:** **None.**		
Leslie 2002 [3977] UK RCT Individual 1–	**Setting:** Large petrochemical worksite (BP Grangemouth), Scotland. **Energy-deficient diet (ED):** *n* = 61 BMI (kg/m^2): 31.5 (SD 3.7) Weight (kg): 98.2 (SD 13.9) Waist (cm): 108.4 (SD 9.3) Age (years): 41.3 (SD 8.1) Gender: 100% male **Generalised low-energy diet (GLE):** *n* = 61 BMI (kg/m^2): 30.4 (SD 3.7) Weight (kg): 94.6 (SD 13.3) Waist (cm): 105.9 (SD 9.3) Age (years): 42.1 (SD 7.8) Gender: 100% male **Control:** Forty-four of the above 122 participants were randomised to an initial control period prior to receiving dietary advice. The baseline characteristics of this subgroup, and non-	To compare the effectiveness of a 600 kcal (2.51 MJ) daily deficit diet and a generalised low calorie (1500 kcal [6.28 MJ]) diet for weight loss, and to compare the inclusion and exclusion of meat in the weight loss diets.	Randomisation was to four different groups, the two diets each with or without meat. However, data are only presented separately for the two diet groups. **ED (meat):** Participants received individualised daily energy prescriptions of 600 kcal (2.51 MJ) less than their estimated daily energy requirement to maintain their initial weight (prescriptions ranged from 1700 to 2600 kcal [7.11 to 10.89 MJ]). They were given eating plans to match their prescriptions based on a food exchange system. They were advised to consume lean cuts of red meat at least five times per week. The initial dietetic consultation took a minimum of 60 min. Participants received individual 15–20 min consultations every 2 weeks for the first 12 weeks. After this, participants' individualised energy prescriptions were recalculated	**Loss to follow-up:** At 12 weeks: ED: *n* = 12 (20%) GLC: *n* = 19 (31%) At 24 weeks: ED: *n* = 16 (26%) GLC: *n* = 21 (34%) **Weight (kg):** An analysis of participants in the control group for the first 12 weeks (*n* = 44) vs. ED (*n* = 40) vs. GLE (*n* = 38) found that there were statistically significant ($p < 0.0001$) weight changes with ED (–4.6 [SD 3.4]) and with GLE (–5.6 [SD 3.7]) but not in the control group (+0.5 [SD 2.2]). There was no significant difference between weight loss in ED and GLE groups, but both diet groups were significantly different ($p < 0.0001$) from the control group. Analysis (including control participants within their allocated diet groups) of completers only found significant increases in weight between weeks 12 and 24 (to levels significantly lower than baseline) in both ED (+0.9 [SD 2.0]) and GLE (+1.4 [SD 1.6]) groups. There was no significant difference between the	No description of randomisation method. Allocation concealment adequately addressed. No mention of blinding. Loss to follow-up >20%. ITT reported for 12-week analysis but not at 24 weeks. Zero weight loss was assumed where only the baseline measure was available. Baseline data and loss to follow-up are not reported for the control vs. intervention groups comparison. Funded by the Meat and Livestock Commission.

	control subgroups, are not provided. **Other relevant information:** Participants were recruited via workplace email. Participants were required to have a BMI >25 kg/m^2. Exclusion criteria included intentional weight loss >3 kg in the previous 3 months.		for weight maintenance and contact was via email every 2 weeks for 12 weeks. **ED (no meat):** Participants received the same intervention as ED (meat) but red meat was not included in their food plans; alternatives included fish, eggs and cheese. **Delivered by:** Not stated. **GLE (meat):** Participants received a 1500 kcal (6.28 MJ) eating plan based on a food exchange system. They were advised to consume lean cuts of red meat at least five times per week. Participants received individual 15–20 min consultations every 2 weeks for the first 12 weeks. Then healthy eating advice was reviewed for weight maintenance and contact was via email every 2 weeks for a further 12 weeks. **GLE (no meat):** Participants received the same intervention as GLE (meat) but red meat was not included in their food plans; alternatives included fish, eggs and cheese.	groups. Inclusion/exclusion of meat had no significant effect on weight loss.	

			Delivered by: Not stated. **Control:** Before receiving dietary advice and starting their assigned diet programme, participants underwent a 12-week control period. No further details were provided. **Delivered by:** Not stated. **Length of follow-up:** 24 weeks. **Other agencies involved:** None reported. **Other information related to delivery:** During the maintenance period, face-to-face consultations were discouraged.		
Muto 2001 [3967] Japan RCT Individual 1–	**Setting**: Building maintenance company, Japan. Health promotion programme. **Intervention:** *n* = 163 total participants, *n* = 70 overweight BMI (kg/m^2): 27.2 (SD 1.5)	**Aim:** To assess the long-term effectiveness of a multi-component worksite health promotion programme targeting cardiovascular	**Intervention:** The main programme was conducted over 4 days at a hot springs resort. Participants were given lectures, practical sessions, individual counselling, and group discussions on nutrition, PA, stress and cardiovascular disease risk factors. The main focus was on	**Loss to follow-up:** (whole group) Intervention: *n* = 11 (6.7%) Control: *n* = 13 (7.9%) The authors do not report loss to follow-up for the overweight sub-group. **BMI (kg/m^2):** Mean change at 6 months follow-up	Randomisation poorly addressed. No mention of allocation concealment or blinding. Loss to follow-up <20% for whole group, unclear for subgroup of interest.

	Weight (kg): 77.2 (SD 6.8) **Control:** *n* = 163 total participants, *n* = 60 overweight BMI (kg/m^2): 27.4 (2.0) Weight (kg): 79.3 (SD 7.9) **Other relevant information:** The authors state that approximately 80% of participants in each group were blue collar workers and 20% were white collar workers. Male employees were recruited from a national company, across its seven branches. Participants were required to have at least one abnormality in BMI (≥25 kg/m^2), blood pressure, cholesterol or blood glucose. All participants were recruited from those who had attended one of six health promotion seminars conducted twice per year over a 3-year period.	disease risk factors.	nutrition and PA. At the end of the programme participants were required to define goals on diet, PA, and other health goals. Self-evaluation of these goals at 3-month intervals for 1 year after the programme was required. Comments on this evaluation were provided by the participants' supervisor and spouse/family member. **Delivered by:** Physician, dietitian, exercise trainer and the programme co-ordinators, who were outside the occupational health service. **Control:** Received an annual health examination in compliance with Industrial Safety and Health Law. If cardiovascular risk factors were identified they were written to by physician or nurse and advised to make changes in their lifestyle. **Length of follow-up:** 18 months. **Other agencies involved:** None reported. **Other information related to delivery:**	Intervention: –0.8 (SD 0.9) Control: –0.1 (SD 0.6) Mean change (from baseline) at 18 months follow-up Intervention: –0.6 (SD 1.1) Control: 0.1 (SD 0.7) The intervention group demonstrated significantly greater BMI reduction compared with the control group at 6 months ($p < 0.001$), and at 18 months ($p < 0.001$). **Weight (kg):** Mean change at 6 months follow-up: Intervention: –2.5 (SD 2.7) Control: –0.1 (SD 1.8) Mean change at 18 months follow-up: Intervention: –1.9 (SD 3.3) Control: +0.2 (SD 2.1) The intervention group demonstrated significantly greater weight loss compared with the control group at 6 months ($p < 0.001$), and at 18 months ($p < 0.001$).	No ITT analysis.

			None.		
Peterson 1985 [11331] USA RCT Individual 1-	**Setting:** Blue-collar company, Texas Instruments Inc, MA, USA. **Professionally led:** *n* = 30 Weight (kg): 82.9 **Volunteer led:** *n* = 33 Weight (kg): 81.6 **Other relevant information:** Participants were at least 10% over their ideal body weight (IBW). **Baseline data for all participants grouped together (*n* = 63):** Age (years): 46.2 (range 22 to 65) Gender: 24% male % Overweight (according to Metropolitan Life Insurance (1959): 36.6%	**Aim:** To determine the effectiveness of a professionally led, and a volunteer-led, self-help worksite weight loss programme.	**Professionally led:** The weight loss programme ‘Learn to be Lean‘ was used. The programme consisted of 12 1-hour group meetings held weekly for the first 8 weeks and then bi-weekly for the next 8 weeks (focussing on maintenance). Workbooks were provided to all participants. Each session consisted of one learning module. Topics included: energy balance, group support skills, self-control skills, choosing a lean cuisine, eating and inactivity triggers, getting other to help, losing weight through aerobic exercise, etc. Maintenance strategies dealt with relapse and lifestyle transition. The programme built on problem solving skills and the use of social support systems at work (buddy system) and at home. **Delivered by:** Pawtucket Heart Health Programme health professionals: one physiologist, and one nutritionist. These health professionals were trained and supervised by two clinical psychologists.	**Loss to follow-up:** Professional-led: Post-intervention (16 weeks) *n* = 12 (40%); 8-month follow-up *n* = 23 (77%) Volunteer-led: Post-intervention (16 weeks): *n* = 7 (21%); 8-month follow-up *n* = 16 (48%). **Weight (kg):** Professional-led: 77.1, post-intervention; 72.1, 8-month follow-up. Volunteer-led: 75.3, post-intervention; 74.0, 8-month follow-up. **Mean Weight Reduction Quotient (WRQ):** (Takes into account baseline weight and ideal weight) Professional-led: Post-intervention 46.6, 8-month follow-up 69.7 Volunteer-led: Post-intervention 20.2, 8-month follow-up 40.6 The authors report that participants in both conditions lost weight over time ($p < 0.01$) but there was no difference between the groups. **Cost-effectiveness:**	Randomisation adequately addressed. No mention of allocation concealment or blinding. Loss to follow-up > 20%. ITT analysis used baseline data for lost participants. Analysis with completers only gave the same results as ITT.

			Volunteer-led: The same protocol and treatment manual as in the professionally led condition was followed. Elected volunteers facilitated the meetings. Volunteer leaders were selected on a 'double endorsement system'. **Delivered by:** Temporarily (meetings 1 and 2) led by health professionals. After which, elected volunteers facilitated the programme. **Length of follow-up:** 8 months. **Other agencies involved:** None reported. **Other information related to delivery:** Volunteer training consisted of a 1 hour weekly session for 5 weeks.	(Based on cost per kg-lost index) Professional-led: Post-intervention US$7.88, 8-month follow-up US$12.55 Volunteer-led: Post-intervention US$4.38, 8-month follow-up US$5.56 (No further details provided.)	
Pritchard 1997 [3959] Pritchard 2002 [3958] Australia RCT	**Setting:** Worksite of a national business corporation. **Diet:** *n* = 22 randomised, data only reported for completers (*n* = 18)	To compare the effects of weight loss through diet with weight loss through exercise on changes in fat and lean tissue in a long-term	**Diet:** Participants were instructed to follow a personalised low-fat diet, and were provided with the Australian Heart Foundation booklet, 'The Weight Loss Guide'.	**Loss to follow-up:** Diet: *n* = 4/22 (18.2%) Exercise: *n* = 1/22 (4.5%) Control: *n* = 1/20 (5.0%) **BMI (kg/m^2):** Percentage change in BMI was significantly different ($p < 0.05$) in both	Some inconsistency between tables in the two papers. Randomisation poorly addressed. No mention of allocation concealment or

Individual 1+ Note: both papers report randomised data on the same participants. All the extracted data was taken from Pritchard 1997, and some additional information was from Pritchard 2002.	BMI (kg/m^2): 29.0 (SD 2.8) Weight (kg): 88.1 (SD 10.5) Age (years): 43.6 (SD 6.0) Gender: 100% male **Exercise:** n = 22 randomised, data only reported for completers (n = 21). BMI (kg/m^2): 29.2 (SD 2.8) Weight (kg): 87.8 (SD 10.1) Age (years): 44.9 (SD 6.5) Gender: 100% male **Control:** n = 20 randomised, data only reported for completers (n = 19) BMI (kg/m^2): 28.6 (SD 2.8) Weight (kg): 87.0 (SD 10.9) Age (years): 42.3 (SD 4.5) Gender: 100% male **Other relevant information:** Male employees with BMI 26–35 kg/m^2 and of satisfactory medical and cardiovascular fitness were eligible to participate. Data were only provided for completers (n = 58).	worksite programme.	**Delivered by:** Not stated. **Exercise:** Participants were instructed to avoid changing their diet, but to follow an aerobic exercise regimen in their leisure time; at least three 30-min sessions per week. They were prescribed a personal heart rate target (65–75% maximum heart rate) but could select the type of exercise (walking, cycling, swimming, jogging, gym). **Delivered by:** Not stated. **Control:** Participants were instructed to follow their usual pattern of activity and to avoid changes in diet. They were told they would move on to a weight-loss programme on completion of 12 months. **Delivered by:** Not stated. **Length of follow-up:** 12 months **Other agencies involved:** None reported.	diet (–8.2% [SD 0.9%]) and exercise (–4.4% [SD 0.7%]) groups compared with control (+1.0% [SD 0.7%]). **Weight (kg):** Percentage change in weight was significantly different ($p < 0.05$) in both diet (–7.2 [SD 0.9]) and exercise (–3.0 [SD 0.8]) groups compared with control (+1.03 [SD 0.6]). **Total fat mass (kg):** Percentage change from baseline was significantly different ($p < 0.05$) in the diet (–19.4 [SD 2.3] from 19.6 [SD 4.3]) and exercise (–11.0 [SD 2.6] from 18.8 [SD 5.0]) groups compared with control (–0.4% [SD 1.6] from 19.2 [SD 3.5]). **Total lean mass (kg):** Percentage change from baseline was significantly different ($p < 0.05$) in the diet (–3.9% [SD 0.5] from 66.7 [SD 6.7]) and exercise (–1.0% [SD 0.5] from 66.3 [SD 7.8]) groups compared with control (+0.2 [SD 0.4] from 64.9 [SD 7.7]).	blinding. Loss to follow-up <20%. No ITT analysis.

			Other information related to delivery: All participants were invited to attend bimonthly motivational group breakfast or lunch meetings at which diet, exercise and health information was delivered by guest speakers or video films. All participants completed 24-hour food recall records at monthly sessions and provided 3-day food diaries at 6 and 12 months. The diet and control group completed activity logs at monthly sessions and the exercise group completed daily activity records.		
Furuki 1999 [8838] Japan CBA 2–	**Setting**: Automobile parts manufacturer, Kyoto Prefecture and other worksite settings. **Intervention:** Whole group *n* = 507, overweight subgroup *n* = 60 BMI (kg/m^2): men 26.3 (SD 1.4), women 26.3 (SD 1.0) Gender: 90% male. **Control:** Whole group *n* = 507; overweight subgroup *n* = 81	**Aim:** To evaluate the effect of a work-based health promotion programme on BMI.	**Intervention:** Four-year (June 1992 – June 1996) THP programme, sponsored by Japan's ministry of Labour. Workers were screened and individuals identified as 'at risk' based on elevated BMI (≥25 kg/m^2), blood pressure, cholesterol or oxygen uptake received health guidance (no further details provided). **Delivered by:** Unclear. **Control:**	**Loss to follow-up:** Not reported. **BMI (kg/m^2):** Change at follow-up: Men Intervention: +0.25 (SD 1.24) Control: +0.02 (SD 1.34), $p < 0.01$ Women Intervention: –1.28 (SD 1.87) Control: +0.45 (SD 1.60) No statistically significant significance between intervention and control group was shown.	Control group selected from those who completed all annual health checks. Unclear how comparable control and intervention groups were at baseline other than BMI.

	BMI (kg/m^2): men 26.8 (SD 1.9); women, 26.2 (SD 1.2) Gender: 79% male Workers in an automobile parts company were offered the 'Total Health Promotion Plan' (THP). In total, 507 employees, aged between 26 and 55 years old entered the programme. Control subjects were matched by gender and age. Control subjects were selected from 20,000 employees in companies across the same region not employing the THP health programme. A subgroup of overweight participants (BMI ≥25 kg/m^2) was identified at the start of the study in both groups. Although the paper provides results for all participants, it is this overweight subgroup that forms the basis of the results presented here. Individuals undergoing medical treatment were excluded from the study.		Participants attended health checks over the study period. **Length of follow up:** 4 years. **Other agencies involved:** None reported. **Other information related to delivery:** None.		

Other non-clinical settings					
Jason 1991 [11310] USA RCT Individual 1–	**Setting**: Television-based programme. All pre-programme and follow-up interviews and/or measurements completed at DePaul University, Chicago, IL, USA. **Support group:** *n* = 38 Scale weight (lb): 208.03 (SD 55.91) (94.7 [SD 25.4] kg) Gender: 14% Male, 76% Female Ethnicity: 86.5% White, 13.5% Black. Socio-economic status (SES)*: 43.00 (SD 10.99) **Non support group:** *n* = 36 Scale Weight (lb) = 199.92 (SD 44.51) Gender: 19% male, 81% female Ethnicity: 83.8% White, 10.8% Black, 2.7% Hispanic, 2.7% other. SES*: 47.91 (SD 9.81) *Using the Hollingshead Scale.	**Aim:** To evaluate the effect of a media-based weight-loss and nutrition programme with, and without, group support.	**Support group:** Weight-loss and nutrition television programme, self-help book and self-help group. Each participant was assigned a 'buddy' (research assistant), to help find appropriate self-help groups. Participants also received telephone support; once a week during the programme. This decreased in frequency after the first few months. **Delivered by:** News-reader, research assistant and support groups. **Non-support group:** Weight loss and nutrition television programme, and self-help booklet. **Programme:** A well-known news-reporter provided step-by-step instructions on how to lose weight and improve nutrition during fifteen 2–4 min broadcasts. Broadcasts were aired Monday–Friday, during the mid-day and evening (9 pm) news programme, for 3 weeks	**Loss to follow-up:** (3-month follow-up) Support group: *n* = 8 (21%). Non-support group: *n* = 8 (22%) **Weight (self reported weight, lb):** Support group: Baseline 204.95 (SD 52.84) (93.0 [SD 24.0] kg) Follow-up 192.96 (SD 54.05) (87.5 [SD 24.5] kg) Non-support group: Baseline 199.00 (SD 42.91) (90.3 [SD 19.5] kg) Follow-up 189.80 (SD 40.05) (86.1 [SD 18.2] kg) A decrease from baseline was found for the non-support group on self-reported measures of weight ($p < 0.05$). **Other outcomes:** 83.8% of the support group attended a self-help group during the intervention compared with none of the comparison group. 97.3% of support group members and 88.9% of non-support group members said they would recommend the programme to others (not statistically significant).	No description of randomisation method. No mention of allocation concealment. Loss to follow-up >20%. No ITT. Measures of weight, nutrition and exercise were based on self-reported data at 3 months. The non-support group had a slightly higher protein intake at baseline than the support group ($p < 0.05$).

	Other relevant information: Study participants were recruited from the respondents to two television announcements, aired on Channel 9, asking for volunteers. Individuals selected to participate in the study met the following inclusion criteria: overweight (at least 50% over IBW); no history of intestinal problems; not currently taking psychoactive drugs.		in November 1986. Manuals were provided to all study participants before the start of the programme. All study participants were encouraged to watch the programme. **Length of follow-up:** 3 months. **Other agencies involved:** None reported. **Other information related to delivery:** **None.**	Based on the Master Questionnaire, from baseline to follow-up, the amount of hopelessness experienced by the support group decreased ($p < 0.05$) and their motivation increased ($p < 0.05$). Stimulus control increased in both groups ($p < 0.05$). It is not reported whether there were statistically significant differences between the groups.	
Kennedy 2005 [259 update] USA RCT 1–	**Setting:** African American church in Baton Rouge, LA, USA. **Group intervention:** $n = 20$ BMI (kg/m^2): 37.5 (SD 6) Weight (kg): 103.7 (SD 17.5) Body fat (%): 47.4 (SD 8.1) Fat free mass (kg): 54 (SD 9.3) Age (years): 44 (SD 10) **Individual intervention:** $n = 20$ BMI (kg/m^2): 39.3 (SD 7.8) Weight (kg): 103.4 (SD 24)	To evaluate a church-based weight loss programme.	**Group intervention:** Nutrition education was delivered during six, monthly group meetings, which involved group discussion. The importance of increasing PA was emphasised. **Individual intervention:** Nutrition education was delivered during 15 one-to-one sessions over 6 months. The first six sessions covered the same topics as the group intervention. There were then additional sessions on diet activity and self-monitoring and assessment. Participants were	**Loss to follow-up**: Group intervention: $n = 4$, 10% Individual intervention: $n = 0$, 0% **BMI, mean change (kg/m^2)** Group intervention: –1.0 (SD 1) Individual intervention: –1.3 (SD 1.3) **Weight (kg)** Group intervention: –3.1 (SD 3.5) Individual intervention: –3.4 (3.5) **Body fat (%) (assessed using dual-emission X-ray absorptiometry [DEXA])** Group intervention: –0.4 (SD 1.1) Individual intervention: –0.5 (SD 1.6)	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up <20%. No ITT analysis. Baseline data provided only on participants who completed the study.

	Body fat (%): 48.8 (SD 6.6) Fat free mass: 52 (SD 9.5) Age (years): 44 (10) **Other relevant information:** There were three male participants across both groups. Participants were recruited using posters, flyers and personal communication from church leaders and members. African American individuals >19 years, who were overweight or obese but otherwise healthy, were eligible.		encouraged to keep a 7-day food diary each month and there was basic dietary assessment using a computer programme. The importance of increasing PA was emphasised. **Delivered by:** Two church members with some background in nutrition and/or health education. They received two days training and were provided with education material. **Length of follow-up:** 24 weeks. **Other agencies involved:** Training was provided by the investigators at a biomedical research centre. **Other information related to delivery:** Each educator worked with ten participants from each intervention group. Participants were paid US$100 for taking part in the study.	**Fat free mass (kg)** Group intervention: –1.2 (SD 1.3) Individual intervention: –1.4 (SD 1.8) There were no statistically significant differences between the two groups in change from baseline to follow-up. There was a statistically significant weight loss (kg), body fat (kg) and fat free mass (kg) from baseline to follow-up in both groups ($p < 0.05$).	
McNabb 1997 [3972] USA	**Setting:** Three urban African American churches **Intervention:**	To test the effectiveness of PATHWAYS, a weight loss programme	**Intervention:** Weekly 1.5-hour facilitator-led group sessions for 14 weeks held in each of the churches. The programme involved	**Loss to follow-up**: Intervention: $n = 4$ (21%) Control: $n = 2$ (10%) (For waist circumference, diet, exercise and behaviour outcomes loss to follow	No description of randomisation method. Outcome assessors were blinded to group

RCT Individual 1+	$n = 19$ BMI (completers only) (kg/m^2): $n = 15$, 33.9 (SD 5.07) Weight (lb, completers only $n = 15$): 199.0 (90.3 kg) Waist circumference (inches, completers only $n = 12$): 38.2 (SD 3.62) (92.0 [SD 9.2] cm) Age (years): 56.5 (SD 14.5) 0% male 42% unemployed 11% education less than high school **Control:** $n = 20$ BMI (kg/m^2) (completers only, $n = 18$): 33.1 (SD 3.70) Weight (lb, completers only $n = 18$): 196.9 (89.3 kg) Waist circumference (inches, completers only $n = 16$): 37.7 (SD 3.75) (95.9 [SD 9.5] cm) Age (years): 56.6 (SD 13.0) 0% male 50% unemployed 15% education less than high school **Other relevant information:** Participants were required	designed specifically for urban African American women, administered in urban churches by trained lay facilitators	assisting participants in eating and behaviour change goal-setting, discussion of progress, problem-solving techniques and instruction in at-home exercise such as walking. **Control:** On waiting list to receive intervention. **Delivered by:** Site co-ordinator and two lay facilitators for each church. The lay facilitators had some health education experience. They had 9 hours of training and ongoing training and feedback from the researchers who attended each session. **Length of follow-up:** 15 weeks. **Other agencies involved:** None reported. **Other information related to delivery:** None reported.	up was: intervention $n = 7$ [37%]; control $n = 4$ [20%]) **BMI (kg/m^2):** Intervention: 32.5 (SD 5.41) Control: 33.7 (SD 4.07) There was a significant reduction ($p < 0.0001$) in BMI (kg/m^2) with the intervention (–1.4 [SD 1.61]) compared with control (+0.6 [SD 0.73]). **Weight (lb):** Intervention: 189.0 (SD 27.69) (85.7 [SD 12.56] kg) Control: 198.8 (SD 27.32) (90.2 [SD 12.39] kg) There was a significant ($p < 0.0001$) reduction in weight with the intervention (–10.0 [SD 10.28]) (–4.5 [SD 4.66] kg) compared with control (+1.9 [SD 4.25]) (+0.86 [SD 1.93] kg). There was no statistically significant difference between the weight loss of high attendees (attended <75% sessions) and low attendees. **Waist circumference (inches):** At follow-up: Intervention: 35.7 (SD 4.46) (90.7 [SD 11.3] cm) Control: 37.3 (SD 3.68) (94.7 [SD 9.3] cm) Waist circumference decreased significantly ($p < 0.02$) with the	allocation. Loss to follow-up >20% in one arm. ITT analysis for weight outcomes only. Eating and exercise behaviours were self-reported.

	to be African American female church members with BMI between 30 and 45 kg/m^2.			intervention (–2.5 [SD 2.39] inches [–6.3 {SD 6.1} cm]) compared with control (–0.4 [SD 1.84] inches [–1.0 {SD 4.7} cm]). **Behaviour and attitude:** (Assessed using the PATHWAYS Weight Loss Behaviour Index) There was a significant ($p < 0.001$) increase in positive eating behaviours and significant ($p < 0.002$) decrease in negative eating behaviours in intervention compared with control. **Attendance:** 75% of participants attended nine or more sessions.	
Perri 1997 [3961] USA RCT Individual 1+	**Setting:** A clinic (for group intervention) or participants' homes, Florida. **Group-based exercise:** *n* = 25 BMI (kg/m^2): 34.04 (SD 4.54) Weight (kg): 89.81 (SD 11.71) Age (years): 48.72 (SD 6.18) **Home-based exercise:** Twenty-four participants were randomised, but baseline data provided for *n* = 23	To compare group- vs. home-based exercise for the treatment of obese women undergoing behavioural weight loss therapy.	**Group-based exercise:** Participants attended weekly 2-hour group BT sessions (12–14 members per group) for 26 weeks, involving behavioural weight management techniques. They were also instructed to follow a 1200 kcal (5.02 MJ)/day diet. For the next 26 weeks they attended biweekly sessions focussing on the maintenance of changes in behaviours. Participants were given individual exercise prescriptions (target level 60–70% maximum heart rate) with a target of exercising 30 min per day 5	**Loss to follow-up:** Group: *n* = 7/25 (28%) Home: *n* = 2/24 (8%) One of the participants lost from the home group was excluded from all analyses. **Weight (kg):** There were significant ($p < 0.0001$) changes over time in both groups. Change from baseline to 6 months was –9.35 (SD 5.24) with group-based exercise and –10.40 (SD 6.29) with home-based exercise. At 15 months the weight change from baseline with home-based exercise (–11.65 [SD 8.99]) was significantly greater than with group-based exercise (–7.01 [SD 8.23]). This analysis took pre-	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20% in one arm. Weight and activity analyses included all participants except one from the home-based exercise group. Missing data were imputed using last observation carried forward or self-reported data

	BMI (kg/m^2): 33.10 (SD 2.85) Weight (kg): 87.14 (SD 10.91) Age (years): 48.91 (SD 4.97) **Other relevant information:** Participants were required to be female, aged between 40 and 60 years, have BMI between 27 and 45 kg/m^2, and were not engaged in a regular routine of aerobic exercise.		days per week. They were instructed to complete three group exercise (walking) sessions per week for the first 26 weeks and two sessions per week for weeks 27–52. Participants were encouraged to exercise in groups of two to seven individuals. Treadmill sessions could be taken at a clinic facility on weekdays between 4 pm and 7 pm. Supervised sessions were scheduled for immediately before the behavioural sessions. Equivalent outdoor walking was also allowed. **Delivered by:** Behavioural sessions were conducted by pairs of clinical psychology graduate students with no previous experience in the behavioural treatment of obesity, supervised by a researcher. The clinic exercise facility was staffed by the graduate students, supervised by an exercise physiologist. **Home-based exercise:** Participants attended the same BT sessions as the group-based exercise group	treatment weight into consideration. **Adherence to programme:** There were no differences between the groups for the first 6 months. The number of weeks of full adherence to the exercise programme was significantly greater with home-based exercise than with group-based exercise in the last 6 months of the programme. Adherence to the BT programme, measured as completion of daily self-monitoring records, was also significantly greater with home-based exercise than group-based exercise. **Therapists:** The authors report that analyses examining the effects of therapists did not show any significant effect on outcomes.	given via telephone. Analyses using completers only gave similar results.

			(described above). Participants were given individual exercise prescriptions and were instructed to complete 30 min of exercise (walking) on 5 days per week in their home (or work) environment. Exercise progress was reviewed at behavioural sessions. **Delivered by:** Behavioural sessions were delivered as described for group-based exercise. Group leaders reviewed exercise progress at these sessions. **Length of follow-up:** 15 months. **Other agencies involved:** None reported. **Other information related to delivery:** **None.**		
Harvey-Berino 1998 [3998] USA CBA 2–	**Setting:** Six television studios at sites representing a mix of rural and urban locations in Vermont and a university classroom. **Interactive television (IT):** *n* = 133	To determine if interactive video-conferencing is a feasible, acceptable, effective and cost-efficient vehicle for delivering a	**Interactive television:** Participants received a 12-week BT programme. This was delivered in weekly 1-hour group sessions held at several television studios. One group were in the same studio as the therapist and other groups at remote sites participated via	**Loss to follow-up:** IT: *n* = 30 (23%) ST: *n* = 6 (18%) **Weight (kg):** There were significant ($p < 0.001$) weight changes with both IT (–7.6 [SD 4.1]) and ST (–7.9 [SD 5.4]). There was no significant difference between	No ITT analysis. Analysis uses baseline data from all participants and follow-up data from completers only. Although participants from one of the sites

	BMI (kg/m^2): 34.5 (SD 5.4) Weight (kg): 97.7 (SD 18.4) Age (years): 45.8 (SD 8.0) Gender: 19% male Ethnicity: 97% White Education: 47% college degree or higher Previous weight loss: 70% had participated in a previous weight –loss programme. **Standard therapy (ST):** *n* = 33 BMI (kg/m^2): 35.4 (SD 5.7) Weight (kg): 102.1 (SD 18.7) Age (years): 44.4 (SD 6.6) Gender: 25% male Ethnicity: 100% White Education: 51% college degree or higher Previous weight loss: 81% had participated in a previous weight loss programme. **Other relevant information:** Recruitment was through newspaper adverts at the six locations. Participants were required to be at least 20% over IBW based on Metropolitan Life Insurance Tables (1983).	behavioural weight-control intervention.	interactive television. They could see and hear the therapist and each other at all times. The programme included behaviour modification and instruction in diet and exercise. Participants were each prescribed a target energy intake, and were required to record daily intake in a diary. They were also given exercise goals and they recorded their activity on a daily basis (The programme was similar to the LEARN programme). **Delivered by:** The behavioural programme was delivered by a trained behavioural therapist. The therapist reviewed weight and self-monitoring diaries of participants at the local site. Each remote site had a site facilitator who was not a trained behaviour therapist but who was trained in how to weigh participants and review diaries. Facilitators included Local Extension Educators and one local dietitian. **Standard therapy:** Participants received the same BT programme as the IT group, but this was delivered in person	the groups. **Cost-effectiveness:** The cost per participant of running the groups was calculated as US$34.71 for IT and US$24.65 for ST. The average price per pound of weight loss was calculated as US$2.56 for IT and US$2.00 for ST.	were randomised to IT and ST groups, randomised data were not reported separately.

			in a university campus classroom. Weight and self-monitoring diaries were monitored by the therapist. Further details are not provided. **Delivered by:** The same trained behavioural therapist as the IT programme. **Length of follow-up:** 12 weeks **Other agencies involved:** None reported. **Other information related to delivery:** **None.**		

EVIDENCE TABLE 1b: EVIDENCE OF EFFICACY (INTERNAL VALIDITY) FOR THE MANAGEMENT OF OVERWEIGHT AND OBESITY IN CHILDREN

All summary data are mean values unless otherwise stated.
Studies are grouped by intervention.
Within each intervention category, studies are listed by study type in the following order: systematic review; randomised trial (RCT); controlled non randomised trial (CCT), controlled before and after study (CBA), interrupted time series (ITS); other study type.
Within each study type, studies are listed in alphabetical order.

First author, country, study design, research type, quality	**Study population**	**Research aim/question**	**Intervention details/length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for the management of overweight and obesity in children					
School-based interventions with family involvement					
Figueroa-Colon 1996 [11292] USA RCT Cluster 1+	**Setting:** Two suburban public schools in New Orleans, serving low to middle socio-economic-level families. **Intervention:** *n* = 12 BMI (kg/m^2): 30.9 (SD 5.4) Weight (kg): 69.6 (SD 21.1) % IBW for height: 171.8 (SD 20.7) Age (years): 10.4 (SD 1.3) Gender: 58% male **Control:** *n* = 7 BMI (kg/m^2): 28.8 (SD 4.2) Weight (kg): 62.2 (SD 15.9)	To test the effectiveness of a hypoenergetic dietary intervention for superobese children in a school setting.	**Intervention:** 1.5-hour sessions held at school weekly for the first 10 weeks and then fortnightly for the following 16 weeks. At least one parent was required to attend with each child. Sessions were held after 5 pm. Sessions involved dietary and exercise instruction, discussion and monitoring, and behavioural modification. Diet for the first 10 weeks was protein-sparing modified fast (PSMF). For the following 16 weeks a hypoenergetic balanced diet was used, with gradual increase in energy content. Individual activity	**Loss to follow-up**: Intervention: *n* = 1 (8%) Control: *n* = 0 (0%) **BMI (kg/m^2):** There was a significant ($p < 0.002$) reduction in BMI in the intervention group (–3.8 [SD 3.2]). There was no significant change in control group BMI (+0.2 [SD 0.9]). **Weight (kg):** There was a significant ($p < 0.02$) reduction in weight in the intervention group (–5.6 [SD 7.1]). There was a significant ($p < 0.0001$) increase in weight in the control group (+2.8 [SD 3.1]).	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up <20%. Of those children invited to participate in the study at screening, enrolment rates were 27% for the intervention school and 37% for the control school. Baseline characteristics of those who enrolled

	% IBW: 164 (SD 20.3) Age (years): 10.8 (SD 1.2) Gender: 57% male **Other relevant information:** Of 755 children screened, 63 were defined by the authors as superobese (>140% IBW) and were invited to participate in the study.		programmes were devised, consisting of five 45-min sessions per week at school and at home. **Delivered by:** The group leaders included a paediatrician, a psychologist, a nutritionist, a physical education instructor and a nurse. **Control:** No intervention control. **Delivered by:** N/a **Length of follow-up:** 6 months. **Other agencies involved:** None reported. **Other information related to delivery:** None.	**% IBW:** There was a significant ($p < 0.002$) decrease in the intervention group (–24.3 [SD 20]). There was no significant change in the control group (–0.3 [SD 5.9]).	and those who refused were compared for each school. At the intervention school % IBW was significantly ($p < 0.002$) lower in those who refused treatment. There were no significant differences at the control school. Statistical analysis reported for within group change only.
Grey 2004 [3054] USA RCT School 1+	**Setting**: Two middle schools in the New Haven, CT, area. **Intervention group:** *n* = 22 BMI (kg/m^2): 35.8 (SD 5.8) Weight (lb): 203.3 (SD 43.1) (92.2 [SD 19.5] kg)	**Aim**: To evaluate the preliminary effects of a school-based nutrition education, PA, and coping skills training (CST) programme on	**Intervention:** Nutrition, PA and CST for 16 weeks. **Nutrition education:** Programme was designed to be family centred, culturally sensitive and interactive. It focused on slowing weight gain and improving glucose	**Loss to follow-up:** There were no dropouts from the programme. The authors report that nine participants did not complete metabolic data, and five participants did not complete psychosocial or behavioural data at 12-month follow-up. The authors do not report which group these individuals	Randomisation adequately addressed. No mention of allocation concealment. Blinding poorly addressed. Loss to follow-up <20% for weight outcomes.

	Central adiposity (inches): 44.7 (SD 6.2) (113.5 [SD 15.7] cm) Age (years): 12.4 (SD 1.2) Gender: 36.4% male Ethnicity: 11 (50%) African American; 10 (45.5%) Hispanic; 1 (4.5%) White. Income: 11 (50%) <US$19,900; 9 (41%) US$20,000–59,999; 1 (5%) ≥$60,000. **Comparison group:** *n* = 19 BMI (kg/m^2): 37.0 (SD 7.1) Weight (lb): 214.9 (SD 54.2) (97.5 [SD 24.6] kg) Central adiposity (inches): 45.0 (SD 3.9) (114.3 [SD 9.9] cm Age (years): 12.6 (SD 0.8) Gender: 36.8% Male Ethnicity: 10 (52.6%) African American, 8 (42.1%) Hispanic, 1 (5.3%) White. Income: 7 (36.8%) <US$19,900; 8 (42%) US$20,000–59,999; 1 (5%) ≥US$60,000. **Other relevant information:** Adolescents screened at	insulin resistance, self-management, and psychosocial well being among inner city youth at risk for type 2 diabetes.	metabolism. Classes were provided weekly, lasting 45 min. A 'non-diet' approach was taught, encouraging regular and nutritious meals with a reduced portion size. Parents were also invited to participate in the nutrition education programme. **Physical activity:** After-school activity of 45 min. Adolescents were included in designing the activity programme. Participants were encouraged to increase their physical activities, and decrease their sedentary behaviours, at home for an additional three days. Parents were encouraged to collaborate with the PA programme. **Coping skills training:** This was taught during nutrition classes. Training included culturally sensitive weight management materials. CST was also reinforced opportunistically during the PA sessions. There was weekly telephone support during the summer in the form of reinforcement and positive feedback.	were assigned to. **BMI (kg/m^2):** At follow-up: Intervention: 35.9 (SD 6.8) Comparison: 37.8 (SD 7.7) **Weight (lb):** At follow-up: Intervention: 214.6 (SD 49.1) (97.3 [SD 22.3] kg) Comparison: 230.3 (SD 58.8) (104.5 [SD 26.7] kg) **Central adiposity (inches):** At follow-up: Intervention: 44.5 (SD 6.7) (113.0 [SD 17.0] cm) Comparison: 46.8 (SD 7.0) (118.9 [SD 17.8] cm) There was no statistically significant difference between groups in change from baseline to 12-month follow-up.	

	school by the by the school nurse practitioner. Families of youths with a BMI ≥95th percentile and a family history of diabetes were contacted regarding the study.		**Delivered by:** Dietitian, licensed personal trainer and research assistant. **Comparison:** Participants received the education and PA programme (as described above), but not the CST for 16 weeks, and monthly telephone contact. **Length of follow-up:** 12-month follow-up. **Other agencies involved:** None reported. **Other information related to delivery:** **None.**		
Lansky 1983 [11322] USA RCT Individual 1–	**Setting:** Three junior high schools. **Intervention:** *n* = 30 Weight (kg): 68.42 % Overweight (% deviation from mean weight for height and age): 43.93 Age (years): 12.9 (SD 1.3*) Gender: 47% male **Control:** *n* = 25 Weight (kg): 71.01 % Overweight: 47.47%	To evaluate the effectiveness of a school-based intervention for adolescent obesity.	**Intervention:** Twelve weekly 45-min group meetings. Children were excused from class to attend meetings. Children were taught self-monitoring of diet and exercise, problem solving, a food-exchange plan and eating behaviour techniques. Half of the sessions involved aerobic activities and the discussion of ways to increase out-of-session exercise levels. Weight was recorded every 3 weeks and children received a lottery ticket for each 0.23 kg lost. Lottery	**Loss to follow-up:** Not stated. **Weight (kg):** There was a significant ($p < 0.01$) difference between weight change in the intervention group (+0.57 [SD 2.94*]) and the control group (+3.29 [SD 3.32*]). **Height (cm):** There was a significant ($p < 0.01$) increase in height from baseline in both groups. The intervention group increased by 1.83 (SD 1.42*) and the control group by 2.03 (SD 1.65*).	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up not stated. Data were also reported on a self-selected control group (data not extracted).

	Age (years): 13.3 (SD 1.3*) Gender: 44% male **Other relevant information:** 114 children were identified as being 10% or more overweight through screening in the schools. 55 (48%) received parental permission to participate in the trial and were randomised. *The authors do not explicitly state whether this is a standard deviation.		prizes included passes for bowling or to a local YMCA. On four different evenings 1.5 hour meetings were held for parents to attend in a group at which the instructor provided feedback and advice regarding the programme. **Delivered by:** A female physical education teacher. **Control:** No intervention (no further details provided). **Delivered by:** N/a **Length of follow-up:** 12 weeks. **Other agencies involved:** None reported. **Other information related to delivery:** **None.**	**% Overweight:** There was a significant (*p* < 0.01) difference between change in % overweight in the intervention group (–5.71 [SD 9.04*]) and the control group (+2.41% [SD 7.57*]). **Attendance:** Only one-third of parents attended a parent meeting. *The authors do not explicitly state whether this is a standard deviation	
Graf 2005 [30] Germany CBA	**Setting:** Seven primary schools randomly selected from schools in the Cologne region. **Intervention:**	**Aim:** To evaluate the effect of a school and family based intervention for overweight and obese children in	**Intervention:** A 9-month programme covering four main areas (diet, PA, parental education and family events). **Diet:**	**Loss to follow-up:** Intervention group: *n* = 81 (66.9%) Control group: *n* = 10 (6.5%) **BMI (kg/m^2):** Change at follow-up: Intervention: +0.27 (SD 0.19)	Unclear loss to follow-up for intervention group. 121 children were selected to participate but the

2+	121 children were invited to participate, but baseline data are for completers only (*n* = 40). Age (years): 8.70 (SD 1.26) BMI (kg/m^2): 22.81 (SD 3.60) Weight (kg): 43.58 (SD 10.21) **Control group:** *n* = 155 Age (years):8.47 (SD 1.27) BMI (kg/m^2): 21.77 (SD 2.66) Weight (kg): 40.84 (SD 9.62) **Other relevant information:** Participants were selected from subjects enrolled in a large study aiming to prevent overweight and obesity in primary schools (*n* = 1678). Of these children 17.7% were obese/overweight. It is from this obese/overweight group that participants for the described study were recruited.	grades 1 through 4 (STEP TWO programme).	Diet based on the OPTIMAX pyramidal programme. Specialists cooked and ate with the participants twice per week. **Physical activity:** Participants undertook 60–90 min of PA (aerobic dance, relay, soccer, etc.) after each supervised meal. **Education:** Information was given to children on healthy foods and the importance of exercise. Parents were involved in events about healthy nutrition (two evening sessions) and importance of physical exercise (one evening session). **Family events:** Two inline skating sessions for participants and their parents were organised. **Delivered by:** Nutritionists, gymnasts, psychologists and medical doctors at the selected schools. **Control:** Did not receive any intervention other than their regular school programme.	Control: +0.66 (SD 0.10) No significant difference between groups was detected at follow-up (*p* = 0.069). BMI standard deviation score (SDS) change at follow-up: Intervention: –0.15 (SD 0.04) Control: –0.05 (SD 0.02) A statistically significant difference between groups was found at follow-up (*p* = 0.028), with the intervention group demonstrating the greatest reduction. **Weight (kg):** At follow-up: Intervention: 46.90 (SD 11.44) Control: 44.66 (SD 10.32) No significant difference between groups was detected at follow-up. **Waist circumference:** The authors state that no significant difference in change of waist circumference was shown between groups (data not reported).	number who agreed to participate was not reported, therefore loss to follow-up may be over-estimated. No ITT analysis. The intervention group had a slightly higher BMI at baseline than the control group (*p* = 0.042).

			Length of follow-up: 9 months. **Other agencies involved:** None reported. **Other information related to delivery:** **None.**		
School-based interventions without specified family involvement					
Carrel 2005 [93 update] USA RCT 1–	**Setting:** Rural school in Wisconsin **Intervention:** *n* = 27 BMI (kg/m^2): 32 (SD 6) Body fat (%): 36.5 (SD 4.7) Age (years): 12.5 (SD 0.5) Gender: 48% male **Control:** *n* = 26 BMI (kg/m^2): 30 (SD 4) Body fat (%): 36.4 (SD 4.6) Age (years): 12.5 (SD 0.7) Gender: 57% male **Other relevant information:** Children with a BMI above the 95th percentile for age were eligible for inclusion.	To investigate whether a school-based fitness programme makes a difference in fitness, fatness and insulin sensitivity.	**Intervention:** Nine-month lifestyle-focused, fitness-oriented physical education classes with 14 students per class. Lifestyle activities such as walking and cycling were emphasised and competitive games de-emphasised. Emphasis was on moving rather than watching and children did not change clothes for the class. Handouts were provided on healthy eating habits. There were five classes every 2 weeks of 45 min. The typical amount of movement time in class was 42 min. **Control:** Nine-month standard physical education classes with 35 to 40 students per class. Students changed clothes for the class. There were five classes every 2 weeks of 45 min. The typical	**Loss to follow-up**: Intervention: *n* = 0 Control *n* = 3 (12%) **BMI (kg/m^2):** Mean score at follow-up Intervention: 33 (SD 10) Control: 30 (SD 5) There was no statistically significant difference between groups in change from baseline to follow-up. **Body fat (%):** (Assessed using DEXA) Mean change Intervention: –4.1% (SD 3.4) Control: –1.9% (SD 2.3) There was a statistically significant greater decrease in body fat in the intervention group compared with control (*p* = 0.04).	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up <20%. No ITT analysis. Baseline data provided only on participants who completed the study.

			amount of movement time in class was 25 min. **Delivered by:** Not stated. **Length of follow-up:** 9 months. **Other agencies involved:** Assessments were conducted at a University exercise laboratory. **Other information related to delivery:** **None.**		
Donnelly 1996 [11289] USA CBA 2–	**Setting**: Elementary schools (grades 3 to 5) from two school districts in rural Nebraska. **Intervention:** *n* = 11 BMI (kg/m^2): 20.3 (SD 4.1) Weight (kg): 91.5 (SD 23.1) % Body fat: 27.8 (SD 5.5) **Intervention school:** Ethnicity: 94.3% White Free/reduced cost lunches: 42% **Control:** *n* = 25 BMI (kg/m^2): 19.9 (SD 2.5)	**Aim**: To implement and assess the effectiveness of a nutrition and activity programme on reducing obesity and improving physical fitness in elementary school children.	**Intervention**: Multi-component programme consisting of nutrition education, modified school lunches, and increased PA. **Nutrition:** Meals were planned, with the existing kitchen staff, to reflect the ‘Lunchpower!’ programme; Lunchpower! is a reduced energy, fat and sodium lunch, developed by the National Livestock and Meat Board. Nutrition education was delivered in 18 modules, nine per year. These modules looked at basic nutrition,	**Loss to follow-up:** Intervention: *n* = unclear Control: *n* = unclear **BMI (kg/m^2):** At 2-year follow-up: Intervention: 21.6 (SD 4.5) Control: 21.3 (SD 3.4) Within-group differences were shown for both the control group and the intervention group ($p < 0.05$) from baseline to 2-year follow-up. There were no statistically significant differences between groups at either time point. **Weight (kg):** At 2-year follow-up:	Supported by the National Livestock and Meat Board, Health Management Resources, and Research Services Council.

	Weight (kg): 86.9 (SD 13.3) % Body fat: 28.8 (SD 6.6) **Control school:** Ethnicity: 93.6% White Free/reduced cost lunches: 44% **Other relevant information:** Programme was initiated across participating schools regardless of an individual's weight status. An overweight subgroup (participants with body fat ≥22%) was identified in both control and intervention schools, and the results presented related to this subgroup. Grades 3 to 5 include children aged between 8 and 11 years old.		relationship between diet and health, nutrition for healthy growth and development, healthy food choices, snack alternatives, reducing fat in the diet, and food safety. **Physical activity:** Activities were designed to promote energy expenditure and decrease time-off-task using guidelines of 'Physical Best'.* Activities were designed to use large muscle groups for 30 to 40 min, 3 days per week. Aerobic activities that could be easily incorporated into lifestyle were emphasized, such as hopping, skipping and aerobic games. *Reston (1988), American Alliance for Health, Physical Recreation and Dance. **Delivered by:** Classroom teachers, doctoral student, graduates and a registered dietitian. **Control:** Participants received usual school lunch and physical education programmes. **Length of follow-up:**	Intervention: 111.6 (SD 28.0) Control: 105.5 (SD 19.5) Within group differences were shown for both the control group and the intervention group ($p < 0.05$) from baseline to 2-year follow-up. There were no statistically significant differences between groups at either time point. **% Body fat:** At 2-year follow-up: Intervention: 25.4 (SD 8.7) Control: 26.1 (SD 7.7) There were no statistically significant within group differences from baseline to follow-up, or differences between groups.	

			2 years. **Other agencies involved:** None reported. **Other information related to delivery:** None.		
Nuutinen 1991 [11329] Finland CBA 2–	**Setting**: Group 1: Clinical setting Group 2: School healthcare setting Group 3: School-based **Intervention (Group 1):** *n* = 32 Weight (kg): 69.3 (SD 21.6) % IBW for height: 160.9 (SD 20.1) Age (years): 11.3 (SD 2.6) Gender: 23 (72%) male **Intervention (Group 2):** *n* = 16 Weight (kg): 54.3 (SD 13.5) % IBW for height: 142.1 (SD 12.8) Age (years): 11.0 (SD 2.3) Gender: 12 (75%) male **Control:** *n* = 29 Weight (kg): 39.6 (SD 14.3) % IBW for height: 100.1 (SD 7.9) Age (years): 11.4 (SD 2.9)	**Aim:** To determine the effects of dietary counselling during an intensive programme of weight control.	**Intervention (group 1):** Clinical setting. Children received BT either individually or in a group setting. These groups were combined for the analysis. **Individually treated group:** Children, accompanied by at least one parent, were seen by a physician once a month during active treatment (year 1), and twice during year 2 (observation year). Participants received five meetings with a nutritionist, each session lasting 30–60 min. Dietary counselling was based on problems identified from food records. Individual meal plans were provided (energy level between 1400 and 2200 kcal [5.86 to 9.21 MJ]). Topics discussed with parents included dietary habits within the family, purchasing of foods, and food preparation.	**Loss to follow-up:** Group 1: *n* = 4 (12.5%) Group 2: appeared to be none Group 3: *n* = 3 (9.4%) **Weight (kg):** The % IBW for height decreased by 16.2% during the treatment year in the intensive treatment group ($p < 0.001$), and at two years was 12.8% lower than baseline ($p < 0.001$). For participants in the school setting % IBW for height was 7.3% lower than baseline at 2 years (not statistically significant).	**At baseline:** The group treated in a clinical setting had proportionally more energy from protein than the normal-weight group ($p < 0.05$). Group treated in a clinical setting consumed less sucrose than either school healthcare group or the normal weight group. Group treated in a clinical setting were heavier ($p < 0.05$), had higher relative weight ($p < 0.001$), and more fat tissue ($p < 0.001$) than the school healthcare group.

	Gender: 22 (76%) male Intervention group 1 was initially divided into two groups of 16 (group 1A, individual treatment, and group 1B, behaviour modification), but subsequently aggregated. Control group comprised of normal weight children from recruited from the same school as group 2.		**Group treatment:** Children, accompanied by at least one parent, were seen by a physician once per month during year 1, and twice during year 2. Children and parents separately received seven group sessions, each lasting 1 hour. Group discussions were aimed at activating participants to make their own decisions with regard to dietary changes. Principles of the dietary counselling were similar to the individually treated group. **Delivered by:** Physician, dietitian, psychologist and psychiatrist. **Intervention (group 2):** School healthcare setting. Children visited the school nurse, without their parents, once a month during year 1, and twice in year 2. Each visit lasted 20–40 min. The nurse encouraged the participant to find their own solution to the dietary problems identified in previous discussions. Children were asked to complete a 7-day food diary before each session. The intervention was individualised according to each child’s interest in weight control.		

			Children were not persuaded to do more than they were interested in doing. **Delivered by:** School nurse. **Control**: No intervention. The control group were normal weight children from the same school. **Length of follow-up:** 2 years. **Other agencies involved:** None reported. **Other information related to delivery:** **None.**		
Home setting					
Jiang 2005 [243 update] China RCT 1–	**Setting:** Family and school setting in Beijing. **Intervention:** *n* = 36 BMI (kg/m^2): 26.6 (SD 1.7) Weight (kg): 70.1 (SD 5.7) Height (cm): 161.2 (SD 4.1 Age (years): 13.3 (SD 0.6) Gender: 61% male **Control**: *n* = 39	To evaluate the impact of a family-based behavioural treatment intervention on obese schoolchildren	**Intervention:** Two-year family-based behavioural treatment. There was individualised targeting of each child's dietary and exercise patterns based on baseline assessment. Adherence to the target behaviours was recorded by the children and monitored by the parents. PA 20–30 min per day, four days per week was advised. A detailed dietary	**Loss to follow-up**: Intervention *n* = 3 (8%) Control: *n* = 4 (10%) **Height** Mean change Intervention: +8.2 (SD 4.3) Control: +8.0 (SD 3.9) **BMI (kg/m^2):** Mean change Intervention: –2.6 (SD 1.6) Control: –0.1 (SD 1.1)	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up <20%. No ITT analysis. Baseline data provided only on participants who completed the study.

	BMI (kg/m^2): 26.1 (SD 1.5) Weight (kg): 71.2 (6.4) Height (cm): 162.7 (SD 3.4) Age (years): 13.2 (0.7) Gender: 60% male **Other relevant information:** Obese children in Grades 7–9 were eligible for inclusion. Obesity was defined as weight-for-height ≥120% of the Chinese reference.		modification plan was developed for each family. Paediatricians visited the families once per month. Daily food intake was recorded in a diary for each child. **Control:** No intervention (usual school and family life) **Delivered by:** Paediatricians. **Length of follow-up:** Two years. **Other agencies involved:** None stated. **Other information related to delivery:** There were follow-up assessments every 6 months.	**Weight (kg)** Mean change Intervention: –0.3 (SD 4.3) Control: +5.5 (SD 3.5) There was a similar increase in height in both groups. There was a statistically significant difference between groups in weight change and in BMI from baseline to follow-up at 2 years ($p < 0.001$).	
White 2004 [55] USA RCT Individual 1+	**Setting:** Geographical area is unclear. Setting was participants' homes. **Intervention (Internet-based behavioural programme):** *n* = 28 Children: BMI (kg/m^2): 35.31	To assess the process variables involved in a family-based weight loss programme presented over the Internet for African American adolescent girls.	**Intervention:** Participants were provided with a personal computer for the home and free Internet access with which to access the Health Improvements Programme for teens (HIP-Teens) intervention website. This website was only accessible to intervention participants, and the readability of its content was set at 6th grade reading level. They	**Loss to follow-up**: Intervention: *n* = 5 (18%) Comparison: *n* = 2 (7%) **BMI (kg/m^2):** Children: There was a significant difference ($p < 0.01$) between the change in the intervention group (–0.24 [SD 1.38]) and the comparison group (+0.71 [SD 1.19].	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up <20%. Missing data were imputed using mean of other participants in each group.

	(SD 7.60) % Body fat (DEXA): 45.46 (SD 8.34) Age (years): 13.14 (SD 1.59) Gender: 0% male Parents: BMI (kg/m^2): 37.90 (SD 7.62) % Body fat (DEXA): 47.68 (SD 7.07) Age (years): 43.53 (SD 6.24) **Comparison (Internet-based educational programme):** *n* = 29 Children: BMI (kg/m^2): 37.34 (SD 8.16) % Fat (DEXA): 46.22 (SD 6.45) Age (years): 13.23 (SD 1.16) Gender: 0% male Parents: BMI (kg/m^2): 39.03 (SD 6.81) % Body fat (DEXA): 48.99 (SD 5.24) Age (years): 42.87 (SD 6.18)		accessed new behavioural modification material on a weekly basis and communicated with a case manager via email, on topics including self-monitoring, goal setting, problem solving, contracting and relapse prevention. The website also featured links to recipes hobbies and activities, and chat rooms for study participants. Participants were required to submit daily food records and received automated feedback. **Delivered by:** Case manager had at least graduate-level clinical psychology training specialising in weight management. **Comparison:** Participants also received a computer and free Internet access. They accessed a control version of the HIP-Teens website and their programme was primarily educational involving basic information about nutrition and PA. **Delivered by:** Case manager was a registered dietitian.	Parents: There was a significant difference (*p* = 0.03) between the change in the intervention group (–0.90 [SD 2.01]) and the comparison group (–0.12 [SD 0.83]). **Weight (kg):** Children: There was a significant difference (*p* = 0.03) between the change in the intervention group (+0.55 [SD 3.26]) and the comparison group (+2.40 [SD 2.86]). Parents: Changes in the intervention group (–2.16 [SD 4.95]) and the comparison group (–0.52 [SD 2.55]) were not significantly different. **% Body fat (DEXA):** Children: There was a significant difference (*p* = 0.02) between the change in the intervention group (–1.04 [SD 2.00]) and the comparison group (+0.38 [SD 2.95]). This effect remained significant when a regression analysis was conducted taking into consideration baseline adiposity. Parents: Changes in the intervention group (–0.51 [SD 2.02]) and the comparison group (+0.13 [SD 1.59]) were not significantly different.	

	Other relevant information: Sixty-one participants were randomised but only 57 completed baseline assessment. Participants were required to have at least one obese parent.		**Length of follow-up:** 6 months. **Other agencies involved:** None reported. **Other information related to delivery:** The length of both programmes appeared to be 6 months.	**Website visits:** Both children and parents in the intervention group visited the website significantly more times over the 6 months than those in the control group.	
Williamson 2005 [2005 update] USA RCT 1+	**Setting:** Home-based using Internet **Intervention:** Adolescents (*n* = 28): BMI (kg/m^2): 35.3 (SD 7.6) Body fat (%): 45.5 (SD 8.3) Age (years): 13.1 (SD 1.6) Gender: 100% female Parents (*n* = 28): BMI (kg/m^2): 37.9 (SD 7.6) Body fat (%): 47.7 (SD 7.1) Age (years) 43.5 (SD 6.2) **Control:** Adolescents (*n* = 29) BMI (kg/m^2): 37.3 (SD 8.2) Body fat (%): 46.2 (SD 6.5) Age (years) 13.3 (SD 1.2) Gender: 100% female Parents (*n* = 29) BMI (kg/m^2): 39 (SD 6.8) Body fat (%): 49.0 (SD 5.2)	To assess the efficacy of an Internet-based lifestyle behaviour modification programme for weight management in African American girls.	**Intervention:** Six months of interactive BT plus nutrition education via the Internet. Lifestyle nutrition and PA habits were targeted. **Control:** Six months of passive education on nutrition and exercise delivered via the Internet. **Delivered by:** Not stated. **Length of follow-up:** Six months. **Other agencies involved:** None stated. **Other information related to delivery:** Both groups received four face-to-face therapy sessions over a	**Loss to follow-up**: Intervention: *n* = 5 (18%) Control: *n* = 2 (7%) **BMI (mean change) (kg/m^2):** Adolescents: Intervention: –0.19 (SE 0.24) Control: +0.65 (SE 0.23) There was a statistically significant difference between groups in the change from baseline to follow-up ($p < 0.05$). **BMI (mean change) (kg/m^2):** Parents: Intervention: –1.03 (SE 0.28) Control: –0.06 (SE 0.77) There was a statistically significant difference between groups in the change from baseline to follow-up ($p < 0.05$)	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up <20%. ITT analysis using baseline value carried forward. Baseline data were not reported for dietary intake. However, baseline scores were treated as covariates in the statistical analyses.

	Age (years): 42.9 (SD 6.2) **Other relevant information:** African American girls aged 11 to 15 years with a BMI >85th percentile with at least one biological parent with a BMI >30 kg/m^2 were eligible. Participants with significant co-morbidities such as diabetes were excluded. Only one overweight parent could participate. Participants had to be willing to pay US$300 towards the cost of a computer with US$700 provided by the researchers. Sixty-one participants were randomised but baseline assessments were not completed by four individuals.		12-week period. The websites for both groups were designed to be culturally specific. Parents received US$30 for completing the 6-month follow-up assessments and the adolescents received a gift worth US$10.	**% Body fat (DEXA):** Adolescents: Intervention: –1.12 (SE 0.47) Control: 0.43 (SE 0.47) There was a statistically significant difference between groups in the change from baseline to follow-up ($p < 0.05$). Parents: Intervention: 0.58 (SE 0.34) Control: +0.18 (SE 0.34) No statistically significant difference.	

EVIDENCE TABLE 2a: EVIDENCE OF EFFICACY (INTERNAL VALIDITY) FOR IMPROVED BEHAVIOURS (DIET AND ACTIVITY) IN ADULTS

All summary data are mean values unless otherwise stated.
Studies are grouped by intervention.
Within each intervention category, studies are listed by study type in the following order: systematic review; randomised trial (RCT); controlled non randomised trial (CCT), controlled before and after study (CBA), interrupted time series (ITS); other study type.
Within each study type, studies are listed in alphabetical order.

First author, country, study design, research type, quality	**Study population**	**Research aim/question**	**Intervention details/length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for improved behaviours (diet and activity) in adults					
Commercial weight loss programmes					
Rippe 1998 [12522] USA RCT Individual 1–	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet (energy intake per day):** Intervention: 1723 (SD 448) kcal (7.21 [SD 1.88] MJ) at baseline. Control: 1905 (SD 436) kcal (7.97 [SD 1.83] MJ) at baseline. The intervention group showed the greatest reduction in their daily energy intake compared with the controls (482 [SD 536] and 164 [SD 353] kcal [2.02 {SD 2.24} and 0.69 {SD 1.48} MJ]) respectively; *p* = 0.03, which did not reach prespecified significance level of *p* < 0.01). **Activity:** Activity level (using the Physical Activity Scale of Ross and Jackson, a seven-point scale where 0 represents minimal	As above in Table 1a.

				daily activity and 7 represents the equivalent of running more than 10 miles/week): Intervention: 0.8 (SD 0.5) at baseline. Control: 1.1 (SD 0.6) at baseline. The intervention group significantly increased their activity compared with controls (+4.4 [SD 2.3] and +0.7 [SD 0.3] respectively; *p* ≤ 0.0001). VO_{2max} (ml/kg per min): Intervention: 28.9 (SD 4.1) at baseline. Control: 32.2 (SD 3.3) at baseline. The intervention group significantly increased their VO_{2max} compared with the controls (+3.8 [SD 3.3] and –2.7 (SD 3.5) respectively; *p* ≤ 0.001).	
Interventions using computers					
Tate 2003 [11287] USA RCT Individual 1+	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet:** (Assessed using Block FFQ) Both groups showed significant reductions (*p* < 0.001) in energy intake at 12 months. The energy consumed from fat decreased by 1% in the Internet-only group and 4% in the behavioural e-counselling group, but there was not a statistically significant difference between the groups. **Activity:** (Assessed using Paffenbarger Activity Questionnaire) There was no significant change in	As above in Table 1a.

				exercise energy expenditure at 12 months in either group.	
Tate 2001 [3942] USA RCT Individual 1+	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet (energy intake per day):** (Assessed using Block FFQ; included only participants who completed all three assessments, *n* = 62.) There was a significant reduction in daily energy intake in both groups over time (*p* = 0.004), but no significant differences between the groups. The change in the BT group was from 1558 (SD 654) kcal (6.52 [SD 2.74] MJ) at baseline to 1062 (SD 395) (4.44 [SD 1.65] MJ) at 3 months and 1146 (SD 450) kcal (4.80 [SD 1.88] MJ) at 6 months. In the education group the change was from 1757 (SD 857) kcal (7.35 [SD 3.59] MJ) at baseline to 1256 (SD 696) kcal (5.28 [SD 2.91] MJ) at 3 months and 1286 (SD 564) kcal (5.38 [SD 2.36] MJ) at 6 months. **Activity (energy expenditure per week):** (Assessed using Paffenbarger Activity Questionnaire; included only participants who completed all three assessments, *n* = 60) There was a significant increase in PA in both groups over time (*p* = 0.03) but no significant differences between the groups.	As above in Table 1a.

				The change in the intervention group was from 1360 (SD 1415) kcal (5.69 [SD 5.92] MJ) at baseline to 1903 (SD 1757) kcal (7.97 [7.35] MJ) at 3 months and 1289 (SD 919) kcal (5.40 [3.85] MJ] at 6 months. In the control group the change was from 1031 (SD 981) kcal (4.32 [4.11] MJ) at baseline to 1500 (SD 1513) kcal (6.28 [6.33] MJ) at 3 months and 1125 (SD 1320) kcal (4.71 [5.53] MJ) at 6 months.	
Taylor 1991 [11346] USA RCT Individual 1–	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Activity (weekly min of exercise):** At 38 weeks, exercise (reported over the phone) was significantly greater in the FFF + CAT group (154 min) than the CAT group (37 min).	As above in Table 1a.
Womble 2004 [57] USA RCT Individual 1+	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Eating-related behaviour:** (Assessed by Eating Inventory; included treatment completers only) There were no statistically significant differences between the groups in self-reported eating restraint, disinhibition and hunger.	As above in Table 1a.
Dennison 1996 [11287] USA	As above in Table 1.	As above in Table 1.	As above in Table 1.	**Diet:** (Assessed using Nutrition Coordinating Centre's Nutrition Data System software package)	As above in Table 1.

CBA 2–				There was a significant ($p = 0.004$) reduction in total daily energy intake in the intervention groups combined, from 2180 kcal (9.13 MJ) at baseline to 1822 kcal (7.63 MJ) at 1 year. There was no significant change in the control group, which was 2217 kcal (9.28 MJ) at baseline and 2263 kcal (9.47 MJ) at 1 year (further details on diet outcomes are available in the paper).	
Work-based setting					
Pritchard 1997 [3959] Pritchard 2002 [3958] Australia RCT Individual 1+ Note: both papers report randomised data on the same participants. All the extracted data was taken from Pritchard 1997, and some additional information was	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet:** (Assessed from analysis of monthly 24-hour food recalls and 3-day food diaries) **Energy intake per day:** Percentage change from baseline was significantly different ($p < 0.05$) in the diet group (–30.4 [SD 3.8]% from 2594 [SD 577] kcal [10.86 {SD 2.42} MJ/]) compared with both exercise (+3.1 [SD 2.7]% from 2486 [SD 379] kcal [10.41 {SD 1.59} MJ) and control (+5.5 [SD 4.7]% from 2225 [SD 444] kcal [9.31 {SD 1.86} MJ]). **% Energy intake as fat:** Percentage change from baseline was significantly different ($p < 0.05$) in the diet group (–32.0 [SD 4.8] from 38.2 [SD 5.8]) compared with both exercise (+1.0 [SD 3.8] from 38.9 [SD 6.8]) and control (+0.4 [SD 1.0] from 38.5 [SD 6.0]).	As above in Table 1a.

from Pritchard 2002.				**Activity:** (Assessed from 24-hour activity logs and 3-day activity diaries) **Energy expenditure per day:** Percentage change from baseline was significantly greater ($p < 0.05$) in the exercise group (+14.6 [SD 2.0]% from 2570 [SD 312] kcal [10.76 {SD 1.31}] MJ]) compared with both diet (+5.9 [SD 1.9]% from 2407 [SD 161] kcal [10.08 {SD 0.67}] MJ) and control (+6.5 [SD 1.5]% from 2508 [SD 294] kcal [10.50 {SD 1.23} MJ]). **Index of activity:** Percentage change from baseline was significantly greater ($p < 0.05$) in the exercise group (+15.6 [SD 10.1]% from 1.35 [SD 0.10]) compared with both diet (+3.4 [SD 1.2]% from 1.30 [SD 0.17]) and control (+6.4 [SD 1.7]% from 1.34 [SD 0.11]).	
Furuki 1999 [8838] Japan CBA 2–	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet and activity:** Outcome data for diet and activity were reported for men in the intervention group only. No data were reported for the control group.	As above in Table 1a.
Other non-clinical settings					
Jason 1991 [11310]	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet:** (Baseline based on 3-day diaries 1–4	As above in Table 1a.

USA RCT Individual 1–				weeks before intervention.) **Mean total energy:** Support group Baseline: 1838 (SD 642) kcal (7.69 [SD 2.69] MJ) Follow-up: 1204 (SD 651) kcal (5.04 [SD 2.73] MJ) Non-support group Baseline: 1843 (SD 615) (7.71 [SD 2.57] MJ) Follow-up: 1320 (SD 544) (5.53 [SD 2.28] MJ) **Mean % energy from protein in diet:** Support group Baseline: 15.86 kcal (SD 3.03) Follow-up: 20.93 kcal (SD 6.23) Non-support group Baseline: 18.37 kcal (SD 4.71) Follow-up: 22.24 kcal (SD 7.88). **Mean % energy from carbohydrate in diet:** Support group Baseline: 47.39 kcal (SD 8.76) Follow-up: 47.72 kcal (SD 11.69) Non-support group Baseline: 45.03 (SD 9.14) Follow-up: 43.10 (SD 10.15) **Mean % energy from fat in diet:** Support group	

				Baseline: 35.25 (SD 7.22) Follow-up: 31.17 (SD 10.87) No-support group Baseline: 35.66 (SD 8.00) Follow-up: 32.38 (SD 7.05) Both support group and non-support group reduced their overall energy intake ($p < 0.05$ and $p < 0.05$), as well as increasing their % of energy as protein ($p < 0.05$ and $p < 0.05$) at follow-up. The support group were also shown to have significantly reduced the % of energy from fat ($p < 0.05$) at follow-up. **Activity:** (Baseline based on 3-day diaries 1–4 weeks prior to intervention) Aerobic exercise (mean number of min over a 3-day period) Support group Baseline: 13.63 (SD 27.93) Follow-up: 32.18 (SD 47.26) Non-support group Baseline: 15.39 (SD 29.18) Follow-up: 34.59 (SD 56.19). Non-aerobic exercise (mean number of min over a 3-day period): Support group Baseline: 55.97 (SD 58.23) Follow-up: 82.07 (SD 80.39)	

				Non-support group Baseline: 47.12 (SD 63.78) Follow-up: 48.79 (SD 74.80). Both the support group (*p* < 0.05) and the non-support group (*p* < 0.05) significantly increased their aerobic exercise from pre-testing to follow-up.	
McNabb 1997 [3972] USA RCT Individual 1+	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet:** (Assessed using Food Behaviour Checklist) The amount of high-fat foods eaten decreased significantly (*p* < 0.05) in intervention compared with control, but change in consumption of high-fibre foods was not significantly different between the two groups. **Activity (min of exercise per week):** Intervention baseline: 5.0 (SD 17.3) Control baseline: 23.8 (SD 36.7) Changes in levels of exercise were not significantly different between intervention (+36.7 [SD 42.5]) and control (+21.3 [SD 22.5]).	As above in Table 1a.
Perri 1997 [3961] USA RCT Individual 1+	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet:** (Assessed using Eating Pattern Assessment Tool (EPAT) Questionnaire; analysis was of completers only) The consumption of high-fat foods decreased significantly (*p* < 0.0001) in both groups over time, with no between group differences. With group-based	As above in Table 1a.

				exercise the change in EPAT score was from 25.94 (SD 5.32) at baseline to 17.67 (SD 3.94) at 6 months and 20.72 (SD 5.56) at 12 months. With home-based exercise the change in EPAT score was from 26.05 (SD 6.36) at baseline to 18.27 (SD 3.59) at 6 months and 20.95 (SD 5.42) at 12 months. The consumption of low-fat foods did not change significantly in either group over the 12 months. **Activity (min of exercise per week):** Activity during months 0–6 was similar in both groups: 104.4 (SD 39.5) for group-based exercise and 104.0 (SD 25.5) for home-based exercise. There were significant decreases in activity in both groups for months 7–12, but activity with home-based exercise (66.2 [SD 21.6]) was significantly higher than with group-based exercise (45.4 [SD 30.5]).	
Harvey-Berino 1998 [3998] USA CBA 2–	As above in Table 1a.	As above in Table 1a.	As above in Table 1a.	**Diet:** (Assessed from 3-day food diaries) There were significant decreases (*p* values not reported) in energy intake and fat intake (% of energy) with both IT and ST. There were no between group differences for either measure. The change in energy intake was –607 (SD 632) kcal (–2.54 [SD 2.65] MJ) from 1959 (SD 692) kcal (8.20 [SD 2.90] MJ) at baseline for IT, and –638 (SD 521) kcal (–2.67 [SD 2.18] MJ)	As above in Table 1a.

				from 2176 (SD 794) kcal (9.11 [SD 3.32] MJ) at baseline for ST. The change in fat intake (% of energy) was –3.4 (SD 7.9)% from 32.2 (SD 6.3)% at baseline for IT, and –2.1 (SD 6.6)% from 32.3 (SD 6.8)% at baseline for ST. **Activity (energy expended):** (Assessed using Paffenbarger Physical Activity Questionnaire) There were significant increases (*p* values not reported) with both IT and ST, but no between group differences. The change was +664 (SD 1346) kcal (+2.28 [SD 5.63] MJ) from 857 (SD 1174) kcal (3.59 [SD 4.91] MJ) at baseline with IT and +245 (SD 943) kcal (+1.02 [SD 3.95 MJ] from 1083 (SD 1202) kcal (4.53 [SD 5.03] MJ) at baseline with ST.	

EVIDENCE TABLE 2b: EVIDENCE OF EFFICACY (INTERNAL VALIDITY) FOR IMPROVED BEHAVIOURS (DIET AND ACTIVITY) IN CHILDREN

All summary data are mean values unless otherwise stated.
Studies are listed by study type in the following order: systematic review; randomised trial (RCT); controlled non randomised trial (CCT), controlled before and after study (CBA), interrupted time series (ITS); other study type.
Within each study type, studies are listed in alphabetical order.

First author, country, study design, research type, quality	**Study population**	**Research aim/question**	**Intervention details/length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/ Comments**
Evidence of efficacy (internal validity) for improved behaviours (diet and activity) in children					
Grey 2004 [3054] USA RCT School 1+	As above in Table 1b.	As above in Table 1b.	As above in Table 1b.	**Diet:** No statistically significant difference in terms of usual food choices, dietary knowledge, dietary self-efficacy, or intake of energy, carbohydrate and saturated fat was shown between groups at follow-up. **Physical activity:** There was no statistically significant difference between groups in change from baseline to 12-month follow-up for PA levels or activity self-efficacy.	As above in Table 1b.
Nuutinen 1991 [11329] Finland CBA 2–	As above in Table 1b.	As above in Table 1b.	As above in Table 1b.	**Food consumption:** In group 1 the consumption of edible fats ($p < 0.001$) and milk products ($p < 0.05$) was reduced after 1 year, and maintained until the end of the observation period ($p < 0.01$ and $p < 0.05$, respectively):	As above in Table 1b.

				Edible fats (butter, margarine, oil): Baseline: 43 (SD 22) g Mean change from baseline: Year 1: –10 (SD 12) g Year 2: –1 (SD 17) g **Milk and milk products:** Baseline: 818 (SD 293) g Mean change from baseline: Year 1: –192 (SD 307) g Year 2: –17 (SD 254) g **Daily nutrient intake** (using four day food record): Children in group 1 decreased their mean daily fat intake at year 1 ($p < 0.001$), and maintained this to the end of the observation period ($p < 0.001$): **Fat:** Baseline: 86 (SD 29) g Mean change from baseline: Year 1: –19 (SD 21) g Year 2: –22 (SD 28) g There was no significant change in school group. Group 1 had a lower level of sucrose consumption than group 2 at year 1 ($p < 0.05$) and at year 2 ($p < 0.001$), but there was no significant change in the	

				school group. No statistically significant changes across the study in nutrient intake were shown in the conventionally treated group.	

EVIDENCE TABLE 3: EVIDENCE OF EFFICACY (INTERNAL VALIDITY) FOR MAINTENANCE OF WEIGHT LOSS AND CONTINUATION OF IMPROVED BEHAVIOURS (DIET AND ACTIVITY)

All summary data are mean values unless otherwise stated.
Studies are listed by study type in the following order: systematic review; randomised trial (RCT); controlled non randomised trial (CCT), controlled before and after study (CBA), interrupted time series (ITS); other study type.
Within each study type, studies are listed in alphabetical order.

First author, country, study design, research type, quality	**Study population**	**Research aim/question**	**Intervention details/length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)**/comments**
Evidence of efficacy (internal validity) for maintenance of weight loss and continuation of improved behaviours (diet and activity)					
Harvey-Berino 2004 [34] USA RCT Individual 1+	**Setting:** Internet-based intervention was wherever participants had Internet access. In person support was set in several television studios in Vermont. **Internet support:** *n* = 77 BMI (kg/m^2): 29.3 (SD 5.2) Weight (kg): 82.7 (SD 16.3) Age (years): 46.5 (SD 9.8) Gender: 19% male Education: 64% college degree or higher **Frequent in person support:** *n* = 77 BMI (kg/m^2): 28.9 (SD 3.8)	To compare the efficacy of an Internet-based weight maintenance programme with frequent and minimal in-person support programmes.	**Intervention:** 12-month weight loss maintenance programme. During this maintenance phase all participants were told to continue with the dietary and exercise prescriptions provided in the treatment phase: to reduce energy intake to 4186–10,465 kJ/d, depending on baseline weight, and to expend at least 1000 kJ/week. **Internet support:** An initial technical orientation session was provided. Participants attended pre-arranged bi-weekly maintenance meetings, held in the form of an Internet chat	**Loss to follow-up:** Internet support: *n* = 25 (32.5%) Frequent in person support: *n* = 16 (20.8%) Minimal in person support: *n* = 15 (19.2%) **Weight (kg):** There was no significant difference in weight change, relative to pre-treatment weight, between the groups: Internet support: -4.7 (SD 6.9) Frequent in-person support: -3.9 (SD 5.9) Minimal in-person support: -4.2 (SD 7.9) There was no significant difference between groups in the number of participants who were able to sustain at least a 5% weight loss (completers only):	No description of randomisation method. No mention of allocation concealment. Blinding poorly addressed. Loss to follow-up >20% in two arms. ITT was used for absolute weight change; analysis of completers only gave the same overall finding, though the actual weight loss was greater when completers only were included in the analysis.

	Weight (kg): 81.2 (SD 14.2) Age (years): 45.2 (SD 8.9) Gender: 16% male Education: 63% college degree or higher **Minimal in person support:** *n* = 78 BMI (kg/m^2): 29.0 (SD 4.3) Weight (kg): 80.5 (SD 14.4) Age (years): 46.5 (SD 7.7) Gender: 14% male Education: 65% college degree or higher **Other relevant information:** All participants received an identical 6-month behavioural weight loss programme conducted over interactive television (ITV). Only those completing the weight loss programme were randomised to a maintenance condition. There was no significant difference among the groups in the amount of weight lost during the initial treatment programme (7.8 kg [SD 5.3] kg) for all groups combined). Participants were required		session, facilitated by a therapist. Lesson topics were introduced at the start of each session by the therapist. Participants also received bi-weekly email contact with the therapist. Participants self-reported weight, dietary intake, and exercise data, on a weekly basis. Group members could contact each other by email, posting questions to the web bulletin board, or by making appointments to chat in the chat room. **Delivered by:** Researchers and therapist (dietitian). **Frequent in person support:** Participants met bi-weekly at their local ITV for 52 weeks. At each session individuals handed in their self-monitoring diaries, were weighed, and participated in group discussions facilitated by a group therapist. Topics focussed on problem solving difficult eating and exercise situations. Participants received a telephone call from the therapist on the weeks that no	Internet support: 62% Frequent in person support: 46% Minimal in person support: 49% **Programme adherence:** Subjects in the frequent in person support group attended significantly more maintenance group meetings than the Internet support group ($p = 0.02$). Subjects in the Internet support condition submitted self-monitoring diaries more frequently ($p < 0.01$), and reported more peer support contacts ($p < 0.01$) than the frequent in person group. Attendance at treatment meetings and chat sessions ($p < 0.01$), and frequency of self-monitoring ($p < 0.01$) significantly correlated with weight loss from baseline to end of maintenance phase. The minimal in person support group was not included in this analysis. **Other outcomes:** The authors report that there were no between group differences in perceived social support and working alliance. Data were not reported.	Supported by the National Institutes of Health.

	to have a computer with Internet access, and have no history of major medical problems. The majority of participants were comfortable with basic computer applications and enjoyed using computers.		meetings were held. During these weeks self-monitoring data was posted to the therapist. Subjects also participated in a social-influence peer-support programme. Each week participants could win adherence points, which were converted into lottery tickets. **Delivered by:** Therapist (dietitian) **Minimal in person support:** Participants met monthly in person at independent television studios for sessions delivered over ITV for the first 6 months. Each group support session lasted 1 hour. Participants were encouraged to continue to self-monitor, although diaries were not monitored by the therapist. Weight measurements were taken at this meeting. There was no group contact between monthly meeting or from months 7–12. **Delivered by:** Therapist (dietitian) **Length of follow-up:** 12 months		

			Other agencies involved: None reported. **Other information related to delivery:** The Internet support condition and the frequent in person support condition were based on the multi-component weight maintenance programmes developed by Perri et al. (1988).		
Harvey-Berino 2002 [3997] USA RCT Individual 1+	**Setting:** Treatment intervention and in-person support were in a clinical setting. Internet maintenance took place wherever participants had Internet access. **Internet support:** *n* = 40 BMI (kg/m^2): 32.2 (SD 4.0) Weight (kg): 89.3 (SD 15.3) Age (years): 46.3 (SD 11.1) Gender: 10% male Ethnicity: 96.9% White Education: 65.0% college degree or higher **Frequent in-person support:** *n* = 41 BMI (kg/m^2): 31.5 (SD 4.8) Weight (kg): 86.5 (SD 10.1)	To investigate the effectiveness of a weight maintenance programme conducted over the Internet.	**Internet support:** Participants attended a 24-week behavioural weight control programme. They then received a technical orientation session teaching them how to access and use the secure study website. For the next 52 weeks, participants were required to enter self-monitoring data, and bi-weekly group maintenance sessions were held online by a therapist in the study chat room. On weeks when there was no meeting, the therapist emailed the participants. Group members could contact one another using email, bulletin board or chat room. By adhering to programme goals participants earned points, which were converted into tickets for a	**Loss to follow-up:** Internet support: *n* = 10 (25%) Frequent in-person support: *n* = 9 (22%) Minimal in-person support: *n* = 13 (32%) **Weight (kg):** Over the 24-week treatment period there was no significant difference in the weight lost by the three groups: Internet support (–8.0 [SD 5]), frequent in-person support (–9.8 [SD 5.9]) and minimal in-person support (–11 [SD 6.5]). During the first 6 months of weight maintenance, weight gain was significantly greater ($p = 0.05$) in the Internet support group (+2.2 [SD 3.8]) than the frequent in-person support group (0 [SD 4]). Weight loss at 18 months from baseline was significantly smaller ($p < 0.05$) with	No description of randomisation method. No mention of allocation concealment or blinding. Loss to follow-up >20%. ITT analysis data not reported although authors state that effects with ITT analysis were the same as for completers only. Diet and activity outcomes were self-reported.

	Age (years): 49.8 (SD 8.4) Gender: 14.3% male Ethnicity: 100% White Education: 68.3% college degree or higher **Minimal in-person support:** *n* = 41 BMI (kg/m^2): 32.8 (SD 4.6) Weight (kg): 90.2 (SD 13.9) Age (years): 49.1 (SD 9.1) Gender: 19.5% male Ethnicity: 97.4% White Education: 56.1% college degree or higher **Other relevant information:** Participants were required to have a computer with Internet access, and have no history of major medical problems. The majority of participants were comfortable with basic computer applications and enjoyed using computers.		weekly lottery to win £25. **Delivered by:** Two of the researchers gave the orientation session. A therapist facilitated online meetings and email contact. **Frequent in-person support:** Participants attended the 24-week weight control programme as above. They then attended bi-weekly group maintenance sessions with a therapist for 52 weeks for review of self-monitoring diaries and group discussion. On weeks when there was no meeting, the therapist telephoned each participant. By adhering to programme goals participants earned points, which were converted into tickets for a weekly lottery to win £25. **Delivered by:** Therapist. **Minimal in-person support:** Participants attended the 24-week weight control programme as above. Then for the next 6 months participants attended a 1-hour meeting each month for weight measurement and encouragement although their	Internet support (–5.7 [SD 5.9]) than both frequent in-person support (–10.4 [SD 6.3]) and minimal in-person support (–10.4 [SD 9.3]). The percentage of participants maintaining a weight loss of 5% or more at 18 months was significantly greater ($p = 0.02$) with minimal in-person support (81.3%) or frequent in-person support (81%) than Internet support (44.4%). **Diet:** (Assessed using the Block FFQ) All groups significantly ($p < 0.001$) decreased energy intake from baseline to 6-month assessment, with no between group differences. Only the frequent in-person support group maintained a significant difference from baseline at 18 months. **Activity:** (Assessed using the Paffenbarger Physical Activity Questionnaire) All groups significantly ($p < 0.01$) increased physical activity from baseline to 6-month assessment with no between group differences. Only the frequent in-person support group maintained a significant difference from baseline at 18 months. **Attendance:** Attendance over the 1-year	

			self-monitoring diaries were not reviewed by a therapist. For the following 6 months they were not contacted. **Delivered by:** Unclear. **Length of follow-up:** 18 months (from initial treatment) **Other agencies involved:** None reported. **Other information related to delivery:** All subjects were seen for assessment measures at baseline and at 6, 12 and 18 months; attendees entered a lottery to win US$50. The frequent in person support and Internet support programmes were based on multi-component weight maintenance programmes (Perri et al. 1998).	maintenance programme was significantly ($p = 0.04$) greater in the frequent in-person support group (54%) than the Internet support group (39%). There was no difference in the submission of self-monitoring data. **Other outcomes:** At baseline acceptability of group assignment was similar in both groups. The percentage of Internet support participants who would prefer to be in the other group had increased at 6 months (from 35% to 70%). There was no change in this measure in Frequent in-person support participants at 6 months.	

Evidence of corroboration (external validity)								
No additional controlled studies conducted in a UK setting met the inclusion criteria.								
Evidence of salience – Is it appropriate for the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Evidence for implementation – Will it work in the UK?								
First author	**Study design**	**Research type**	**Research quality**	**Study Population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**
Evidence of cost-effectiveness								
First author	**Study design**	**Research type**	**Research quality**	**Study Population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**

SEARCH STRATEGIES

1. exp obesity/
2. Weight Gain/
3. Weight Loss/
4. obes$.ti,ab.
5. (weight gain or weight loss).ti,ab.
6. (overweight or over weight or overeat$ or over eat$).ti,ab.
7. weight change$.ti,ab.
8. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab.
9. body mass.ti,ab.
10. or/1-9
11. ((slim or slims or slimm$) adj3 (program$ or facilit$ or centre$ or center$ or organi?ation$ or association$ or product$ or aid or aids or regime$ or scheme$ or group or groups or class$ or strateg$ or club$)).ti,ab.
12. ((dieting or diet or weight loss or weight manag$ or weight reduc$ or weight control$ or weight maint$) adj3 (program$ or facilit$ or centre$ or center$ or organi?ation$ or regime$ or scheme$ or class$ or strateg$ or club$)).ti,ab.
13. (weightwatcher$ or weight watcher$).ti,ab.
14. ((slim or slims or slimm$ or dieting or diet or weight loss or weight manag$ or weight reduc$ or weight control$ or weight maint$) adj3 (internet or web or online or computer$ or correspond$ or mail or email or postal)).ti,ab.
15. internet/
16. electronic mail/
17. correspondence/
18. meal replace$.ti,ab.
19. food provision.ti,ab.
20. ((fat or diet$ or weight$) adj3 (camp or camps or camping)).ti,ab.
21. camping/
22. ((exercis$ or fitness or fit or activit$ or sport$ or leisure) adj3 (program$ or facilit$ or centre$ or center$ or organi?ation$ or regime$ or scheme$ or class$ or strateg$ or club$ or service$)).ti,ab.
23. ((jog$ or swim$ or walk$ or aerobics or danc$ or gym) adj3 (program$ or facilit$ or centre$ or center$ or organi?ation$ or regime$ or scheme$ or class$ or strateg$ or club$ or service$)).ti,ab.
24. ((exercis$ or fitness or fit or activit$ or sport$ or leisure) adj3 (referral$ or prescrip$ or prescrib$)).ti,ab.
25. ((jog$ or swim$ or walk$ or aerobics or danc$ or gym) adj3 (referral$ or prescrip$ or prescrib$)).ti,ab.
26. (selfhelp or self help or self cure$).ti,ab.
27. self help groups/
28. ((lay or communit$ or agenc$) adj3 support).ti,ab.
29. ((neighbo?rhood$ or peer$ or lay or communit$) adj3 (group or groups or network$ or program$ or scheme$)).ti,ab.
30. ((parent or parents or guardian$ or friend$ or wife$ or wives or husband$ or spouse$ or partner or partners or family or families or peer$ or carer$) adj3 (involv$ or encourag$ or support$ or help$ or aid$ or manag$ or treat$ or interven$)).ti,ab.
31. ((communit$ or home or neighbo?rhood$) adj3 (treat$ or interven$ or manag$)).ti,ab.
32. ((communit$ or home or local or family or families or neighbo?rhood$) adj3 (program$ or activit$ or facilit$ or club$ or centre$ or center$ or organi?ation$ or group or groups or scheme$ or class$ or strateg$ or regime$ or service$)).ti,ab.
33. ((work$ or job$ or office$ or employ$) adj3 (program$ or activit$ or facilit$ or club$ or centre$ or center$ or organi?ation$ or group or groups or scheme$ or class$ or strateg$ or regime$ or service$)).ti,ab.
34. ((work$ or job$ or office$ or employ$) adj3 (interven$ or treat$ or manag$)).ti,ab.
35. ((school$ or afterschool$ or preschool$ or college$ or nurser$ or universit$) adj3 (program$ or activit$ or facilit$ or club$ or centre$ or center$ or organi?ation$ or group or groups or scheme$ or class$ or strateg$ or regime$ or service$)).ti,ab.

36. ((school$ or afterschool$ or preschool$ or college$ or nurser$ or universit$) adj3 (interven$ or treat$ or manag$)).ti,ab.
37. ((media or television$ or radio$ or newspaper$ or press or magazine$ or tv$) adj3 campaign$).ti,ab.
38. ((government$ or public or local$ or national$ or international$ or communit$) adj3 campaign$).ti,ab.
39. (canteen$ or refector$ or cafeteria$).ti,ab.
40. (church$ or pub or pubs or hairdresser$).ti,ab.
41. or/11-40
42. 10 and 41
43. animal/
44. human/
45. 43 not (43 and 44)
46. 42 not 45
47. limit 46 to yr=1990-2005

Data sources

The following information sources were searched to June 2005:

Cochrane Database of Systematic Reviews (Cochrane Library 2005, issue 2) (www.thecochranelibrary.com)
Database of Abstracts of Reviews of Effects (http://www.york.ac.uk/inst/crd/crddatabases.htm)
HTA Database (http://www.york.ac.uk/inst/crd/crddatabases.htm)
What Works in Public Health: evidence from systematic reviews relevant to implementing the 'wider public health' agenda (forthcoming online database) Centre for Reviews and Dissemination 2005.
HDA Evidence Base Briefing Documents (http://www.hda-online.org.uk/evidence/)
National Research Register (2005, issue 2) (http://www.update-software.com/National/)
Health Evidence Bulletins Wales (http://hebw.cf.ac.uk/index.html)
National Guideline Clearinghouse (http://www.guideline.gov/)
NHS Health Technology Assessment Programme (http://www.ncchta.org/
National Institute for Health and Clinical Excellence (http://www.nice.org.uk/)
Clinical Evidence (http://www.clinicalevidence.com/ceweb/conditions/index.jsp)
Scottish Intercollegiate Guidelines Network (http://www.sign.ac.uk/index.html)
Turning Research into Practice Database (Trip) (http://www.tripdatabase.com/)
MEDLINE (1966-2005 July week 1) (OVID)
MEDLINE In-Process & Other Non-Indexed Citations (July 14, 2005) (OVID)
CINAHL (1982–2005 July week 2) (OVID)
Embase (1980-2005 week 28) (OVID)
AMED Alternative and Complementary Medicine (1985-2005 July) (OVID)
Psycinfo (1872-2005/07 week 1) (SilverPlatter)
ASSIA (1987 – current) (CSA Illumina)
Sociological Abstracts (1963 – current) (CSA Illumina)
ERIC (Educational Resources Information Center) (1966-current) (CSA Illumina)
Social Science Citations Index (1981-2005 July 16th) (ISI Web of Knowledge)
Biosis Previews (1969-2005 Jul w3) (Dialog)
CAB Abstracts (1972-2005/Jun) (Dialog)
Food Science & Technology Abstracts (1969-2005/Jul w3) (Dialog)
Cochrane Central Register of Controlled Trials (Cochrane Library 2005, issue 2) (http://www.thecochranelibrary.com)
Campbell Collaboration Social, Psychological, Educational and Criminological Trials Register (C2-SPECTR) (1950-02.17.2005.pdt) (http://geb9101.gse.upenn.edu/RIS/RISWEB.ISA)
SIGLE (1980-2004/12) (SilverPlatter)
Zetoc (1993-updated daily) (http://zetoc.mimas.ac.uk/)
ReFeR (http://www.info.doh.gov.uk/doh/refr_web.nsf/Home?OpenForm)
EPPI-Centre in-house databases (http://eppi.ioe.ac.uk/EPPIWeb/home.aspx)
Department of Health website (http://www.dh.gov.uk/Home/fs/en)

The electronic search strategies were developed in Medline and adapted for use with the other information sources.

Update searches were conducted on 1 December 2005. The following databases were searched using the same search strategy as the original searches:

MEDLINE (1996-2005 November week 3) (OVID)
MEDLINE In-Process & Other Non-Indexed Citations (November 30, 2005) (OVID)
CINAHL (1982–2005 November week 3) (OVID)
Embase (1996-2005 week 47) (OVID)
Psycinfo (2000-2005 November week 2) (OVID)
ERIC (Educational Resources Information Center) (1966-current) (CSA Illumina)
Cochrane Central Register of Controlled Trials (Cochrane Library 2005, issue 4) (http://www.thecochranelibrary.com)
Cochrane Database of Systematic Reviews (Cochrane Library 2005, issue 4) (www.thecochranelibrary.com)
Database of Abstracts of Reviews of Effects (CRD administration database)

EXCLUDED REFERENCES

Papers not received in time for the review

Paper	Reason for exclusion
Diet meals: Healthy Choice vs. Lean Cuisine vs. Weight Watchers. *Consumer Reports* 2004;69:16–8.	Excluded Does not evaluate an intervention. Article on diet meals.
Bartlett SJ, Faith MS, Fontaine KR, Cheskin LJ, Allison DB. Is the prevalence of successful weight loss and maintenance higher in the general community than the research clinic? *Obesity Research* 1999;7:407–13.	Excluded Does not evaluate an intervention
Paradis G, Levesque L, Macaulay AC et al. Impact of a diabetes prevention program on body size, physical activity, and diet among Kanien'keha:ka (Mohawk) children 6 to 11 years old: 8-year results from the Kahnawake Schools Diabetes Prevention Project. *Pediatrics* 2005:115: 333–9.	Excluded Primary prevention. Separate data not available for overweight/obese children.
Savoye M, DeStefano R, Caprio S. Effect of the Bright Bodies weight management program for kids on pediatric obesity. *Obesity Research* 2000;8:PB67.	Excluded No control group
Strass D, Korsten-Reck U, Granacher M, Wolfarth B, Berg A, Keul J. Effects of a six-week swimming program on characteristics of physical fitness in obese children. *International Journal of Sports Medicine* 1998;19:S82.	Excluded Setting unclear and length of follow-up was less than 3 months.

Papers excluded as not non-clinical setting

Paper	Reason for exclusion
Current approaches to obesity management in UK Primary Care: the Counterweight Programme. *Journal Human Nutrition and Dietetics* 2004;17:183–90.	Not non-clinical setting.
Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: the evidence report, Rep. No. NIH publication no. 98-4083. National Institutes of Health, National Heart Lung and Blood Institute, 1998; Bethesda: MD.	Not non-clinical setting.
Andersen RE, Wadden TA, Bartlett SJ, Zemel B, Verde TJ, Franckowiak SC. Effects of lifestyle activity vs structured aerobic exercise in obese women: a randomized trial. *Journal of the American Medical Association* 1999;281:335	Not non-clinical setting.
Anderson JW, Hamilton CC, Crown-Weber E, Riddlemoser M, Gustafson NJ. Safety and effectiveness of a multidisciplinary very-low-calorie diet program for selected obese individuals. *Journal American Dietetic Assocation* 1991;91:1582–4.	Not non-clinical setting.
Ashley JM, St. Jeor ST, Perumean-Chaney S, Schrage J, Bovee V (2001) Meal replacements in weight intervention. *Obesity Research* 2001;9:312S–20.	Not non-clinical setting.
Ashutosh K, Methrotra K, Fragale-Journalackson J. Effects of sustained weight loss and exercise on aerobic fitness in	Not non-clinical setting.

obese women. *Journal Sports Medicine and Physical Fitness* 1997; 37:252–7.	
Aude YW, Agatston AS, Lopez-Journalimenez F et al. The national cholesterol education program diet vs a diet lower in carbohydrates and higher in protein and monounsaturated fat: a randomized trial. *Archives of Internal Medicine* 2004;164:2141–6.	Not non-clinical setting.
Avenell A, Broom J, Brown T et al. Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement. Health Technology Assessment 2004;8:1–194.	Setting unclear.
Ayyad C, Andersen T. Long-term efficacy of dietary treatment of obesity: a systematic review of studies published between 1931 and 1999. *Obesity Reviews* 2000;1:113–9.	Setting unclear.
Bacon L, Keim NL, Van Loan MD Derricote M, Gale B, Kazaks A, Stern JS. Evaluating a 'non-diet' wellness intervention for improvement of metabolic fitness, psychological well-being and eating and activity behaviors. *International Journal of Obesity and Related Metabolic Disorders* 2002;26,854–65.	Not non-clinical setting.
Bjorkelund CV, Bengtsson C, Carazo B, Palm L, Tarschys G, Wassen A. Effects of a community risk factor reducing programme on weight, body fat distribution, and lipids in obese women. *International Journal of Obesity* 1991;15:251–8.	Not non-clinical setting.
Blumenthal JA, Sherwood A, Gullette EC et al. Exercise and weight loss reduce blood pressure in men and women with mild hypertension: effects on cardiovascular, metabolic, and hemodynamic functioning. *Archives of Internal Medicine* 2000;160:1947–58.	Not non-clinical setting.
Borg P, Kukkonen-Harjula K, Fogelholm M, Pasanen M. Effects of walking or resistance training on weight loss maintenance in obese, middle-aged men: a randomized trial. *International Journal of Obesity and Related Metabolic Disorders* 2002;26: 676–83.	Setting unclear.
Bowerman S, Bellman M, Saltsman P et al. Implementation of a primary care physician network obesity management program. *Obesity Research* 2001;9(Suppl 4): S321–5.	Not non-clinical setting.
Braet C, Van Winckel M, Van Leeuwen K. Follow-up results of different treatment programs for obese children. *Acta Paediatrica* 1997;86:397–402.	Not non-clinical setting.
Braet C, Van Winckel M. Long-term follow-up of a cognitive behavioral treatment program for obese children. *Behavioral Therapy* 2000;31:55–74.	Not non-clinical setting.
Ciliska D, Kelly C, Petrov N, Chalmers J. A review of the weight loss interventions for obese people with non-insulin-dependent diabetes mellitus. *Canadian Journal of Diabetes Care* 1995;19:10–15.	Not non-clinical setting. Management of overweight with diabetes.
Cordero-MacIntyre ZR, Peters W, Libanati CR, Espana RC, Howell WH, Lohman TG. Effect of a weight-reduction program on total and regional body composition in obese postmenopausal women. *Annals of the New York Academy of Sciences* 2000;904:526–35.	Not non-clinical setting.
Cousins JH, Rubovits DS, Dunn JK, Reeves RS, Ramirez AG, Foreyt JP. Family versus individually oriented intervention for weight loss in Mexican American women. *Public Health Reports* 1992;107:549–55.	Setting unclear.
Cox KL, Burke V, Morton AR, Beilin LJ, Puddey IB. The independent and combined effects of 16 weeks of vigorous	Setting unclear.

exercise and energy restriction on body mass and composition in free-living overweight men: a randomized controlled trial. *Metabolism* 2003;52:107–15.	
Dalle Grave R, Todesco T, Banderali A, Guardini S. Cognitive-behavioural guided self-help for obesity: a preliminary research. *Eating and Weight Disorders* 2004;9: 69–76.	Not non-clinical setting.
Dallow CB, Anderson J. Using self-efficacy and a transtheoretical model to develop a physical activity intervention for obese women. *American Journal of Health Promotion* 2003;17:373–81.	Setting unclear.
Dansinger ML, Gleason JA, Griffith JL, Selker HP, Schaefer EJ. Comparison of the Atkins, Ornish, Weight Watchers, and Zone diets for weight loss and heart disease risk reduction: a randomized trial. *Journal of the American Medical Association* 2005;293:43–53.	Not non-clinical setting.
De Mello ED, Luft VC, Meyer F [Individual outpatient care versus group education programs: which leads to greater change in dietary and physical activity habits for obese children?]. *Journal of Pediatrics (Rio Journal)* 2004;80,468–74.	Not non-clinical setting.
Deforche B, De Bourdeaudhuij I, Tanghe A, Hills AP, De Bode P. Changes in physical activity and psychosocial determinants of physical activity in children and adolescents treated for obesity. *Patient Educuation and Counselling* 2004; 55:407–15.	Not non-clinical setting.
Deforche B, De Bourdeaudhuij I, Tanghe A, Debode P, Hills AP, Bouckaert J. Post-treatment phone contact: a weight maintenance strategy in obese youngsters. *International Journal of Obesity* 2005;29:543–6.	Not non-clinical setting.
Deforche B, De Bourdeaudhuij I, Debode P, Vinaimont F, Hills AP, Verstraete S, Bouckaert J. Changes in fat mass, fat-free mass and aerobic fitness in severely obese children and adolescents following a residential treatment programme. *European Journal of Pediatrics* 2003;162:616–22.	Not non-clinical setting.
Dornelas EA, Wylie-Rosett J, Swencionis C. The DIET study: long-term outcomes of a cognitive-behavioral weight-control intervention in independent-living elders. Dietary intervention: evaluation of technology. *Journal of the American Dietetic Association* 1998;98:1276–81.	Not non-clinical setting.
Douketis JD, Feightner JW, Attia J. Periodic health examination, 1999 update: 1. Detection prevention and treatment of obesity. *Canadian Medical Association Journal* 1999;160:513–25.	Not non-clinical setting.
Epstein LH, Goldfield GS. Physical activity in the treatment of childhood overweight and obesity: current evidence and research issues. *Medicine and Science in Sports and Exercise* 1999;31:S553–9.	Setting is not the focus of the review.
Epstein LH, Paluch RA, Gordy CC, Saelens BE, Ernst MM. Problem solving in the treatment of childhood obesity. *Journal of Consulting and Clinical Psychology* 2000;68:717–21.	Not non-clinical setting.
Epstein LH, Wing RR, Koeske R, Valoski A. Effects of diet plus exercise on weight change in parents and children. *Journal of Consulting and Clinical Psychology* 1984;52:429–37.	Not non-clinical setting.
Epstein LH, Wing RR, Koeske R, Ossip DSB. A comparison of lifestyle change and programmed aerobic exercise on weight and fitness changes in obese children. *Behavioral Therapy* 1982;13:651–65.	Not non-clinical setting.

Facchini M, Malfatto G, Sala L et al. Changes of autonomic cardiac profile after a 3-week integrated body weight reduction program in severely obese patients. *Journal of Endocrinological Investigation* 2003;25:138–42.	Not non-clinical setting.
Flodmark CE, Ohlsson T, Rydén O, Sveger T. Prevention of progression to severe obesity in a group of obese schoolchildren treated with family therapy. *Pediatrics* 1993;91:880–4.	Not non-clinical setting.
Foreyt J, Ramirez A, Cousins J. Cuidando El Corazon: a weight-reduction intervention for Mexican Americans. *American Journal of Clinical Nutrition* 1991;53;1639S–41.	Setting unclear.
Glenny AM, Omeara S, Melville A, Sheldon TA, Wilson C. The treatment and prevention of obesity – a systematic review of the literature. *International Journal of Obesity* 1997; 21:715–37.	Not non-clinical setting.
Grant S, Todd K, Aitchison TC, Kelly P, Stoddart D. The effects of a 12-week group exercise programme on physiological and psychological variables and function in overweight women. *Public Health* 2004;118: 31–42.	Setting is not the focus of the study.
Green MW, Elliman NA, Kretsch MJ. Weight loss strategies, stress, and cognitive function: supervised versus unsupervised dieting. *Psychoneuroendocrinology* 2005;30:908–18.	Setting is not the focus of the study.
Gwinup G. Weight loss without dietary restriction: efficacy of different forms of aerobic exercise. *American Journal of Sports Medicine1987*;15:275–9.	Setting unclear.
Hakala P, Karvetti RL, Roennemaa T. Group vs. individual weight reduction programmes in the treatment of severe obesity: a five year follow-up study. *International Journal of Obesity* 1993;17:97–102.	Not non-clinical setting.
Harvey EL, Glenny AM, Kirk, SF, Summerbell CD. An updated systematic review of interventions to improve health professionals' management of obesity. *Obesity Reviews* 2002;3:45–55.	Setting is not the focus of the review.
Harvey EL, Glenny AM, Kirk SFL. *Improving health professionals' management and the organisation of care for overweight and obese people (Cochrane Review).* Cochrane Review; 2001.	Setting is not the focus of the review.
Heber D, Ashley JM, Wang HJ, Elashoff RM. Clinical evaluation of a minimal intervention meal replacement regimen for weight reduction. *Journal of the American College of Nutrition* 1994;13:608–14.	Not non-clinical setting.
Hellerstedt WL, Jeffery RW. The effects of a telephone-based intervention on weight loss. *American Journal of Health Promotion* 1997;11:177–82.	Not non-clinical setting.
Hillsdon M, Thorogood M, White I, Foster C. Advising people to take more exercise is ineffective: a randomized controlled trial of physical activity promotion in primary care. *International Journal of Epidemiology* 2002;31:808–15.	Not non-clinical setting. Not management of overweight/obesity.
Hipsky J, Kirk S. HealthWorks! weight management program for children and adolescents. *Journal of the American Dietetic Assocation* 2002;102:S64–7.	Not non-clinical setting.
Irwin ML, Yasui Y, Ulrich CM et al. Effect of exercise on total and intra-abdominal body fat in postmenopausal women: a randomized controlled trial. *Journal of the American Medical Association* 2003;289,323–30.	Setting not the focus of the study.
Irwin ML, Tworoger SS, Yasui Y et al. Influence of demographic, physiologic, and psychosocial variables on adherence to a yearlong moderate-intensity exercise trial in	Setting unclear. No control/comparison group.

postmenopausal women. *Preventive Medicine* 2004;39:1080–6.	
Jacobsen DJ, Donnelly JE, Snyder-Heelan K, Livingston K. Adherence and attrition with intermittent and continuous exercise in overweight women. *International Journal of Sports Medicine* 2003;24:459–64.	Not non-clinical setting.
Jakicic JM, Winters C, Lang W, Wing RR. Effects of intermittent exercise and use of home exercise equipment on adherence, weight loss, and fitness in overweight women: a randomized trial. *Journal of the American Medical Association* 1999;282:1554–60.	Not non-clinical setting.
James LC, Folen RA, Page H, Noce M, Brown J, Britton C. The Tripler LE3AN Program: a two-year follow-up report. *Military Medicine* 1999;164:389–95.	Not non-clinical setting.
James LC, Folen RA, Garland FN et al. The Tripler Army Medical Center LEAN Program: a healthy lifestyle model for the treatment of obesity. *Military Medicine* 1997;162:328–32.	Not non-clinical setting.
Jirapinyo P, Limsathayourat N, Wongarn R, Limpimwong V, Bunnag A, Chockvivatvanit S. A summer camp for childhood obesity in Thailand. *Journal of the Medical Association of Thailand* 1995;78;238–46.	Not non-clinical setting.
Kaliski EM, Cahill K. Positive Moves: a teen weight management program. *HMO Practice* 1993;7:168–9.	Not non-clinical setting.
Kaplan TA, Campbell MH, Moccia-Loos G. Effects of a 3-month exercise and nutrition program for childhood obesity on anthropometrics, physical fitness, and serum lipids. *International Pediatrics* 1996;11:31–7.	Setting unclear.
Logue E, Sutton K, Jarjoura D, Smucker W, Baughman K, Capers C. Transtheoretical model – chronic disease care for obesity in primary care: a randomized trial. *Obesity Research* 2005;13:917–27.	Not non-clinical setting.
Maziekas MT, LeMura LM, Stoddard NM, Kaercher S, Martucci T. Follow up exercise studies in paediatric obesity: implications for long term effectiveness. *British Journal of Sports Medicine* 2003;37:425–9.	Settings unclear.
McTigue KM, Hess R, Ziouras J. *Diagnosis and treatment of obesity in the elderly*. Agency for Healthcare Research and Quality (AHRQ) 2003; Rockville.	Not non-clinical settings.
Mellin LM, Slinkard LA, Irwin CE. Adolescent obesity intervention: validation of the SHAPEDOWN program. *Journal of the American Dietetic Association* 1987;87:333–8.	Not non-clinical setting.
Miller Y, Dunstan D. The effectiveness of physical activity interventions for the treatment of overweight and obesity and type 2 diabetes. *Journal of Science and Medicine in Sport* 2004;7:52–9.	Settings unclear.
Miyatake N, Nishikawa H, Morishita A et al. Daily walking reduces visceral adipose tissue areas and improves insulin resistance in Japanese obese subjects. *Diabetes Research and Clinical Practrice* 2002;58;101–7.	Setting unclear. No control/comparison group.
Neumark-Sztainer D, Kaufmann NA, Berry EM. Physical activity within a community-based weight control program: program evaluation and predictors of success. *Public Health Reviews* 1995;23:237–51.	Not non-clinical setting.
Noakes M, Foster PR, Keogh JB, Clifton PM. Meal replacements are as effective as structured weight-loss diets for treating obesity in adults with features of metabolic syndrome. *Journal of Nutrition* 2004;134:1894–9.	Not non-clinical setting.
Norris S, Zhang X, Avenell A et al. Long-term non-pharmacologic weight loss interventions for adults with type 2	Not non-clinical settings. Participants have

diabetes. In: *The Cochrane Database of Systematic Reviews*. John Wiley & Sons 2005; Chichester.	diabetes.
Norris S, Zhang X, Avenell A, Gregg E, Schmid CH, Lau J. Long-term non-pharmacological weight loss interventions for adults with prediabetes. In: *The Cochrane Database of Systematic Reviews*. John Wiley & Sons 2005; Chichester.	Some studies have obese/overweight inclusion criteria but settings of these are unclear.
Norris SL, Zhang X, Avenell A et al. Long-term effectiveness of lifestyle and behavioral weight loss interventions in adults with type 2 diabetes: a meta-analysis. *American Journal of Medicine* 2004;117:762–774.	Not non-clinical settings. Participants have diabetes.
Nunn RG, Newton KS, Faucher P. 2.5 years follow-up of weight and body mass index values in the Weight Control for Life! program: a descriptive analysis. *Addict Behavior* 1992;17:579–85.	Not non-clinical setting.
Okazaki T, Himeno E, Nanri H, Ikeda M. Effects of a community-based lifestyle-modification program on cardiovascular risk factors in middle-aged women. *Hypertension Research* 2001;24:647–53.	Setting unclear. No control/comparison group.
Pavlou KN, Krey S, Steffee WP. Exercise as an adjunct to weight loss and maintenance in moderately obese subjects. *American Journal of Clinical Nutrition* 1989;49:1115–23.	Not non-clinical setting.
Petrella RJ, Lattanzio CN. Does counseling help patients get active? Systematic review of the literature. *Canadian Family Physician* 2002;48:72–80.	Not non-clinical settings. Not management of overweight/obesity.
Pirozzo S, Summerbell C, Cameron C, Glasziou P. Advice on low-fat diets for obesity. In: *The Cochrane Library*. Update Software, Oxford.	Not non-clinical settings.
Powell LA, Nieman DC, Melby C et al. Assessment of body composition change in a community-based weight management program. *Journal of the American College of Nutrition* 2001;20:26–31.	Setting unclear. No control/comparison group.
Powell JJ, Tucker L, Fisher AG, Wilcox K. The effects of different percentages of dietary fat intake, exercise, and calorie restriction on body composition and body weight in obese females. *American Journal of Health Promotion* 1994;8:442–8.	Not non-clinical setting.
Ready AE, Drinkwater DT, Ducas J, Fitzpatrick DW, Brereton DG, Oades SC. Walking program reduces elevated cholesterol in women postmenopause. *Canadian Journal of Cardiology* 1995;11:905–12.	Not non-clinical setting. Not management of overweight/obesity.
Reilly DJJ, McDowell ZC. Physical activity interventions in the prevention and treatment of paediatric obesity: systematic review and critical appraisal. *Proceedings of the Nutrition Society* 2003;62:611–619.	Not non-clinical settings.
Reilly JJ, Wilson ML, Summerbell CD, Wilson DC. Obesity: diagnosis, prevention, and treatment; evidence based answers to common questions. *Archives of Disease in Childhood* 2002;86:392–395.	Not non-clinical settings.
Rothacker DQ, Staniszewski BA, Ellis PK. Liquid meal replacement vs traditional food: a potential model for women who cannot maintain eating habit change. *Journal of the American Dietetic Association* 2001;101:345–7.	Not non-clinical setting.
Saelens BE, Sallis JF, Wilfley DE, Patrick K, Cella JA, Buchta R. Behavioral weight control for overweight adolescents initiated in primary care. *Obesity Research* 2002;10, 22–32.	Not non-clinical setting.
Shaw K, O'Rourke P, Del Mar C, Kenardy J. Psychological interventions for overweight or obesity. In *The Cochrane*	Not non-clinical settings.

Database of Systematic Reviews. John Wiley & Sons 2005; Chichester.	
Shimamoto H, Adachi Y, Takahashi M, Tanaka K. Low impact aerobic dance as a useful exercise mode for reducing body mass in mildly obese middle-aged women. *Applied Human Science* 1998;17:109–14.	Not non-clinical setting.
Simpson M, Earles J, Folen R, Trammel R, James L. The Tripler Army Medical Center's LE3AN program: a six-month retrospective analysis of program effectiveness for African-American and European-American females. *Journal of the National Medical Assocation* 2004;96:1332–6.	Not non-clinical setting.
Slentz CA, Duscha BD, Johnson JL et al. Effects of the amount of exercise on body weight, body composition, and measures of central obesity: STRRIDE – a randomized controlled study. *Archives of Internal Medicine* 2004;164:31–9.	Not non-clinical setting.
Sum CF, Wang KW, Choo DC, Tan CE, Fok AC, Tan EH. The effect of a 5-month supervised program of physical activity on anthropometric indices, fat-free mass, and resting energy expenditure in obese male military recruits. *Metabolism* 1994;43:1148–52.	Not non-clinical setting.
Summerbell CD, Ashton V, Campbell KJ, Edmunds L, Kelly S, Waters E. *Interventions for treating obesity in children*. In The Cochrane Library 2003, Issue 3. John Wiley & Sons, Ltd; Chichester.	Settings either clinical or unclear.
Taylor VC, Baranowski T, Young DR. Physical activity interventions in low-income, ethnic minority, and populations with disability. *American Journal of Preventive Medicine* 1998;15:334–343.	Studies on overweight/obesity are in clinical settings.
Trent LK, Stevens LT. Evaluation of the Navy's obesity treatment program*. Military Medicine* 1995;160:326–30.	Not non-clinical setting.
Wadden TA, Foster GD, Letizia KA, Stunkard AJ. A multicenter evaluation of a proprietary weight reduction program for the treatment of marked obesity. *Archives of Internal Medicine* 1992:152;961–6.	Not non-clinical setting.
Walsh MF, Flynn TJ. A 54-month evaluation of a popular very low calorie diet program. *Journal of Family Practice* 1995;41:231–6.	Not non-clinical setting.
Wylie-Rosett J, Swencionis C, Peters MH et al. A weight reduction intervention that optimizes use of practitioner's time, lowers glucose level, and raises HDL cholesterol level in older adults. *Journal of the American Dietetic Association* 1994;94:37–42.	Not non-clinical setting.
Yoshinaga M, Sameshima K, Miyata, K, Hashiguchi J, Imamura M. Prevention of mildly overweight children from development of more overweight condition. *Preventive Medicine* 2004;38: 172–4.	Not non-clinical setting.

Papers excluded as not management of overweight/obesity

Paper	**Reason for exclusion**
An evaluation report of the Glasgow Exercise Referral Scheme. Greater Glasgow Health Board 2001; Glasgow.	Not all participants overweight. Data not reported separately for overweight participants.
Agron P, Takada E, Purcell A. *California Project LEAN's Food on the Run program: an evaluation of a high school*.	Not management of overweight/obesity.

Journal of the American Dietetic Association 2002;102(Suppl 3):s103-5.	
Aldana SG, Jacobson BH, Kelley PL, Quirk M. The effectiveness of a mobile worksite health promotion program in lowering employee health risk. *American Journal of Health Promotion* 1994;8:254	Not all participants overweight. Data not reported separately for overweight participants.
Andersen RE, Franckowiak SC, Snyder J, Bartlett SJ, Fontaine KR. Can inexpensive signs encourage the use of stairs? Results from a community intervention. *Annals of Internal Medicine* 1998;129:363	Not targeted at overweight population. No follow-up data for overweight subgroup.
Anderson JV, Mavis BE, Robison JI, Stoffelmayr BE. A work-site weight management program to reinforce behavior. *Journal of Occupational Medicine* 1993;35:800–4.	Not all participants overweight. Data not reported separately for overweight participants.
Angelico F, Del Ben M, Fabiani L, Lentini P, Pannozzo F, Urbinati GC, Ricci G. Management of childhood obesity through a school-based programme of general health and nutrition education. *Public Health* 1991;105:393–8.	Not all participants overweight. Data not reported separately for overweight participants.
Baranowski T, Baranowski JC, Cullen KW, Thompson DI, Nicklas T, Zakeri IE, Rochon J. The Fun, Food, and Fitness Project (FFFP): the Baylor GEMS pilot study. *Ethnicity and Disease* 2003;13:S30–9.	Not all participants overweight. Data not reported separately for overweight participants.
Beech BM, Klesges RC, Kumanyika SK et al. Child- and parent-targeted interventions: the Memphis GEMS pilot study. *Ethnicity and Disease* 2003;13:S40–53.	Not all participants overweight. Data not reported separately for overweight participants.
Bell AC, Swinburn BA, Amosa H, Scragg RK. A nutrition and exercise intervention program for controlling weight in Samoan communities in New Zealand. *International Journal of Obesity and Related Metabolic Disorders* 2001;25:920–7.	Not all participants overweight. Data not reported separately for overweight participants.
Bosse, MC, Davis, SC, Puhl, SM et al. Effects of Zone diet macronutrient proportions on blood lipids, blood glucose, body composition, and treadmill exercise performance. *Nutrition Research (Los Angeles)* 2004;24:521–30.	Not all participants overweight. Data not reported separately for overweight participants.
Bowen DJ, Beresford SA, Vu T et al. Baseline data and design for a randomized intervention study of dietary change in religious organizations. *Preventive Medicine* 2004;39:602–11.	Not management of overweight/obesity.
Brodie D, Dugdill L. Health promotion at work. *Journal of the Royal Society of Medicine* 1993;86:694–6.	Not all participants overweight. Data not reported separately for overweight participants.
Brown WJ, Lee C, Oyomopito R. Effectiveness of a bilingual heart health program for Greek-Australian women. *Health Promotion International* 1996;11:117–25.	Not all participants overweight. Data not reported separately for overweight participants.
Brownson RC, Smith CA, Pratt M et al. (1996) Preventing cardiovascular disease through community-based risk reduction: the Bootheel Heart Health Project. *American Journal of Public Health* 1996;86:206–13.	Not management of overweight/obesity.
Bruno R, Arnold C, Jacobson L, Winick M, Wynder E. Randomized controlled trial of a nonpharmacologic cholesterol reduction program at the worksite. *Preventive Medicine* 1983;12:523–32.	Not management of overweight/obesity.
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S. Physical activity and nutrition programs for couples: a randomized controlled trial. *Journal of Clinical Epidemiology* 2003;56:421–32.	Not all participants overweight. Data not reported separately for overweight participants.
Byrne SM, Cooper Z, Fairburn CG. Psychological predictors	Not management of

of weight regain in obesity. *Behavioral Research Therapy* 2004;42:1341–56.	overweight/obesity. No intervention evaluated.
Caballero B, Clay T, Davis SM et al. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *American Journal of Clinical Nutrition* 2003;78:1030–8.	Not all participants overweight. Data not reported separately for overweight participants.
Calfas KJ, Sallis JF, Zabinski MF et al. Preliminary evaluation of a multicomponent program for nutrition and physical activity change in primary care: PACE+ for adults. *Preventive Medicine* 2002;34:153–61.	Not all participants overweight. Data not reported separately for overweight participants.
Carroll P, Ali N, Azam N. Promoting physical activity in South Asian muslim women through exercise on prescription. *Health Technology Assessment* 2002;6:101.	Not management of overweight/obesity.
Chan CB, Ryan DA, Tudor-Locke C. Health benefits of a pedometer-based physical activity intervention in sedentary workers. *Preventive Medicine* 2004;39:1215–22.	Not all participants overweight. Data not reported separately for overweight participants.
Cheung CYW, Ng GYF. An eight-week exercise programme improves physical fitness of sedentary female adolescents. *Physiotherapy* 2003;89:249–55.	Not management of overweight/obesity. Setting unclear.
Clemmens D, Hayman LL. Increasing activity to reduce obesity in adolescent girls: a research review. *Journal of Obstetric, Gynecologic, and Neonatal Nursing* 2004;33:801–8.	Interventions not targeted at overweight/obese populations.
Cohen RY, Stunkard AJ, Felix MR. Comparison of three worksite weight-loss competitions. *Journal of Behavioral Medicine* 1987;10:467–79.	Not all participants overweight. Data not reported separately for overweight participants.
Coleman KJ, Tiller CL, Sanchez J et al. Prevention of the epidemic increase in child risk of overweight in low-income schools: the El Paso coordinated approach to child health. *Archives of Pediatric and Adolescent Medicine* 2005:159; 217–24.	Not all participants overweight. Data not reported separately for overweight participants.
Connell CM, Sharpe PA, Gallant MP. Effect of health risk appraisal on health outcomes in a university worksite health promotion trial. *Health Education Research* 1995;10:199–209.	Not management of overweight/obesity.
Cook C, Simmons G, Swinburn B, Stewart J. Changing risk behaviours for non-communicable disease in New Zealand working men: is workplace intervention effective? *New Zealand Medical Journal* 2001;114:175–8.	Not management of overweight/obesity.
Cox KL, Burke V, Morton AR, Gillam HF, Beilin LJ, Puddey IB Long-term effects of exercise on blood pressure and lipids in healthy women aged 40–65 years: the Sedentary Women Exercise Adherence Trial (SWEAT). *Journal of Hypertension* 2001;19:1733–43.	Not all participants overweight. Data not reported separately for overweight participants.
Dart L, Frable PJ, Bradley PJ, Bae S, Singh K. Working with families to prevent obesity: a community–campus partnership. *Journal of Family and Consumer Sciences* 2005;97:20–8.	Not all participants overweight. Data not reported separately for overweight participants.
Dastani HB, Brown CM, O'Donnell DC. Combating the obesity epidemic: community pharmacists' counseling on obesity management. *Annals of Pharmacotherapy* 2004;38:1800–4.	Not management of overweight/obesity.
Day F, Nettleton B. The Scottish Borders general practitioners exercise referral scheme (GPERS). *Health Bulliten* 2001;59:343–6.	Not management of overweight/obesity.
Del Prete L, English C, Caldwell M, Banspach SW, Lefebvre C (1993) Three-year follow-up of Pawtucket Heart Health's	Not all participants overweight. Data not

community-based weight loss programs. *American Journal of Health Promotion* 1993;7:182–7.	reported separately for overweight participants.
DeVahl J, King R, Williamson JW. Academic incentives for students can increase participation in and effectiveness of a physical activity program. *Journal of the American College of Health* 2005;53:295–8.	Not management of overweight/obesity.
Donnelly JE, Jacobsen DJ, Whatley JE. Obesity and metabolic fitness: effects of a school intervention of nutrition and physical activity. *Food and Nutrition News* 1995;67:7–10.	Not all participants overweight. Data not reported separately for overweight participants.
Dunn AL, Andersen RE, Jakicic JM. Lifestyle physical activity interventions – history, short- and long-term effects, and recommendations. *American Journal of Preventive Medicine* 1998;15:398–412.	Not management of overweight/obesity.
Dzator JA, Hendrie D, Burke V et al. A randomized trial of interactive group sessions achieved greater improvements in nutrition and physical activity at a tiny increase in cost. *Journal of Clinical Epidemiology* 2004;57:610–9.	Not all participants overweight. Data not reported separately for overweight participants.
Englert HS, Diehl HA, Greenlaw RL. Rationale and design of the Rockford CHIP, a community-based coronary risk reduction program: results of a pilot phase. *Preventive Medicine* 2004;38:432–41.	Not all participants overweight. Data not reported separately for overweight participants.
Ewart CK, Young DR, Hagberg JM. Effects of school-based aerobic exercise on blood pressure in adolescent girls at risk for hypertension. *American Journal of Public Health* 1998;88: 949–51.	Not management of overweight/obesity.
Fardy PS, Azzollini A, Herman A. Health-based physical education in urban high schools: the PATH program. *Journal of Teaching Physical Education* 2004;23:359–71.	Not management of overweight/obesity.
Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. *Journal of Pediatrics* 2005;146:618–25.	Not all participants overweight. Data not reported separately for overweight participants.
Flores R. Dance for health: improving fitness in African American and Hispanic adolescents. *Public Health Reports* 1995;110:189–93.	Not all participants overweight. Data not reported separately for overweight participants.
Fogelholm M, Lahti-Koski M. Community health-promotion interventions with physical activity: does this approach prevent obesity? *Scandinavian Journal of Nutrition/Naringsforskning* 2002;46:173–177.	Interventions not targeted at overweight/obese populations.
Forster JL, Jeffery RW, Sullivan S, Snell MK. A work-site weight control program using financial incentives collected through payroll deduction. *Journal of Occupational Medicine* 1985;27:804–8.	Not all participants overweight. Data not reported separately for overweight participants.
Frenn M, Malin S, Bansal N et al. Addressing health disparities in middle school students' nutrition and exercise. *Journal of Community Health Nursing* 2003;20:1–14.	Not management of overweight/obesity.
Fukahori M, Aono H, Saito I, Ikebe T, Ozawa H. Program of exercise training as Total Health Promotion Plan and its evaluation. *Journal of Occupational Health* 1999;41:76–82.	Not all participants overweight. Data not reported separately for overweight participants.
Gance-Cleveland B, Harri, M, Ward-Begnoche W. Family-centered care: working with schools to connect with families of overweight children. *Journal for Specialist in Pediatric Nursing*;2005:10, 40–3.	Not management of overweight obesity. Description of screening programme.
Gidlow C, Johnston LH, Crone D, James D. Attendance of exercise referral schemes in the UK: a systematic review.	No details about weight status of participants.

Health Education Journal 2005;64:168–86.	
Goetzel RZ, Kahr TY, Aldana SG, Kenny GM. An evaluation of Duke University's live for life health promotion program and its impact on employee health. *American Journal of Health Promotion* 1996;10:340–2.	Not management of overweight/obesity.
Gomel M, Oldenburg B, Simpson JM, Owen N. Work-site cardiovascular risk reduction: a randomized trial of health risk assessment, education, counseling, and incentives. *American Journal of Public Health* 1993;83:1231–8.	Not all participants overweight. Data not reported separately for overweight participants.
Goodman RM, Wheeler FC, Lee PR. Evaluation of the Heart To Heart Project: lessons from a community-based chronic disease prevention project. *American Journal of Health Promotion* 1995;9:443–55.	Not all participants overweight. Data not reported separately for overweight participants.
Goran MI, Reynolds K. Interactive multimedia for promoting physical activity (IMPACT) in children. *Obesity Research* 2005;13:762–71.	Not all participants overweight. Data not reported separately for overweight participants.
Grodstein F, Levine R, Troy L, Spencer T, Colditz GA, Stampfer MJ. Three-year follow-up of participants in a commercial weight loss program: can you keep it off? *Archives of Internal Medicine* 1996;156:1302–6.	Weight status of participants unclear. No control/comparison group.
Hambleton, H. Fit 4 Fun. *Community Practitioner* 2004;77:367–8.	Not management of overweight/obesity.
Harland J, White M, Drinkwater C, Chinn D, Farr L, Howel D. The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *British Medical Journal* 1999;319:828–32.	Weight status of participants unclear.
Harrell JS, Gansky SA, McMurray RG, Bangdiwala SI, Frauman AC, Bradley CB. School-based interventions improve heart health in children with multiple cardiovascular disease risk factors. *Pediatrics* 1998;102:371–80.	Not all participants overweight. Data not reported separately for overweight participants.
Harrell JS, McMurray RG, Bangdiwala SI, Frauman AC, Gansky SA, Bradley CB. Effects of a school-based intervention to reduce cardiovascular disease risk factors in elementary-school children: the Cardiovascular Health in Children (CHIC) study. *Journal of Pediatrics* 1996;128,797–805.	Not all participants overweight. Data not reported separately for overweight participants.
Hennrikus DJ, Jeffery RW. Worksite intervention for weight control: a review of the literature. *American Journal of Health Promotion*;1996;10:471–498.	Not all studies are targeted at overweight/obese participants.
Hermann JR, Kopel BH, McCrory ML, Kulling FA (1990) Effect of a cooperative extension nutrition and exercise program for older adults on nutrition knowledge, dietary-intake, anthropometric measurements, and serum-lipids. *Journal of Nutrition Education* 1990;22:271–4.	Not all participants overweight. Data not reported separately for overweight participants.
Hoke CN, Franks S. Work site, physician's office, or medical university clinic: the effect of setting on success in a multidisciplinary weight-loss program. *Eating Behavior* 2002;3:93–100.	Not management of overweight/obesity.
Hourihan F, Krass I, Chen T. Rural community pharmacy: a feasible site for a health promotion and screening service for cardiovascular risk factors. *Australian Journal of Rural Health* 2003;11:28–35.	Not all participants overweight. Data not reported separately for overweight participants.
Jackson C. *Exercise by prescription in North Yorkshire: an evaluation*. North Yorkshire Specialist Health Promotion Service. North Yorkshire Health Authority 1997; Harrogate.	Not management of overweight/obesity.
James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. *British Medical Journal*	Not all participants overweight. Data not reported separately for

2003;328:1237.	overweight participants.
Jeffery RW, McGuire M, Brelje K et al. Recruitment to mail and telephone interventions for obesity in a managed care environment: the Weigh-To-Be Project. *American Journal of Managagement Care* 2004;10: 378–82.	Not management of overweight/obesity.
Jeffery RW, Gray CW, French SA et al. Evaluation of weight reduction in a community intervention for cardiovascular disease risk: changes in body mass index in the minnesota Heart Health Program. *International Journal of Obesity and Related Metabolic Disorders* 1995;19:30–9.	Not management of overweight/obesity.
Jeffery RW, Forster JL, Baxter JE, French SA, Kelder SH. An empirical evaluation of the effectiveness of tangible incentives in increasing participation and behavior change in a worksite health promotion program. *American Journal of Health Promotion* 1993;8:98–100.	Weight status of participants unclear. Insufficient before and after data.
Jeffery RW, Forster JL, French SA et al. The Healthy Worker Project: a work-site intervention for weight control and smoking cessation. *American Journal of Public Health* 1983;83: 395–401.	Not all participants overweight. Data not reported separately for overweight participants.
Johnson CC, Nicklas TA, Arbeit ML et al. Cardiovascular intervention for high-risk families: the Heart Smart Program. *Southern Medicine Journal* 1991;84:1305–12.	Not all participants overweight. Data not reported separately for overweight participants.
Kaats GR, Keith SC, Pullin, D et al. Safety and efficacy evaluation of a fitness club weight-loss program. *Advances in Therapy* 1998;15:345–61.	Not all participants overweight. Data not reported separately for overweight participants.
Kahn EB, Ramsey LT, Brownson RC et al. The effectiveness of interventions to increase physical activity – A systematic review. *American Journal of Preventive Medicine* 2002;22:73–108.	Not management of overweight/obesity.
Kain J, Uauy R, Albala Vio F, Cerda R, Leyton B. School-based obesity prevention in Chilean primary school children: methodology and evaluation of a controlled study. *International Journal of Obesity and Related Metabolic Disorders* 2004;28:483–93.	Not management of overweight/obesity.
Kalten MR, Ardito DA, Cimino C, Wylie-Rosett J. A Web-accessible core weight management program. *Diabetes Educator* 2000;26:929–36.	Weight status of participants unclear. Description of a programme without evaluation.
King AC, Haskell WL, Taylor CB, Kraemer HC, DeBusk RF. Group- vs home-based exercise training in healthy older men and women: a community-based clinical trial. *Journal of the American Medical Association* 1991;266:1535–42.	Not all participants overweight. Data not reported separately for overweight participants.
Knutsen SF, Knutsen R. The Tromso survey: The family intervention study: the effect of intervention on some coronary risk factors and dietary habits, a 6-year follow-up. *Preventive Medicine* 1991;20:197–212.	Not all participants overweight. Data not reported separately for overweight participants.
Krass I, Hourihan F, Chen T. Health promotion and screening for cardiovascular risk factors in NSW: a community pharmacy model. *Health Promotion Journal of Australia* 2003;14:101–7.	Not management of overweight/obesity.
Kumanyika SK, Charleston JB. Lose weight and win: a church-based weight loss program for blood pressure control among black women. *Patient Education and Counseling* 1992;19:19–32.	Not all participants overweight. Data not reported separately for overweight participants.
Lamb SE, Bartlett HP, Ashley A, Bird W. Can lay-led walking programmes increase physical activity in middle aged adults?	Not management of overweight/obesity.

a randomised controlled trial. *Journal of Epidemiology and Community Health* 2002;56:246–52.	
Larsen P, Simons N. Evaluating a federal health and fitness program: indicators of improving health. *AAOHN Journal* 1993;41:143–8.	Not management of overweight/obesity.
Lionis C, Kafatos A, Vlachonikolis J, Vakaki M, Tzortzi M, Petraki A. The effects of a health education intervention program among Cretan adolescents. *Preventive Medicine* 1991;20:685–99.	Not management of overweight/obesity.
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Lowe MR, Miller-Kovach K, Frye N, Phelan S. An initial evaluation of a commercial weight loss program: short-term effects on weight, eating behavior, and mood. *Obesity Research* 1999;7:51–9.	Not management of overweight/obesity.
Luepker RV, Perry CL, McKinlay SM et al. Outcomes of a field trial to improve children's dietary patterns and physical activity: the Child and Adolescent Trial for Cardiovascular Health [CATCH]. *Journal of the American Medical Association* 1996;275:768–76.	Not management of overweight/obesity.
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McMurray RG, Harrell JS, Bangdiwala SI, Bradley CB, Deng S, Levine A. A school-based intervention can reduce body fat and blood pressure in young adolescents. *Journal of Adolescent Health* 2002;31:125–32.	Not all participants overweight. Data not reported separately for overweight participants.
Miles A, Rapoport, L, Wardle J, Afuape T, Duman M. Using the mass-media to target obesity: an analysis of the characteristics and reported behaviour change of participants in the BBC's 'Fighting Fat, Fighting Fit' campaign. *Health Education Research* 2001;16:357–72.	Not all participants overweight. Data not reported separately for overweight participants.
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Murie J, Tuohy AP, Carroll D. Impact of a health promotion programme on multiple risk factors for CHD: a preliminary evaluation. *Scottish Medical Journal* 1994:39;12–6.	Not management of overweight/obesity.
Nader PR, Stone EJ, Lytle LA et al. Three-year maintenance of improved diet and physical activity: the CATCH cohort (Child and Adolescent Trial for Cardiovascular Health). *Archives of Pediatric and Adolescent Medicine* 1999;153: 695–704.	Weight status of participants unclear.
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Nilsson PM, Klasson EB, Nyberg P. Life-style intervention at the worksite: reduction of cardiovascular risk factors in a randomized study. *Scandinavian Journal of Work and Environmental Health* 2001;27: 57–62.	Not all participants overweight. Data not reported separately for overweight participants.
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based intervention on cardiovascular risk reduction. *Ethnicity and Disease* 2001;11:817–22.	overweight. Data not reported separately for overweight participants.
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Okada K. Effects of long-term corporate fitness program on employees' health. *Journal of Nutritional Science and Vitaminology (Tokyo)* 1991;37(Suppl):S131–8.	Not all participants overweight. Data not reported separately for overweight participants.
Pelletier KR. Clinical and cost outcomes of multifactorial, cardiovascular risk management interventions in worksites: a comprehensive review and analysis. *Journal of Occupational and Environmental Medicine* 1997;39:1154–69.	Not management of overweight/obesity.
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Rowland TW, Varzeas MR, Walsh CA. Aerobic responses to walking training in sedentary adolescents. *Journal of Adolescent Health* 1991;12:30–4.	Not all participants overweight. Data not reported separately for overweight participants.
Sahota P, Rudolf MC, Dixey R, Hill AJ, Barth JH, Cade J. Randomised controlled trial of primary school based intervention to reduce risk factors for obesity. *British Medical Journal* 2001;323:1029–32.	Not all participants overweight. Data not reported separately for overweight participants.
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Shephard RJ. Worksite fitness and exercise programs: a review of methodology and health impact. *American Journal of Health Promotion* 1996;10:436–52.	Not management of overweight/obesity.

Steinhardt MA, Bezner JR, Adams TB. Outcomes of a traditional weight control program and a nondiet alternative: a one-year comparison. *Journal of Psychology* 1999;133:495–513.	Weight status of participants unclear.
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Taylor AH, Doust J, Webborn N. Randomised controlled trial to examine the effects of a GP exercise referral programme in Hailsham, East Sussex, on modifiable coronary heart disease risk factors. *Journal of Epidemiology and Community Health* 1998;52, 595–601.	Not all participants overweight. Data not reported separately for overweight participants.
Thorsteinsson, R, Johannesson A, Jonsson H, Thorhallsson T, Sigurdsson JA. Effects of dietary intervention on serum lipids in factory workers. *Scandinavian Journal of Primary Health Care* 1994;12:93–9.	Not all participants overweight. Data not reported separately for overweight participants.
Tudor-Smith C, Nutbeam D, Moore L, Catford J. Effects of the Heartbeat Wales programme over five years on behavioural risks for cardiovascular disease: quasi-experimental comparison of results from Wales and a matched reference area. *British Medical Journal* 1998;316: 818–22.	Not all participants overweight. Data not reported separately for overweight participants.
Vandongen R, Jenner DA, Thompson C et al. (1995) A controlled evaluation of a fitness and nutrition intervention program on cardiovascular health in 10- to 12-year-old children. *Preventive Medicine* 1995;24:9–22.	Not all participants overweight. Data not reported separately for overweight participants.
Webber LS, Osganian SK, Feldman HA et al. Cardiovascular risk factors among children after a 2 1/2-year intervention: the CATCH Study. *Preventive Medicine* 1996;25:432–41.	Weight status of participants unclear.
Weight Watchers (UK) & Islington Primary Care Trust. *Evaluation of GP referral to Weight Watchers: qualitative research of a pilot referral scheme between the Goodinge Health Centre and Weight Watchers*. Views of health professionals, patients and Weight Watchers leaders. Debrief notes. Weight Watchers (UK) in collaboration with Islington PCT 2004.	Not management of overweight/obesity.
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Yanek LR, Becker DM, Moy TF, Gittelsohn J, Koffman DM. Project Joy: faith based cardiovascular health promotion for African American women. *Public Health Reports* 2001;116:68–81.	Weight status of participants unclear.

Papers excluded for other reasons

Paper	**Reason for exclusion**

Family-based programmes to tackle obesity. *Community Practitioner* 2003;76:406.	Not a primary study. News article.
Surestart schemes forging partnerships with the commercial slimming sector. Surestart Salford. Surestart Dino Runcorn. Slimming World.	Not a primary study. Brief description of ongoing scheme.
Weight management counseling of overweight adults. American College of Preventive Medicine – Medical Specialty Society 2001.	Not a systematic review. Not non-clinical setting.
Obesity in women. A guide to assessment and management. Brigham and Women's Hospital (Boston) – Hospital/Medical Center 2003.	Not a systematic review. Not non-clinical setting.
Evaluation and treatment of childhood obesity. University of Texas at Austin School of Nursing, Family Nurse Practitioner Program – Academic Institution 2004.	Only summary available from British Library. Setting unclear.
Prevention and management of obesity (mature adolescents and adults). Institute for Clinical Systems Improvement 2004; Bloomington, MN.	Not a systematic review. Not non-clinical setting.
Abrams DB, Follick MJ. Behavioral weight-loss intervention at the worksite: feasibility and maintenance. *Journal of Consulting and Clinical Psychology* 1983;51:226–33.	Insufficient before and after data.
Aldana SG, Jacobson BH, Harris CJ, Kelley PL. Mobile work site health promotion programs can reduce selected employee health risks. *Journal of Occupational Medicine* 1993;35:922	No control/comparison group.
Aldarondo F. Adherence among individuals in an exercise, nutrition, and weight loss program. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 1999;60:0353.	Thesis not available from British Library.
Anonymous. Popular diets equally effective for losing weight. Journal of Family Practice 2005;54:306.	Not a primary study.
Anonymous. School anti-'fizzy drinks' programme helps to prevent obesity in children. Evidence Based Healthcare 2004;8:368-9.	Not a primary study. Summary of James 2004.
Anwyl V. *Community development training initiative to treat adult obesity*. Department of Nutrition and Dietetics, Tameside and Glossop Primary Care Trust, Hyde; 2004.	No control/comparison group. Insufficient before and after data.
Appleton CL, Summerbell C, Finn P et al. Preliminary results of the effectiveness of a commercial weight-loss programme compared with usual care in primary care. *Proceedings of the Nutrition Society 2004*;63:81A.	Abstract only. Otherwise meets inclusion criteria.
Ard JD, Rosati R, Oddone EZ. Culturally-sensitive weight loss program produces significant reduction in weight, blood pressure, and cholesterol in eight weeks. *Journal of the National Medical Association* 2000;92:515–23.	No control/comparison group. Follow-up less than 3 months.
Asp NG, Bjorntorp P, Britton M et al. Obesity – problems and interventions. Swedish Council on Technology Assessment in Health Care (SBU), Stockholm; 2002.	Only summary available in English; not enough information provided. Full report is in Swedish.
Astrup A, Rossner S. Lessons from obesity management programmes: greater initial weight loss improves long-term maintenance. *Obesity Reviews* 2000;1,17–9.	Not a primary study.
Atkinson RL, Nitzke SA. School based programmes on obesity: increase knowledge about nutrition but do not change eating habits by much. *British Medical Journal* 2001; 323:1018–9.	Not a primary study. Commentary.
Avery AJ, Lavin JH, Rees E, Barth JH, Whitehead SM. Improvements in mental well being during weight loss on a slimming on referral programme. *Proceedings of the Nutrition Society* 2004;63:135A.	Abstract only. Insufficient detail.

Awramenke M. Help yourself to health. *Practice Nurse* 1997;13:598–602.	Not a primary study. Description of a scheme.
Ball, GD, Marshall, DJ, McCargar LJ. A comparison of two weight management programs for obese children. *Obesity Research* 2000; 8(Suppl 1):O128.	Abstract only. Setting unclear.
Barnes JT. Weight status during and after a 12-week weight loss program at the worksite. *Research Quarterly for Exercise and Sport* 2004;75:A15–6.	Abstract only. Insufficient detail.
Bar-Or O. Prescribing activity. Managing juvenile obesity with enhanced physical activity. *Canadian Family Physician* 2001; 47:2165–7.	Not a primary study.
Barton SB, Walker LL, Lambert G, Gately PJ, Hill AJ. Cognitive change in obese adolescents losing weight. *Obesity Research* 2004;12:313–9.	No control/comparison group. Follow-up less than 3 months.
Bessell TL, McDonald S, Silagy CA, Anderson JN, Hiller JE, Sansom LN. Do internet interventions for consumers cause more harm than good? A systematic review. *Health Expectations* 2002;5:28–37.	Includes one study on weight loss intervention but before and after data points are not reported.
Bjorvell H, Rossner S. Long-term effects of commonly available weight reducing programmes in Sweden. *International Journal of Obesity and Related Metabolic Disorders* 1987;11:67–71.	Pre-1990 and not an RCT.
Bland JS, Dibiase F, Ronzio R. Physiological effects of a doctor-supervised versus an unsupervised over-the-counter weight-loss program. *Journal of Nutritional Medicine* 1992;3:285–93.	Follow-up less than 3 months.
Blomquist B, Borjeson M, Larsson Y, Persson B, Sterky G. The effect of physical activity on body measurements and work capacity of overweight boys. *Acta Paediatrica Scandinavica* 1965;54:566–72.	Pre-1990 identified through reference check.
Bohnker BK. Get moving Navy: a program to improve fitness and reduce obesity. *Aviation, Space, and Environmental Medicine* 2005;76:186.	Abstract only. Insufficient detail.
Booth AO, Nowsen CA, Worsley T, Margerison C, Jorna MK. Dietary approaches for weight loss with increased fruit, vegetables and dairy. *Asia Pacific Journal of Clinical Nutrition* 2003;12(Suppl):S10.	Abstract only. Insufficient detail.
Botvin GJ, Cantlon A, Carter BJ, Williams CL. Reducing adolescent obesity through a school health program. *Journal of Pediatrics* 1979;95:1060–4.	Follow-up less than 3 months. Insufficient before and after data.
Bradshaw A, Katzer L, Horwath CC et al. A randomised trial of three non-dieting programs for overweight women. *Asia Pacific Journal of Clinical Nutrition* 2004;13:S43.	Not available from British Library.
Briley ME, Montgomery DH, Blewett J. Worksite nutrition education can lower total cholesterol levels and promote weight loss among police department employees. *Journal of the American Dietetic Association* 1992;92:1382–4.	No control/comparison group. Insufficient before and after data.
Brownell KD, Kaye FS. A school-based behavior modification, nutrition education, and physical activity program for obese children. *American Journal of Clinical Nutrition* 1982;35:277–83.	Follow-up less than 3 months.
Bye C, Avery A, Lavin J. *Influence of Slimming World's lifestyle programme on diet, activity levels and health of the whole family: draft Slimming World report*. Slimming World, Alfreton, 2005.	Draft report of magazine survey. Weight status of participants unclear.
Bye C, Avery A, Lavin J. Tackling obesity in men: preliminary evaluation of men-only groups within a commercial slimming organization. *Journal of Human Nutrition and Dietetics* 2005;18:391–4.	No control/comparison group. Insufficient before and after data.

Cameron R, MacDonald MA, Schlegel RP et al. Toward the development of self-help health behaviour change programs: weight loss by correspondence. *Canadian Journal of Public Health* 1990;81:275–9.	Insufficient before and after data.
Canty LM. Teen obesity addressed in the military. *Military Medicine* 2003;168:139–42.	No control/comparison group. Follow-up time unclear. Insufficient before and after data.
Castro CM, King AC. Telephone-assisted counseling for physical activity. *Exercise and Sport Sciences Reviews* 2002;30:64–68.	Not a systematic review. Not management of overweight/obesity.
Cho S, Alberding J, Sadler B, Johnson KJ, Clark C. Worksite weight loss program with meal and snack replacement system: twelve-week results. *American Journal of Clinical Nutrition* 2002;75:383S.	Abstract only. Insufficient before and after data.
Chomitz VR, Collins J, Kim J, Kramer E, McGowan R. Promoting healthy weight among elementary school children via a health report card approach. *Archives of Pediatric and Adolescent Medicine* 2003;157:765–72.	Follow-up less than 3 months. Insufficient data for overweight participants.
Christakis G, Sajecki S, Hillman RW, Miller E, Blumenthal S, Archer M. Effect of a combined nutrition education and physical fitness program on the weight status of obese high school boys. *Federation Proceedings* 1966;25:15–9.	Pre-1990 identified through reference check.
Christakis G, Miller-Kovach K. Maintenance of weight goal among Weight Watchers lifetime members. *Nutrition Today* 1996;31:29–31.	No control/comparison group. Insufficient before and after data.
Clifton PM, Noakes M, Keogh J, Foster P. How effective are meal replacements for treating obesity? *Asia Pacific Journal of Clinical Nutrition* 2003;12:S51.	Abstract only. Insufficient detail.
Coday M, Klesges LM, Garrison RJ, Johnson KC, O'Toole M, Morris GS. Health Opportunities with Physical Exercise (HOPE): social contextual interventions to reduce sedentary behavior in urban settings. *Health Education Research* 2002;17:637–47.	Not a primary study. Description of project without evaluation.
Cohen CJ, McMillan CS, Samuelson DR. Long-term effects of a lifestyle modification exercise program on the fitness of sedentary, obese children. *Journal of Sports Medicine and Physical Fitness* 1991;31:183–8.	No control/comparison group.
Croteau KA (2004) A preliminary study on the impact of a pedometer-based intervention on daily steps. *American Journal of Health Promotion* 2004;18:217–20.	No control/comparison group. Follow-up less than 3 months.
Dallas MI. Exercise walking for obesity management in older adult women. *Issues on Aging* 1997;20:8–12.	Not available from British Library.
Daniel K. Tackling teenage obesity. *Community Practice* 2001;74:456–7.	Not a primary study. Description of programme without evaluation.
Datar A, Sturm R. Physical education in elementary school and body mass index: evidence from the early childhood longitudinal study. *American Journal of Public Health* 2004;94:1501–6.	No control/comparison group. Insufficient before and after data.
DeWolfe JA, Jack E. Weight control in adolescent girls: a comparison of the effectiveness of three approaches to follow-up. *Journal of School Health* 1984;54:347–49.	Pre-1990 identified through reference check.
Domel SB, Alford BB, Cattlett HN, Rodriguez ML, Gench BE. A pilot weight control program for Hispanic women. *Journal of the American Dietetic Association* 1992;92:1270–1.	Follow-up time unclear.
Egger G, Bolton A, O'Neill M, Freeman D. Effectiveness of an abdominal obesity reduction programme in men: the	Insufficient before and after data.

GutBuster 'waist loss' programme. *International Journal of Obesity* 1996;20:227–31.	
Englberger L, Halavatau V, Yasuda Y, Yamazaki R. The Tonga Healthy Weight Loss Program 1995–97. *Asia Pacific Journal of Clinical Nutrition* 1999;8:142–8.	No control/comparison group. Insufficient before and after data.
Epstein LH. Exercise in the treatment of childhood obesity. *International Journal of Obesity* 1995;19:S117–21.	Not a systematic review. Not non-clinical setting.
Epstein LH, Coleman KJ, Myers MD. Exercise in treating obesity in children and adolescents. *Medicine and Science in Sports and Exercise* 1996;28:428–35.	Some studies are in non-clinical settings but before and after data points are not reported.
Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. *Pediatrics* 1998;101:554–570.	Not a systematic review. Not non-clinical setting.
Erfurt JC, Foote A, Heirich MA, Gregg W. Improving participation in worksite wellness programs: comparing health education classes, a menu approach, and follow-up counseling. *American Journal of Health Promotion* 1990;4: 270–8.	No outcomes of interest.
Faith MS, Berman N, Heo MS et al. Effects of contingent television on physical activity and television viewing in obese children. *Pediatrics* 2001;107:1043–8.	Follow-up less than 3 months. No outcomes of interest.
Fardy PS, O'Neill J, Indig B, Azzollini A. Effects of school-based wellness on obesity and related health measures in urban teens: the PATH program. *Research Quarterly on Exercise and Sport* 2005;76:A37.	Abstract only. No control/comparison group. Insufficient before and after data.
Forster JL, Jeffery RW, Snell MK. One-year follow-up study to a worksite weight control program. *Preventive Medicine* 1988;17:129–33.	No control/comparison group. Insufficient before and after data.
Foster GD, Wadden TA, Brownell KD. Peer-led program for the treatment and prevention of obesity in the schools. *Journal of Consulting and Clinical Psychology* 1985;53:538–40.	Pre-1990 and not an RCT.
Frable PJ, Dart L, Bradley PJ. The Healthy Weigh/El Camino Saludable: a community campus partnership to prevent obesity. *Journal of Interprofessional Care* 2004;18:447–9.	Study description only. No evaluation.
French SA, Hannan PJ, Story M. School soft drink intervention study. *British Medical Journal* 2004;329:E315–6.	Not a primary study. Commentary.
Gately PJ, Butterly RJ, Cooke CB. The effects of an 8-week diet and exercise programme on a sample of children attending a weight-loss camp. *Journal of Sports Science* 1996;14:82–3.	Abstract only. Insufficient detail.
Gately PJ, Cooke CB, Butterly RJ, Mackreth P, Carroll S. The effects of a children's summer camp programme on weight loss, with a 10 month follow-up. *International Journal of Obesity and Related Metabolic Disorders* 2000;24:1445–52.	No control/comparison group.
Gately PJ, Mackreth P, Cooke CB, Butterly RJ. The effects of an 8 week diet and exercise programme on body composition in a sample of overweight and obese children. *Journal of Sports Science* 1998;16:47–8.	Abstract only. No control/comparison group. Follow-up less than 3 months.
Gately PJ, Cooke CB, Barth JH, Bewick BM, Radley D, Hill AJ. Children's residential weight-loss programs can work: a prospective cohort study of short-term outcomes for overweight and obese children. *Pediatrics* 2005;116:73–7.	Follow-up less than 3 months.
Gately PJ, Cooke CB, Butterly RJ, Knight C, Carroll S. The acute effects of an 8-week diet, exercise, and educational camp program on obese children. *Pediatric Exercise Science* 2000;12:413–23.	No control/comparison group. Follow-up less than 3 months.
Gately PJ, Cooke CB, Butterly RJ. Long-term effects of an 8 week diet and exercise programme on a sample of children	Abstract only. No control comparison group.

attending a weight-loss camp. *Journal of Sports Science* 2000;18:23–4.	Insufficient before and after data.
Gill DS. Testing a biopsychosocial model of health behavior: A community intervention for reducing obesity in Mexican-American women. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 1999;59:5082.	Thesis not available from British Library.
Gittelsohn J, Anliker JA, Ethelbah B et al. A food store intervention to reduce obesity in two American Indian communities: impact on food choices and psychosocial indicators. *FASEB Journal* 2005;19:A1021.	Abstract only. Not management of overweight/obesity.
Goetzel R, Sepulveda M, Knight K et al. Association of IBM's "A Plan for Life" health promotion program with changes in employees' health risk status. *Journal of Occupational Medicine* 1994;36:1005–9.	Insufficient before and after data.
Gortmaker SL, Peterson K, Wiecha J et al. Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Archives of Pediatric and Adolescent Medicine* 1999;153:409–18.	Insufficient before and after data.
Gosselin C, Cote G. Weight loss maintenance in women two to eleven years after participating in a commercial program: a survey. *BMC Womens Health* 2001;1(2).	No control/comparison group.
Greene GW, Riebe D, Ruggiero L, Caldwell M, Blissmer B. A pilot home-based, healthy lifestyle weight management program. *Topics in Clinical Nutrition* 2003;18:136–42.	No control/comparison group.
Gregg W, Foote A, Erfurt JC, Heirich MA. Worksite follow-up and engagement strategies for initiating health risk behavior changes. *Health Education Quarterly* 1990;17:455–78.	No control/comparison group. Insufficient before and after data.
Hagen RL. Group therapy versus bibliotherapy in weight reduction. *Behavior Therapy* 1974;5:222–34.	Pre-1990 identifed through reference check.
Harvey PW, Steele J, Bruggemann JN, Jeffery RW. The development and evaluation of lighten up, an Australian community-based weight management program. *American Journal of Health Promotion* 1998;13:8–11.	No control/comparison group.
Harvey-Berino J, Pintauro SJ, Gold EC. The feasibility of using Internet support for the maintenance of weight loss. *Behavior Modification* 2002;26:103–16.	Feasibility study for two included studies.
Heath GW, Wilson RH, Smith J, Leonard BE. Community-based exercise and weight control: diabetes risk reduction and glycemic control in Zuni Indians. *American Journal of Clinical Nutrition* 1991;53:S1642S-6.	Participants have diabetes.
Heirich MA, Foote A, Erfurt JC Konopka B. Work-site physical fitness programs: comparing the impact of different program designs on cardiovascular risks. *Journal of Occupational Medicine* 1993;35:510–7.	Insufficient before and after data.
Hemmingsson E, Page A, Fox K, Rossner S. Influencing adherence to physical activity behaviour change in obese adults. *Scandinavian Journal of Nutrition/Naringsforskning* 2001;45:114–9.	Some studies may be relevant but there is not sufficient information for data extraction.
Heshka S, Greenway F, Anderson JW et al. Self-help weight loss versus a structured commercial program after 26 weeks: a randomized controlled study. *American Journal of Medicine* 2000;109:282–7.	Longer follow-up report is included.
Heshka S, Anderson J, Atkinson R, Gadde KM, Nanchahal K. Commercial weight reduction programme reduces weight more than self-help materials. *Evidence Based Healthcare* 2003;7:179–81.	Not a primary study. Commentary.
Hildebrandt VH, Koning M, Proper KI, Bosscher RI, van der Beek AJ, van Mechelen W. The effectiveness of worksite physical activity programs on health related outcomes: a	Conference abstract. Not management of obesity/overweight.

systematic review. *Medicine and Science in Sports and Exercise* 2001;33:S255.	
Hills AP, Byrne NM. Exercise prescription for weight management. *Proceedings of the Nutrition Society* 1998;57:93–103.	Not a systematic review. Not non-clinical setting.
Hillsdon M. *A randomised controlled trial of physical activity promotion in primary care*. London University, London; 2000.	PhD thesis. Not management of overweight/obesity.
Hogan BE, Linden W, Najarian B. Social support interventions: do they work? *Clinical Psychology Review* 2002;22:381–440.	No outcomes of interest. Search not limited to obese/overweight population.
Hughes JM. *Factors influencing successful weight loss and weight loss maintenance in slimming clubs*. London University, London; 1992.	PhD thesis. Not management of overweight/obesity.
Igarashi K, Fujita K, Yamase T et al. Sapporo Fitness Club Trial (SFCT): design, recruitment and implementation of a randomized controlled trial to test the efficacy of exercise at a fitness club for the reduction of cardiovascular risk factors. *Circulation Journal* 2004;68:1199–204.	Follow-up less than 3 months. Insufficient before and after data.
Illuzzi S, Cinelli B. A coordinated school health program approach to adolescent obesity. *Journal of School Nursing* 2000;16, 12–9.	Not a primary study.
James LC, Folen RA, Earles J. Behavioral telehealth applications in the treatment of obese soldiers: a feasibility project and a report on preliminary findings. *Military Psychology* 2001;13:177–86.	Insufficient before and after data.
Jeffery RW, Sherwood NE, Brelje K et al. Mail and phone interventions for weight loss in a managed-care setting: Weigh-To-Be one-year outcomes. *International Journal of Obesity and Related Metabolic Disorders* 2003;27:1584–92.	Insufficient before and after data.
Jeffery RW, Hellerstedt WL, Schmid TL. Correspondence programs for smoking cessation and weight control: a comparison of two strategies in the minnesota Heart Health Program. *Health Psychology* 1990;9:585–98.	Insufficient before and after data.
Jeffery RW, Forster JL, Snell MK. Promoting weight control at the worksite: a pilot program of self-motivation using payroll-based incentives. *Preventive Medicine* 1985;14:187–94.	Insufficient before and after data.
Jeffery RW. Community programs for obesity prevention: the Minnesota Heart Health-Program. *Obesity Research* 1995;3:S283–8.	Not a primary study. Overview of several programmes.
Jeffery RW, Danaher BG, Killen J, Farquhar JW, Kinnier R. Self-administered programs for health behavior change: smoking cessation and weight reduction by mail. *Addictive Behavior* 1982;7:57–63.	Insufficient before and after data.
Jen KL, Djuric Z, DiLaura NM et al. Improvement of metabolism among obese breast cancer survivors in differing weight loss regimens. *Obesity Research* 2004;12:306–12.	Participants are breast cancer survivors.
Jette M, Barry W, Pearlman L. The effects of an extracurricular physical activity program on obese adolescents. *Canadian Journal of Public Health* 1977;68:39–42.	Pre-1990 identified through reference check.
Kang KJ. Effectiveness of weight control program for obese children in Chuncheon. *Nutritional Sciences* 2001;4:39–46.	No control/comparison group. Follow-up less than 3 months.
Karanja N, Stevens VJ, Hollis JF, Kumanyika SK. Steps to soulful living (steps): a weight loss program for African-American women. *Ethnicity and Disease* 2002;12:363–71.	No control/comparison group.
Kirsch SED, Lewis FM. Using the World Wide Web in health-	Includes one relevant

related intervention research: a review of controlled trials. *Computers, Informatics, Nursing* 2004;22:8–18.	study but before and after data not reported.
Krake SM. Exercise prescription as an adjunct to weight loss in obesity. *Canadian Journal of CME* 2000;12:187–94.	Not a primary study.
Lansky D, Brownell KD. Comparison of school-based treatments for adolescent obesity. *Journal of School Health* 1982;52:384–7.	Pre-1990 identified through reference check.
Lasater TM, Sennett LL, Lefebvre RC, DeHart KL, Peterson G, Carleton RA. Community-based approach to weight loss: the Pawtucket "weigh-in". *Addictive Behavior* 1991;16:175–81.	No control/comparison group. Follow-up less than 3 months.
Latner JD, Stunkard AJ, Wilson GT, Jackson ML, Zelitch DS, Labouvie E. Effective long-term treatment of obesity: a continuing care model. *International Journal of Obesity and Related Metabolic Disorders* 2000;24:893–8.	No control/comparison group. Insufficient before and after data.
Latner JD, Wilson GT, Stunkard AJ, Jackson ML (2002) Self-help and long-term behavior therapy for obesity. *Behavior Research Therapy* 2002;40:805–12.	No control/comparison group. Insufficient before and after data.
Lavalle A. ACTIVATE: a childhood overweight prevention initiative. *School Nurse News* 2004;21:40–1.	Not available from British Library.
Lee H-I, Kuo H-W, Lee M-C, Hung L-C. The intervention program of body weight reduction on knowledge attitude and behavior toward nutrition among elementary school childrens. *Nutritional Sciences Journal* 1998;23:213–226.	Not available from British Library.
Leermakers EA, Jakicic JM, Viteri J, Wing RR. Clinic-based vs. home-based interventions for preventing weight gain in men. *Obesity Research* 1998;6:346–52.	Insufficient before and after data.
Lim SJ, Kyoung EJ. A nutrition education program for the children of obese or unbalanced dietary habits. *Korean Journal of Nutrition* 1990;23:279–86.	Full paper available in foreign language only.
Linde JA, Jeffery RW, Levy RL, Pronk NP, Boyle RG. Weight loss goals and treatment outcomes among overweight men and women enrolled in a weight loss trial. *International Journal of Obesity and Related Metabolic Disorders* 2005;29: 1002–5.	No control/comparison group. Follow-up less than 3 months. Insufficient before and after data.
Lindstrom L-L, Balch P, Reese S. In person versus telephone treatment for obesity. *Journal Behavior Therapy and Experimental Psychiatry* 1976;7:367–9.	Insufficient before and after data.
Lowe MR, Thaw JM, Miller-Kovach K. Long-term follow-up assessment of successful dieters in a commercial weight-loss program. *International Journal of Obesity* 2004;28:S29.	Abstract only. No control/comparison group. Insufficient before and after data.
Lowe MR, Miller-Kovach K, Phelan S. Weight-loss maintenance in overweight individuals one to five years following successful completion of a commercial weight loss program. *International Journal of Obesity and Related Metabolic Disorders* 2001;25:325–31.	No control/comparison group. Insufficient before and after data.
Malaysian Health Technology Assessment Unit. *Management of obesity in childhood*. Malaysian Health Technology Assessment Unit (MHTAU), Kuala Lumpur; 2004.	Some studies may be relevant but there is not sufficient information for data extraction.
Manios Y, Boreham C, Kafatos A. Childhood obesity: the role of physical activity and diet. *Bahrain Medical Bulletin* 2000;22:103–112.	Not a systematic review.
Martin C, Woolf-May K. The retrospective evaluation of a general practitioner exercise prescription programme. *Journal of Human Nutrition and Dietetics* 1999;12:32–42.	No control/comparison group. Follow-up less than 3 months. No outcomes of interest. Insufficient before

	and after data.
McDermott IE. Internet express. E-exercise and eating right: weight loss on the Web. *Searcher: The Magazine for Database Professionals* 2003;11:45–9.	Not a primary study. Magazine article.
Melanson KJ, Dell Olio, J, Carpenter MR et al. The influence of a 12-week walking program, with and without weight loss, on cardiovascular risk factors in obese adults. *Obesity Research* 2001;9:PF39.	Abstract only. Setting unclear.
Melin A, Lenner R, Hedin A, Nordenberg AM, Nilsson NO. Treatment of obesity from first degree at school: the HOPP Project. *Acta Paediatrica* 2005:Suppl 448:55b-55.	Abstract only. Otherwise meets inclusion criteria.
Mello ED, Luft VC, Meyer F. Obesidade infantil: como podemos ser eficazes? [Childhood obesity – towards effectiveness]. *Journal de Pediatria* 2004;80:173–82.	Not a systematic review. Not all participants >2 years of age.
Merisalo LJ. Audio weight loss program curbs obesity. *Report on Medical Guidelines Outcomes Research* 2000;11:1–2,5.	Not a primary study. Magazine article.
Meyers AW, Graves TJ, Whelan JP, Barclay DR. An evaluation of a television-delivered behavioral weight loss program: are the ratings acceptable? *Journal of Consulting and Clinical Psychology* 1996;64:172–8.	Insufficient before and after data.
Miller WC, Eggert KE, Wallace JP, Lindeman AK, Jastremski, C. Successful weight loss in a self-taught, self-administered program. *International Journal of Sports Medicine* 1993;14:401–5.	Insufficient before and after data.
Muller MJ, Asbeckl I, Mast M, Langnase K, Grund A. Prevention of obesity: more than an intention. Concept and first results of the Kiel Obesity Prevention Study (KOPS). *International Journal of Obesity* 2001;25:S66–74.	Insufficient before and after data.
Mulvihill C, Quigley R. *The management of obesity and overweight: an analysis of reviews of diet, physical activity and behavioural approaches*. Health Development Agency; 2003.	Not a systematic review.
NHS Centre for Reviews and Dissemination. *A systematic review of interventions in the treatment and prevention of obesity*, Rep. No. CRD Report 10. Centre for Reviews and Dissemination (CRD), York; 1997.	Some studies may be relevant but there is not sufficient information for data extraction.
NHS Centre for Reviews and Dissemination. The prevention and treatment of childhood obesity. *Effective Health Care* 2002;7:12.	Some studies may be relevant but there is not sufficient information for data extraction.
Noakes M, Foster PR, Keogh JB, Clifton PM. Are meal replacements an effective strategy for treating obesity in adults with features of metabolic syndrome? *Asia Pacific Journal of Clinical Nutrition* 2004;13:S63.	Abstract only. Setting unclear.
O'Meara S, Glenny AM, Sheldon T, Melville A, Wilson C. Systematic review of the effectiveness of interventions used in the Management of obesity. *Journal of Human Nutrition and Dietetics* 1998;11:203–6.	Some studies may be relevant but there is not sufficient information for data extraction.
O'Reilly J, Carr L, West P. Cost effectiveness of meal replacement products in weight control. *International Journal of Obesity* 2004;28:S143.	Abstract only. Not non-clinical setting.
Powell C, Lavin J, Russell J, Barker M. Factors associated with successful weight loss and attendance at a commercial slimming group. *International Journal of Obesity* 2004;28:S144.	Abstract only. Insufficient detail.
Prochaska JO, Norcross JC, Fowler JL, Follick MJ, Abrams DB. Attendance and outcome in a work site weight control program: processes and stages of change as process and predictor variables. *Addictive Behavior* 1992;17:35–45.	Insufficient before and after data.

Pronk NP, Wing RR. Physical activity and long-term maintenance of weight loss. *Obesity Research* 1994;2, 587–99.	Not a primary study. Not a systematic review.
Ray CR. Effectiveness of a church-based nutrition intervention among African American women. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2004;64:4291.	Thesis not available from British Library.
Reed J, Van Vrancken C, Loftin M, Singley C, Udall J, Sothern M. Self-reported increases in physical activity in obese youth after a 10-week specialized moderate intensity exercise program. *Obesity Research* 2001;9(Suppl 3):O196.	Abstract only. Not non-clinical setting.
Reed B, Jackson J, Harborne J, Roberts R. Study to evaluate the effect of dietary advice and the role of exercise in obese women who are trying to lose weight. *Journal of Human Nutrition and Dietetics* 1999;12:61–70.	No control/comparison group.
Resnicow K, Yaroch AL, Davis A et al. GO GIRLS!: development of a community-based nutrition and physical activity program for overweight African-American adolescent females. *Journal of Nutrition Education* 1999;31:287–9.	Description of study. No results.
Resnicow K, Yaroch AL, Davis A et al. GO GIRLS!: results from a nutrition and physical activity program for low-income, overweight African American adolescent females. *Health Education and Behavior* 2000;27:616–31.	No control/comparison group.
Rinderknecht K, Smith C. Social cognitive theory in an after-school nutrition intervention for urban Native American youth. *Journal of Nutrition Education and Behavior* 2004;36:298–304.	No control/comparison group.
Robinson TN. Can a school-based intervention to reduce television use decrease adiposity in children in grades 3 and 4 ? *Western Journal of Medicine* 2000;173:40.	Not a primary study. Commentary.
Roudier MD, Tomblin BE, Nabi SF. Childhood obesity: school-based nutrition and exercise intervention. *Public Health Reports* (1994) 109, 179–80.	Not a primary study. Description of programme.
Rudolf MCJ. *WATCH IT: A community based programme for obese children and adolescents*. Draft report – unpublished.	Draft report- unpublished. No control/comparison group.
Sacher PM, Chadwick P, Wells JC, Williams JE, Cole TJ, Lawson MS. Assessing the acceptability and feasibility of the MEND Programme in a small group of obese 7–11-year-old children. *Journal of Human Nutrition and Dietetics* 2005;18:3–5.	No control/comparison group.
Sanders TA, Woolfe R, Rantzen E. Controlled evaluation of slimming diets: use of television for recruitment. *Lancet* 1990;336:918–20.	Follow-up less than 3 months.
Sbrocco T, Carter MM, Lewis EL et al. Church-based obesity treatment for African-American women improves adherence. *Ethnicity and Disease* 2005;15, 246–55.	Insufficient before and after data.
Scottish Intercollegiate Guidelines Network. *Obesity in Scotland: integrating prevention with weight management*. SIGN, Edinburgh; 1996.	Not a systematic review. Not non-clinical settings.
Scottish Intercollegiate Guidelines Network (2003) *Management of obesity in children and young people*. SIGN, Edinburgh; 2003.	Not a systematic review.
Seltzer CC, Mayer J. An effective weight control program in a public school system. *American Journal Public Health Nations Health* 1970;60:679–89.	Pre-1990 and not an RCT.
Sharpe PA. Community-based physical activity intervention. *Arthritis and Rheumatism* 2003;49:455–62.	Not a primary study. Not a systematic review.
Sherman JB, Alexander MA, Gomez D, Kim M, Marole P.	No control/comparison

Intervention program for obese school children. *Journal of Community Health Nursing* 1992;9:183–90.	group. Follow-up less than 3 months. No outcomes of interest. Insufficient before and after data.
Shick SM, Wing RR, Klem ML, McGuire MT, Hill JO, Seagle H. Persons successful at long-term weight loss and maintenance continue to consume a low-energy, low-fat diet. *Journal of the American Dietetic Association* 1998;98:408–13.	No control/comparison group. Insufficient before and after data.
Shigematsu R, Tanaka K, Ohshima Y, Mimura K-I. Water exercise as a prescription exercise for obese women. *Japanese Journal of Physical Fitness and Sports Medicine* 1996;45:179–87.	Full paper available in foreign language only.
Shintani TT, Hughes CK, Beckham S, O'Connor HK. Obesity and cardiovascular risk intervention through the ad libitum feeding of traditional Hawaiian diet. *American Journal of Clinical Nutrition* 1991;53:1647S–51.	No control/comparison group. Follow-up less than 3 months.
Shintani T, Beckham S, O'Connor HK, Hughes C, Sato A. The Waianae Diet Program: a culturally sensitive, community-based obesity and clinical intervention program for the Native Hawaiian population. *Hawaii Medical Journal* 1994;53:136–41.	No control/comparison group. Follow-up less than 3 months.
Singapore Association for the Study of Obesity. *Obesity*. Singapore Ministry of Health, Singapore; 2004.	Not a systematic review. Not non-clinical setting.
Slimming World, Greater Derby Primary Care Trust, Central Derby Primary Care Trust. *Tackling obesity in primary care: a feasibility study to assess the practicalities of working in partnership with the commercial slimming sector*. Slimming World, Alfreton, Derbyshire; 2004.	No control/comparison group. Insufficient before and after data.
Stenchever MA. Structured weight loss program helps achieve and maintain weight loss. *ACOG Clinical Review* 2003;8:12–3.	Not a primary study. Commentary.
Stewart AL, Verboncoeur CJ, McLellan BY et al. Physical activity outcomes of CHAMPS II: a physical activity promotion program for older adults. Journal of Gerontology A Biological Sciences and Medical Science 2001;56:M465–70.	Insufficient before and after data.
Story M. School-based approaches for preventing and treating obesity. *International Journal of Obesity* 1999;23: S43–51.	Not a systematic review.
Stunkard AJ, Brownell KD. Work-site treatment for obesity. *American Journal of Psychiatry* 1980;137:252–3.	Insufficient before and after data.
Symons LM, Luxmore J.The benefits of an ‘exercise on prescription programme’ for overweight patients. *Journal of Sports Science* 1998;16:24–5.	Abstract only. Setting unclear.
Tate D, Wing R, Winett RA. Development and evaluation of an internet behaviour therapy for weight loss. *Obesity Research* 1999;7:19S.	Abstract only. Insufficient detail.
Tate DF, Jackvony EH, Wing RR, Kudva YC. An internet behavioural counselling weight loss programme reduced weight and BMI in patients at risk of type 2 diabetes. *Evidence Based Medicine* 2003;8:181.	Not a primary study. Commentary.
Thiels C, Troop NA, Schmidt UH, Todd G, Treasure JL. Help for self-treatment [German]. *Nervenarzt* 1995;66:505–510.	Not a systematic review.
Thorogood M, Hillsdon M, Summerbell C. Lifestyle interventions for maintaining weight loss. In: *Clinical evidence*. BMJ, 2003: London.	Not a systematic review.
Thorogood M, Hillsdon M, Summerbell C. Lifestyle interventions for sustained weight loss. In: *Clinical evidence*. BMJ, 2003: London.	Not a systematic review.

Tod AM, Lacey A. Overweight and obesity: helping clients to take action. *British Journal of Community Nursing* 2004;9:59–66.	No control/comparison group. Follow-up less than 3 months. No outcomes of interest. Insufficient before and after data.
Tsai AG, Wadden TA. Systematic review: an evaluation of major commercial weight loss programs in the United States. *Annals of Internal Medicine* 2005;142:56–66.	Relevant individual studies were unpicked and included.
Walker LL, Gately PJ, Bewick BM, Hill AJ. Children's weight-loss camps: psychological benefit or jeopardy? *International Journal of Obesity and Related Metabolic Disorders* 2003;27: 748–54.	Follow-up less than 3 months.
Westenhoefer J, von Falck B, Stellfeldt A, Fintelmann S. Behavioural correlates of successful weight reduction over 3 y: results from the Lean Habits Study. *International Journal of Obesity and Related Metabolic Disorders* 2004; 28:334–5.	No control/comparison group.
White MA. Mediators of weight loss in an internet-based intervention for African-American adolescent girls. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2004;64:3546.	Thesis not available from British Library.
Wilcox S, Parra-Medina D. Physical activity interventions in primary care: review and analysis of effect sizes. *Medicine and Science in Sports and Exercise* 2001;33:S211.	Conference abstract. Not a systematic review. Not non-clinical settings. Not management of obesity.
Williams J, Sultan M. Evaluation of an Asian women's healthy eating and exercise group. *Journal of Human Nutrition and Dietetics* 1999;12:91–8.	No control/comparison group.
Williamson DF. The effectiveness of community-based health education trials for the control of obesity. *Progress in Obesity Research* 1996;7:331–335.	Not a systematic review. Not targeting overweight/obese populations.
Wing RR. Physical activity in the treatment of the adulthood overweight and obesity: current evidence and research issues. *Medicine and Science in Sports and Exercise* 1999;31: S547–52.	Not a systematic review. Not non-clinical settings.
Wing RR, Tate DF. Lifestyle changes to reduce obesity. *Current Opinion in Endocrinology and Diabetes* 2000;7:240–246.	Not a systematic review.
Winick C, Rothacker DQ, Norman RL. Four worksite weight loss programs with high-stress occupations using a meal replacement product. *Occupational Medicine (London)* 2002:52:25–30.	No control/comparison group.
Winkleby MA, Feldman HA, Murray DM. Joint analysis of three us community intervention trials for Reduction of cardiovascular disease risk. *Journal of Clinical Epidemiology* 1997;50:645–658.	Not a systematic review.
Wochenko CJ. Program evaluation of the TOPS Club, Inc, weight-loss program. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2002;63:2348.	Thesis not available from British Library.
Wong ML, Koh D, Lee MH, Fong YT. Two-year follow-up of a behavioural weight control programme for adolescents in Singapore: predictors of long-term weight loss. *Annals of the Academy of Medicine, Singapore* 1997;26:147–53.	Insufficient before and after data.
Zandee GL, Oermann MH. Effectiveness of contingency contracting: component of a worksite weight loss program. *AAOHN Journal* 1996;44:183–8.	Insufficient before and after data.

Excluded studies from update searches 1 December 2005

Anonymous. Intense diet, behavior, and physical activity intervention effective for obese children. *Journal of Family Practice* 2005;54(7):579.	Clinical setting.
Anonymous. Safety warning issued on slimming aids. *Pharmaceutical Journal* 2005;275(7368):360.	News item.
Bautista-Castano I, Doreste J, Serra-Majem L. Effectiveness of interventions in the prevention of childhood obesity. *European Journal of Epidemiology* 2004;19(7):617–622.	Prevention.
Beckham S, Bradley S, Washburn A. One health center's response to the obesity epidemic: an overview of three innovative, culturally appropriate, community-based strategies. *Hawaii Medical Journal* 2005;64(6):151–5.	Descriptive paper.
Carrel A, Meinen A, Garry C, Storandt R. Effects of nutrition education and exercise in obese children: the Ho-Chunk Youth Fitness Program. *Wisconsin Medical Journal* 2005;104(5):44–7.	Not a controlled study.
Fitzgibbon ML, Stolley MR, Ganschow P et al. Results of a faith-based weight loss intervention for black women. *Journal of the National Medical Association* 2005;97(10):1393–402.	Not a proper nonclinical setting. Participants included patients in a hospital as well as staff and visitors.
Gotthelf L, Tsai AG, Wadden TA. Commercial weight loss programs. *Annals of Internal Medicine* 2005;142(12 pt I):1023–5.	Letter.
Harrison RA, Roberts C, Elton PJ. Does primary care referral to an exercise programme increase physical activity one year later? A randomized controlled trial. *Journal of Public Health* 2005;27(1): 25–32.	Outcomes not reported separately for overweight participants.
Katz DL, O'Connell M, Yeh MC et al. Public health strategies for preventing and controlling overweight and obesity in school and worksite settings: a report on recommendations of the Task Force on Community Preventive Services. *Morbidity & Mortality Weekly Report Recommendations & Reports* 2005;54(RR-10):1–12.	Systematic review: Prevention and treatment synthesised together – tables of individual studies not available online to 2006.
Keogh JB, Clifton PM. The role of meal replacements in obesity treatment. *Obesity Reviews* 2005;6(3):229–34.	Not a systematic review.
LeCheminant JD, Jacobsen DJ, Hall MA, Donnelly JE. A comparison of meal replacements and medication in weight maintenance after weight loss. *Journal of the American College of Nutrition* 2005;24(5):347–53.	Clinical setting.
Mukherjee D. Comparison of the Atkins, Ornish, Weight Watchers, and Zone diets for weight loss and heart disease risk reduction: a randomized trial. *ACC Current Journal Review* 2005;14(4):19.	Commentary paper on excluded study.
Ornish D. Comparison of diets for weight loss and heart disease risk reduction.*Journal of the American Medical Association* 293;13:1589–90.	Letter.
Poston WSC, Haddock CK, Pinkston MM et al. Weight loss with meal replacement and meal replacement plus snacks: a randomized trial. *International Journal of Obesity* 2005;29(9): 1107–114.	Setting not the focus of this study. Counselling took place at the research centre.
Rooney BL, Gritt LR, Havens SJ, Mathiason MA, Clough EA Growing healthy families: family use of pedometers to increase physical activity and slow the rate of obesity. *Wisconsin Medical Journal* 2005;104(5):54–60.	Adult participants had co-morbidities. Data on children available separately but included children who were not overweight.
Rosser WW. Seeking the balance between individual and community-based nutritional interventions. *European Journal of Clinical Nutrition* 2005;59(Suppl. 1):S102–105.	Discussion paper.

Scholz GH, Flehmig G, Scholz M et al. Evaluation of the self-help programme 'I lose weight' weight loss, dietary pattern and acceptance in overweight subjects after a 1-year advisor-supported intervention [German]. *Ernahrungs-Umschau* 2005;52(6): 226–31, 214.	German language paper.
Strong WB, Malina RM, Blimkie CJR et al. Evidence based physical activity for school-age youth. *Journal of Pediatrics* 2005;146(6):732–7.	Systematic review – details of setting not provided on individual studies; treatment and prevention not synthesised separately.
Wald ER, Ewing L, Cluss P, Goldstrohm S, Cipriani L, Colborn K. Establishing a family-based intervention for overweight children in pediatric practice. Annals of Family Medicine 2005;3(Suppl 2): S45–7.	Clinical setting.

Review of interventions in a non-clinical UK setting for people with co-morbidities

The GDG considered that due to the lack of evidence identified, no specific recommendations could be made.

Evidence statement(s)

Evidence statement	Grading
A combination of home and clinic visits (approximately seven contacts over a period of 12 months) can be effective for weight loss (approximately 1.5 kg at 12 months) in people with diabetes	1–

Evidence review

This review aims to provide evidence from the UK on the effectiveness of an intervention delivered in a *non-clinical setting*, designed to address the management of overweight or obesity in adults and children with comorbidities. The inclusion criteria were as follows:

- Interventions

  Any intervention which targeted the management of obesity and aimed to improve provider practice or patient outcomes or target the individual (such as diet, PA, etc.). If the intervention was primarily aimed at the management of the comorbidity, not weight loss, this was excluded. Only studies conducted in the UK were included.

- Setting

  Only those interventions conducted in a non-clinical setting were included. Other settings are covered in other evidence reviews.

- Participants

  All qualified healthcare professionals and lay people involved in the management of obesity and/or all individuals classified as overweight or obese (mean initial BMI ≥28 kg/m^2 for adults).Overweight or obese adults and children had to have at least one identified comorbidity.

- Outcomes

  Studies reporting weight, diet or PA outcomes were included provided that baseline and follow-up data were provided.

- Length of follow-up
  At least 12 weeks duration. Length of follow-up was measured from commencement of the intervention.

- Study design
  Only studies with a control or comparison group were included.

Excluded studies are listed below. Due to time constraints, a staged approach was adopted. We searched the York CRD database on non-clinical settings for studies focussing on people with key comorbidities (diabetes, hypertension and dyslipidaemia) and also for any studies based in the UK. These were scanned for inclusion using the criteria as above. The CRD review on non-clinical settings was cross-referenced, as were other relevant reviews.

Interventions for the management of obesity and overweight in children

No relevant studies were identified for children.

Interventions targeted at individuals (adults)

One study meeting our inclusion criteria was found (Manning et al. 1998; Jakicic et al. 1999). However, some methodological issues were identified (see Evidence table for details). Manning and colleagues compared the effectiveness of clinic visits, BT and home visits on weight loss and glycaemic control in people with diabetes. No significant differences were seen, although the people who had a combination of home and clinic visits did appear to have some success in losing weight (see below).

Evidence tables

Weight loss

Manning 1995 and 1998 RCT

Aim
To evaluate the effectiveness of regular dietetic advice given in the clinic, at both the clinic and at home, BT and dexfenfluramine.

Participants
Adults aged 16 to 70 years, with insulin dependent and non-insulin dependent diabetes, who were overweight (BMI 28–45 kg/m^2).
Mean (SD) age (years): 56.4 (10.1) clinic (n = 32); 58.2 (9.2) BT (n = 36), 55 (12.1) home (n = 29), 53.3 (12.4) routine. Mean (SD) BMI (kg/m^2): 31.8 (3.5) clinic, 32.3 (5.2) BT, 31.8 (3.6) home, 32.0 (3.4) routine.

Intervention
Clinic: Individual dietetic consultations at the Diabetes Centre at 6 weekly intervals for the first 6 months then 2 monthly for the rest of the year. Diet was 50–55% energy from carbohydrate, 30–35% energy from fat, 10–15% energy from protein. Energy restriction according to history, weight, sex, age and PA.
BT: Physiotherapist-, clinical psychologist- and dietitian-led. Groups of up to ten people at fortnightly intervals for 3 months, then 2 monthly intervals for rest of the year. Diet as above.
Home: Individual dietetic consultations at the Diabetes Centre and home visits at 6 weekly intervals for the first 6 months then 2 monthly for the rest of the year. First and fourth visits were at home, with all other at the Diabetes Centre. Diet as above.

Comparison
Routine care: Access to dietitian if requested or referred (within service level of 5 hours per week dietetic advice available at the practice at that time) and had dietetic advice when diagnosed.

Length of follow-up
4 years

Results

Weight change (kg)	**Clinic (n = 37)**	**BT (n = 38)**	**Home (n = 35)**	**Routine (n = 54)**
3 months	–1.59	–1.20	–1.69	N/r
6 months	–1.70	–1.21	–1.30	N/r
12 months	–1.21 (–2.33 reported for n = 34 in 1998 paper)	–1.82 (–3.41 reported for n = 36 in 1998 paper)	–1.14 (–1.59 reported for n = 29 in 1998 paper)	+1.00
48 months	–1.20 (n = 34)	–2.42	–1.00	+0.35

No significant differences were seen either within or between groups at any time point. (Only significant differences were seen in the drug group – not reported here.) All groups were reported as being better than routine care up to 12 months (1995 paper).

% of people who achieved weight loss of ≥3 kg	**Clinic**	**BT**	**Home**	**Routine**
12 months	16	22	21	7
48 months	16	33	38	24

[Where is asterix in table? – deleted and added to comments below]
Significant difference seen between the home visits and the clinic visits ($p \le 0.05$).

Quality and comments
Only the results for clinic based, clinic and home, and BT are reported here.
SDs calculated from confidence intervals (CI).
No details of randomisation. (Limited) baseline assessment done, and no significant differences. Blinded assessment not clear. ITT analysis done. Results differed between papers.

Sponsor details
Servier Laboratories.

Other outcomes

Manning 1995 and 1998 RCT					
Results	Change in HbA_{1c}	**Clinic**	**BT**	**Home**	**Routine**
	Baseline	7.60 (7.70 from 1998 paper)	6.04 (5.97 from 1998 paper)	6.59 (6.72 from 1998 paper)	7.02
	3 months	–0.36	–0.05	–0.34	+0.54
	6 months	–0.39	+0.11	+0.02	+0.18
	12 months	–0.01	+0.32	+0.34	+0.96
	48 months (from 1998 paper with different baseline)	+0.29	+0.82	+1.17	+0.72
	Initial HbA_{1c} level reported as being no different, but Clinic group appears to be higher. No significant reductions were seen or maintained. At 12 months, the majority of people had no change to their medication, with 5.1% of the clinic group, 18.4% BT, 25.7% home and 5.3% routine care having a reduction in diabetic medication.				
Quality and comments	–				

Harms

Manning 1995 and 1998 RCT	
Harms	None reported.
Quality and comments	–

Generalisability

Manning 1995 and 1998 RCT	
Country and setting	UK (Scotland). Outpatient diabetes clinic.
Participants (inc/exc)	Included if aged 16–70 years, had diagnosis of diabetes, BMI between 28 and 45 kg/m^2. Excluded if lost >3 kg during previous 12 months. Also pregnant women, unstable thyroid, known psychiatric disorders, taking oral corticosteroids.
Recruitment	Selected from clinic patient records.
Randomisation	No details.
Intervention (mode and intensity)	Clinic: Individual dietetic consultations at the Diabetes Centre at 6 weekly intervals for the first 6 months then 2 monthly for the rest of the year. BT: Physiotherapist and clinical psychologist and dietitian led. Groups of up to ten people at fortnightly intervals for 3 months, then 2 monthly intervals for rest of the year. Home: Individual dietetic consultations at the Diabetes Centre and home visits at 6-weekly intervals for the first 6 months then 2-monthly for the rest of the year. First and fourth visits were at home, with all other at the Diabetes Centre. .
Duration of active intervention	12 months.
Comparison (mode and intensity)	Routine care: Access to dietitian if requested or referred (within service level of 5 hours per week dietetic advice available at the practice at that time) and had dietetic advice when diagnosed.
Delivery of intervention/comparison (who)	See above.
Dropout rates	At 12 months, 39% clinic, 43% BT, 29% home and not clear routine.
Treatment of dropouts (return to baseline, or last measurement?)	No details.

Excluded studies

Study	Source	Reason
Cheyette C. Weight management programme for type 2 diabetes patients on insulin. *Journal of Diabetes Nursing* 2004;8:52–6.	CRD searches	Intervention delivered in a hospital setting.
Gamsu DS, Sutton MS, Bennett L, Ward JD. The development of a psychoeducational group intervention for overweight women with type 2 diabetes mellitus: a service evaluation. *Practical Diabetes International* 2002;19:43–50.	CRD searches	Setting not clear – described as a new service, so assumed to be within clinical setting.
Gidlow C, Johnston LH, Crone D, James D. Attendance of exercise referral schemes in the UK: a systematic review. *Health Education Journal* 2005;64(2):168–86.	CRD searches	Review – cross referenced. Only one study relevant, and excluded as not only people who were overweight (see Excluded from CRD review).
Hampshire M. For good measure. *Nursing Standard* 2004;18:18–20.	CRD searches	Discussion article on Moore and Counterweight studies.
Harland PSEG, Watson MJ, Ashworth L. The effect of metabolic programming on atherosclerosis and obesity risk factors in UK adolescents living in poor socioeconomic areas. *Annals of the New York Academy of Sciences* 1997;817:361–4.	CRD searches	Not intervention evaluation.
Hughes J, Todorovic V, Kemp H. 'The Sugar Buddies': An intervention programme for 'obese' patients with poorly controlled diabetes. *Journal of Human Nutrition and Dietetics* 1999;12(Suppl 1):71–78.	CRD searches	Setting not clear, but appears to be in a clinical setting.
Mengham LH, Morris BF, Palmer CR, White AJS. Is intensive dietetic intervention effective for overweight patients with diabetes mellitus? A randomised controlled study in a general practice. *Practical Diabetes International* 1999;16:5–8.	CRD searches	Intervention delivered in primary care setting.
Murphy C, Simkins M, Helowicz R. Diabetes exercise project. *Journal of Human Nutrition and Dietetics* 1999;12(Suppl 1):79–90,.	CRD searches	Not only people who were overweight.
Rose G, Tunstall-Pedoe HD, Heller RF. UK heart disease prevention project: incidence and mortality results. *Lancet* 1983;1(8333):1062–6.	CRD searches	Not people who were overweight.
Williams K, Prevost AT, Griffin S et al. The ProActive trial protocol – a randomised controlled trial of the efficacy of a family-based, domiciliary intervention programme to increase physical activity among individuals at high risk of diabetes. *BMC Public Health* 4:48, 2004. Wareham DN. *The development of a family-based intervention to prevent obesity in a high risk group*. Anonymous National; 2004.	CRD searches	Protocol only, no publication of results found.

Reference list

Jakicic JM, Winters C, Lang W, Wing RR. Effects of intermittent exercise and use of home exercise equipment on adherence, weight loss, and fitness in overweight women: a randomized trial. *Journal of the American Medical Association* 1999;282:1554–60.

Manning RM, Jung RT, Leese GP, Newton RW. The comparison of four weight reduction strategies aimed at overweight patients with diabetes mellitus: four-year follow-up. *Diabetic Medicine* 1998;15:497–502.

Appendix 13

BMI	Body Mass Index
BPD	Biliopancreatic Diversion
BT	Behaviour Therapy
CBCL	Child Behaviour Checklist
CBT	Cognitive Behavioural Therapy
CCT	Controlled Non-randomised Trial
CDI	Children’s Depression Inventory
ChEAT	Children’s Eating Attitudes Test
CHO	Carbohydrate
DBNQ	Dutch Eating Disorder Questionnaire
DS	Duodenal Switch
EDD	Endothelium-Dependent Dilation
EDI	Eating Disorder Inventory
FP	Family Paediatrician
GI	Glycaemic Index
GSI	Global Severity Index
HH	Healthy Habits
IBW	Ideal Body Weight
ITT	Intention To Treat
KEDS	Kid’s Eating Disorder Survey
LAGB	Laparoscopic Adjustable Gastric Banding
NIH	National Institutes for Health
PA	Physical Activity
PCSC	Perceived Competence Scale for Children
PSMF	Protein-Sparing Modified Fast
RCT	Randomised Controlled Trial
Roux-en-Y Gastric Bypass	RYGBP
SCL-90	Symptom Checklist-90
SPPC	Self-Perception Profile for Children

STAIC	State Trait Anxiety Inventory for Children
TC	Typical Care
VBG	Vertical Banded Gastroplasty
WHO	World Health Organization

Appendix 14

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Contents

Appendix 13

Children

1 Evidence tables

1.1 Comparison of guidelines included in the syntheses

COMPARISON OF SCOPE AND CONTENT	
Objectives and scope	
AAP (2003)	• To propose strategies to foster prevention and early identification of overweight and obesity in children
AHA (2005) **New**	• To examine the patho-physiology and epidemiology of overweight in children and adolescents • To present updated information on the adverse outcomes associated with childhood overweight and discuss approaches for the prevention and treatment of overweight in young individuals
RNAO (2005)	• To provide best practice guidelines focused on the primary prevention of obesity in children from birth to age 18 years • To provide direction for nurses who work with children and families across diverse practice settings and at population, family, and/or individual levels **Note**: Treatment of obesity is not within the scope of this guideline.
SIGN (2003)	• To provide recommendations based on current evidence for best practice in the management of obesity in children and young people, up to the age of 18 years • To review the definition of childhood obesity and information on prevalence of childhood obesity in the UK and recent trends in the prevalence of obesity • To identify the immediate consequences of obesity in childhood and possible consequences in adulthood • To identify subgroups of children at high risk for developing obesity • To review preventive interventions for childhood obesity • To discuss the treatment of childhood obesity and the goals of therapy, particularly management in the community and management beyond primary care, including advice on healthy eating • To make recommendations for research for systematic evaluation of childhood obesity **Note**: Appraising the role of screening for obesity in children was not within the remit of this guideline.

SINGAPORE MOH (2004)	• To assist health care professionals who have a role in managing overweight or obese patients • To provide current evidence-based clinical practice recommendations on various aspects of obesity management found across various medical disciplines • To provide a framework to assist doctors in the management of overweight and obesity without restricting the physician's individual judgment • To provide a review of the various medical, surgical, and ancillary intervention modalities in the management of obesity • To aid primary care physicians in basic management of obesity and subsequent referrals to specialists for more resistant cases
USPSTF (2005) **New**	• To summarise the US Preventive Services Task Force (USPSTF) recommendations on screening for overweight in children and adolescents and the supporting scientific evidence
Target population	
AAP (2003)	• USA • Children
AHA (2005) **New**	• USA • Infants, children and adolescents in the general population *(prevention)* • Overweight or obese children and adolescents with or without co morbidities *(prevention and treatment)*
RNAO (2005)	• Canada • Children from birth to age 18 years
SIGN (2003)	• Scotland • Children and young people up to the age of 18 years who are suspected of being obese
SINGAPORE MOH (2004)	• Singapore • Children and adolescents who are obese or overweight, or who are at risk of obesity **Note**: The guideline also targets adults who are obese or overweight or who are at risk for obesity. This target group is addressed in a companion synthesis.

USPSTF (2005) **New**	- USA - Asymptomatic children and adolescents (aged 6 to 19 years) seen in primary care
Intended users	
AAP (2003)	Healthcare Providers; Physicians
AHA (2005) **New**	Healthcare Providers; Physicians
RNAO (2005)	Advanced Practice Nurses; Nurses
SIGN (2003)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physician Assistants; Physicians; Psychologists/Non-physician Behavioural Health Clinicians
SINGAPORE MOH (2004)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physician Assistants; Psychologists/Non-physician Behavioural Health Clinicians; Public Health Departments; Respiratory Care Practitioners
USPSTF (2005) **New**	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Healthcare Providers; Health Plans; Managed Care Organisations; Nurses; Physician Assistants; Physicians
Interventions and practices considered	
AAP (2003)	**Assessment** 1. Body mass index (BMI) percentile (for age and sex) 2. Routine assessment of eating and PA patterns for early recognition 3. Assessment of risk factors (including genetic, biological, psychological, socio-economic and environmental factors) **Prevention** 1. Promoting healthy eating patterns and breastfeeding, encouraging PA, and limiting television and video time 2. Parent and caregiver involvement 3. Recognising and monitoring changes in obesity-associated risk factors for adult chronic disease **Note**: Physician advocacy interventions directed at parents, teachers, and policy makers/legislators, etc., are also provided.

AHA (2005) **New**	**Assessment** 1. Evaluation of growth, including height, weight, and BMI percentile for age and sex 2. Medical evaluation for co morbidities, including medical history, blood pressure, physical assessment for orthopaedic abnormalities, laboratory studies, as indicated, and echocardiography **Prevention** *Population-specific approaches* 1. Breastfeeding (infants) 2. Establishing behaviour targets (toddlers) • increased consumption of fruits and vegetables • increased consumption of fibre-containing grain products • switching from full-fat to 1% or fat-free dairy products after 2 years of age • preparing and eating family meals at home • increasing daily physical activity (PA) • limiting sedentary time 3. Theory-based interventions including classroom curricula, physical education curricula, changes in school meals, vending machines, cafeterias and after-school programmes (school-age children and adolescents) 4. Implementation of tailored strategies that are well matched to the social and cultural contexts of children in ethnic minority populations *Setting-specific approaches* 1. Targeting institutions that provide access to groups of children (e.g. schools, Head Start programmes, healthcare settings, homes, community and government programmes) 2. Community-wide approaches including coordinated interventions in multiple settings 3. Providing social and physical environments where healthful choices are available **Treatment** 1. Age-specific dietary modification 2. PA (30–60 min of regular exercise daily) 3. Pharmacological treatment 4. Surgical treatment (reserved for full-grown adolescents with the severest obesity-related morbidity)

RNAO (2005)	**Assessment** 1. Lifestyle history, including discussing/documenting dietary and PA patterns, and identifying individual and family risk factors for childhood obesity 2. Monitoring growth, including accurate height and weight measurement 3. Calculating and plotting BMI percentile, and monitoring for changes over time **Prevention** 1. Promotion of healthy eating and PA at population, community, family, and individual levels 2. Support of exclusive breastfeeding until 6 months of age 3. Referral to allied healthcare professionals as needed **Note**: Other interventions and practices addressed in the guideline but not considered here include recommendations for nursing academic and continuing education programmes, research studies and implementation planning.
SIGN (2003)	**Assessment and preventive counselling** 1. BMI percentile (for age and sex) 2. Recognition of risk factors for obesity, including parental obesity 3. School, family, and societal interventions for obesity prevention **Treatment/management** 1. Healthier eating 2. Increased habitual PA (e.g. brisk walking) to a minimum of 30 min/day 3. Reduction in physical inactivity (e.g. watching television and playing computer games) to <2 hours/day or 14 hours/week 4. Weight maintenance 5. Referral to hospital or community paediatric consultants 6. Modest weight loss of no more than 0.5 kg/month* *For obese children >7 years old who can demonstrate prolonged weight maintenance and who are cared for by secondary services
SINGAPORE MOH (2004)	**Assessment** 1. Full clinical evaluation including BMI percentile (for age and sex) 2. Consideration of predisposing risk factors and secondary causes

	of obesity **Management of obesity in children and adolescents** 1. Nutritionally balanced diet designed to meet growth requirement 2. Age-appropriate PA 3. Weight loss programmes that include BT (BT) 4. Family involvement in weight loss efforts 5. Bariatric surgery (only in high-risk adolescents) **Note**: Interventions for assessment and management of overweight and obesity in adults are also considered in this guideline. These interventions are addressed in another synthesis.
USPSTF (2005) **New**	Routine screening for overweight in children and adolescents using BMI percentile (not specifically recommended). The evidence for effectiveness of behavioural, pharmacological and surgical interventions is discussed.

1.2 Measures other than BMI

Detailed evidence tables not included, as narrative describes the studies in appropriate detail.

1.3 Measures and morbidity in ethnic populations[1]

Detailed evidence tables not included, as narrative describes the studies in appropriate detail.

1.4 Lifestyle interventions

1.4.1 Interventions emphasising a combination of diet and/or physical activity and behavioural modification component

Epstein 1995 (in Cochrane) RCT [946]	
Aim	To assess the effects of increasing PA vs. decreasing sedentary behaviours.
Country and setting	USA. Setting unclear. Probably outpatient clinic at University medical school.
Participants	Sixty-one families, with children ranging from 8 to 12 years. Weight entry criteria between 20 and 100% overweight. Neither parent greater than 100% overweight, one parent willing to attend treatment meetings, no family member on an alternative weight-control programme, no child or parent having current psychiatric problems, and no medical conditions preventing exercise. Mean weight on entry: 51.8% overweight for height.

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[1] Evidence tables only done for UK studies.

Recruitment	Radio announcements, television commercials, posters, and referred by physicians and nurses.
Intervention	Groups: 1) focus on a reduction in sedentary behaviours (sedentary); 2) focus on an increase in PA (exercise); and 3) focus on a reduction in sedentary behaviours and an increase in PA (combined). Diet: the traffic light diet[2] was prescribed to the subjects. Activity: subjects in the exercise group were reinforced for increasing PA, and subjects in the combined group were reinforced for both decreasing their sedentary activity and increasing their PA. Sedentary behaviour was to involve a decrease from a goal of 35 hours or less per week of the targeted sedentary activities at level 1 to 15 hours or less per week at level 5, decreasing in 5 hour increments across the five levels. PA goals involved an increase from a goal of 30 points per week at level 1 to a goal at level 5 of 150 points per week, with level goals increasing in 30-point increments. Behavioural principles: subjects received a personalised system of instruction, self-monitoring, stimulus control and reinforcement.
Delivery of intervention	Not clear.
Control	Three treatment groups.
Length of follow-up	1 year.
Results (4 month treatment and 1 year follow)	Three comparisons: for the first comparison (decreased sedentary behaviours group vs. increased exercise and decreased sedentary behaviours [combined] group), the decreased sedentary behaviours group had a greater decrease in percentage overweight than did the combined group (–18.7 [sedentary] vs. –10.3% [combined]). Post hoc tests showed significant differences ($p < 0.05$) in percentage overweight for children in the sedentary group vs. children in the combined group at 1 year. For the second comparison (decreased sedentary behaviours group vs. the increased exercise group), the decreased sedentary behaviours group had a greater reduction in percentage overweight than did the exercise group (–18.7 [sedentary] vs. –8.7% [exercise]). The difference in percentage overweight between the groups was statistically significant.

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[2] The majority of the studies from Epstein et al (which are extensively used as evidence throughout interventions to treat childhood obesity) are based on the traffic light diet. This is a energy-based food-exchange system. Foods are divided into five groups (fruits and vegetables, grains, proteins, dairy and other foods) and the foods in each group are colour coded according to nutrient density: green for ‘go’, yellow for ‘eat with care’ and red for ‘stop’. Green foods are foods containing <20 kcal (84 kJ) per serving, yellow foods are the staple of the diet and provide most of the basic nutrition, and red foods are those foods high in fat and simple carbohydrates. All sweets and sugared beverages are classified as red foods. Families are then instructed to ‘count calories’ and cannot have more than four red foods per week.

	For the third comparison (increased exercise group vs. the combined group), after 1 year, percentage overweight had decreased in both groups (–10.3 [combined], –8.7 [increased exercise]).
Other outcomes	Child fitness improved significantly over time ($p = 0.011$), with no differential changes by group ($p > 0.05$). Fitness increased from baseline to both 4 and 12 months. Significant treatment effect was observed for child preference of high intensity activities ($p = 0.02$), with children in the sedentary group increasing preferences more than children in the exercise group ($p = 0.004$). Child energy intake estimated from habit books was significantly different across the groups after 4 months of treatment ($p < 0.001$), with significantly greater intake per day ($p < 0.001$) for the exercise vs. combined or sedentary groups.
Dropout rates	9.8%
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only data from those who completed treatment. Unclear.
Quality and comments	Dropouts 9.8%. Blinding unclear. Random allocation not described.

Epstein 1985a (in Cochrane) RCT [925]	
Aim	To assess the effectiveness of lifestyle exercise vs. programmed aerobic exercise and low-intensity callisthenics for the long-term treatment of childhood obesity.
Country and setting	USA. Unclear nature of setting.
Participants	Obese parents and children from 41 families were selected for participation in the study. Entry requirements included: 1) child between the ages of 8 and 12 years; 2) child and at least one participating parent >20% over ideal weight for height; 3) parent and child showing no problems that would interfere with regular exercise.
Recruitment	Unclear.
Intervention (8-week treatment followed by 10-month maintenance and 12- and 24-months follow-up)	Three groups: aerobic exercise group ($n = 13$); lifestyle exercise group ($n = 12$); and the callisthenics group ($n = 10$). The aerobic exercise consisted of a walk, run, bicycle or swim programme, based on family's preference, three times per week beginning at 1 mile (1.6 km) of walking or running, 2 miles (3.2 km) of bicycling or 0.25 mile (0.4 km) of swimming, and advancing in regular intervals up to 3 miles (4.8 km) of running or walking, 6 miles (9.7 km) of bicycling, or 0.75 miles (1.2 km) of swimming. All participants were

	trained to exercise at 60–70% of their age-adjusted maximal heart rate. The lifestyle exercise was designed to be isoenergetic to the aerobic exercise, allowing participants to choose from a range of exercises, although they were not instructed to exercise at any specific intensity. As for example, while the aerobic subjects would run for 1 mile (1.6 km) in the evening at aerobic intensity, the lifestyle subjects could walk 0.5 miles (0.8 km) back and forth from school. For the callisthenics programme, participants performed 6 to 12 callisthenics per week. The expenditure for the six most intense exercises done at the maximal number of repetitions was approximately one-third the expenditure for the first level of aerobic or lifestyle exercise. Participants were instructed with four behavioural components: self-monitoring, modelling, contingency contracting and parent management, and given the traffic light diet[3], a 1200 kcal (5.20 MJ) diet that provides a colour-coded food reference guide that includes energy content per serving.
Delivery of intervention	Unclear.
Control	Not reported.
Length of follow-up	Up to 24 months.
Results	For the first comparison (the aerobic exercise group vs. the lifestyle exercise group), statistically significant decreases in percentage overweight were observed for both groups during the year of the treatment, (at 6 and 12 months). Despite this, in the following year of observation, children in the lifestyle group maintained their weight change, while children in the aerobic exercise group gained significant amounts of weight: aerobic exercise group percentage overweight 47.8 (SD 15.2) at baseline, 31.5 (SD 15.4) at 12 months 41.0 (SD 17.5) at 24 months; lifestyle exercise group percentage overweight 48.3 (SD 17.2) at baseline, to 32.2 (SD 21.3) at 12 months, 30.3 (SD 24.3) at 24 months. After 24 months the lifestyle exercise group had significantly lower ($p < 0.05$) percentage overweight than the aerobic group. For the second comparison (aerobic exercise vs. the callisthenics group) significant decreases in percentage overweight from baseline were observed for both groups during the year of treatment (at 2, 6 and 12 months). During the following year of observation, children in both groups gained significant amounts of weight: aerobic exercise group percentage overweight 47.8 (SD 15.2) at baseline, 31.5 (SD 15.4) at 12 months, 41.0 (SD 17.5) at 24 months; callisthenics group percentage overweight 48.0 (SD 23.2) at baseline, 30.5 (SD 26.0) at 12 months and 40.8 (SD 27.0) at 24 months. After 6 and 24 months the difference in percentage

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[3] See Glossary

	overweight between the aerobic group and the callisthenics group was not significant. In third comparison (lifestyle exercise vs. the callisthenics group), significant decreases in percentage overweight from baseline were observed for both groups during the year of treatment (at 2, 6 and 12 months): lifestyle exercise group percentage overweight 48.3 (SD 17.2) at baseline, 32.2 (SD 21.3) at 12 months, and 30.3 (SD 24.3) at 24 months; callisthenics group percentage overweight 48.0 (SD 23.2) at baseline, 30.5 (SD 26.0) at 12 months and 40.8 (SD 27.0) at 24 months. After 24 months the difference in percentage overweight between the lifestyle exercise group (large reduction in sedentary behaviours) and the callisthenics group was significant ($p < 0.05$). At 24 months, the lifestyle group had maintained relative weight changes while the callisthenics group had returned to baseline levels.
Other outcomes	No significant improvements in fitness were observed for children after 2 months. After 6 months children in the lifestyle group showed significant ($p < 0.05$) improvement in fitness from pre to 6 months, but they returned to baseline levels of fitness at 1 year. Children in the aerobic exercise group were the only subjects to show significant ($p < 0.05$) effects at 1 year. No changes in fitness were observed for children in the callisthenics group. Children showed significantly improved eating behaviour ($p < 0.001$) from pre to 6 months and 1 year, with no differences across groups. The relationship between parent and child relative weight changes increased across time, with $p < 0.10$ from 0–6 months, $p < 0.01$ from months 6 to 12, and $p < 0.01$from months 12 to 36.
Dropout rates	14.6%
Treatment of dropouts (return to baseline, or last measurement?)	Only data for those who finished treatment and follow-up.
Quality and comments	Dropout rate 14.6%. Blinding unclear. Random allocation not described. Absence of adherence data beyond the initial 8 weeks.

Epstein 2000 (in Cochrane) RCT [898]	
Aim	To compare the influence of targeting decreases in sedentary behaviour vs. increases in PA in the treatment of obesity in children.
Country and setting	USA. Childhood obesity research clinic.
Participants	Ninety obese 8–12-year-old children and their parents were

	recruited in two cohorts that began 1 year apart. Children had to be between 20 and 100% overweight, neither parents more than 100% overweight, one parent willing to attend treatment meetings, no parent or child with current psychiatric problems, and no dietary or exercise restrictions on the participating parent or child.
Recruitment	Through physician referrals, posters, and newspaper and television advertisements.
Intervention	Families were randomised to four groups that varied the targeted behaviours (sedentary behaviours vs. PA. Low and high doses for the decrease sedentary or increase PA groups were 10 or 20 hours/week of targeted sedentary behaviours, or the equivalent energy expenditure of 16.1 or 32.2 km/week, respectively. The 6-month treatment included 16 weekly meetings, followed by two biweekly and two monthly meetings. Families were followed up. Families received parent and child workbooks, which included introduction to weight control and self-monitoring, the traffic light diet, the specific activity programme, behaviour change techniques, and maintenance of behaviour change. At treatment meetings, families met with an individual therapist for 15 to 30 min, and they attended separate 30 min parent and child group meetings. Parents and children were taught positive reinforcement techniques including praise for targeted behaviours and reciprocal contracts in which parents and children set goals and reinforcers to be provided by the parent based on meeting the goal. Participants assigned to the increase PA group were reinforced for increasing PAs in addition to those enrolled at the beginning of the programme. Participants assigned to the decrease sedentary activity group were reinforced for reducing sedentary behaviours. Not all sedentary activities were targeted, allowing participants to substitute non-targeted sedentary activities for targeted ones.
Delivery of intervention	Individual therapists.
Control	Not reported.
Length of follow-up	2 years.
Results (6-month treatment and 2-year follow-up)	Three comparisons were made. The first was decreasing sedentary behaviours vs. increasing PA. Results showed that targeting decreased sedentary behaviour or increased PA was associated with significant decreases in percentage overweight, body fat and improved aerobic fitness. In the low dose increased PA group (*n* = 18), the percentage overweight decrease from baseline was –25.6 (SD 8.1) at 6 months and –12.4 (SD 13.3) at 24 months. In the high dose increased PA group (*n* = 19) the values were –26.4 (SD 10.5) at 6 months and –13.2 (SD 16.4) at 24 months. In the decreased sedentary behaviour group the differences in percentage overweight from baseline were –22.4 (SD 12.6) (low dose, *n* = 19),

	–27.4 (SD 10.7) (high dose, *n* = 20) at 6 months and –11.6 (SD 21.9) (low dose), –14.3 (SD 16.9) (high dose) at 24 months. Both the decreased sedentary behaviour groups and the increased PA groups showed similar decreases in percentage overweight but the differences were not statistically significant. The second comparison was high vs. low doses of increased PA. Both groups showed significant decreases in percentage overweight from baseline to 6 and 24 months but the differences between the high and low dose increased PA groups were not statistically significant. The last comparison was high vs. low doses of reducing sedentary behaviours. Results were similar to increasing PA.
Other outcomes	Physical work capacity improved significantly, with increases of 33% ($p < 0.001$) from baseline to 6 months, and an increase of 55% from 6 months to 24 months ($p < 0.001$). A significant increase in percentage of time being active was observed from baseline to 2 years ($p < 0.05$). Targeted sedentary behaviours showed a significant decrease from baseline at 6 ($p < 0.001$) and 24 ($p < 0.05$) months
Dropout rates	15.5%
Treatment of dropouts (return to baseline, or last measurement?)	Analyses were conducted based on the subjects who attended the follow-up measurements, as well as intention to treat (ITT) analyses.
Quality and comments	Dropouts 15.5%. Blinding unclear. Random allocation stratified by gender and degree of child and parent obesity. Financial deposit of US$75 returned dependent on completion of intervention and families paid US$50 for attending the 24-month follow-up.

Epstein 1985b (in Cochrane) RCT [927]	
Aim	To evaluate the effects of adding exercise to diet for weight control in obese children.
Country and setting	USA.
Participants	Girls between the ages of 8 and 12 years. Inclusion criteria were: 1) child with at least 20% over her ideal weight for height and age; 2) absence of medical problems that would contraindicate weight loss, exercise or fitness testing; and 3) at least one parent willing to participate in the programme.
Recruitment	By physician and school nurse referral and in response to media coverage.
Intervention (8-week treatment followed by 10-month	Twenty obese girls distributed in two groups: diet and exercise (group 1) and diet (group 2). All families were provided with an intensive 8-week treatment

maintenance and 12-months follow-up)	programme followed by ten monthly maintenance sessions. Parents and children met separately for treatment sessions. Children in group 1 met for their exercise programme an additional three mornings per week during the initial 6 weeks of treatment. The two groups were given the same information on diet, nutrition and behaviour management techniques. For the diet, the traffic light diet was used, with a maximum of 1200 kcal (5.02 MJ) and a minimum of 900 kcal (3.77 MJ). Regarding PA, children in group 1 received an aerobic exercise programme designed to increase energy expenditure, During the first 6 weeks children met three mornings per week for sessions that included 10 min of stationary aerobic exercise, warm-up games and a 3 mile (4.8 km) walk or run. During the maintenance phase, parents were instructed to walk 3 miles (4.8 km) with their children three times per week. Both groups received behavioural methods such as: self-monitoring, praise and modelling, therapist contact, contracting and measurement.
Delivery of intervention	Therapists.
Control	Not reported.
Length of follow-up	Up to 12 months.
Results	Statistically significant decreases from baseline weight, and in percentage overweight, were observed for both groups during the year of treatment. Percentage overweight in the diet plus exercise group decreased from 48.0 (SD 23.2) at baseline to 20.5 (SD 22.6) at 6 months and after 12 months was 22.6 (SD 29.3). In the diet only group, percentage overweight was 48.1(SD 17.6) at baseline, 29.3 (SD 22.3) at 6 months and 29.4 (SD 22.5) at 12 months. The differences in percentage overweight between the groups were statistically significant ($p < 0.05$) at 6 months but not at 12 months.
Other outcomes	Fitness showed improvements for children in group 1 from 0 to 2 months ($p < 0.05$), improvement maintained at 6 months ($p < 0.05$) and further improvement from 6 to 12 months. Children in group 2 showed no significant changes from baseline levels. The groups differed significantly ($p < 0.01$) in fitness at 1 year. The Leisure Time Activity Survey showed significant differences only for the medium activity level from baseline to 6 months ($p < 0.01$), which included the exercise prescribed for the walking programme. The levels for children in the exercise group went from 45 (SD 29.9) to 145.5 (59.6), whilst those for children in the no-exercise group were 47.4 (36.0) at baseline and 58.0 (32.9) at 6 months.
Dropout rates	17%

Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Dropout rate 17%. Blinding unclear. Random allocation stratified by age, percentage overweight and physical work capacity. Each family deposited US$80 before treatment; one US$20 cheque was returned for each of the following: 1) attending a minimum of three-quarters of the weekly treatment meetings; 2) the child's attendance at two all-day assessment sessions; 3) parent and child's attendance at the 6 months assessment; and 4) parent and child's attendance at the 1 year assessment.

Amador 1990 RCT [937]	
Aim	To examine the benefits of a non-restrictive diet for preservation of growth and maturation rates during the treatment of obese children at early stages of their puberty.
Country and setting	Cuba. Outpatient service at the Paediatric Hospital of La Havana.
Participants	Ninety-four obese children aged 10.6 to 12.9 years with no evidence of endocrine or metabolic disease which could lead to overweight; no slimming treatment at least 6 months before the study; not receiving drugs which could affect energy metabolism or lipolysis–lipogenesis mechanisms; triceps and subscapular skinfold thicknesses above the 90th percentile; relative fat weight >25% in males and >30% in females; and stage of sexual development genitals 2 in males or breast 2 in females.
Recruitment	Not reported.
Intervention	Groups were created: the experimental group (EG; non-restricted) and the control (CG; restriction to 30% of energy requirements). Energy intake in the diet was the only difference between the two groups: 0.25 MJ/kg of expected body weight for height in EG, 0.17 MJ/kg in CG. Energy restriction was maintained up to 6 months, when a reduction in body fat reached about 20%. From 6 to 12 months both groups received a non-restrictive diet. A programme of PA comprising jogging, walking and running with progressive loads was created. A programme of nutritional education, including individual and group activities, was created: children and parents were invited in order to change attitude and habits of the child and their family regarding food consumption and PA.
Delivery of intervention	Paediatricians, psychologists, psychiatrists, nutritionists, dietitians, anthropometrists and phys**iotherapist**

Control	Restriction to 30% of energy requirements
Length of follow-up	Up to 12 months
Results	Body weight decreased 7.55 ± 2.76 kg ($p < 0.01$) at 6 months and 5.54 ± 2.54 kg ($p < 0.00$) at 12 months for the control group. In the experimental group, body weight decreased 4.51± 2.72 kg at 6 months ($p < 0.01$) and 2.19 ± 3.14 kg ($p < 0.01$) at 12 months.
Other outcomes	No other outcomes were reported.
Dropout rates	17%
Treatment of dropouts (return to baseline, or last measurement?)	Only data from subjects who completed follow-up.
Quality and comments	No details of randomisation. No blinding.

Nova 2001 CCT [902]	
Aim	To compare two types of intervention intended to reduce weight in obese children that can be carried out in the family paediatrician's (FP) office.
Country and setting	Italy. FP's office.
Participants	Children with excess weight ≥20% of ideal body weight (IBW), aged 3–12 years, who attended the FP during the period from 15 November 1997 to 31 March 1998.
Recruitment	From the FP's office.
Intervention	A total of 18 from the 139 FPs from different regions in Italy who were contacted, agreed to participate and were randomised into two groups. FPs would then obtain information about the amount of PA; time spent watching television or using the computer, outdoor games, consumption of snacks during the day, and scholastic results. In group A (*n* = 114), the given leaflets contained only general information regarding obesity and associated risks, general advice on healthy eating and an invitation to practice some PA. In group B (*n* = 72), a specific diet (approximately 1400 kcal [5.86 MJ]), detailed guidelines regarding PA and active parental commitment, and an alimentary diary with instructions for use were supplied to the children and their families. The FP then reviewed the diary with the child and parents in order to reinforce the family's compliance in regard to changes in eating behaviour.
Delivery of intervention	FP.

Control	Two treatment groups.
Length of follow-up	12 months.
Results	Compared with baseline, percentage overweight decreased in both group A (–2.9 ± 8.5, –2.9 ± 10.8 at 6 and 12 months respectively) and group B (–8.8 ± 6.6, –8.5 ± 9.7 at 6 and 12 months respectively). Results were statistically significant for both groups. The reduction in percentage overweight was significantly greater in children whose parents had a good level of commitment compared with parents with a sufficient or poor level of commitment ($p = 0.005$ for group A and $p = 0.02$ for group B).
Other outcomes	Not reported.
Dropout rates	Average of 30% at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed.
Quality and comments	No details of randomisation. No blinding occurred. Methodological flaws.

Figueroa-Colon 1993 CCT [928]	
Aim	To examine whether a protein-sparing modified fast (PSMF) diet and a hypoenergetic balanced diet are safe and effective for children in an outpatient weight reduction programme.
Country and setting	USA. Outpatient weight reduction programme.
Participants	Nineteen children with weight for height >40% above the mean weight for age, sex, and height using standards from the national centre for health statistics. All children weighed between 45 and 131% more than the IBW for their height. All in good health, not taking any medication and from a middle socio-economic class.
Recruitment	By referral by either a physician or a parent.
Intervention	First group: ten children, assigned to a high-protein, low-carbohydrate (CHO), low-energy diet or PSMF. Second group: nine children, assigned to a hypoenergetic balanced diet. After the first 10 weeks, patients from both groups were placed on a 4200 kJ balanced diet; energy intake was increased in 3 months to 5040 kJ and maintained for 1 year. Group 1 were placed on a PSMF diet, consisting of 1.5–2 g of high-biological quality protein/kg IBW per day up to 100 g. Total dietary fat intake was low and ranged from 27 to 36 g/day. Moreover, children were given multivitamin and mineral daily supplements.

	group 2 were prescribed a hypoenergetic balanced diet (3360 to 4200 kJ). Children in this group did not receive vitamin and mineral supplements and were instructed to maintain a reasonable intake of milk and vegetables. Children reported any side effects and their degree on a checklist provided by the examiner. Children received information about lifestyle change related to activity. The amount of daily activity was regulated using Cooper's aerobic point system. Aerobic activity was conducted for 20 min/day. One parent or guardian was asked to participate in all sessions. The behavioural component included self-monitoring of food intake and PA, as well as discussions and applications of behavioural change techniques. The change techniques included stimulus control, cue elimination, behaviour chains and preplanning, cognitive restructuring, and exploring alternatives to overeating.
Delivery of intervention	Nutritionist is only mentioned deliverer.
Control	Two treatment groups.
Length of follow-up	Up to 14.5 months.
Results	Children on the PSMF diet had a significantly higher weight loss (–11.2 ± 4.4 kg) at 10 weeks then the hypoenergetic balanced group (–5.1± 4.1 kg; $p < 0.01$). At 6 months the PSMF group had lost –11.2 vs. –5.8 kg for the hypoenergetic balanced group. Differences between baseline and 6-month values were not statistically different for dietary groups. Nevertheless, the PSMF showed a significant change in the percentage overweight compared with the hypoenergetic group (–32.2 ± 13.4 vs. –17.5 ± 15.2; $p < 0.05$) and change in BMI (–5.6 ± 2.5 vs. –3.0 ± 2.6 kg/m^2; $p < 0.05$). The mean weight at 14.5 months for both dietary groups had returned to baseline levels. The decrease in the percentage of overweight (–23.3 ± 19.2) in the PSMF group at 14.5 months compared with baseline was statistically different
Other outcomes	Changes in systolic and diastolic blood pressures did not reach statistical significance. No additional mineral supplements were required for children on PSMF. When groups were combined, the initial serum cholesterol value (4.47 ± 0.79 mmol/l) decreased significantly at 10 weeks (3.74 ± 0.84 mmol/l), while the decrease in triacyglycerol levels (1.25 ± 0.57 vs. 0.98 ± 0.47 mmol/l) did not reach statistical significance.
Reported harms	Almost half the children in both dietary groups experienced decreased appetite. Hunger, fatigue, weakness, and muscle cramps

	were more common in the hypoenergetic balanced group. Bad breath was more common in the PSMF group (11%) than in the HCB group (3%) during the first 10 weeks. 5% of the PSMF group also reported diarrhoea/vomiting, whilst 19% of the HCB reported headaches and abdominal pain.
Dropout rates	No dropouts.
Treatment of dropouts (return to baseline, or last measurement?)	Data from all subjects.
Quality and comments	Authors report that randomisation was performed, although it is not clear. Group leaders were not blinded.

Epstein 1984[4] and 1989 RCT [929]	
Aim	To assess the effects of weight change on serum lipid changes.
Country and setting	USA. Unclear but appears to be specialist programme.
Participants	Children between 8 and 12 years old; at least one child and one natural parent who were >20% over ideal weight for age, sex, and height; child's triceps skinfold thicknesses greater than the 95th percentile for age and sex; and no history of psychiatric contact for the children.
Recruitment	Subjects were recruited by newspaper advertisements, fliers distributed by schools and physician referrals.
Intervention	Subjects were assigned to one of three treatment groups: 1) diet (*n* = 18); 2) diet plus lifestyle and exercise (*n* = 19); and 3) no treatment-control group (*n* = 19). The two treatment groups entered a 15-session programme. The first eight sessions were conducted weekly, with the other seven sessions spread out over the next 20 weeks with three biweekly meetings and the other four meetings at monthly intervals, where information on diet, exercise, stimulus control, reinforcement, modelling, and contingency contracting was presented to parents and their children. Each of the 15 sessions involved reviewing a short module given to participants the previous week and discussing the application of the technique or information described. Families were seen in groups, with parents and children separated. At each treatment meeting, trained therapists individually reviewed parent and child habit books, assessing progress in eating and exercise habit changes, implementation of the point economy and use of social reinforcers.

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[4] Although this study is earlier than the 1985 cut-off, we decided to include it as it has a follow-up of 5 years (Epstein 1989).

	Parents were encouraged to provide earned incentives, to spend some time each day reviewing child habit books, and to use praise for motivation. Parents were provided social reinforcement from the therapists for their own habit changes and for correct implementation of the child programme. Subjects were prescribed the traffic light diet, and those in the diet-plus-exercise group were given a lifestyle change exercise programme that required increasing voluntary energy expenditure above normal through a series of gradual steps, from 1400 kcal [5.86 MJ] at week 1 to 2800 kcal [11.72 MJ] by week 12.
Delivery of intervention	Trained therapists.
Control	No treatment control.
Length of follow-up	Up to 5 years.
Results	From baseline to 6 months, significant improvements in weight ($p < 0.001$) and percentage overweight ($p < 0.001$) were reported in the treated vs. the control group. Treated groups had decreased in weight 3.6 kg and in percentage overweight of 17.4, while the control group gained 5.2 kg. Over the 5 years, significant increases in weight ($p < 0.001$) were reported, but no differences in the percentage overweight compared to baseline values.
Other outcomes	Fitness improved significantly ($p = 0.002$) about 33 percentile points for the treated children and remained unchanged for the control group. Significant group effects in changes in serum cholesterol ($p = 0.03$), were reported with decreases of 0.27 mmol/l for the treated children and an increase of 0.09 mmol/l for controls. There was a significant difference in HDL-cholesterol levels over the 6 months of the study ($p = 0.007$), with greater increases in the treated children (+0.20 mmol/l) than in the control children (+0.06 mmol/l). Serum triacyglycerol levels decreased significantly over 6 months ($p = 0.01$) with greater decreases in the treated groups (–0.55 mmol/l) than in the control children (–0.12 mmol/l). At 5 years the HDL-cholesterol level was significantly improved compared with baseline levels ($p = 0.003$).
Dropout rates	20% at 5 years.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be with data from only those who completed the study.
Quality and comments	The two treatment groups were combined for purposes of evaluating the effects of weight change on serum lipid change, as no

	significant differences were found in the two treatment groups.

Eliakim 2002 CCT [525]	
Aim	To assess the effects of a weight management programme on body weight, BMI and fitness in obese children and adolescents.
Country and setting	Israel. Obesity treatment programme at the Child Health and Sports Centre, Meir general Hospital, Tel Aviv University.
Participants	Children aged 6 to 16 years.
Recruitment	Not specified.
Intervention	Participants visited the dietitian once per month. In children aged 6–8 years, only parents were invited for the first two meetings and then children joined thereafter. Each family was instructed to come to the first meeting with a 24-h dietary record. The first appointment was dedicated to learning about the reasons for childhood obesity, receiving information about food choices, dietary and cooking habits, understanding the motivation for weight loss, as well as trying to enrol the entire family. The subsequent appointments were devoted to nutritional education. Subjects were prescribed with a balanced hypoenergetic diet, consisting of 1200–200 kcal [5.02–0.84 MJ] depending on the age and weight of the child, or of an energy deficit of about 30% of the reported intake. All subjects participated in a twice-weekly training programme (1 hour). The intervention was designed to copy the type and intensity of exercise that elementary and high school children normally perform. The physicians who worked in the programme participated regularly in the training sessions for encouragement. To promote personal responsibility, subjects were instructed to add and extra 30–45 min of walking. Subjects were also encouraged throughout the programme by physicians, nutritionist and coaches to reduce inactivity (as for example television viewing, video games, use of stairs instead of lifts, play outside instead of inside).
Delivery of intervention	Physicians and dietitians of the child health and sports centre. Also professional youth coaches.
Control	Group of 25 obese children and adolescent who were followed in the obesity clinic and were unable to participate in the dietary and exercise programme due to other obligations and transportation. These were referred every 3 months to an outpatient nutritional consultation and were instructed to perform PA three times per week on their own.
Length of follow-up	Up to 6 months.
Results	The decrease in body weight (from 55.8 ± 1.2 kg to 54.9 kg) and BMI (from 26.1 ± 0.3 to 25.4 ± 0.3kg/m^2) was statistically

	significant. Changes in body weight and BMI following the 3-month programme were not significantly affected by gender, pubertal status, degree of obesity or by parental overweight. In the control group there was a significant increase in body weight and BMI. None of the control groups lost weight. At 6 months the decrease in body weight and BMI was significantly greater compared with those who discontinued the programme after 3 months (body weight –0.58 ± 0.18 vs. –1.25 ± 0.36 kg in 3 months and 6 months subjects respectively ($p < 0.05$); BMI –0.53 ± 0.09 vs. –0.95 ± 0.16 kg/m^2 in 3 and 6 months respectively ($p < 0.01$). During the second 3 months of the programme, participants without parental overweight had significantly favourable BMI changes compared to subjects who had both obese parents.
Other outcomes	Endurance time increased significantly in both groups, but the increase in the intervention participants was significantly greater (from 629 ± 24 to 793 ± 24 s and from 560 ± 55 to 586 ± 42 s in the intervention and control subjects, respectively; $p < 0.0005$).
Dropout rates	13%
Treatment of dropouts (return to baseline, or last measurement?)	Only those who completed both the 3-month and 6-month programme.
Quality and comments	

Sothern 2000 CCT [930]	
Aim	To assess the safety, feasibility and efficacy of a resistance training programme preadolescent obese children.
Country and setting	USA. Weight management programme at the Children's Hospital of New Orleans.
Participants	Nineteen preadolescent obese children, aged 7 to 12 years of age, and 48 control subjects (with a baseline age of <12 years). Subjects were not enrolled if weight was <120% of IBW and if there was evidence of cardiovascular disease, diabetes or other chronic systemic diseases. The subjects in the control group received the intervention approximately 1.5 years before the subjects in the treatment group.
Recruitment	Not reported.
Intervention	Treatment and control subjects participated in a 10-week intensive period, and at the very beginning, treatment subjects were given handbooks that explained all aspects of the acute weight loss the handbooks were colour-coded according to the initial severity of obesity. The colour-coding was used as positive reinforcement as

	subjects dropped from one obesity classification level into less severe category. During the acute 10-week phase, both groups attended a weekly 2-hour weight reduction clinic, they were instructed concerning the PSMF diet, nutrition and a moderate-intensity progressive exercise programme; walking programme (control) and behaviour modification. During the 10-week weight loss phase, dietary adherence was monitored through self-reported urine ketone records. Exercise: The treatment subjects were given a home-based exercise programme that included and instructional video. Subjects and family members participated in 30 to 45 min of moderate intensity (45–55% VO_{2max}) exercise during weekly intervention meetings. MPEP included aerobic, muscular flexibility, and muscular strength exercises. The resistance-training programme, was a balanced routine of 6 to 12 different exercises designed for obese youth. Severely obese children initially performed six different strength exercises per session. Two to three additional exercises were added to each phase of the programme as the subjects progressed from one phase to another.
Delivery of intervention	Exercise professional.
Control	Control subjects were instructed to walk three times per week for 60 min at an intensity of approximately 65 to 70% VO_{2max} or 75 to 80% of maximum heart rate.
Length of follow-up	1 year.
Results	For the treatment group, weight changed from 65.3 ± 21.0 to 56.7 ± 18.2 kg at 10 weeks ($p < 0.0003$) and the controls changed from 61.95 ± 20.3 to 54.3 ± 19.9 kg at 10 weeks ($p < 0.0001$). BMI in the treatment group changed from 28.6 ± 6.3 kg/m^2 to 24.4 ± 6.2 kg/m^2 at 10 weeks ($p < 0.0001$) and for the control group, results were 30.8 ± 5.8 kg/m^2 at baseline and 26.6 ± 5.8 kg/m^2 at 10 weeks ($p < 0.0001$). The decrease in total body weight over the 1-year period in both groups was significant ($p < 0.0003$). Post hoc contrasts in the treatment subjects showed that the baseline weight was significantly higher than the weight at 10 weeks and at 1-year follow-up ($p < 0.001$). In both treatment and control subjects, the decrease in BMI over the 1-year period was significant ($p < 0.0001$). Post hoc contrasts showed that the baseline BMI was significantly higher than the BMI at 10 weeks and at 1-year follow-up ($p < 0.0001$). Nevertheless, the difference in BMI between that at 10 weeks and at the 1-year follow-up points in both groups was not significant. Post hoc contrasts showed that the baseline %IBW was significantly higher than the %IBW at 10 weeks and at 1-year follow-up

	($p < 0.001$) (treatment) and ($p < 0.0001$) (control).
Other outcomes	No other outcomes were reported.
Dropout rates	21.1% for the treatment group and 64.6% for the controls.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only data from those who finished the programme.
Quality and comments	No randomisation, blinding or concealment was made. Weight and BMI values at 1 year were not given. Only statistical significance.

Flodmark 1993 (in Cochrane) RCT [931]	
Aim	To examine the differences between conventional behavioural treatment, conventional treatment combined with family therapy and no treatment.
Country and setting	Sweden. Screened in schools and attended sessions with paediatrician.
Participants	Ninety-four obese children. Mean age range 10–11 years. 48% male. BMI >23.0 kg/m^2. Treatment groups mean BMI on entry 22.0 kg/m^2. Control group mean BMI on entry 25.1 kg/m^2.
Recruitment	Unclear.
Intervention	Two treatment intervention groups: 1) conventional treatment (*n* = 19) which consisted of dietary counselling by a dietitian and regular visits to an experienced paediatrician The prescribed diet contained 1500 to 1700 kcal [6.28–7.12 MJ] and the families were also advised to reduce their fat intake by 30%; 2) family therapy (*n* = 24), which received the same dietary counselling and medical check-ups by another paediatrician, and also the paediatrician and psychologist offered six family therapy sessions over 1 year. During therapy, the therapists tried to reinforce the resources of the family and to create an optimal emotional climate for helping the obese child. The therapist supported the family's own belief systems in different ways with a view to encourage mutual respect and a confident environment. There was also a control group (*n* = 50).
Delivery of intervention/control	Dietitian and paediatrician.
Dropout rates	21% for the conventional treatment group at 1 year. 37.3% for the family therapy group at 1 year. No details for control group.
Control	No intervention.

Length of follow-up	1 year.
Results (14–18 months intervention and 1 year follow-up)	For the family therapy and conventional treatment group vs. the conventional treatment group, BMI increased from 24.7 (SD 0.36) to 25.8 (SD 0.73) kg/m^2 in the first group, and increased from 25.5 (SD 0.53) to 27.1 (SD 0.88) kg/m^2 in the second group. For the conventional treatment group vs. untreated control group, BMI increased from 25.5 (SD 0.5) to 27.1 (SD 0.9) kg/m^2 for the first group and from 25.1 (SD 0.4) to 27.9 kg/m^2 for the control. For the family and conventional treatment group vs. the untreated control group, BMI changed from 24.7 (SD 0.4) to 25.8 (SD 0.7) kg/m^2 for the first group and from 25.1 (SD 0.4) to 27.9 (SD 0.6) kg/m^2 for the control.
Other outcomes	Physical fitness improved significantly in the family therapy group at 1-year follow-up. No untreated control group was available for comparison of physical fitness data.
Treatment of dropouts (return to baseline, or last measurement?)	All available data, except for the pilot case was included in the analysis. ITTperformed.
Quality and comments	Dropouts 7%. Blinding unclear. No description of the randomisation.

Mellin 1987 (in Cochrane) RCT [932]	
Aim	To evaluate the effectiveness of the SHAPEDOWN programme, an adolescent obesity intervention that includes a range of cognitive, behavioural and affective techniques over 15 months.
Country and setting	USA. University research centre.
Participants	Sixty-six obese adolescents, aged 12 to 18 (mean 15.6) years. No details of weight entry criteria. Weight on entry: 78 kg and 33% overweight for age, sex and height.
Recruitment	Group leaders recruited participants through announcements in local papers and notices to physicians and school personnel.
Intervention	The test participants paid intervention fees for 14 × 90 min sessions using the materials of the SHAPEDOWN programme plus two parent sessions. The programme included a range of cognitive, behavioural, affective and interactional techniques adapted to the needs of adolescents. It encourages adolescents to make continuous, sustainable, small modifications in diet, exercise, relationships, lifestyle, communications and attitudes. Very-low-energy or restrictive diets were avoided in the programme. The control group participants did not receive any treatment and did not pay any fees.
Delivery of intervention/control	Four volunteered nutritionists. Three of them were registered dietitians; three had Masters degrees; and all were women.

	None had conducted adolescent obesity group interventions previously or had clinical experience with obese adolescents.
Dropout rates	16% (although details are unclear).
Control	No treatment.
Length of follow-up	12 months.
Results (3-months intervention and 12-months follow-up)	In the SHAPEDOWN group, mean weight decreased from 79.2 kg at baseline to 77.8 kg at 6 months, In the control group, mean weight was decreased from 77.0 kg at baseline to 75.9 kg at 6 months.
Other outcomes	Participants of the SHAPEDOWN showed improvements in weight-related behaviour, depression and knowledge of weight management concepts at post-treatment and at 12-months follow-up compared with the control group. At 3 and 15 months, the test group showed significant improvement in weight-related behaviour ($p < 0.005$, $p < 0.05$), self-esteem ($p < 0.005$, $p < 0.001$) and weight management knowledge ($p < 0.001$, $p < 0.001$), and less depression ($p < 0.005$, $p < 0.005$), whilst the control group only improved in self-esteem.
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed.
Quality and comments	No blinding was performed and no detailed description of the methodology was given.

Israel 1990 CCT [933]	
Aim	To compare the parental involvement in two different roles in a behavioural weight loss programme for children.
Country and setting	USA. Unclear setting.
Participants	Forty children ranging from 9 years, 5 months to 13 years, 4 months with at least one parent. Children had to: be at least 20% above ideal weight for height, age, and gender; obtain a medical release; have no involvement in other weight or psychological treatment(s); have at least one parent who agreed to attend all treatment and measurement sessions. Helper group $n = 28$, weight loss group $n = 12$.
Recruitment	Through referrals from local medical personnel, school health personnel, and notices through local school systems.
Intervention	Separate child and parent groups involved member from four to eight families for eight weekly 90-min sessions, which was the intensive phase of treatment. Extended treatment consisted of six additional sessions over the next 18 weeks, with increasing time intervals between sessions..

	The treatment was a behavioural programme based on four-prong CAIR (cues, activity, intake and reward) approach. The parents were required to select one of two roles at week 4 of treatment. Parents could choose to engage in their own weight loss effort (WL), which was a weight reduction programme that paralleled that of their child. These parents monitored behaviours and engaged in behaviour change efforts in the four CAIR areas. Weekly habit records included items such as staying below prescribed energy limit, meeting a PA goal and eating in only one place. Optionally, parents could engage to target those behaviours that would directly help their child's weight loss effort (Helper [H] condition) and not engage in their own weight-loss effort. Weekly habit records in this condition included items such as helping their child fill out eating records, keeping high-energy foods out of sight, and making low-energy snacks available. To summarise, in the WL condition, parental involvement was programmed by targeting the parents own weight loss behaviours, whilst in the other condition (H) behaviours directed at assisting the child's weight loss efforts were targeted. Parents in the H were not involved in their own weight loss efforts, and parents in the WL condition did not monitor their helping behaviour explicitly.
Delivery of intervention/control	Not clear.
Dropout rates	Helper group 14.3% at follow-up. Weight loss group 8.3% at follow-up.
Control	Comparison of two treatment groups.
Length of follow-up	1 year.
Results (26 weeks treatment and 1 year follow-up)	During the treatment period, percentage overweight in the H group changed from 42. 2 ± 16.4 at week 1 to 32.5 ± 19.0 at week 26, whilst the WL group went from 51.9 ± 17.2 at week 1 to 40.8 ± 17.8 at week 26. During follow-up the H group changed from 42.8 ± 17.4 at week 1 to 38.4 ± 24.7 at year 1, while the WL group changed from 51.8 ± 18.0 to 47.7 ± 24.8.
Other outcomes	No other outcomes were reported.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from subjects who completed both treatment and follow-up.
Quality and comments	No details of randomisation. No blinding or concealment methods were reported.

Epstein 1986 and 1987 (in Mclean review) RCT [934] [935]	
Aim	To assess the effect of parent weight and parent control vs. child self-control on weight loss of obese preadolescent

	children.
Country and setting	USA. Unclear setting
Participants	Forty-nine families with 8- to 12-year-old children between 20 and 80% over their IBW; having triceps skinfold thickness values greater than the 85th percentile; and with no psychiatric contact or learning disability; 24 children had at least one obese parent, and 17 had parents who were not currently obese.
Recruitment	Unclear.
Intervention	Two treatment groups: parent control and child control. These two treatments involved eight weekly treatment meetings with ten monthly meetings where parents and children were seen separately over a period of 1 year. Both children and parents were prescribed a 1200 kcal (5.02 MJ) diet and a lifestyle exercise programme. Non-obese parents were prescribed an energy level to maintain their weight, and were given the same exercise programme. In both groups, determination of when goals were met and awarding of points were made initially by therapists, with parents being trained to take over contingency control.
Delivery of intervention/control	Therapists.
Dropout rates	20% at 5 years.
Control	Not reported.
Length of follow-up	Up to 36 months.
Results (26 weeks intervention and 6 months, 1, 3 and 5 years follow-up)	Significant ($p < 0.01$) decreases were reported from baseline to 6 months for children of both non-obese (–17.2%) and obese (–14.3%). At year 1, children of non-obese parents were significantly lighter ($p < 0.01$) than baseline (–16.3%) and lighter ($p < 0.01$) than children of obese parents (–7.7%). At year 3, neither group was significantly different from baseline for children of non-obese and obese parents. The *p* value was not reported (Epstein, 1986) The proportion of children who were non-obese at 5 years was higher for children with non-obese parents than for children with obese parents, although these differences were not significant ($p > 0.05$). Obese parents had a greater percentage overweight then the non-obese parents at baseline, although changes for obese and non-obese parents from baseline to 6 months (–10.4, –7.5) and 12 months (–8.3, –5.0) were similar. At 36 months, parents in both groups were equally above baseline (+1.42, 0.74). At 60 months, parents in both groups were equally above baseline relative weight (+5.0, +5.7). No relationship between initial child percentage overweight and relative weight change were observed from baseline to 6, 12, 26, or 60 months.

	Significant correlations between parent and child were reported at 6 months and 3 years ($p < 0.01$), but not at 1 or 5 years ($p > 0.05$) (Epstein 1987).
Other outcomes	Children with non-obese parents were more compliant than those with obese parents for energy limit ($p = 0.01$), exercise goal ($p = 0.02$) and recording completely ($p = 0.03$). Obese children with non-obese parents had better eating behaviour across all measurements ($p < 0.01$). Planned comparisons showed that the rate of improvement in eating behaviour from 0 to 6 months was greater ($p < 0.05$) for children of non-obese than of obese parents.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed follow-up.
Quality and comments	Unclear blinding and concealment. Randomisation method not described.

1.4.2 Interventions emphasising diet and physical activity

Schwingshandl 1999 (in Cochrane) RCT [912]	
Aim	To evaluate the effect of a standardised training programme focusing on maintenance of fat-free mass during weight reduction by energy reduction in obese children.
Country and setting	Austria. Not clear nature of setting but appears to be obesity research clinic.
Participants	Children were randomised to two groups: Group A (physical training programme and dietary advice): six boys and eight girls; mean age 11.0 (SD 2.5) years; mean standard deviation score for BMI 5.58 (2.46). Group B (dietary advice alone): seven boys and nine girls; mean age 12.2 (2.7) years; mean BMI 5.33 (1.79) kg/m^2.
Recruitment	Unclear.
Intervention (12-week treatment and 1-year follow-up)	The dietary intervention included general dietary advice given by group teaching that comprised: energy requirements; relation of the different nutrients in a balanced diet (20%/30%/50%) of total energy ***[specify protein, fat, CHO?]***); and the importance of fibre, vitamins, minerals and fluids. Energy intake was reduced to 4180 kJ/day; children >14 years old were restricted to 5016 kJ/day (girls) and 5852 kJ/day (boys). At each visit (at baseline; after 4, 8 and 12 weeks; and after 6 and 12 months) each participant received re-education on an individual basis. Training sessions were performed twice weekly in a public gym, with a duration of approximately 60–70 min each session. The volume increased after 2 weeks, working up to as many as three to

	four sets for each exercise. In group A, participants received standardised dietary advice for weight reduction by a dietitian at baseline and after 4, 8 and 12 weeks of the study, and participated in a training programme twice weekly. In group B, participants had the dietary intervention only.
Delivery of intervention	Dietary advice given by a dietitian.
Control	Not reported
Length of follow-up	1 year.
Results	The main outcome of this study was fat-free mass. This was estimated from the resistance index, obtained by bioelectrical impedance analysis at baseline and at 12 weeks. After 12 weeks the children given physical training and dietary advice (Group A) had significantly greater mean change in fat free mass (2.7 [SD 3.7] kg) than that of the children given dietary advice alone (Group B) (0.4 [SD 1.7] kg)
Other outcomes	No other outcomes were reported.
Dropout rates	33%
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Dropouts 33%. Blinding unclear. Random allocation not described. Although follow-up at 6 and 12 months is discussed in the paper only 12-week fat free mass data were reported and no further information was available from the authors.

Woo 2004 RCT [139]	
Aim	To evaluate the effects of dietary and exercise interventions on vascular dysfunction in obese children.
Country and setting	Hong Kong. Unclear, but appears to be research clinic at university.
Participants	Eight-two overweight or obese children (BMI ≥21 kg/m^2). Children had to have no known medical illness and no alternative cause for their obesity, no family history of premature cardiovascular disease, be taking no regular medications or vitamin supplementation, and have resting brachial artery diameter >2.5 mm. Children with a history of diabetes, renal disease, cardiovascular disease or those whose sexual maturity status was more advanced than Tanner stage 2 were excluded.
Recruitment	Invitations to participate were sent to apparently obese children 9–12 years of age by school teachers in 13 local primary schools

Intervention	The children were prescribed with a 900 to 1200 kcal (3.77 to 5.02 MJ) hypoenergetic diet, which varied according to the children's ages and eating habits. The diet was low in fat (20–25% of energy), high in complex CHO (50–60% of energy), and sufficient in protein (25–30% of energy). The exercise intervention was carried out in the hospital and supervised by the same physiotherapist team, and was circuit style. Each child had to go through nine stations in each session, twice per week for 6 weeks and then once weekly for 1 year. Each training session lasted 75 min, including 10 min of warm up, 30 min of resistance training, 10 min of aerobic exercise, 10 min of agility training, 5 min of cool-down, and short periods between stations.
Delivery of intervention	Dietitian and trained physiotherapists.
Control	Not reported.
Length of follow-up	1 year.
Results (6 week intervention and 1 year follow-up).	After 6 weeks, waist-to-hip ratio decreased significantly in both groups, although there was no significant change in weight, BMI, body fat content or fat free mass. At 1 year, there were significant changes in body fat content from baseline in the combined group but not in the diet only group. No change in weight was reported, although BMI showed no significant changes in either group.
Other outcomes	At 1 year, a significant decrease was seen in total cholesterol from baseline in the diet group, but not in the combined group. LDL-cholesterol improved significantly from baseline in both groups, with improved HDL levels in the combined group only. Fasting glucose ($p < 0.002$) reduced slightly in the exercise group only. An improvement in endothelium-dependent dilation (EDD) but not nitroglycerin-induced dilation of brachial artery was visible in both groups after 6 weeks, although more evident after diet plus exercise than diet alone ($p = 0.01$).
Dropout rates	After 6 weeks, 22 of the 41 children assigned to the diet plus exercise agreed to continue the weekly exercise programme, and the other 19 children stopped regular supervised exercise but continued two monthly diet monitoring programme, as the original 41 diet-only children.
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	After 6 weeks, 22 of the 41 children assigned to the diet plus exercise agreed to continue the weekly exercise programme, and the other 19 children stopped regular supervised exercise but continued

	2-monthly diet-monitoring programme, as the original 41 diet-only children. Compliance with the intervention in both groups was promoted with an incentive award of a sporty-look souvenir watch on completion. Unclear blinding of children. Dietitian blinded to the exercise programme allocation.

Rolland-Cachera 2004 RCT [192]	
Aim	To compare the influence of weight-reducing diets containing different amounts of protein and CHO on body composition in obese adolescents and to examine dietary and PA behaviours during follow-up.
Country and setting	France. Specialised centre for obesity treatment.
Participants	One hundred and twenty-one obese children with a BMI exceeding the 97th centile of the French reference values, age between 11 and 16 years, and no pathologies contributing to obesity and no use of regular medication.
Recruitment	By referral from their general practitioner.
Intervention	The subjects lived for one school year in a medical centre specialised in the treatment of obese children. During treatment parameters were recorded on four occasions: at inclusion (P1), 2 weeks following inclusion (P2), when the body weight goal determined by the physician was achieved (P3) and at the end of the stabilisation phase (P4). During follow-up, nutritional intakes and PA were recorded at home 1 year (P5) and 2 years (P6) after treatment. The treatment encompassed diet, physical exercise and psychological support. Subjects were allocated either to a PROT + diet (19% of energy as protein and 50% of energy as CHO; protein content was 85 g/day; meat, fish or eggs were served twice per day) or to a PROT– diet (15% of energy as protein and 54% of energy as CHO; protein content was 65 g/day when total energy was 1750 kcal (7.33 MJ); and meat, fish or eggs were only consumed once per day). Fat content was identical in both diets (31% of energy). Energy intake was restricted to 1750 kcal (7.33 MJ)/day until reaching the body weight goal (P1–P3). After this, daily energy intake was increased progressively, in 1-week steps until about 2200 kcal (9.21 MJ) (on average depending on age and sex). The maintenance diet was then followed for 4 weeks (P3–P4). Both children and parents were advised to maintain the same level of energy and nutrient intake after leaving the centre (P4–P6). PA consisted of 7 hours/week of vigorous sports and 7 hours/week of outdoor activities (such as playing or walking). The children were not able to watch television in the centre, but could spend time

	reading, acting, singing, talking or strolling in the centre.
Delivery of intervention	Physician is only the professional reported.
Control	Not reported.
Length of follow-up	2 years.
Results (9 month intervention and 2 years follow-up).	BMI values changed from 36.1 (SD 4.6) kg/m^2 at baseline to 24.2 (SD 2.6) kg/m^2 at the end of treatment (P4) for the PROT– group. In the PROT+ group, BMI changed from 36.4 (SD 5.4) kg/m^2 at baseline to 24.0 (SD 2.5) kg/m^2 at the end of treatment. After treatment, mean BMI *z*-scores increased until P6. No significant difference in BMI *z*-scores from P1 to P6 was recorded between the two dietary groups. Height increased over the 9-month period, while all other measurements (except the subscapular/triceps skinfold thickness and the waist-to-hip ratio) significantly decreased.
Other outcomes	No difference in urinary growth hormone/creatinine ratio was observed between dietary groups at P1. Between P1 and P2 urinary growth hormone significantly increased in PROT– group ($p = 0.02$), whereas no significant change occurred in PROT+ group ($p = 0.92$). Between the first and second year, energy intake increased by 171 kcal (716 kJ). PA decreased and time watching television increased. No difference was observed between PROT– and PROT+.
Dropout rates	18% of children dropped out until the end of the treatment, and 40% until the end of the follow-up.
Treatment of dropouts (return to baseline, or last measurement?)	Only for those who completed the treatment and follow-up.
Quality and comments	Study supported by Lesieur and Nestle France companies. 18% of children dropped out until the end of the treatment, and 40% until the end of the follow-up. Random allocation not described.

Reybrouck 1990 CCT [936]	
Aim	To compare the effectiveness of combining a low-energy diet and exercise against diet only.
Country and setting	Belgium. Outpatient paediatric clinic.
Participants	Fifteen girls and 10 boys, aged 3.9 to 16.4 years. Endocrine disorders were excluded in all patients.

Recruitment	No reported.
Intervention	Group 1 consisted of eleven patients treated by a low-energy diet of 800 to 1000 kcal (3.35 to 4.19 MJ)/day, which was carefully explained by a dietitian. Group 2 included 14 patients who in addition to keeping the same low-energy diet were instructed to perform daily PA programme. The total duration of the exercise programme was adjusted to the actual body weight of the patient in order to consume about 250 kcal (1.05 MJ) per exercise session. The children could choose their favourite exercise from a list of equienergetic PAs. Consent was obtained from parents. The parents were encouraged to accompany their children when performing their exercises, in order to improve compliance.
Delivery of intervention	Dietitian, paediatrician and physical therapist.
Control	Two treatment groups.
Length of follow-up	8 months.
Results	After 4 months of treatment, the mean decrease in overweight was significantly ($p < 0.05$) greater for the children treated with diet and exercise therapy (–25.5 ± 13.5%) than in those treated with diet only (–15.8 ± 10.5%). In the combined treatment group, the decrease in percentage overweight after 4 months correlated significantly ($p < 0.05$) with the initial value of percentage overweight. No significant correlation ($p > 0.25$) was found between both variables for the patients of the other group. From 4 to 8 months, the mean decrease of the percentage overweight was much smaller and similar in both groups: –4.1 ± 5.6 for the children treated with diet and exercise and –3.5 ± 3.4 for the children treated with diet only.
Other outcomes	No other outcomes reported.
Dropout rates	48% at 8 months.
Treatment of dropouts (return to baseline, or last measurement?)	Only for those who completed 4- and 8-months follow-up.
Quality and comments	Follow-up at 8 months was available for only four children of the diet group and eight in the diet/exercise group. Very small study. High dropout rate at 8 months.

1.4.3 Interventions emphasising diet only

Spieth 2000 Cohort study [938]	
Aim	To examine the effects of a low-glycaemic-index (GI) diet compared with a standard reduced-fat diet in the management of paediatric obesity.
Country and setting	USA. Optimal Weight Life programme at Children's Hospital, Boston, MA. Academic medical centre.
Participants	One hundred and ninety patients. Mean age and BMI were 10.6 (SD 4.0) years and 32.5 (SD 7.3) kg/m^2 for the low-GI group and 10.2 (SD 3.1) years and 34.5 (SD 7.2) kg/m^2 for the reduced-fat group. Patients with Cushing syndrome, hypothyroidism, hypothalamic disease, diabetes mellitus or an obesity-associated genetic syndrome, or those concurrently following a very-low-energy diet. Cohort had 107 patients.
Recruitment	Unclear.
Intervention	All patients received a comprehensive medical evaluation, dietary counselling and lifestyle counselling. Counselling sessions included the child and at least one parent. Specific goals were individualised, taking into account the patients developmental level and readiness to change. In addition, problem-focused BT was provided, where a specific nutritional of PA goal was identified as a primary treatment target. Subsequently, a behavioural programme was then created, by applying positive reinforcement for meeting the specified goal. One group was given a standard balanced, hypoenergetic reduced-fat diet. Intake of high-fat, high-sugar and energy-dense foods was limited and intake of grain products, vegetables and fruits increased. Energy restriction was about 250 to 500 kcal (1.05 to 2.09 MJ)/day compared with usual energy intake. Specific macronutrient goals were 55–60% of energy from CHO, 15–20% of energy from protein and 25–30% of energy from fat. The other group was given a low-GI diet, designed to achieve the lowest glycaemic response possible while providing adequate dietary CHO. This diet differed from the standard diet not only in the GI of the CHO content, but also in the macronutrient ratio. A low-GI pyramid was used as a teaching tool. This pyramid placed vegetables, legumes and fruits at the base, lean proteins and dairy products on the second level, wholegrain products on the third level, and refined grain products, potatoes and concentrated sugars at the top. Specific macronutrient goals were 45–50% of energy from CHO, 20–25% of energy from protein and 30–35% of energy from fat.
Delivery of intervention	Subspecialty-trained paediatrician, dietitian, paediatric nurse practitioner and programme psychologist.
Control	Unclear if standard diet was control.
Length of follow-	4.3 months.

up	
Results	The low-GI had a significantly larger decrease in BMI than the standard diet ($p < 0.02$ for each comparison). Compared with the standard diet, a greater percentage of patients in the low-GI group experienced a decrease in BMI of at least –3 kg/m^2 ($p = 0.03$). The overall mean change in BMI for the low-GI group was –1.53 kg/m^2, compared with –0.06 kg/m^2 for the standard diet ($p < 0.001$). This difference remained statistically significant after adjusting for age, sex, ethnicity, length of follow-up, baseline BMI and behavioural therapy referral. Similar results were achieved in subjects that did not receive behavioural treatment: –1.47 kg/m^2 for low-GI diet ($n = 31$) and –0.20 kg/m^2 for the standard diet ($n = 28$) ($p < 0.001$). For white subjects the results were: –1.73 kg/m^2 for the low-GI diet ($n = 54$) and –0.29 kg/m^2 for the standard diet ($n = 23$) ($p < 0.01$).
Other outcomes	No other outcomes were reported.
Dropout rates	56.3%
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Eighty-three subjects were excluded for lack of follow-up and/or incomplete data. No randomisation. Short follow-up. The macronutrient composition of the low-GI diet differed from that of the reduced-fat diet. Retrospective cohort study.

1.4.4 Interventions comparing problem-solving with usual care or behaviour therapy

Graves 1988 (in Cochrane) RCT [973]	
Aim	To determine whether the inclusion of parental problem-solving training in a family-based BT programme would help weight loss in children.
Country and setting	USA. University outpatient weight reduction programme
Participants	Forty obese children and their parents. Age range 6 to 12 (mean 9.3) years. At least 20% overweight for age, sex and height. Mean weight on entry 124.5 lb (56.5 kg).
Recruitment	Through media announcement.
Intervention (including details of the BT)	The behavioural group was trained in behavioural weight loss methods (training in self-monitoring, diet information, exercise information, stimulus control strategies, family support, cognitive restructuring, peer relations and

	maintenance strategies). The problem-solving group was under the same BT plus problem-solving exercises aimed at problems associated with children's weight control. The instruction-only group were presented with the same diet and exercise information as the problem-solving group and were asked to exercise for 15 min during treatment sessions. Three comparisons were performed: problem-solving group plus BT vs. instruction-only group; problem-solving group vs. BT group only; and BT vs. the instruction only group.
Delivery of intervention/control	Unclear.
Dropout rates	23%
Control	Unclear if the instruction-only is the control group.
Length of follow-up	6 months.
Results (8 weeks intervention and 3 and 6 months follow-up)	Children in the problem-solving plus BT group (53.0% baseline) had a percentage overweight of 28.6 at 6 months, and the instruction only group (baseline 51.8) had presented at 42.3 at 6 months. In the second comparison, the percentage overweight in the problem-solving group decreased from 53.0 to 28.6 at 6 months, whereas in the BT-only group the percentage overweight decreased from 56.3 (SD 36.2) to 47.7 (SD 35.7) at post-treatment and 46.1 (SD 39.1) at 6 months. In the third comparison, the percentage overweight in the BT group decreased from 56.3 (SD 36.2) to 47.7 (SD 35.7) at post-treatment and 46.1 (SD 39.1) at 6 months. For the instruction group the percentage overweight at pre-treatment was 51.8 (SD 22.0), decreasing to 47.1 (SD 23.5) at post-treatment and 42.3 (SD 18.6) at 6 months.
Other outcomes	Post hoc analyses showed the parents in the problem-solving group increased their problem-solving ability from pre-treatment to post-treatment, whereas behavioural and instruction-only parents did not. Significant changes from pre-treatment to the 3- and 6-month follow-up sessions existed for parents in the problem-solving group only. Children in both the problem-solving and behavioural groups increased their consumption of green food and decreased their consumption of red foods significantly more than instruction only children.
Treatment of dropouts (return to baseline, or last measurement)	Data only from those who finished trial.
Quality and comments	Dropouts 22.5%. Blinding was unclear.

Epstein 2000 (in Cochrane) RCT [832]	
Aim	To determine whether problem-solving taught to child and parent increases treatment effectiveness of standard family-based treatment.
Country and setting	USA. Appears to be a University outpatient obesity treatment programme.
Participants	Sixty-seven families, Age mean 10.3 (SD 1.1) years. 48% male. 20% overweight, mean weight on entry 59.8 (SD 53.1) kg.
Recruitment	From referrals from physicians and previous participants and in response to newspaper and poster advertising.
Intervention	Three groups: problem-solving taught to parent and child; problem-solving taught to child; and standard family-based treatment. Didactic training in problem-solving was provided in group formats for parents and/or children. Parents and children in problem-solving groups were provided problem-solving worksheets and problem-solving homework. Families in the non-problem-solving groups were provided similar homework assignments not based on problem-solving. All parents and children were given workbooks with information on the traffic light diet, a 1200 kcal (5.02 MJ) diet that provides a colour-coded food reference guide that includes energy content per serving; PA: walk, run, bicycle or swim programme, three times per week beginning at 1 mile (1.61 km) of walking or running, 2 miles (3.22 km) of bicycling or 0.25 miles (0.40 km) of swimming, and advancing in regular intervals up to 3 miles (4.83 km) of running or walking, 6 miles (9.66 km) of bicycling, or 0.75 miles (1.21 km) of swimming. All participants were trained to exercise at 60–70% of their age-adjusted maximal heart rate; and behaviour change techniques (self-monitoring, positive reinforcement, stimulus control and preplanning). The 6-month treatment programme comprised 16 weekly meetings followed by two-monthly meetings. At treatment meetings, family members were weighed, met with and individual therapist for 15–30 min, and attended separate 30-min group meetings (one for parents and one for children).
Delivery of intervention/control	Unclear.
Dropout rates	7.5%
Control	Unclear if standard family based treatment is control.
Length of follow-up	24 months.
Results (6 months intervention	In the parent and child group, weight decreased from 64.2 (SD 13.2) kg at baseline to 57.4 (SD 11.8) kg, compared with

and 12 and 24 months follow-up)	a reduction from 57 (SD 11.4) kg at baseline to 50.8 kg in the control group at 6 months. In the child alone group, mean weight decreased from 58.2 kg at baseline to 51.2 kg. At 12 months the mean weight was 63 (SD 12.6) kg for the parent and child group; 55.8 (SD 13.4) kg for the child alone group; and 55.7 (SD 11.4) kg in the control group. No reduction in weight was observed for the problem-solving group vs. problem-solving with family.
Other outcomes	Significant improvement in Symptom Checklist-90 (SCL-90; based on the global Severity Index [GSI]) were observed at 6 months ($p < 0.005$) with a loss of improvement from 6 to 24 months ($p < 0.003$). A significant reduction in the percentage of parents with clinically significant GSI distress scores was observed from 18% at baseline to 4% at 6 months. Improvements in problem-solving for both parents and children was reported for the problem-solving group vs. problem-solving with family
Treatment of dropouts (return to baseline, or last measurement)	Appears to be data from those who finished trial.
Quality and comments	Dropouts 7.5%. Blinding was unclear. Attrition was 11% and 15% at 12 and 24 months. Details of initial randomisation were not provided.

1.4.5 Interventions where the main focus was behavioural treatment in comparison with no treatment or usual care

Epstein 1985 (in Cochrane) RCT [940]	
Aim	To determine the effectiveness of BT with emphasis on parent management.
Country and setting	USA. University outpatient weight control programme
Participants	Twenty-four obese girls aged 5–8 years old. girls had to be 20–80% overweight, and no history of psychiatric disorder or medical condition contraindicating weight loss or exercise. Mothers were required to participate and to attend all treatment meetings.
Recruitment	By school nurse and physician referrals, and in response to media coverage.
Intervention (Including details of BT)	Comparison between a BT programme with parent management orientation, and a control group with equal education and attention, but with no behavioural component. Both groups undertook the traffic light diet. Children under the age of 7 years were given an upper limit of 1000 kcal

	(4.19 MJ)/day. While parents and children >7 years were given an upper limit of 1200 kcal (4.02 MJ)/day. Minimum of 900 kcal (3.77 MJ/day) was given to all participants. The behavioural group received training in self-monitoring, praise and modelling, and also contracts for the participants to encourage health habits changes that were in line with the programme objectives. Both groups received the same amount of therapist contact time during treatment.
Delivery of intervention/control	Therapist.
Dropout rates	20.8%
Control	The control group provided equal education and attention, although did not have a behavioural orientation.
Length of intervention	12-month treatment programme, no follow-up
Results (12-months intervention)	BMI decreased from 22.8 (SD 2.6) kg/m^2 at baseline to 19.1 (SD 2.8) kg/m^2 after 12 months in the behavioural group, and from 22.7 (SD 3.0) to 21.4 (SD 3.3) kg/m^2 in the control group.
Other outcomes	Significant interactions of treatment × time were observed for children eating behaviours ($p < 0.001$), but not for their mothers. Post hoc examination of treatment means suggests that the treated children had improved eating habits compared with the control.
Treatment of dropouts (return to baseline, or last measurement?)	Data only for those who completed treatment.
Quality and comments	Dropouts 20.8%. Blinding was unclear. Randomisation was not described.

Senediak 1985 (in Cochrane) RCT [939]	
Aim	To examine whether frequency has repercussions on the effectiveness of the BT.
Country and setting	Australia. Appears to be University outpatient weight control programme
Participants	Forty-five overweight children. Age range 72 to 150 (mean 123.61) months. 66% male. Weight entry criteria: >20% overweight for height, age and sex. Mean weight on entry 37.22%.
Recruitment	After responding to newspaper and radio advertisements and publicity issued to medical practitioners, community health centres and parents’ organisations in the Sydney metropolitan area.
Intervention	Four groups: 1) rapid behavioural group (*n* = 12), where sessions were carried out on a group basis with five or six

	parent–child pairs. The eight sessions were conducted twice weekly for 4 weeks, with follow-up evaluations taking place at 11 and 21 weeks after treatment each session lasted 90 min and was focused on a range of dietary, nutritional and environmental approaches; 2) gradual behavioural procedure (*n* = 12), included eight treatment sessions that were spaced over a period of 15 weeks, having sessions 1 to 4 on weekly basis, sessions 5 to 6 on a fortnight basis, and sessions 7 to 8 after a 3-week interval. This group only received an 11-week after follow-up; 3) non-specific control condition (*n* = 11), where treatment and follow-up were scheduled in the same way as the rapid group, with the same kind of therapists, although no information concerning the energy values of food or exercise activities were provided; 4) and a waiting list control group (*n* = 10), that were informed that because of the great response to the programme, there would be a delay in the star of their treatment. Assessments were performed at weeks 1 and 4.
Delivery of intervention/control	Two therapists were involved: qualified clinical psychologist and a Master's student in clinical psychology.
Dropout rates	31%
Control	Two control groups, as described above.
Length of follow-up	Regarding follow-up, groups 1 and 3 received 21 weeks, group 2 received 10 weeks and no follow-up for group 4.
Results	Percentage overweight in the rapid behavioural group decreased from 32.9 (SD 13.98) at baseline to 19.9 (SD 14.2) after 6 months. For the gradual behavioural group, percentage overweight decreased from 35.9 (SD 12.2) at baseline to 16.6 (SD 11.5) at 6 months. In the non-specific control group, mean percentage overweight decreased from 36.7 (SD 5.5) to 30.80 (SD 10.4) at 6 months. No significant differences were found between the rapid and gradual groups over 6 months. No valid data was available for the comparison between treatment and no treatment groups, as the waiting list control group was only monitored for 4 weeks.
Other outcomes	There was a significant reduction of daily energy intake at post-treatment for the two combined groups (week 4 for the rapid group and week 15 for the gradual group) ($p < 0.01$).
Treatment of dropouts (return to baseline, or last measurement?)	Only data from subjects present at the two assessment occasions.
Quality and comments	Dropouts 31%. Double blinding. No description of the randomisation.

Saelens 2002 RCT [628]	
Aim	To evaluate the short-term follow-up efficacy of a behavioural

	weight control programme.
Country and setting	USA paediatric primary care clinics.
Participants	Participants were on average 14.2 (SD 1.2) years old with a BMI of 30.7 (SD 3.1) kg/m^2, 59.1% were male and self-identified as 70.5% White, 15.9% Hispanic, 4.5% African American, 2.3% Asian and 6.8% multi-ethnic.
Recruitment	Waiting room flyers and by encouraging paediatricians in the clinics to elicit discussion on possible study participation with eligible adolescents.
Intervention	*n* = 23 participants for the Healthy Habits (HH) group, which consisted of a multi-component behavioural intervention, that included computer interaction and physician counselling in the paediatric primary care clinic, followed by 4 months of telephone and mail-based behavioural counselling; and *n* = 21 participants for the Typical Care (TC) group, that received single session physician counselling (included encouragement of adolescent's motivation for weight related behaviour change, provision of information about short- and long-term health consequences of high weight status and benefits of better weight control, recommendations for healthy eating, review PA recommendations for adolescents, and encourage consistency and persistence with health behaviour changes).
Delivery of intervention/control	Paediatrician and counsellors.
Dropout rates	15.9%
Control	Two treatment groups.
Length of follow-up	4 months.
Results	BMI for the HH changed from 31.0 (SD 3.5) kg/m^2 at baseline to 30.9 (SD 3.8) kg/m^2 at post-treatment to 31.1 (SD 4.5) kg/m^2 at follow-up. For the TC, BMI changed from 30.7 (SD 3.1) to 31.8 (SD 3.4) to 32.1 (SD 3.8) kg/m^2. Weight values for the HH group changed from 85.5 (SD 13.9) kg at baseline to 86.1 (SD 14.0) kg at post-treatment and 87.5 (SD 16.0) kg at follow-up. For the TC, weight changed from 80.5 (SD 13.5) to 84.1 (SD 13.8) and 85.8 (SD 14.6) kg.
Other outcomes	There were no significant changes by condition from baseline to post-treatment for total energy or dietary fat intake, PA, sedentary behaviour, or problematic eating and weight-related behaviour or beliefs.
Treatment of dropouts (return to baseline, or last measurement?)	Conservative ITT analysis on the primary outcome conducted by replacing missing values of HH adolescents at post-treatment and follow-up with the mean change of the TC condition from the baseline to post-treatment and post-treatment to follow-up, respectively.

Quality and comments	Blinding of providers, unclear if children blinded. Adequate description of randomisation process.

1.4.6 Interventions comparing behavioural treatment at varying degrees of family involvement

Golan 1998 (in Cochrane) and Golan 2004 RCT [941] [45]	
Aim	To examine the effectiveness of BT when responsibility of the parents vs. responsibility of the child.
Country and setting	Israel. University Research Centre (outpatient).
Participants	Sixty obese children. Mean age range from 6 to 11 (mean 9.2, SD 1.0) years. 38% male. Inclusion criteria: 20% or above overweight for age, height and sex. Weight on entry: 39% overweight.
Recruitment	From the public school system of the middle class town of Rchovot.
Intervention	One treatment intervention group: family based approach. In this group only parents participated in the sessions. The parents were subdivided into two groups that attended 14 1-hour sessions conducted by a clinical dietitian. The first four sessions were held weekly, the next three biweekly, and the last six, once very 6 weeks. Parents were taught to change the family sedentary lifestyle, provide a prudent diet, decrease the family's exposure to food stimuli, apply behavioural modifications and practice relevant parenting skills.
Delivery of intervention	Clinical dietitian.
Dropout rates	16.6%
Control	Conventional child approach, where only children participated. A 6.3 MJ/day diet was prescribed to each child. Children were also divided to two groups to attend 30 1-hour sessions conducted by a clinical dietitian. They were taught how to follow a prudent diet, restrict energy intake, increase exercise, control food stimuli, techniques in self-monitoring, practice problem-solving and cognitive restructuring.
Length of follow-up	1 and 7 years.
Results (1-year follow-up, second study follow-up was at 7-years.	There were significant reductions in degree of overweight and mean weight, although the decreases were greater in the family-based intervention (14.6 vs. 8.4%, *p* < 0.05). After 7 years, the children in the parent-only group achieved a significantly higher reduction in percentage overweight compared with the children in the child-only group (14.6 vs. 8.43%; *p* < 0.03). Both groups demonstrated substantial weight loss, although the mean reduction in overweight was 29% in children

	in the parent-only group and 20.2% in those of the child-only group ($p < 0.05$).
Other outcomes	Stimulus exposure: There was a significant difference between groups in the overall reduction of food stimuli in the home ($p < 0.05$) and in the reduction of snacks, sweets and cakes ($p < 0.001$, $p < 0.05$, $p < 0.05$, respectively). Children's behaviour to food stimuli: At termination of the programme, a significant increase in the children's asking permission on both counts was noted only in the experimental group ($p < 0.001$) for taking and ($p < 0.01$) for buying. Eating style: The overall reduction in prevalence of poor eating habits was significantly greater in the experimental group. Moreover, the reduction in eating outside the dinning room was significant only in the experimental intervention ($p < 0.001$). Finally, a significant reduction in the rate of eating, after the intervention, was only observed in the experimental group ($p < 0.05$) and a significant reduction in the request for second helpings at mealtimes ($p < 0.05$).
Treatment of dropouts (return to baseline, or last measurement)	Unclear.
Quality and comments	Dropouts 16.6%. Blinding unclear. No description of the randomisation.

Israel 1985 (in Cochrane) RCT [944]	
Aim	To compare BT with a parental responsibility orientation vs. BT with a conventional parent/child behavioural weight reduction programme.
Country and setting	USA. Outpatient weight reduction programme.
Participants	Thirty-three overweight children (30 families, where 24 were treatment and six control). Age range from 8 to 12 years (mean 11 years 4 months). 30% male. Weight inclusion criteria: 20% overweight for height. Mean weight on baseline not stated.
Recruitment	Through letters to paediatricians and school nurses and advertisements in a local newspaper.
Intervention	Two treatment groups: Weight reduction only group ($n = 12$), where parents and children undertook a multi-component behavioural weight reduction programme on a nine weekly 90-min session basis, and a parent training group ($n = 12$), where parents attended the same weight reduction programme (same frequency) and also 2-hour long sessions where they received behavioural child management skills.
Delivery of	Therapists: Advanced graduate student in clinical psychology. Two

intervention	other graduate student co-therapists assisted in conducting meetings and made between-session phone calls to assist parents with homework assignments,, provide motivational input, and individualise the treatment. Each children's group was led by two undergraduate students who were trained and supervised by the parents' group leader.
Dropout rates	Only values reported relate to family dropouts. Thirty families at the start of the programme, and 20 at the end.
Control	Waiting list control group (*n* = 9).
Length of follow-up	1 year.
Results (9 weeks intervention and 1 year follow-up)	When comparing the weight reduction group vs. waiting list control group, the latter group showed an increase in weight. In the weight reduction group the percentage overweight of the children decreased from 46.8 (SD 15.6) at the first week to 33.6 (SD 17.0) at the end of the treatment period, and was 45.5 (SD 21.2) at 1 year. For the parent training group vs. the weight reduction only group, the first group went from 50.6 (SD 17.5)% at baseline to 43.4 (SD 21.6)% at the end of the treatment, and to 40.4(SD 32.9) % at 1 year. The second group went from 46.8% overweight (SD 15.6) at baseline to 33.6 (SD 17.0)% at post-treatment, and to 45.5 (SD 21.2)% at 1 year. For the parent training group vs. control group, the first group lost weight, going from 50.6 (SD 17.5)% at baseline to 43.4 (SD 21.6)% at post-treatment and to 40.4 (SD 32.9)% at 1 year. The control group gained weight, although comparable follow-up values are not quoted for this group.
Other outcomes	Scores on the EHC decreased over the follow-up for both treatment conditions ($p < 0.001$), with no differences between the PT and WRO groups. The difference between EHC scores at 1-year follow-up of children who achieved non-obese status vs. those who were successful during treatment but did not achieve non-obese status during the follow-up period was significant ($p < 0.05$).
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only data from completers.
Quality and comments	Dropouts 39%. No blinding for children and providers, unclear for the outcome assessors. Randomly assigned to conditions from stratified blocks based on child % overweight and age. Attrition rates for children are unclear.

Wadden 1990 (in Cochrane) RCT [942]	
Aim	To compare BT with a parental responsibility orientation vs. BT with a conventional parent/child behavioural weight reduction

	programme.
Country and setting	USA. Outpatient weight control programme
Participants	Thirty-six black female adolescents. Age range from 12 to 16 (mean 13.8) years. Weight inclusion criteria: above 10 kg overweight for age, sex and height. Weight on baseline: 95.1 kg (mean).
Recruitment	By advertisements in community newspapers; school nurses in district 1 of the Philadelphian school system; and by attending physicians and residents at the Children's Hospital of Philadelphia.
Intervention	Behavioural weight control programme with three groups: 1) child alone (*n* = 19); 2) mother–child together (*n* = 14); and 3) mother–child separately. Sixteen weekly 1-hour treatment sessions based on the weight reduction and pride (WRAP) programme. The programme instructed children to: record their food and energy intake; consume low-fat well-balanced meals of 1000 to 1500 kcal (4.19 to 6.28 MJ)/day; understand macronutrients, vitamins, and minerals; limit their consumption of high-energy snacks and fast foods; limit times and places of eating; slowing their rate of eating; modifying self-defeating thoughts concerning weight and food; and increasing their PA by walking and other lifestyle behaviours. Sessions also included homework assignment and a quiz.
Delivery of intervention	Investigator, two clinical psychologists, a nutritionist and therapists.
Dropout rates	Paper reports 22% although 31/47 completed, which equals 34%.
Control	Not reported.
Length of follow-up	6 months.
Results (16 weeks intervention and 6 months follow-up)	For the mother and child group vs. child alone group, at post-treatment children in the second group had lost 1.6 kg weight, children in the mother and child in the same session group had lost 3.7 kg and children in the mother and child in different sessions group had lost 3.1 kg. For mother and child treated in the same session vs. mother and child treated in separate but concurrent sessions, the mother and child together group had lost 3.7 kg and children in the group that treated mother and child in different sessions had lost 3.1 kg. None of the results were statistically significant.
Other outcomes	Total cholesterol concentration decreased significantly during treatment from 178.8 to 164.2 mg/dl ($p < 0.01$). HDL-cholesterol decreased from 47.5 to 44.7 mg/dl ($p < 0.06$). Subjects with higher initial values of total cholesterol, LDL-cholesterol and HDL-cholesterol tended to show larger end of treatment reductions. Subjects scores on the Pier–Harris scale increased significantly ($p < 0.05$) during treatment from 57.6 to 59.9 suggesting enhanced self-esteem. Scores on the Child Depression Inventory decreased significantly ($p < 0.01$) from 9.7 to 6.8, which shows reductions in

	feelings of depression. Changes on these two measures did not correlate significantly with changes in weight or fat percentage.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed the programme.
Quality and comments	Dropouts: paper reports 22% although 31/47 completed, which equals 34%. Blinding unclear. Randomisation not described

Israel 1994 (in Cochrane) RCT [943]	
Aim	To compare behavioural treatment with focus on child responsibility vs. focus on parent responsibility.
Country and setting	USA. Appears to be outpatient childhood obesity treatment programme
Participants	Twenty obese children aged 8 to 13 (mean 10) years and parents. Weight inclusion criteria: above 20% overweight for weight, height and sex. Mean weight on baseline: 47% overweight for age, height and sex. No details given of male percentage.
Recruitment	Through newspaper articles, letters to paediatricians, and letters to school nurses.
Intervention	Two treatment groups: standard treatment condition (ST) (*n* = 18), which consisted of a multi-component behavioural intervention where parents were given primary responsibility for following programme prescription; and enhanced child involvement (Early Child Development) (*n* = 16), which provided the same basic intervention but with greater emphasis on, and training in, child self-regulation. Children in the enhanced treatment group received comprehensive training in self-management skills and the children were assigned homework exercises to practice the new skills. Parents also rewarded their children for engaging in self-management skills. Parents met separately for eight × 90 min sessions followed by nine biweekly sessions for a total of 26 weeks. Treatment involved discussions and homework assignments.
Delivery of intervention/control	Unclear.
Dropout rates	41% at follow-up.
Control	Not reported.
Length of follow-up	1 and 3 years.
Results (26 weeks intervention	Percentage overweight in the standard treatment group was 45.9 (SD 17.1) at baseline, 33.4 (SD 17.0) at the end of the 6-

and 1 and 3 years follow-up)	month treatment period, 45.2 (SD 23.9) at 1-year follow-up and 52.3 (SD 24.4) after 3 years. In the enhanced child involvement group, percentage overweight was 48.1 (SD 18.3) at baseline, 32.6 (SD 17.4) at 6 months, 42.3 (SD 22.5) at 1 year and 43.3 (21.2) after 3 years. The results clearly show a trend of weight reduction during treatment, and of weight gain during follow-up.
Other outcomes	Children adopted a significantly more internal locus of control (LOCSC) from week 1 to week 26.Likewise, an analysis of the Eating and Activity Self-Control Scale (EASC) indicated an increase in children's self-control and parental control regarding weight-related behaviours ($p < 0.001$) and ($p < 0.05$), respectively. Parental judgements from the Self-Control Rating Scale (SCRS) also indicated significantly more self-controlled behaviours at week 26 than at week 1 ($p < 0.05$).
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Dropouts: 41% at follow-up. Unclear blinding. Randomisation method not described.

Wrotniak 2004 Secondary data analysis of three RCTs [971]	
Aim	To determine whether parent-standardised body mass index (BMI *z*-score) change predicts child BMI *z*-score change.
Country and setting	USA. University paediatric obesity research clinic
Participants	One participating parent and one 8–12-year-old child from each of 142 families were recruited for one of three family-based weight control programmes. Inclusion criteria were: children with greater than the 85th BMI percentile and participating parents greater that the 70th BMI percentile who were willing to attend treatment meetings.
Recruitment	Not reported.
Intervention	Participating parents were asked to change their eating and activity patterns and home environment. If the parents were not overweight, they were asked to eat more fruits and vegetables and low-fat dairy products and be more physically active, so all parents could make positive health changes, even if they were not obese. All families were provided with an educational programme based on the traffic light diet and a PA programme. Families were also taught how to rearrange their environment to support eating-related behaviour change, by making unhealthy choices more difficult to access or by making healthy choices more appealing. Families were taught how to limit the amount of red

	foods in the house and to increase the amount of green foods. Behaviour change was accomplished by the use of contracts negotiated between the parent and child and by social reinforcement.
Delivery of intervention/control	Unclear.
Dropout rates	Not applicable.
Control	Not reported.
Length of follow-up	24 months.
Results	Children of the parents in the greatest BMI *z*-score change quartile had greater reductions in weight for height and in percentage overweight (weight –7.2 kg; percentage overweight –27.6) after 6 months compared with children of the parents in the other three categories (weight –4.0 kg; percentage overweight –20.9). After 2 years, children of the parents in the greatest BMI *z*-score change quartile gained less weight for height and had greater percentage overweight changes (–16.8%) compared with children in the lowest tree parent BMI *z*-score change quartiles. Parent BMI *z*-score change significantly predicted child BMI *z*-score change from 0–6 months ($p < 0.001$) and from 0–24 months ($p < 0.009$). Parents in the highest quartile of BMI *z*-score change had children with significantly greater BMI *z*-score change than that of children with parents in the other quartiles.
Other outcomes	No other outcomes were reported.
Treatment of dropouts (return to baseline, or last measurement?)	Only families with complete parent and child data at all time points were included for analyses.
Quality and comments	No details of randomisation given. Unclear if blinded. Participants included in this report are from three studies that differed in their goals and study hypotheses (Epstein 2000a,b, 2004), which are included in this review.

Epstein 1981 and 1987 (in Mclean review) RCT [947] [946]	
Aim	To assess the importance of targeting the child or parent and child in a family based obesity programme with high-risk, preadolescent obese children.
Country and setting	USA. Outpatient university research centre
Participants	Seventy-six families met the inclusion criteria of: 1) at least one child and one parent between 115 and 180% of the ideal weight for height and age; 2) having triceps skinfold thickness values >95% of children their age; 3) height not below the 25th percentile for children their age; 4) no psychiatric contact; 5) both parents at home; 6) target parent

	willing to participate in the weight loss programme, and 7) ability to attend at least 12/14 treatment sessions.
Recruitment	Through newspapers advertisements, fliers distributed at schools, and physicians.
Intervention	Three treatment groups: Parent/child target (group 1), child target (group 2) and non-specific target (group 3). The three groups were given identical information on diet (each group undertook the 'traffic light diet', in which each family was provided with a colour-coded food reference guide that included caloric content per serving. Participants were taught how to keep a diet diary and to chart daily weights, energy intake, and number of red foods eaten, for a 1200 or 1500 kcal (5.02 or 6.28 MJ) limit, exercise (each group received information on aerobic exercise, stretching and spot reducing) and behavioural procedures (such as contracting, self-monitoring, social reinforcement and prompts, therapist contact, and contingency management). Each of the groups was provided with a 14 session treatment programme, which included eight weekly sessions and six sessions distributed over the next 6 months, which were held 2.5, 3, 4, 5, 6.5 and 8 months after the beginning of the treatment. At the 5-year measurement, both parents and children completed a retrospective questionnaire to assess the use of the behaviour change techniques taught during the programme.
Delivery of intervention/control	Therapists.
Dropout rates	Unclear.
Control	Unclear if non-specific group is control.
Length of follow-up	Up to 13 months after the termination of the treatment, or 21 months after the beginning.
Results (8 months treatment and 21 and 60 (Epstein 1987) months follow-up)	All groups changed in percentage overweight. A significant decrease ($p < 0.01$) was observed from 0 to 2 months, with a further decrease from 2 to 8 months ($p < 0.01$). Adults also showed significant percentage overweigh changes. Parents in group 1 lost more weight than parents in groups 2 and 3 ($p < 0.01$) at 8 months. At the end of the treatment, a significantly greater ($p < 0.05$) proportion of group 2 children compared with group 3 were non-obese. At 21 months, a greater proportion of non-obese (non-significant) from group 1 than in groups 2 and 3. 32% of the adults were non-obese at the end of treatment, with only 19% non-obese at follow-up. The proportion of non-obese parents was less in group 3 at 8 and 21 months, although non-significant. At 5 years significant univariate changes were shown for

	percentage overweight ($p = 0.001$) but not for weight or height. The percentage overweight in children in the parent-plus-child group decreased (–12.7%), whereas that of children in the other two groups increased (4.3 and 8.2%, respectively). At 5 years the percentage of children in the parent plus child, child alone and non-specific groups who were not obese were 33, 19 and 4.5% ($p = 0.048$), respectively (Epstein 1987).
Other outcomes	The consumption of red, yellow and green foods at the start and end of treatment was compared. The results showed significant pre-post ($p < 0.001$); food group ($p < 0.001$); pre-post × food group ($p < 0.001$); and treatment × pre-post × food group ($p < 0.05$) effects. Significant increased ($p < 0.0001$) in height of 22.8 cm and significant decreases ($p < 0.0001$) in height percentile from the 72nd to the 60th percentile were observed. No differences were observed between groups in height change, and subsequent height analyses are based on the total sample.
Treatment of dropouts (return to baseline, or last measurement?)	Results for each analysis were based only on families who attended at least the last weekly treatment meeting, the 6.5- or 8-months treatment meeting, and the 13-month follow-up.
Quality and comments	Dropouts: unclear. Unclear blinding and concealment. Stratified random assignment.

Epstein 1990 [970]	
Aim	To examine the effects of behavioural family-based treatment on percentage overweight and growth over 10 years in obese 6 to 12-year-old children.
Country and Setting	USA. University research centre.
Recruitment	Not clear.
Participants	Seventy-six families with children aged 6 to 12 years were eligible for randomisation after which one child was removed from the sample due to unreported psychiatric problems. Inclusion criteria was as follow: greater than 20% over ideal weight for age, height, and sex, triceps skinfold thickness greater than 95th percentile for children their age, no history of psychiatric contact for children; both parents living at home, at least one obese parent, and a parent willing to attend treatment meetings with their child.
Intervention	Participants were randomised to one of three groups: child and parent target (group 1), child target (group 2), or non-specific target (group 3). All families were provided with eight weekly treatment meetings and six additional meetings distributed during the next 6 months.

	They were then seen at 21-, 60- and 120-month follow-up Participants were given the traffic light diet, and all subjects were given information on aerobic exercise, stretching, and spot reducing and were instructed to begin an aerobic exercise programme according to Cooper. A range of behavioural procedures were used across the three groups to differentially reinforce families for behaviour change and weight loss: contracting; self-monitoring; and social reinforcement and modelling.
Control	Three treatment groups.
Length of follow-up	10 years
Results	At the 5-year follow-up, data was available on 67 of the 75 eligible families. At 10 years, one death occured, and data were collected from 61 of 66 families. Significant percentage overweight differences ($p < 0.05$) were shown at both 5 and 10 years between children in groups 1 and with children in group 2 midway between the other groups. Children in group 1 showed a decrease from baseline in percentage overweight after 5 and 10 years, whilst children in groups 2 and 3 showed an increase in percentage overweight from baseline to 5 and 10 years. Differential weight gain across the three groups was observed so that after 10 years children in group 3 had gained 12.6 kg more (+46.6 kg) than children in group 2 (+34.0 kg) while children in group 2 had gained 9.1 kg more than children in group 1. Children in groups 2 and 3 were significantly heavier ($p < 0.05$) than children in group 1. No significant differences across groups were shown in percentage overweight changes for parents at 10 years. There was little relationship between long-term child and parent changes in percentage overweight.
Dropouts	19% at 10 years.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those that completed follow-ups.
Quality and comments	No details of randomisation. No blinding or concealment methods mentioned.

1.4.7 Interventions focusing on cognitive behaviour therapy

Duffy 1993 (in Cochrane) RCT [974]	
Aim	To examine the effectiveness of cognitive self-management training as an adjunct to the behavioural management of childhood obesity.
Country and setting	Australia. Not clear but probably clinic.
Participants	Age range (mean) 7–13 years (118.71 months, SD 20.16). % Male: 21%. Weight inclusion criteria: 15% overweight for age, height and sex. Weight on entry (mean): 48.6% overweight for age, height and sex (SD 22.12).
Recruitment	Through articles in local and State newspapers.
Intervention	8-week 90-min cognitive behaviour therapy (CBT) sessions with the intervention group (*n* = 9) receiving additional cognitive self-management sessions and the control group (BT + **APC**, *n* = 8) receiving relaxation training. Children were encouraged to do aerobic exercise and avoid 'red light foods'. Food intake was recorded for 7 days. A behavioural contract approach was used in which parents paid a redeemable US$30.
Delivery of intervention/control	Unclear.
Dropout rates	37%
Control	As described above.
Length of follow-up	6 months.
Results (8 weeks intervention and 6 months follow-up)	Percentage overweight decreased in the relaxation control group from 46.3 (SD 19.3) at pre-treatment to 37.0 (SD 18.3) at post-treatment, 38.2 (SD 20.7) at 3-month follow-up and 37.1 (SD 21.7) at 6-month follow-up. In the CBT group percentage overweight decreased from 46.0 (SD 18.6) to 37.6 (SD 19.6) at post-treatment, 39.1 (SD 19.3) at 3-month follow-up and 37.0 (SD 24.6) at 6-month follow-up.
Other outcomes	No other outcomes were reported.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed the treatment and follow-up.
Quality and comments	Dropouts 37%. Unclear how many children were randomised to each treatment group. No children and provider blinding, unclear blinding of the outcome assessor. Randomisation method not described.

Warschburger 2001 (in Cochrane) RCT [975]	
Aim	To compare the effectiveness of CBT with relaxation therapy.

Country and setting	Germany. Rehabilitation hospital.
Participants	$n = 197$. Age range 9 to 19 (mean 13.8, SD 1.1) years in experimental group, mean 13.1 (SD 1.1) in the control group. % Male: No details. Weight inclusion criteria: above 20% overweight for height and weight on baseline (mean): % overweight experimental group 63.8 ± 25.4, control group 64.6 ± 23.7.
Recruitment	Unclear.
Intervention	Two groups: 1) Experimental group (CBT)[5] which participated in 'obesity training' that included specific skills to facilitate behaviour change and also behaviour management skills to encourage habit change. Self-monitoring, contract-management, stimulus control, modelling, eating management and reinforcement principles were applied; 2) comparison group which undertook the same diet and exercise programmes but received muscle-relaxation training instead of the psychological intervention component.
Delivery of intervention/control	Unclear.
Dropout rates	No details given.
Control	Comparison group.
Length of follow-up	6 and 12 months.
Results (6 weeks intervention and 6 and 12 months follow-up)	The mean percentage overweight in the experimental group was 62.8 (SD 25.1) at admission; 47.4 (SD 22.9) at discharge at 6 weeks; 46.4 (SD 23.3) 6 months later; and 48.5 (SD 28.1) 1 year later. The mean percentage overweight in the comparison group was 62.5 (SD 23.5) at admission; 48.6 (SD 23.1) at discharge; 45.4 (SD 21.9) 6 months later and 46.8 (SD 27.0) 1 year later. The mean BMI (kg/m^2) in the experimental group was 31.1 (SD 5.0) at admission; 28.6 (SD 5.3) at discharge; 29.2 (SD 4.7) 6 months later; and 30.4 (SD 5.7) 1 year later. The mean BMI in the comparison group was 31.7 (SD 4.6) at admission; 28.8 (SD 4.4) at discharge; 29.0 (SD 5.5) 6 months later and 30.1 (SD 5.9) 1 year later.
Other outcomes	Pre- vs. post-tests showed significant improvements in self-reported eating behaviours for the experimental group compared with the control group ($p < 0.05$). No age or sex differences were found. Both groups showed improvements in their quality of life over time ($p < 0.01$); neither the group nor the interaction effect occurred. During the first 6 months self-reported quality of life increased slightly but not significantly more in the

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[5] Details of this CBT programme are in Warschburger 1999 study (German language).

	experimental group than in the control group ($p = 0.08$).
Reported harms	High degree of stress-induced eating behaviours and a high level of anxiety in the muscle relation group.
Treatment of dropouts (return to baseline, or last measurement?)	Data from completers.
Quality and comments	Dropouts: no details given. Unclear blinding. Randomisation method not described.

Braet 1997, 2000 CCT [976] [804]	
Aim	To assess the additional benefits of introducing a ‘healthy eating’ lifestyle programme instead of a strict diet prescription, in combination with the principles of CBT.
Country and setting	Belgium. Outpatient and inpatient.
Participants	Obese children ($n = 259$). All White and of normal intelligence. The children were between 7 and 16 years of age and were at least 20% overweight. Overweight ranged from 20 to 100%. All socio-economic classes were represented equally. Subjects were free of other medical problems such as diabetes, or did not suffer from any syndromic obesity.
Recruitment	From media advertisements and physician referral.
Intervention	Self-instructions, self-observation, self-evaluation and self-reward techniques were introduced in each session. Modelling, behaviour rehearsal and homework were used to train self-regulation skills. Problem-solving skills were taught in different high-risk eating situations. Contracts were established including what a child would receive if it followed the programme. Parents were asked to praise their children for good performance. Children were taught about the benefits of exercise and energy expenditure. Exercises were promoted with a frequency of 30 min each day in combination with lifestyle changes such as taking the stairs, walking instead of going by car, helping in the garden or cleaning the house. Moderate intensity in order to keep the exercises up for 30 min, and children were not instructed to exercise at a particular intensity. Changes in eating habits were proposed in small steps, and children were given the chance to make their own choices. They were instructed on how to eat in a healthy way many times a day including many vegetables. ‘Counting calories’ was not permitted. Subjects were assigned to four different treatment groups: group; individual, advice; and camp. Summer camp: 18 subjects in one camp, organised three times. They received healthy food (1500 kcal [6.28 MJ]/day) and daily lifestyle exercises. The outpatient

	programme (group or individual) consisted of an intensive part for the child only, including seven sessions of 90 min (twice per month) and seven family follow-up sessions (once per month). There were no differences between the programme of the group and the individual training. For some families, the treatment was not feasible because of other family plans, so children could be assigned to and advice in one session group. In all treatment conditions children received the same package of information. Parents were given a treatment manual for parents of obese children and the child had his own workbook.
Delivery of intervention/control	Unclear.
Dropout rates	19.9% at 4.6 years, which accounted for 27 children.
Control	Fifty-four non-clinical obese children with no treatment.
Length of follow-up	At year 1 and 4.6 years.
Results	

	During treatment	**After treatment**	**1-year follow-up**
Condition			
Group	3.31	8.44	13.08
Individual	5.72	8.34	9.84
Advice	–	–	6.84
Camp	8.22	15.59	14.67
Control	–	–	–2.52

The above table summarises the results for mean weight loss (%) for all the condition and control groups. All results were significant ($p < 0.001$).

At 4.6 years follow-up, mean % overweight were as follows: group ($n = 19$) 34 (SD 19); individual $n = 13$ (39) (SD 24); summer camp ($n = 30$) 45 (SD 21); and advice ($n = 47$) 45 (SD 30). In total the children had a mean percentage overweight of 42%.

Paired *t* tests revealed significant time effects in four different treatment groups at 4.6 years follow-up: treatment in group ($p < 0.001$); individual treatment ($p < 0.05$); summer camp ($p < 0.001$); and advice group ($p < 0.001$). No significant results were found in comparing the 1-year follow-up with the 4.6-year follow-up.

Other outcomes[6]	In a pilot study, the authors contend that they noticed that eating patterns changed during the treatment.

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[6] Details of these outcomes are in the Harms section.

	Paired *t* test on the subscales of the Dutch Eating Disorder Questionnaire (DEBQ) revealed a significant reduction in external eating ($p < 0.001$), a significant increase in restrained eating ($p < 0.001$), and no difference between pre-testing and the 4.6-year follow-up for emotional eating. Mean score on the drive for thinness (DT) subscale of the EDI was 5.6 (SD 5); for the body dissatisfaction (BD) subscale the mean score for the total sample was 13.2 (SD 7) and for the bulimia (B) subscale the mean score was 1.2 (SD 3).
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed treatment and follow-up.
Quality and comments	The percentage overweight of the non-clinical control group was lower than in the subjects in the other conditions, although this was taken into account in the analysis. Overall methodologically limited study, with no randomisation.

Braet 2003 [801]	
Aim	To assess the effect of an inpatient multi-component treatment programme for obese children and adolescents on their weight and psychological well-being
Country and setting	Belgium. Inpatients treatment centre.
Participants	Seventy-six children and adolescents were referred to the centre. Median age in both groups was 13 (range 10–17) years. At baseline median BMI of the study group was 33 (range 22–46) kg/m^2 and the control group 33 (range 24–51) kg/m^2. Children with Prader–Willi syndrome were not recruited.
Recruitment	By referral from physicians for inpatient treatment due to obesity.
Intervention	Every fifth children on the alphabetical list of patients starting treatment in September 1996, 1997 and 1998 was included in this study, resulting in a sample of 38 patients, or 20% of the total group treated. The diet consisted of 30% energy as fat, 15% energy as protein, and 55% energy as CHO, consisting of servings of fruits, three servings of vegetables, 100 g of meat or 150 g of fish, semi-skimmed milk and low-fat cheese, and high fibre staples. It provided between 1500 and 1800 kcal (6.28 and 7.54 MJ)/day. All children received an adapted individual PA training programme for 4 hours/week. Before and after school, the children were encouraged to exercise for 10 hour/week or even more if they wanted.

	Children also received a 12-week CBT programme in small groups, followed by personalised problem-solving-based booster sessions every week. To change their lifestyles, the children were taught self-regulation skills, such as self-observation, self-instruction, self-evaluation and self-reward. A problem-solving approach was introduced to teach the children how to cope with different high-risk situations, and were trained to cope with different stressful situations, such as feeling hungry. Interaction with parents was limited, and children saw the parents every 2 weeks. They received leaflets on how to prepare healthy food and how to (re)organise their shopping habits. Children stayed in the centre for one school year (10 months), and twice per month the children returned home for the weekend. The other two weekends and half of the school-holidays they stayed in the centre.
Delivery of intervention/control	Standardised treatment was developed and supervised by two behaviour therapists and two medical doctors. It was carried out with the help of one dietitian, one psychologist, one social worker, one medical doctor, one physiotherapist and six group leaders.
Dropout rates	Seven children left the programme during the study. At 6 months, data for three children could not be collected, and at 14 months one additional child could not be traced.
Control	For each 38 children, a case-control (based on age and gender) was selected from the waiting list of the centre.
Length of follow-up	14 months.
Results	During treatment, the children in the study group showed a decrease in the median adjusted BMI of –48 (range –4 to –102)%. Median weight loss was –19 (range +2 to –41) kg. At 6 months after finishing the treatment, the median adjusted BMI was 135 (range 105–192)% and at 14 months, it was 143 (range 104–198)%. This was a result of an increase in the adjusted BMI at 6 months follow-up of +6 (range –19 to –37)% and at 14 months follow-up an additional increase of +4 (range –30 to +41)%. At the 14-month follow-up, 13/27 children showed an increase in their overweight of <10% or continued to lose weight compared with their post-treatment weight and 14/27 children had an increase of >10% overweight (up to +41%).
Other outcomes[7]	Eating behaviours showed no increase in eating psychopathology during the 10-month treatment. On the subscales of the EDI, a significant reduction on the drive for thinness subscale was reported ($p < 0.001$) and no change was reported on the bulimia subscale. The scores on the emotional eating and restrained eating showed an insignificant trend, whilst

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[7] Details of these outcomes are in the Harms section.

	the scores on the subscale 'external eating' declined significantly, $p < 0.001$. On the Self Perception Profile for Children (SPPC), the scores on three subscales increased significantly during the 10-months treatment: physical appearance, $p < 0.001$; athletic competence, $p < 0.05$; and social competence, $p < 0.05$. On the subscales academic competence, behavioural conduct and global self-worth, no significant trends were found.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only from those who completed the study.
Quality and comments	The therapists were blinded for the study. Not randomised study. Overall poor quality study.

1.4.8 Interventions comparing reinforcement or stimulus control of sedentary behaviours

Epstein 2004 RCT [20]	
Aim	The main goal of the study was to assess whether different methods of reducing targeted sedentary behaviours are associated with differences in the pattern of change in sedentary and active behaviours and in percentage overweight change.
Country and setting	USA. Unclear setting.
Participants	Seventy-two families with 8–12-year-old children with the following inclusion criteria: child being over the 85th BMI percentile, one parent willing to attend treatment meetings, no family members participating in another weight control programme, no child or parent with current psychiatric problems or dietary or exercise restrictions, and child able to read the manuals and complete the self-monitoring of food and activity.
Recruitment	Through physician referral, brochures, fliers, and newspaper advertisements.
Intervention	Families were randomised into one of two treatment groups: reinforced reduced sedentary behaviour or stimulus control of sedentary behaviours. The treatment programme included 16 weekly meetings, followed by two biweekly meetings and two monthly meetings during the 6-month intensive treatment. Families received parent an child family-based weight control workbooks, which included four main sections: 1) introduction to weight control and self-monitoring; 2) the traffic light diet; 3) behaviour change techniques; and 4) maintenance of behaviour change. Families in both groups were taught to praise children for meeting goals specific to their group, and children were also

	provided a contract reinforcement system to motivate children for behaviour change. Preplanning was taught to facilitate eating and exercise control when difficult eating and activity situations could be anticipated, such as parties, holiday gatherings, and school or work functions. All subjects were instructed to reduce hours of targeted sedentary activity to ≤15 per week. Children in the reinforcement group were provided points for reducing their sedentary behaviours to no more than 15 hours/week. The reinforcement group had shaping steps of 25, 20 and 15 hours/week to reduce their sedentary time and were rewarded for meeting their goals. goals were set on the basis of the children's baseline values. Praise and contract goals specific to decreasing targeted sedentary behaviours were used in this group. Children in the stimulus control group were positively reinforced for recording their sedentary behaviours but not for behaviour change. They were also instructed to change their environment to prevent them from engaging in the targeted behaviours and to establish rules regarding the sedentary behaviours. They also received instructions to help sedentary behaviour change, which involved posting signs indicating the sedentary limit and unplugging targeted sedentary activities such as television or computers. In the reinforced reduction group positive reinforcement was contingent on reducing targeted sedentary behaviours, whilst in the stimulus control group positive reinforcement was contingent on recording targeted sedentary behaviours.
Delivery of intervention/control	Therapist.
Dropout rates	8%
Control	Only two treatment groups reported.
Length of follow-up	12 months.
Results (6 month treatment and 12 months follow-up)	There were significant changes in BMI *z*-score, with significant treatment effects observed at both 6 months ($p < 0.001$) and 12 months ($p < 0.001$), but there were no significant differences in the rate of change between groups. BMI *z*-score values for the stimulus control group were 3.3 ± 1.0, 2.3 ± 1.0, and 2.4 ± 1.0, at 0, 6, and 12 months, respectively, whilst the values for the reinforced reduction group at the same time were 3.2 ± 1.0, 2.2 ± 1.1 and 2.6 ± 1.0. Analysis of changes in BMI *z*-score over time as a function of substituters and non-substituters showed significant differences in the rate of change between the two groups ($p < 0.01$), with those who substituted showing greater change at 6 months (BMI *z*-score –1.21 vs. –0.76) ($p < 0.02$) and 12 months (BMI *z*-score –1.05 vs. –0.51) ($p < 0.02$).

	Those who showed complementary relationships between high-energy-density foods and changes in sedentary behaviours also showed stronger BMI *z*-score changes over time ($p < 0.03$), with those who complemented showing greater change at 6 months (BMI *z*-score –1.17 vs. –0.69) ($p < 0.02$), but not at 12 months (BMI *z*-score –0.93 vs. –0.51) ($p = 3.24$).
Other outcomes	Significant decreases in high energy-density (red) foods (–2.6 ± 2.2 servings were observed from 0–6 months ($p < 0.001$), and also significant increases servings of fruits and vegetables (0.6 ± 2.3) ($p < 0.05$). There was also a significant decrease (–2.2 ± 7.4) in percentage of time in targeted sedentary behaviours ($p < 0.05$). There was an effect of substituting PA for targeted sedentary behaviours on targeted sedentary behaviours ($p < 0.001$), with greater decreases at 6 months for those who substituted. greater increases in moderate to vigorous PA were observed at 6 months for those who substituted vs. those who did not substitute ($p < 0.001$). Greater increases in activity level for those who substituted were also observed ($p < 0.001$).
Treatment of dropouts (return to baseline, or last measurement?)	Only complete data from subjects was included for analyses.
Quality and comments	No details of randomisation were given. Subjects were blinded.

Epstein 1994 (in Cochrane) RCT [977]	
Aim	To compare mastery criteria and contingent reinforcement with BT.
Participants	$n = 44$ randomised, 39 completed. Age range (mean): 8–12 (10.2 ± 1.1) years. % Male: 26. Weight inclusion criteria: between 20 and 100% overweight for height. Weight on baseline (mean): 59.6% ± 22.0% over the 50th percentile for BMI.
Intervention	Comparison of two behavioural treatments groups: the experimental group ($n = 17$) was targeted and reinforced for mastery of diet, exercise, weight loss and parenting skills; and the control group ($n = 22$) was taught behaviour change strategies and provided non-contingent reinforcement at a pace linked to that of the experimental group. Treatment was given over 26 weekly meetings and 6-monthly meetings.
Control	As described above.
Length of follow-up	2 years.
Results (26 weeks intervention and 6 monthly follow-ups	Mean percentage overweight decreased in the experimental group from 60.6 (SD 25.3) at baseline to 30.5 at 6 months and 34.1 at 1 year. In the control group mean percentage overweight decreased from 58.8 (SD 19.6) at baseline to 38.8 at 6 months and then

up to 2 years)	increased to 42.1 at 1 year.
Other outcomes	Significant changes in red foods per week ($p < 0.05$), days with complete recording ($p < 0.001$), and days within the energy range ($p < 0.025$). No significant differences were observed for graphing weight, child meetings per week, or meeting the exercise goal ($p = 0.12$). Parents showed a significant improvement in knowledge of behavioural principles across time ($p < 0.001$), with equivalent improvements across experimental and control groups.
Quality and comments	Dropouts 11%. Blinding was unclear. Details of randomisation were not provided.

1.5 Pharmacological interventions

1.5.1 Orlistat

Weight loss

Chanoine 2005 RCT	
Aim	To determine the efficacy and safety of orlistat in the weight management of adolescents
Participants	Adolescents (aged 12–16 years) who were overweight (BMI ≥2 kg/m^2 above 95th centile). Total *n* = 533 (357 female, 176 male). Mean age: 13.6 (SD 1.3) years; orlistat (*n* = 352) 13.5 (SD 1.2) years; control (*n* = 181) Mean age 13.6 (SD 1.2) Mean BMI (kg/m^2): 35.7 (SD 4.2) control; 35.4 (SD 4.1) placebo.
Intervention	Diet: Maintained on a nutritionally balanced, hypoenergetic diet designed to produce an initial weight loss of 0.5 to 1.0 kg/week. The energy distribution of the diet was 30% of energy as fat (10% saturated, 10% monounsaturated and 10% polyunsaturated; 70 g/d maximum), 50% as CHO and 20% as protein. Maximum intakes of cholesterol and calcium were 300 mg/d and 1300 mg/d, respectively. Daily energy intake was adjusted during the double-blind treatment period if the participant reached a BMI of 22 kg/m^2 or if the participant was losing weight too rapidly (>1 kg/week). At each study visit, the dietitian spoke with the patient about compliance with diet. Participants in both treatment groups received a commercially available daily multivitamin supplement throughout the study. Activity: Guidelines were provided to encourage regular PA and reduce sedentary behaviour. Strength, flexibility and aerobic activities were included as part of the exercise plan wherever possible. A behavioural psychologist spoke about compliance with the exercise programme at each study visit. Behaviour modification: All centres had behavioural modification programmes in place, but used a study-specific manual as a guideline.

	generally involved recording food intake and activity; limiting high-energy and high-fat foods in the household; restricting food intake to the dining area at meal times; eating slowly; avoiding snacking; encouraging participants to understand their cues for overeating; and substituting new behaviours for overeating. Staff supported and reinforced behavioural modification techniques regularly. Drug: Orlistat 120 mg three times per day.
Control	As above except: Drug: Placebo three times per day.
Length of follow-up	54 weeks (including 2-week pre-treatment phase).
Results	Compared with baseline, both groups lost weight during the first 4 weeks of the study, although participants receiving orlistat lost more weight. Starting at week 4, participants treated with orlistat continued to lose weight steadily to a maximum weight loss at week 12. In contrast, placebo-treated participants' weight was stable during weeks 4 through 12. Subsequently, both groups regained weight, but the effect attributable to the drug (i.e. the between-group difference in body weight) after 6 months was sustained. Significant differences were seen between the orlistat and placebo groups at 12 months for weight change (+0.53 vs. +3.14 kg, $p < 0.001$) and BMI (–0.55 vs. +0.31 kg/m^2, $p = 0.001$). At 12 months, 26.5% of the orlistat group compared with 15.7% of the placebo group lost 5% or more of initial BMI ($p = 0.005$). At 12 months, 13.3% of the orlistat group compared with 4.5% of the placebo group lost 10% or more of initial BMI ($p = 0.002$).
Quality and comments	Blinded assessment not reported explicitly, but described as 'triple blind'. Modified ITT analysis done. Good concealment of allocation (central computerised allocation).
Sponsor details	Hoffman-La Roche.

McDuffie 2004	**Before and after study**
Aim	To study the safety, tolerability and potential efficacy of orlistat in adolescents with obesity and its co-morbid conditions.
Participants	Adolescents (aged 12–17 years) who were obese (BMI >95th centile for age, race, sex). Total $n = 20$: ten female, ten male. Mean age 14.6 (SD 2.0) years. Mean BMI 44.1 (SD 12.6) kg/m^2.
Intervention	Diet: 500 (2.09 MJ) kcal deficit/day diet with ≤30% of energy from fat. given multivitamin supplement. Activity: Encouraging 30 min of daily aerobic exercise and inclusion of lifestyle exercise whenever possible, monitored by pedometer readings; and on-site PAs and education led by a recreation therapist for 15–30 min

	of each weekly meeting. Behaviour modification: Goals of the programme were to reinforce dietary principles, encourage PA, discourage inactivity, and provide psychosocial support. The programme used three avenues to achieve these goals: nutrition education, an exercise programme and behaviour modification skills training. Nutrition education review used a game format for 15–30 min during each weekly meeting and homework assignments supplied in a programme manual provided to each subject. The behaviour modification programme concentrated on stimulus control and eating management skills. Compliance was gauged through self-monitoring of medication taken, food eaten, activity performed, amount of inactive time spent and pedometer readings, recorded in a progress book reviewed by the group leaders each week. Points toward winning prizes were awarded each week contingent on a minimum 0.5 lb (0.23 kg) weight loss and a completed progress book. Drug: Orlistat 120 mg three times per day with meals.
Control	No control group – results compared with before treatment.
Length of follow-up	6 months.
Results	At 3 months, mean weight change was –4.4 (SD 4.6) kg ($p < 0.001$), or –3.8 (SD 4.1)% of initial body weight. Mean BMI change was –1.9 (SD 2.5), $p < 0.0002$. At 6 months, mean weight change was –5.4 (SD) ($p < 0.02$) kg, or –3.5 (SD 6.0)% of initial body weight. Mean BMI change was –2.0 ($p = 0.001$) kg/m^2. At 6 months, 30% had lost 5% or more of initial weight and 15% had lost 10% or more. An analysis of the ten African American compared with White participants found that African Americans showed significantly less improvement in weight ($p < 0.05$) and BMI ($p < 0.01$).
Quality and comments	ITT done. Not RCT.
Sponsor details	NICHD grant and National Centre on Minority Health and Health Disparities

Norgren 2003 Before and after study	
Aim	To investigate orlistat treatment in obese pre-pubertal children with regard to tolerance, safety and psychological well-being.
Participants	Pre-pubertal children (aged 7–12 years) who were overweight (BMI >4 SDs above normal). Total n =11: seven female, four male. Mean age 10.7 (range 8.3–12.3) years. BMI standard deviation score range of 5.3 to 9.2.
Intervention	Diet: Given detailed information on sources of fat and recommended intake of dietary fat.

	Drug: Orlistat 120 mg with each eating/meal about three times per day (occasionally four times per day).
Control	No control group.
Length of follow-up	12 weeks.
Results	Over the 12 weeks preceding treatment, the children were not subjected to any form of intervention and exhibited a median weight change of +2.6 (range 0.9–6.4) kg, $p = 0.003$. All participants completed the 12-week treatment, resulting in a median weight change of –4.0 (range –12.7 to +2.5) kg, $p = 0.016$. Median BMI changed from 33.3 (range 27.6–37.5) to 31.4 (range 24.4–34.2) kg/m^2, $p = 0.008$.
Quality and comments	Not RCT.
Sponsor details	Swedish Medical Foundation and Swedish Medical Research Council.

Ozkan 2004 Quasi-RCT	
Aim	To investigate the efficacy and tolerability of orlistat in adolescents who were obese.
Participants	Adolescents (aged 10–16 years) who were obese (weight for height index >140%). Total $n = 42$: 20 female, ten male (completers only). Mean age 12.9 (SD 2.4) years orlistat ($n = 15$), 12.5 (SD 2.2) control ($n = 15$). Median BMI (kg/m^2) 32.5 orlistat, 31.2 control. Results for completers only. Not sure if age at beginning or end of study.
Intervention	Diet: 20% reduction in daily energy intake. Activity: At least 30 min moderate exercise per day. Drug: Orlistat 120 mg three times per day.
Control	As above except: Drug: No placebo offered.
Length of follow-up	Mean duration of follow-up (months): 11.7 (SD 3.7) orlistat, 10.2 (SD 3.7) control (not significant).
Results	Compared with initial body weight, the orlistat group showed a mean weight change of–6.27 (SD 5.4) kg, while the control group showed a mean weight change of +4.16 (SD 6.45) kg, $p < 0.001$. Compared with initial BMI, the orlistat group showed a mean change of –4.09 (SD 2.9) kg/m^2, while the control group showed a mean change of +0.11 (2.49) kg/m^2, $p < 0.001$. Compared with initial body weight, the orlistat group showed a mean weight change of –7.65 (SD 6.5)%, while the control group showed a mean weight change of +5.70 (SD 8.30)%, $p < 0.001$.
Quality and	Significantly higher BMI in the orlistat group at beginning of study

comments	($p = 0.018$). Not placebo controlled. Quasi-randomised (alternation). Concealment of allocation and outcome assessment assessed as addressed. Blinding and ITT not reported.
Sponsor details	Turkish Academy of Sciences.

Zhi 2003 RCT	
Aim	To assess whether orlistat has an effect on the physiologic balance of minerals (calcium, phosphorus, magnesium, iron, zinc, copper).
Participants	Adolescents (aged 12–16 years) who were obese (BMI ≥85th centile adjusted for age and gender). Total $n = 32$: 19 female, 13 male. Mean age (years): 14 (SD 1) orlistat ($n = 16$), 14 (SD 1) placebo ($n = 16$). Mean BMI (kg/m^2): 34 (SD 6) orlistat, 34 (SD 8) placebo.
Intervention	Diet: Approximately 18% and 28–40% lower than average energy intake for female and male participants responses. Approximately 30% of energy from fat. Drug: Orlistat 120 mg three times per day
Control	As above except: Drug: Placebo three times per day.
Length of follow-up	21 days.
Results	At 3 weeks, mean weight change from initial body weight was –7.0% for the orlistat group and –7.8% for the placebo group.
Quality and comments	Aim was not weight loss. Randomisation, blinding and ITT not reported. Concealment of allocation and baseline comparison assessed as poor.
Sponsor details	Hoffman-La Roche.

Other outcomes

Chanoine 2005 RCT	
Results	No significant differences were found between the two groups with regard to changes in lipid or glucose levels. Participants treated with orlistat experienced significantly greater decreases from baseline to end-point in both waist circumference (–2.67 vs. –0.89 cm, $p = 0.01$) and hip circumference (–1.52 vs. –0.10 cm, $p = 0.01$) than participants receiving placebo. At 12 months, diastolic blood pressure decreased in participants treated with orlistat and increased in placebo recipients (–0.51 vs. +1.30 mmHg, $p = 0.04$). There was no statistically significant change in systolic blood pressure, lipid, triacylglycerol or fasting plasma glucose levels. In general, levels of vitamins A, D and E and beta-carotene were within the

	normal range and increased in both groups during treatment. The levels of oestradiol among girls decreased from baseline in the orlistat group compared with a slight increase in the placebo group (–7.5 vs. +0.7 pg/ml; $p = 0.05$) at study end. There was no significant difference in height gain between groups. Participants in both groups experienced normal sexual maturation, as shown by changes in Tanner stage over the 52 weeks of the study. In the subgroup of participants undergoing dual-energy X-ray absorptiometry (DEXA) evaluation, bone mineral content (+182 g in the orlistat group and +177 g in the placebo group) and bone mineral density (+0.04 g/cm^2 in both groups) increased similarly in the two treatment groups independently of sex. Participants in the orlistat group (+2312 g) gained a similar amount of fat-free body mass as those in the placebo group (+2116 g). However, participants in the orlistat group lost significantly more fat mass than those in the placebo group (–2401 g in the orlistat group vs. –380 g in the placebo group; $p = 0.03$).
Quality and comments	All participants were given a multivitamin tablet.

McDuffie 2004 Before and after study	
Results	At 6 months, mean total cholesterol levels had decreased from 4.46 (SD 0.03) to 3.88 (SD 0.12) mmol/l ($p < 0.0001$), and LDL decreased significantly ($p < 0.001$) from 3.01 (SD 0.03) to 2.51 (SD 0.03) mmol/l. No significant changes were seen for HDL-cholesterol, HDL/LDL ratios or serum triacylglycerol. Fasting insulin and fasting glucose were significantly ($p < 0.02$ and $p < 0.003$, respectively) after treatment. No significant changes were seen in serum vitamin A and E levels. Serum iron rose ($p < 0.02$) but was within the normal range. Mean vitamin D levels were significantly reduced ($p < 0.02$) after 1 month of orlistat treatment.
Quality and comments	Converted mg/dl to mmol/l.

Norgren 2003 Before and after study	
Results	Plasma cholesterol and triacylglycerol did not change significantly during treatment. Neither did the cholesterol and triacylglycerol content of the high-, low- or very-low-density lipoprotein fractions. Serum levels of vitamin D (1,25-hydroxycholecaliferol) did not decrease significantly, while the levels of vitamin E and A showed minor U-shaped variation profiles. The eating attitudes of the participants were influenced by treatment, as investigated by the Children's Eating Attitudes Test (ChEAT). The maximal total score is 78, and a score above 20 has been taken to suggest anorexia nervosa. The mean ChEAT score of randomly selected Swedish

	children of similar age as the participants in this study (fifth graders) is 2.0 for girls and 2.5 for boys. The median total score of the participants increased from 7 to 10 (*p* = 0.011). The median score reflecting 'dieting' increased from 3 to 5 (*p* = 0.041) and the score reflecting 'oral control' (personal and social control of eating behaviour) from 3 to 4 (*p* = 0.034), while the score reflecting 'bulimia' did not change. There was no indication of clinical depression before or after treatment as assessed by Children's Depression Inventory (CDI). Instead, treatment resulted in a non-significant trend towards improved self-image. After treatment, the children identified their own physique with a thinner silhouette, while the silhouette they aspired to remained the same. In addition, they perceived losing weight to be less difficult after treatment, and there was a non-significant trend towards increased motivation to lose weight.
Quality and comments	–

Ozkan 2004 Quasi-RCT	
Results	No other outcomes reported.
Quality and comments	–

Zhi 2003 RCT	
Results	Dietary fat absorption was inhibited by approximately 27%. No significant changes were seen in mineral balance between the groups, or in serum or urine electrolytes, or urinary creatinine excretion.
Quality and comments	–

Reported harms

Chanoine 2005 RCT	
Harms	In total, 97% of participants in the orlistat group and 94% in the placebo group reported at least one adverse event during the 1-year study. Twelve orlistat and three placebo participants discontinued treatment because of adverse events. The most common adverse events were gastrointestinal tract-related; these were more common in the orlistat group. The majority of participants reporting gastrointestinal tract adverse events reported one event. Gastrointestinal tract adverse events were mostly mild to moderate in intensity and led to discontinuation in 2% of the orlistat group. The decrease in BMI was not affected by gastrointestinal tract adverse events in the orlistat group. Overall, 3% of participants in each group had at least one serious adverse event. The five serious adverse events in the placebo group were acute demyelinating encephalomyelitis, facial palsy, pneumonia, worsening of asthma, and pain in the right side. The 11 serious adverse events in the orlistat group were pilonidal abscess, depression (*n* = 2), asthma attack,

	seizure, admission for repair of deviated nasal septum, appendicitis, cholelithiasis, gallbladder disorder followed by cholecystectomy, adenoidal hypertrophy and aseptic meningitis. Only the symptomatic cholelithiasis that led to cholecystectomy in a 15-year-old girl treated with orlistat was considered possibly related to study medication by the investigators; the patient had lost 15.8 kg by the time of the adverse event. Ultrasound revealed multiple tiny gallbladder calculi but no gallbladder thickening, pericholecystic fluid, or dilated biliary tree. No child developed acute cholecystitis during the study. One placebo and ten orlistat recipients developed abnormalities during the study that were detected on electrocardiograms. None of these were believed to be related to the medication based on review by an independent cardiologist. Pulse (76 beats per min) and QT segment length (410 ms) were similar in both groups and were not affected by the intervention.
Quality and comments	–

McDuffie 2004 Before and after study	
Harms	One participant withdrew due to gastrointestinal events. At 3 months, gastrointestinal events were generally mild and transient.
Quality and comments	–

Norgren 2003 Before and after study	
Harms	All suffered diarrhoea on at least one occasion, but only after intake of high-fat products. Two children had frequent diarrhoea and two children reported mildly increased flatulence.
Quality and comments	–

Ozkan 2004 Quasi-RCT	
Harms	Mild gastrointestinal complaints were experienced in all participants receiving orlistat. Seven withdrew due to intolerable side effects.
Quality and comments	–

Zhi 2003 RCT	
Harms	Fifteen orlistat and 13 placebo participants experienced at least one adverse event. Incidence was similar in both groups for most body systems. But a higher proportion of those in the orlistat group experienced gastrointestinal events (25 vs. 13). Adverse events were of mild or moderate intensity, and

	resolved without discontinuation of treatment. No serious adverse events were reported. No clinically significant findings were noted in vital signs or laboratory test parameters.
Quality and comments	–

Generalisability

Chanoine 2005 RCT	
Country and setting	Canada and USA? Institutions with paediatric obesity programmes.
Participants (included/excluded)	Included if adolescents (aged 12–16 years) with BMI 2 units or higher than the US weighted mean for the 95th percentile based on age and sex, had a parent or guardian prepared to attend study visits with them, and were willing to be actively involved in behavioural modification. Excluded if BMI ≥44 kg/m^2 (to increase homogeneity of the group); body weight of ≥130 or <55 kg; weight loss of ≥3 kg within 3 months prior to screening; diabetes requiring antidiabetic medication; obesity associated with genetic disorders; history or presence of psychiatric disease; use of dexamphetamine or methylphenidate; active gastrointestinal tract disorders; ongoing bulimia or laxative abuse; and use of anorexiants or weight-reduction treatments during the 3 months before randomisation.
Recruitment	Advertisements in clinics, direct referrals from family physicians, newspaper advertisements.
Intervention (mode and intensity)	Eighteen visits total – every 2 weeks for first four months, then every 2 months until study end.
Duration of active intervention	52 weeks (2-week pre-treatment phase).
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Dietitian spoke with participants about compliance with diet at each study visit. Behavioural psychologist spoke about compliance with the exercise programme at each study visit. Staff at the study centres supported and reinforced the behavioural modification techniques regularly.
Dropout rates	34% orlistat and 35% placebo at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	Last observation carried forward.

McDuffie 2004 Before and after study

Country and setting	USA.
Participants (included/excluded)	Included if BMI greater than the National Health and Nutrition Examination Survey (NHANES) I (1971 to 1974) 95th percentile for age, sex, and race and the presence of one of the following obesity-related co-morbidities: hypertension, type 2 diabetes or glucose intolerance, hyperinsulinaemia (insulin 15 µU/l), hyperlipidaemia (total triacylglycerol 200 mg/dl, total cholesterol >200 mg/dl or LDL-cholesterol 130 mg/dl), hepatic steatosis or sleep apnoea documented by a formal sleep study. Excluded if a major pulmonary, hepatic, cardiac or musculoskeletal disorder, had a history of substance abuse or other psychiatric disorder that would impair compliance with the study protocol, had used an anorexiant in the past 6 months, or had lost weight in the past 2 months. Each adolescent, along with a parent, gave written consent for protocol participation.
Recruitment	Newspaper advertisements and letters to local physicians.
Intervention (mode and intensity)	6 months – three inpatient assessments (baseline, 3 months and 6 months). Follow-up evaluations every month after end of 12-week behavioural programme.
Duration of active intervention	6 months.
Control (mode and intensity)	No control group.
Delivery of intervention/control (who)	Registered dietitian gave and reviewed dietary advice. Behavioural modification programme led by two registered dietitians, one of whom had graduate psychology training, and a recreation therapist who was also a health fitness instructor. Clinical system pharmacist reviewed medication and unexpected events.
Dropout rates	15% at 6 months.
Treatment of dropouts (return to baseline, or last measurement?)	Last observation carried forward.

Norgren 2003 Before and after study	
Country and setting	Sweden. National Centre for Childhood Obesity.
Participants (included/excluded)	Included if aged 7–12 years and primary obesity with a body mass index standard deviation score (BMI SDS) of more than 4 SD above normal Excluded if recognisable syndromes, chromosomal aberrations, eating disorders, severe psychological disorders, endocrine disorders other than those generally considered

	secondary to obesity, growth retardation and severe asthma.
Recruitment	Successive referrals to the centre.
Intervention (mode and intensity)	Assessed at the clinic at weeks 1, 2, 4, 8, 12. Weekly telephone contact.
Duration of active intervention	12 weeks.
Control (mode and intensity)	No control.
Delivery of intervention/control (who)	Weekly telephone contact with a specialist paediatric nurse.
Dropout rates	0% at 12 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	No missing data.

Ozkan 2004 Quasi-RCT	
Country and setting	Turkey. Study centres – no details.
Participants (included/excluded)	Included if aged 10–16 years, severe exogenous obesity (weight for height index >140%), otherwise healthy, Tanner stage 2 or higher. Excluded if obesity associated with endocrinopathy, genetic syndromes or medications.
Recruitment	Recruited from referrals – no further details.
Intervention (mode and intensity)	Seen monthly by the dietitian and in the outpatient clinic every 2 months.
Duration of active intervention	Varied (approximately 10–11 months).
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Programme administered by paediatric endocrinologist, paediatrician and dietitian at each centre.
Dropout rates	32% orlistat and 25% control at study end.
Treatment of dropouts (return to baseline, or last measurement?)	Not reported.

Zhi 2003 RCT	
Country and setting	USA. Research centre.
Participants	Included if aged 12–16 years, obese (BMI ≥85th centile

(included/excluded)	adjusted for age and gender), otherwise healthy. Excluded if menstruating or expected to menstruate within study period (due to differences in mineral balance).
Recruitment	No details.
Intervention (mode and intensity)	Inpatient unit for 21 days.
Duration of active intervention	21 days.
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Dietitian prepared diet regimen.
Dropout rates	6% orlistat, 6% placebo at 21 days.
Treatment of dropouts (return to baseline, or last measurement?)	Not reported.

1.5.2 Sibutramine

Weight loss

Berkowitz 2003	
Aim	To assess whether increased weight loss in obese adolescents is induced when sibutramine is added to a family-based, behavioural weight control programme.
Participants	Eighty-two boys and post-menarcheal girls aged 13–17 years who had a BMI of 32 to 44 kg/m^2.
Intervention	Thirty-nine assigned to receive BT and placebo, and 42 assigned to receive BT and sibutramine. Behavioural programme: Both groups received the same family-based behavioural weight-loss programme. In phase 1 participants attended 13 weekly group sessions followed by six biweekly group sessions. In phase 2, group sessions were held biweekly from months 7 to 9 and monthly from months 10 to 12. Diet: Both groups were instructed to consume a 1200–1500 kcal (5.02–6.28 MJ)/day diet of conventional foods, with approximately 30% of energy from fat, 15% from protein, and the remainder from CHO. PA: Goal of walking or similar aerobic activity for 120 min per week or more. Drug: During phase 1 all participants received placebo the first week. At week 2, they received either placebo or 5 mg of sibutramine/day. In the treatment group, sibutramine was increased to 10 mg/day at week 3 and to 15 mg/day at week 7. In participants whose systolic or diastolic blood pressure increased from baseline by 10 mmHg or more for two or more visits had their dosage reduced in 5 mg decrements until acceptable blood pressure and pulse rate were restored. Sibutramine was discontinued in participants in whom dose reductions did not reverse the 10 mmHg or more increase or in which systolic or diastolic blood pressure increased 20 mmHg or more at any single visit.
Control	Behavioural protocol and placebo up to 6 months. Following this all the participants received the same titration schedule as for phase 1.
Length of follow-up	12 months.
Results	At month 6, participants in the BT and sibutramine group had a mean weight change of –7.8 (SD 6.3) kg and had a mean change of –8.5 (SD 6.8)% in BMI, which was significantly more than weight change of –3.2 (SD 6.1) kg and change in BMI of –4.0 (SD 5.4)% in the BT and placebo group (*p* = 0.001). From months 7 to 12, adolescents initially treated with sibutramine had a mean weight change of 0.8 (SD 10.5) kg, corresponding to a BMI change of 0.2 (SD 5.4)%, with continued use of the medication, whereas those who switched from placebo to sibutramine had an additional weight change of –1.3 (SD 5.4) kg, corresponding to a mean BMI change of –2.4 (SD 5.0)%. The difference between groups was not significant. From baseline to month 12, participants with BT and sibutramine had a weight change of –7.0 (SD 9.3) kg equal to a BMI change of –8.6 (SD 9.9)%. Participants in the BT and placebo group who changed at

	month 7 to sibutramine had a weight change of –4.5 (SD 8.8) kg corresponding to a BMI change of –6.4 (SD 8.3)%. The difference between groups was not significant.
Quality and comments	Randomised, double-blind, placebo-controlled trial. Parents, participants and all study personnel were blinded to treatment condition during phase 1, with only the research pharmacist being aware of the process. Placebo capsules were identical to the sibutramine ones, and were dispersed in the same way. Adolescents with a BMI >44 kg/m^2 or who had already developed type 2 diabetes were excluded.
Sponsor details	Grant from the NIH and grant from the General Clinical Research Centre of the Children's Hospital of Philadelphia. Knoll Pharmaceutical Co. and Abbott Laboratories provided sibutramine and placebo and unrestricted educational grant.

Godoy-Matos 2005	
Aim	To determine the efficacy and safety of sibutramine in obese adolescents.
Participants	Sixty boys and girls aged 14–17 years, with a BMI of 30–45 kg/m^2. *n* = 30 to each group.
Intervention	Diet: All patients received dietary counselling to achieve an energy deficit of 500 kcal (2.10 MJ)/day at the start of the run-in phase. The recommended diet composition was approximately 30% of energy from fat, 20% from protein and 50% from CHO. PA: Aerobic moderate exercises for at least 30 min/day. Drug: During the single-blind run-in period, all participants received a placebo capsule. Subjects who completed the run-in period and returned less than 25% of the prescribed capsules were randomised to receive sibutramine (10 mg/day) or matching placebo capsules without regard to weight loss during the run-in period. Subjects were instructed to take their capsule in the morning.
Control	Placebo and same diet and PA as described above.
Length of follow-up	4 weeks followed by 6 months.
Results	Compared with baseline, participants in the sibutramine group had a weight change of –10.3 (SD 6.6) kg, and those in the placebo group –2.4 (SD 2.5) kg ($p < 0.001$). The mean BMI change was also significantly greater in the sibutramine group –3.6 (SD 2.5) kg/m^2 than in the placebo group –0.9 (SD 0.9) kg/m^2; $p < 0.001$.
Quality and comments	Randomised, double-blind, placebo-controlled trial.
Sponsor details	Abbott Laboratories.

1.5.3 Other outcomes

Berkowitz 2003	
Results	Significantly greater reductions in hunger (*p* = 0.002) also were reported by participants who received BT and sibutramine. There were no differences between groups during phases 1 or 2 in changes in lipids, triacylglycerol, serum insulin, serum glucose or homeostasis model of insulin sensitivity. At month 12 there was a significant increase in HDL-cholesterol (*p* = 0.001) and significant reductions in serum insulin (*p* < 0.001). Systolic blood pressure decreased 3.6 (SD 8.6) mmHg at 3 months in the BT and placebo compared with a significant increase of 1.8 (SD 10.7) mmHg in the sibutramine group. At month 6 values were –4.0 (SD 8.9) and 0.4 (SD 9.0) mmHg, respectively. There were no other significant differences between groups at any period in changes in systolic or diastolic blood pressure
Quality and comments	–

Godoy-Matos 2005	
Results	No statistical difference was observed between groups in cardiovascular parameters. Nonetheless, systolic and diastolic pressures as well as heart rate tended to decrease more in the placebo than in the sibutramine group. There was a significant decrease in triacylglycerol and very-low-density-lipoprotein-cholesterol levels at week 24 (*p* < 0.05) in the sibutramine group compared with the baseline figures.
Quality and comments	–

1.5.4 Reported harms

Berkowitz 2003	
Results	Sibutramine was discontinued in ten participants (six due to increased blood pressure and or pulse rate; two for ecchymoses, one had ventricular premature complexes (VPCs), and 1 due to rash of unclear aetiology. One participant had VPCs after 6 months of treatment, and continued to have VPCs in the following 6 months after discontinuation. A second adolescent reported to have VPCs at month 9, 3 weeks after discontinuation of the medication because of elevation of blood pressure and pulse rate.
Quality and comments	–

Godoy-Matos 2005	
Results	The only difference that was statistically significant between groups was for constipation (*p* = 0.039), having 40% in the sibutramine group and 13% in the placebo group. No significant event was reported or withdrawal due to adverse events.
Quality and comments	–

1.5.5 Generalisability

Berkowitz 2003	
Country and setting	USA. University outpatient research weight control programme.
Participants (included/excluded)	Contraindications for participation in the study: cardiovascular disease; type 1 or 2 diabetes mellitus, major psychiatric disorders; pregnancy; use of a weight-loss medication or a weight-loss of ≥5 kg in the previous 6 months; use of medications promoting weight gain; use of medications contraindicated with use of sibutramine; or cigarette smoking.
Recruitment	Not clear.
Intervention (mode and intensity)	Behavioural programme: Both groups received the same family-based behavioural weight-loss programme. In phase 1 participants attended 13 weekly group sessions followed by six biweekly group sessions. In phase 2, group sessions were held biweekly from months 7 to 9 and monthly from months 10 to 12. Groups were led by dietitians, psychologists or psychiatrists. Diet: Both groups were instructed to consume a 1200–1500 kcal (5.02–6.23 MJ)/day diet of conventional foods, with approximately 30% of energy from fat, 15% from protein, and the remainder from CHO. PA: Goal of walking or similar aerobic activity for 120 min per week or more. Drug: During phase 1 all participants received placebo the first week. At week 2, they received either placebo or 5 mg of sibutramine/day. In the treatment group, sibutramine was increased to 10 mg/day at week 3 and to 15 mg/day at week 7. In participants whose systolic or diastolic blood pressure increased from baseline by 10 mmHg or more for two or more visits had their dosage reduced in 5 mg decrements until acceptable blood pressure and pulse rate were restored. Sibutramine was discontinued in participants in whom dose reductions did not reverse the 10 mmHg or more increase or in which systolic or diastolic blood pressure increased 20 mmHg or more at any single visit.
Duration of active intervention	12 months.
Control (mode and intensity)	Behavioural protocol and placebo up to 6 months. Following this all the participants received the same titration schedule as for phase 1.
Delivery of intervention/control (who)	Behavioural assessment performed by staff psychologist or psychiatrist. Adolescent's primary care physician performed a history and physical examination to exclude the possible contraindications.
Dropout rates	12%
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed using the baseline-carried forward technique.

Godoy-Matos 2005	
Country and setting	Brazil. Outpatient University Research Centre.
Participants (included/excluded)	Boys and girls aged 14–17 years, with a BMI of 30–45 kg/m^2. To avoid growth variation, all participants were required to have adult bone age, determined by left-hand radiography. Contraindications to be enrolled in the study were: diabetes mellitus, endocrine disease predisposing to obesity, severe hyperlipidaemia, systemic of major psychiatric disorders, history of bulimia or anorexia, uncontrolled hypertension or other cardiovascular diseases, weight loss of ≥3 kg within 2 months or use of weight loss or weight gain drugs within 3 months before recruitment, drug or alcohol abuse, recent tobacco cessation or intention to quit during study period, and pregnancy or lactation.
Recruitment	Not reported.
Intervention (mode and intensity)	Diet: All patients received dietary counselling to achieve an energy deficit of 500 kcal (2.09 MJ)/day at the start of the run-in phase. No additional visits to the dietitian were allowed. The recommended diet composition was approximately 30% of energy from fat, 20% from protein, and 50% from CHO. This study was designed to reproduce a regular clinical setting so structured behavioural counselling was not employed. PA instructions were delivered by the attendant doctor in a brief written protocol aimed to obtain mainly aerobic moderate exercises for at least 30 min/day. Drug: During the single-blind run-in period, all participants received a placebo capsule. Subjects who completed the run-in period and returned less than 25% of the prescribed capsules were randomised to receive sibutramine (10 mg/day) or matching placebo capsules without regard to weight loss during the run-in period. Subjects were instructed to take their capsule in the morning
Duration of active intervention	4 weeks followed by 6 months.
Control (mode and intensity)	Placebo and same diet and PA as described above.
Delivery of intervention/control (who)	Dietary counselling provided by dietitian. PA instruction was delivered by the attendant doctor.
Dropout rates	16.6%
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed using the last observation carried forward technique.

1.6 Surgery

1.6.1 Restrictive Surgery

Laparoscopic adjustable gastric banding

Abu-Abeid 2003	
Aim	To evaluate the surgical management of severe morbid obesity in adolescents.
Country and setting	Israel.
Participants	Eleven adolescents aged 11–17 years, mean BMI was 46.6 (range 38–56.6) kg/m^2 and all patients fulfilled the NIH criteria for morbid obesity. One patient suffered from heart failure and pulmonary hypertension. Two additional patients had amenorrhea and another had gallstones. Three patients suffered from recurrent boils, two from skin rashes, and another seven from stretch marks. The most common complaint of patients before surgery was offensive body odour and unpleasant appearance.
Intervention	Before referral to the centre, the adolescents had been under the care of a dietitian for at least 1 year and had failed to loose weight even with a low-energy diet of 800 kcal (3.35 MJ)/day. Additionally three patients had their jaws wire-clamped, and two patients had been hospitalised for protracted fasting of 3 to 6 months. All patients underwent psychological evaluation preoperatively, and were counselled with their families about the lifestyle change that need to occur as a result of the surgery. Postoperative emotional support was provided for patients and their families in addition to the appropriate physical follow-up. All patients underwent laparoscopic adjustable gastric banding (LAGB). Patients were observed for 24 hours postoperatively and then were discharged after and additional meeting with a dietitian. Abdominal ultrasound scan was done 6 months postoperatively in all patients. All patients received vitamin supplements after surgery and were followed up closely for deficiencies.
Length of follow-up	23 months.
Results	Mean BMI fell to 32.1 kg/m^2 during the 23-months follow-up.
Other outcomes	The two patients with high triacylglycerol levels before surgery, had normal levels after weight reduction; however, cholesterol levels remained elevated in the patient with abnormal preoperative

	levels. There was one patient who was very ill with debilitating heart failure and pulmonary hypertension, and did very well after the surgery and was able to return to school without being hospitalised since surgery. All adolescents reported and improvement in overall well-being; they were more physically active, more socially involved with their peers and reported feeling happier than before surgery. Four girls required additional iron supplements for iron deficiency anaemia and menstruation began in the two girls suffering from amenorrhea before surgery.
Reported Harms and complications	One patient remained under observation for and additional 24 hours because of severe postoperative co-morbid disease. No patient suffered perioperative complications, and there were no late complications during the follow-up period. None of the patients had choleslithiasis during the follow-up period.
Quality and comments	Overall very poor case series. No statistical power information given. No information on excess weight loss.

Dolan 2003 (only adolescents) and 2004	
Aim	To compare LAGB in adolescents and adults.
Country and setting	Australia.
Participants	Adolescents aged 12–19 years, median weight and BMI were 127.9 (range 82.9–218.8) kg and 42.2 (range 30.3–70.5) kg/m^2, respectively. The ages of the adults ranged from 23 to 70 (median 41) years. Preoperatively, their median weight and BMI were 110.9 (range 77.2–221.5) kg and 41.8 (range 30.1–71.5) kg/m^2, respectively.
Intervention	Before referral to the centre, the adolescents had been under the care of a dietitian for at least 1 year and had failed to lose weight even with a low-energy diet of 800 kcal (3.35 MJ)/day. Additionally three patients had their jaws wire-clamped, and two patients had been hospitalised for protracted fasting of 3 to 6 months. All patients underwent psychological evaluation preoperatively, and were counselled with their families about the lifestyle change that need to occur as a result of the surgery. Postoperative emotional support was provided for patients and their families in addition to the appropriate physical follow-up. All patients underwent LAGB. Patients were observed for 24 hours postoperatively and then were discharged after and additional meeting with a dietitian. Abdominal ultrasound scan was done 6 months postoperatively in

	all patients. All patients received vitamin supplements after surgery and were followed up closely for deficiencies
Length of follow-up	25 months for adolescents and 26 months for adults.
Results	Postoperatively there were no significant differences in weight loss between the adolescents and the adults. BMI fell to 32.3 (range 22.4–52.6) kg/m^2 at 12 months and further to 30.2 (range 22.6–39.4) kg/m^2 at 24 months, compared with 32.5 (range 25.5–54.0) kg/m^2 and 33.1 (range 28.1–41.3) kg/m^2 in adults. Adolescents lost a median of 49 (range 30.1 to 82.3)% of their excess weight body weight at 12 months, compared with 43.6 (range 23.9–80.6)%. In adults. At 24 months, excess weight loss was 69.3 (range 46.8–111.8)% in adolescents and 52.8 (range 29.9 to 84.4)% in adults. At 24 months follow-up, 81.8% of adolescents and 63.6% of adults had lost ≥50% of their excess body weight.
Other outcomes	No other outcomes reported.
Reported Harms and complications	In one patient, the band slipped 11 months after insertion and was repositioned laparoscopically; another patient required replacement of a leaking port. Only one adult suffered a port site infection.
Quality and comments	Overall very poor case series. No statistical power information given.

Horgan 2005	
Aim	To describe the first US experience in LAGB in morbidly obese adolescents.
Country and setting	USA.
Participants	Four patients (two adolescent girls aged 17 and 19 years, and two adolescent boys aged 17 and 18 years). Mean weight and BMI were 147 ± 25 (range 118–165) kg and 51 ± 9 (range 40–61) kg/m^2 respectively. Two patients had symptoms of heartburn without documented gastroesophageal reflux disease and two patients complained of joint and musculoskeletal complaints requiring over-the-counter antacids and analgesics for symptom relief. One patient had a previous laparoscopic cholecystectomy.
Intervention	All patients were fully ambulating within 1 hour after surgery and discharged on the same day.
Length of follow-up	Up to 30 months.

Results	The first patient had a 57% excess weight loss at 30 months, the second patient had a 34% excess weight loss at 12 months and the third patient at 7 months had a excess weight loss at 87%. The fourth reported 15% at 4 months.
Other outcomes	No other outcomes reported.
Reported harms and complications	No early complications were reported. A late complication occurred in the patient with the most rapid weight loss who developed a cholecystitis 6 months postoperatively and was discharged uneventfully after outpatient laparoscopic cholecystectomy.
Quality and comments	Retrospective case series. Poor quality, no statistical power information provided.

Widhalm 2004	
Aim	To evaluate LAGB in severely obese adolescents.
Country and setting	Germany.
Participants	All patients had previously underwent several therapies such as diet camps, diet counselling and BT, some where placed on very-low-energy diets and some took drugs like sibutramine or orlistat for a short period of time. All gained weight after the time. Furthermore, the patients had psychological problems and did not want to continue with any kind of dietary programme. One patient with Prader–Willi syndrome was also included due to continuous weight gain despite treatment with sibutramine. The Depression Inventory for Adolescents (DIKJ) showed that all the patients suffered from depressive symptoms and a very low self-esteem.
Intervention	Psychological tests were carried out in order to exclude eating disorders and to find out if there were any psychological disturbances.
Length of follow-up	10.5 ± 6 months.
Results	The mean weight loss was 25.0 ± 3.8 kg, which corresponds to 15.9% reduction of the initial body weight.
Other outcomes	All parents reported that the adolescents were now able to eat without having extreme hunger or appetite, and that they felt that loosing weight was after all possible.
Reported Harms and complications	In all eight patients, no major problems were reported.
Quality and comments	Case study. Poor quality, poor statistical power information provided.

Knerr 2002	
Aim	To evaluate LAGB in a 13-year-old girl with severe obesity and end-stage renal insufficiency.
Country and setting	Germany.
Participants	13-year-old girl with type 2 diabetes mellitus and arterial hypertension, present with nausea and chronic fatigue. Weight 101 kg, BMI 36.7 kg/m^2, Tanner stage 4, age at menarche 12 years, uraemic odour, pallor and arterial hypertension were evident (blood pressure 149/99 mmHg, hypertensive retinopathy grade IV). End-stage renal failure with renal anaemia hyperkalaemia, metabolic acidosis and preserved diuresis with isostenuria. A hand radiograph revealed features of renal osteopathy due to severe secondary hyperparathyroidism. Therapy with antihypertensive drugs was started and vitamin D, calcium supplementation, calcium acetate, bicarbonate, iron and erythropoietin were given. A renal biopsy was not possible due to the patient's extreme fat mass and fibrotic, hypoplastic kidneys. Normal growth.
Intervention	From the start, dietary recommendations (restriction of energy intake to 1200 kcal (5.02 MJ)/day, restriction of fat, potassium and phosphate) and psychological support for handling the diagnosis and weight reduction were given, and PA was recommended. The severe obesity did not improve even with in-patient exercise programme, dietary restriction to 800 kcal (3.35 MJ)/day for 6 weeks. Daily energy intake was still restricted to 1200 kcal (5.02 MJ)/day and PA was recommended at least twice per week. A token system was started for positive feedback and psychological supervision was given once per week.
Length of follow-up	Up to 30 months.
Results	Changes in her eating habits led to a weight stabilisation at 100 kg. During the following 3 months a weight loss of 14 kg was observed. Her total weight loss was 24 kg. Her weight after 3 months was 80 kg, and BMI 28 kg/m^2 (2.2 SDs, 97–99.5th percentile).
Other outcomes	No other outcomes reported.
Reported harms and complications	Eight weeks after the implantation the gastric band was tightened with a single injection of 2 ml of physiological saline solution. A Cimino stunt was installed for renal replacement therapy, but disturbed wound healing and shunt thrombosis led to early shunt impairment.
Quality and	Case study. Poor quality, poor statistical power information

comments	provided.

Angrisani et al. 2005	
Aim	The aim of this study is to evaluate results of LAGB in obese teenagers
Country and setting	Italy. Italian Collaborative Study group.
Participants	Criteria for patients to be considered for surgery were as follows: BMI ≥40 or ≥35 kg/m^2 with co-morbidities, supportive family environment, failure to obtain weight loss after ≥1 years of conservative medical treatment, psychological maturity of patients with demonstration of decisional capacity, and willingness to be operated on and to follow postoperative guidelines. Preoperative assessment was obtained by a multidisciplinary team on the basis of internist and psychiatric evaluations. Patients affected by psychiatric or genetic disorders (i.e. Prader–Willi syndrome) were excluded. Fifty-eight (1.5%) of 3813 patients operated on with the Lap-Band System from January 1996 to December 2003 were ≤19 years old. There were 47 female/11 male; mean age was 17.96 ± 0.99 (range 15–19) years; mean BMI was 46.1 ± 6.31 (range 34.9 – 69.25) kg/m^2; and mean % excess weight was 86.4 ± 27.1 (range 34–226). Sixteen of the 58 (27.5%) patients were super-obese (BMI ≥50 kg/m^2). In 27/58 (46.5%) patients, one or more co-morbidities were diagnosed: anxiety or depression (*n* = 11), hypertension (*n* = 8), dyslipidaemia (*n* = 6), diabetes (*n* = 8), osteoarthropathy (*n* = 12), sleep apnoea (*n* = 10) and amenorrhea (*n* = 4).
Intervention	The band was placed via perigastric access in all but three patients, in whom the pars flaccida technique was completed. On the first postoperative day, intravenous saline, proton pump inhibitors and antiemetics were given. Patients were discharged when able to tolerate oral fluids with oral therapy.
Length of follow-up	Up to 7 years.
Results	Patient follow-up at 1, 3, 5, and 7 years was 48/52 (92.3%), 37/42 (88.1%), 25/33 (75.7%) and 10/10, respectively. At the same times, mean BMIs were 35.9 ± 8.4, 37.8 ± 11.27, 34.9 ± 12.2 and 29.7 ± 5.2 kg/m^2. Mean %EWL at the same time was 45.6 ± 29.6, 39.7 ± 29.8, 43.7 ± 38.1 and 55.6 ± 29.2. Five of 25 (20%) patients had ≤25% EWL at 5 years follow-up, while none of the ten patients subject to follow-up at 7 years had ≤25% EWL.
Other outcomes	No other outcomes reported.
Reported harms	Laparotomic conversion was necessary in one patient with gastric

and complications	perforation on the anterior wall during perigastric band positioning. This patient did not report intragastric migration in following controls. The overall postoperative complication rate was 6/58 (10.3%): band slippage was observed in one patient and was treated by laparoscopic repositioning after 4 days, gastric pouch dilatation was observed in two patients and was treated by band repositioning, and intragastric migration was observed in three patients and was treated with band removal. The band also was removed in two patients for psychological intolerance, and one patient was converted 2 years after surgery (BMI 31 kg/m^2) to laparotomic gastric bypass. The overall band removal rate was 6/58 (10.3%). Biliopancreatic diversion (BPD) with gastric preservation and band left in situ (Band–Inaro) was performed in two patients (3.4%)
Quality and comments	Retrospective study. Poor quality, poor statistical power information provided.

Restrictive/malabsorptive

Gastric bypass

Breaux 1995	
Aim	To undertake a retrospective review on bariatric surgery in children with and without sleep apnoea.
Country and setting	USA.
Inclusion/exclusion criteria	BPD was done only on super-obese sleep apnoea patients.
Participants	Twenty-two children aged 8–18 years, with an average BMI >40 kg/m^2.
Intervention	Vertical banded gastroplasty (VBG), Roux-en-Y gastric bypass (RYGBP) and BPD were performed. All patients having RYGBP or BPD were placed on a supplemental multivitamin, vitamin B_{12} 1000 μg, ferrous sulfate 325 mg, and two calcium tablets per day. Additionally BPD patients were instructed to take three capsules daily of water-dispersed vitamin A and D.
Length of follow-up	50 months.
Results	The gallbladder was removed in five patients who were found to have gallstones and in two patients as part of the BPD. One female patient with sleep apnoea had a tumour of the brain-stem, which was biopsied 5 years prior to obesity surgery. In the group without sleep apnoea, BMI was improved from 56.4 kg/m^2 to a mean postoperative BMI of 35.5 kg/m^2. The mean percentage excess weight loss was 59%. In the group with sleep apnoea, BMI improved from 70.3

	kg/m^2 to a mean of 46.5 kg/m^2 for an average excess weight loss of 45%.
Other outcomes	In the nine sleep apnoea patients, the low oxygen saturation during sleep improved from a mean of 73% to a mean of 93% BMI ranging from 65 to 195 kg/m^2. Of the nine patients who had long-term follow-up, all had resolution of sleep apnoea.
Reported harms and complications	One male patient from the without apnoea group who weighed 145 kg at age 17 years and lost 100 kg by age 18 years, regained 145 kg at age 28 years and requested further therapy. One female patient had a VBG at age 16 years and developed gallstones at age 22 years. Since she had only lost 26% of her excess weight, she requested further surgery at the time of the cholecystectomy. Revision was done in one sleep apnoea patient. There were nine postoperative complications. The two vitamin deficiencies in two BPD patients responded to supplementation. Protein deficiency occurred in three BPD patients. There were two late deaths (one as complications arising out of morbid obesity and the other with a multisystem organ failure).
Quality and comments	Poor quality. Retrospective review. No statistical power information.

Strauss 2001	
Aim	To review retrospectively all patients undergoing surgery at a large university medical centre.
Country and setting	USA.
Participants	All adolescents were well informed, motivated and had demonstrated serious attempts at weight loss in diet and behaviour modification programmes. All families were instructed to contact patients in a gastric bypass support group who had undergone the operation. All adolescents were developmentally and genetically normal, with no evidence of Prader–Willi syndrome or other genetic obesity-related syndromes. All adolescents were >100% above their IBW, and all were at least 100 lb (45.4 kg) over their IBW and had previously been unsuccessful in multiple attempts at weight loss. The men weight before surgery was 148 ± 37 kg. Co-morbid included severe sleep apnoea, hypertension, vertebral fracture, and severe school avoidance. Three children had undergone psychological evaluation before surgery.

Intervention	After surgery all children started a 1000 kcal (4.19 MJ)/day modified liquid diet for 4 to 6 weeks. Subsequently, adolescents were given a new diet consisting of a variety of low-energy, soft-solid foods.
Length of follow-up	Up to 12 months.
Results	The mean weight loss was 53.6 ± 25.6 kg for the nine adolescents who had persistent weight loss, representing approximately 62% of their excess weight.
Other outcomes	Not reported.
Reported Harms and complications	No early postoperative complications occurred. The most serious complication occurred in one patient with a distal gastric bypass who had protein–energy malnutrition and micronutrient deficiency (vitamin A, vitamin D, iron and zinc) approximately 1 year after gastric bypass. Two adolescents had symptomatic cholelithiasis requiring laparoscopic cholecystectomy. Minor nutritional complications included iron deficiency in five adolescents, and transient folic acid deficiency occurred in three adolescents.
Quality and comments	Poor quality. Retrospective review. No statistical power information provided. Patients were identified through a computerised database of all patients undergoing bariatric surgery from April 1985 to May 1999.

Stanford 2003	
Aim	To examine the outcome of adolescents undergoing laparoscopic RYGBP.
Country and setting	USA.
Participants	Patients under the age of 20 years, which met the established criteria by the NIH for candidacy for bariatric surgery. Patients also had to have: BMI of 35 kg/m^2 with co-morbid conditions or >40 kg/m^2 with or without co-morbid conditions; have a co-morbidities that should be improved by the surgery; be able to comprehend the risks and benefits and the surgical procedure; have no glandular aetiology for their obesity; have attempted to lose weight by conventional mean and be willing to be observed over a long period.
Intervention	On postoperative day 1, patients had an upper gastrointestinal study to look for an anastomotic leak and or delayed emptying. Patients with a normal study finding were started on a clear liquid diet, and their diet would be advanced as tolerated.

Length of follow-up	2 years.
Results	The patients lost an average of 87% of their excess body weight. Excluding one patient, the mean BMI postoperatively was 28 kg/m^2. The patients with a follow-up of almost 2 years maintained their weight loss.
Other outcomes	Co-morbid conditions identified in the group: sleep apnoea, hypertriacylglycerolaemia, hypercholesterolemia, degenerative joint disease, gastroesophageal reflux disease and asthma.
Reported Harms and complications	No complications or harms were reported.
Quality and comments	Poor quality. Retrospective review. No statistical power information provided.

Rand 1994	
Aim	To evaluate obesity surgery in adolescents.
Country and setting	Appears to be USA.
Participants	All adolescents that were studied were morbidly obese patients in private practice. Age ranged from 11 to 19 years. Preoperatively, patients weighed an average of 131 kg and had an average BMI of 47 kg/m^2. Almost all patients (94%) felt unattractive before surgery.
Intervention	Patients received either the RYGB or the VBG between January 1979 and December 1990.
Length of follow-up	6 years.
Results	At follow-up, patients average BMI was 32 kg/m^2. Patients average excess body weight loss was 66%, 73% of patients had an excess body weight loss of approximately 50%.
Other outcomes	76% of the patients reported their current physical health as excellent or good, problems reported were hypoglycaemia, anaemia, gallbladder disease, probable anaemia and thyroid problems. The large majority of patients (82%) consider themselves attractive after the operation. Most patients (74%) felt less embarrassed about their appearance after the operation than before.
Reported harms and complications	Patients were hospitalised for 5 or 6 days postoperatively, although no major postoperative complication was reported. During the follow-up period, three patients with inadequate weight loss had revisional surgery to reduce the size of the

	stomach pouch. An additional two patients who had regained more than 18 kg were scheduled for revisional surgery to have the stomach pouch size reduced. Thirty of the adolescents received the RYGB, only 13% reported taking vitamin B_{12} and calcium as instructed. 73% took multivitamins and 70% took vitamin B_{12}.
Quality and comments	Poor quality. Retrospective review. No statistical power information provided.

Soper 1975	
Aim	To review experience with gastric bypass operations in 25 morbidly obese children and adolescents.
Country and setting	USA.
Participants	Twenty-five morbidly obese patients ≤20 years of age, with a median preoperative weight of 143 kg. For purposes of comparison the patients were divided into two groups: 18 genetically normal individuals and seven children with Prader–Willi syndrome. Children had to have at least double weight for 5 years, absence of severe disease which not be improved by weight loss, and absence of a primary endocrine cause for obesity. Due to the natural history of the Prader–Willi syndrome, the twice ideal weight requirement for acceptance was not applied in the seven patients.
Intervention	–
Length of follow-up	Up to approximately 36 months.
Results	Genetically normal children lost more weight than children with Prader–Willi syndrome. Genetically normal males lost significantly more weight than did females ($p < 0.005$).
Other outcomes	–
Reported harms and complications	Early: Three wound infections, three patients with respiratory difficulty, one patient with thrombophlebitis, one patient with upper gastrointestinal tract bleeding, one patient with urinary tract infection and one patient with protracted vomiting. Late: Four patients with incisional hernia. Subsequent operations include: Four revisions, three panniculectomies, three incisional hernias, three cholecystectomy and one appendectomy.
Quality and comments	Poor study. Only *p* value for difference between weight loss in males vs. females.

Anderson 1980	
Aim	To summarise experience with gastric bypass in 41 children and adolescents.
Country and setting	USA.
Participants	Forty-one morbidly obese adolescents and children aged <20 years old. Of these, 30 were genetically normal and 11 had Prader–Willi syndrome. The criteria for selection included: twice IBW; good health except for obesity related disorders; and potential for PA.
Intervention	A liquid diet was recommended for the first 6 weeks following gastroplasty and a soft diet for 6 weeks following gastric bypass. Cautious dietetic counselling was given to each patient and his parents prior to discharge from the hospital.
Length of follow-up	5 years.
Results	For the 30 genetically normal patients their preoperative weight was 238% IBW, which dropped to an average of 171% IBW. By 5 years postoperatively, the average weight was back up to 187% IBW. For the Prader–Willi patients, the average preoperative weight was 231% IBW and at 5 years was 176% IBW.
Other outcomes	–
Reported Harms and complications	Early stage: Three wound infections; two were slow to ‘open’ due stomach obstruction, and one required revision; atelactasis developed in three patients and pneumonia in two others; one patient developed a subphrenic abscess. Subsequent operations included: Four revisions, three panniculectomies, three incisional hernia, three cholecystectomy and one appendectomy Three deaths occurred. One of them died on the third day possibly due to massive pulmonary embolism; another died suddenly and unexpectedly at 36 months; and the single death among the Prader–Willi patients was caused by congestive heart failure 50 months postoperatively.
Quality and comments	Poor quality. No statistical power information provided.

Malabsorptive/restrictive

Duodenal switch and biliopancreatic diversion

Breaux 1995	
Aim	To undertake a retrospective review on bariatric surgery in children with and without sleep apnoea.
Country and setting	USA.
Inclusion/exclusion criteria	BPD was done only on super-obese sleep apnoea patients.
Participants	Twenty-two children aged 8 to 18 years, with an average BMI >40 kg/m^2.
Intervention	VBG, RYGBP and the BPD were performed. All patients having RYGBP or BPD were placed on a supplemental multivitamin, vitamin B$_{12}$ 1000 µg, ferrous sulfate 325 mg, and two calcium tablets per day. Additionally BPD patients were instructed to take three capsules daily of water-dispersed vitamin A and D.
Length of follow-up	50 months
Results	The gallbladder was removed in five patients who were found to have gallstones and in two patients as part of the biliopancreatic diversion. One female patient with sleep apnoea had a tumour of the brain stem that was biopsied 5 years prior to obesity surgery. In the group without sleep apnoea, BMI was improved from 56.4 kg/m^2 to a mean postoperative BMI of 35.5 kg/m^2. The mean percentage excess weight loss was 59%. In the group with sleep apnoea, BMI improved from 70.3 kg/m^2 to a mean BMI of 46.5 kg/m^2 for an average excess weight loss of 45%.
Other outcomes	In the nine sleep apnoea patients, the low oxygen saturation during sleep improved from a mean of 73% to a mean of 93% BMI ranging from 65 to 195 kg/m^2. Of the nine patients who had long-term follow-up, all had resolution of sleep apnoea.
Reported Harms and complications	One male patient from the without apnoea group who weighed 145 kg at age 17 and lost 100 kg by age 18 years, regained 145 kg at age 28 years and requested further therapy. One female patient had a VBG at age 16 years and developed gallstones at age 22 years. Since she had only lost 26% of her excess weight, she requested further surgery at the time of the cholecystectomy. Revision was done in one sleep apnoea patients. There were nine postoperative complications. The two vitamin deficiencies in two BPD patients responded to supplementation. Protein deficiency occurred in three BPD

	patients. There were two late deaths (one as complications arising out of morbid obesity and the other with a multisystem organ failure).
Quality and comments	Poor quality. Retrospective review. No statistical power information.

1.7 Harms associated with weight loss or weight management programmes

1.7.1 Effects of professionally prescribed weight loss programmes on eating behaviour

Weight loss

Braet 2003 [801]	
Aim	To assess the effect of an inpatient multi-component treatment programme for obese children and adolescents on their weight and psychological well-being.
Participants	Seventy-six children and adolescents were referred to the centre. Median age in both groups was 13 (range 10–17) years. At baseline median BMI of the study group was 33 (range 22–46) kg/m^2 and the control group 33 (range 24–51) kg/m^2. Children with Prader–Willi syndrome were not recruited
Intervention	Every fifth children on the alphabetical list of patients starting treatment in September 1996, 1997 and 1998 was included in this study, resulting in a sample of 38 patients, or 20% of the total group treated. The diet consisted of 30% energy as fat, 15% energy as protein, and 55% energy as CHO, consisting of servings of fruits, three servings of vegetables, 100 g of meat or 150 g of fish, semi-skimmed milk and low-fat cheese and high fibre staples. It provided 1500–1800 kcal (6.28–7.53 MJ)/day. All children received an adapted individual PA training programme for 4 hours per week. Before and after school, the children were encouraged to exercise for 10 hours per week or even more if they wanted. Children also received a 12-week CBT programme in small groups, followed by personalised problem-solving-based booster sessions every week. To change their lifestyles, the children were taught self-regulation skills, such as self-observation, self-instruction, self-evaluation and self-reward. A problem-solving approach was introduced to teach the children how to cope with different high-risk situations, and they were trained to cope with different stressful situations, such as feeling hungry. Interaction with parents was limited, and children saw the parents

	every 2 weeks. They received leaflets on how to prepare healthy food and how to (re)organise their shopping habits. Children stayed in the centre for one school year (10 months), and twice per month the children returned home for the weekend. The other two weekends and half of the school-holidays they stayed in the centre.
Control	For each 38 children, a case-control (based on age and gender) was selected from the waiting list of the centre.
Length of follow-up	14 months.
Results	During treatment, the children in the study group showed a decrease in the median adjusted BMI of –48 (range –4 to –102)%. Median weight loss was –19 (range +2 to –41) kg. At 6 months after finishing the treatment, the median adjusted BMI was 135 (range 105–192)% and at 14 months it was 143 (range 104–198)%. This was a result of an increase in the adjusted BMI at 6 months follow-up of +6 (range –19 to –37)% and at 14 months follow-up an additional increase of +4 (range –30 to +41)%. At 14% follow-up, 13/27 children showed an increase in their overweight of less than 10% or continued to lose weight compared with their post-treatment weight and 14/27 children had an increase of more than 10% overweight (up to +41%).
Quality and comments	The therapists were blinded for the study. Not randomised study. Overall poor quality study.

Braet 2000 [804]	
Aim	The primary aim of the study was to prevent further weight gain. Furthermore, a cognitive-behavioural modification programme was designed to help the child change his of her lifestyle, to enhance self-regulation skills and specific problem-solving skills in different eating situations.
Participants	Subjects were children seeking for obesity treatment at the local University Children’s Hospital. All children involved in the stuffy (*n* = 136) were involved in the follow-up. At baseline, children had a mean age of 11 (SD 2.5) (range 7–17) years. Mean weight of the subjects was 62 (SD 16) kg and mean height was 150 (SD 12) cm. Mean overweight was 55 (SD 21)% and all subjects were at least 20% overweight. All children were White and of normal intelligence and they did not suffer from any syndromic obesity.
Intervention	Subjects were assigned to three different treatment groups: individual treatment, group treatment and summer camp training group. For some families, the treatment was not feasible because of other family plans, so children could be assigned to and advice in one session group.

	In all treatment conditions children received the same package of information. Parents were given a treatment manual for parents of obese children and the child had his own workbook. Self-instructions, self-observation, self-evaluation and self-reward techniques were introduced in each session. Modelling, behaviour rehearsal and homework were used to train self-regulation skills. Problem-solving skills were taught in different high-risk eating situations. Contracts were established including what a child would receive if it followed the programme. Parents were asked to praise their children for good performance. Children were taught about the benefits of exercise and energy expenditure. Exercises were promoted with a frequency of 30 min each day in combination with lifestyle changes such as taking the stairs, walking instead of going by car, helping in the garden or cleaning the house. Moderate intensity in order to keep the exercises up for 30 min, and children were not instructed to exercise at a particular intensity. Changes in eating habits were proposed in small steps, and children were given the chance to make their own choices. They were instructed on how to eat in a healthy way many times a day including many vegetables. ‘Counting calories’ was not permitted.
Control	Three treatment groups.
Length of follow-up	4.6 years.
Results	Two types of psychological measurements were used in the 4.6 years follow-up, and three at baseline. Both the parent version of the DEBQ and the EDI were given at the follow-up. At baseline, children were also given the Perceived Competence Scale for Children (PCSC). At baseline, mean % overweight were as follows; group $n = 19$, 53 (SD 13); individual $n = 13$, 50 (SD 19); summer camp $n = 30$, 60 (SD 23); and advice $n = 47$, 52 (SD 22). At 4.6 years follow-up, mean % overweight were as follows; group $n = 19$, 34 (SD 19); individual $n = 13$, 39 (SD 24); summer camp $n = 30$, 45% (SD 21); and advice $n = 47$, 45% (SD 30). Total children had a mean percentage overweight of 42. Paired *t* tests revealed significant time effects in four different treatment groups at 4.6 years follow-up: treatment in group ($p < 0.001$); individual treatment ($p < 0.05$); summer camp ($p < 0.001$); and advice group ($p < 0.001$). No significant results were found in comparing the 1-year follow-up with the 4.6 year follow-up.
Quality and comments	The therapists were blinded for the study. Subjects who dropped out had a higher degree of overweight at baseline ($p < 0.05$), lower self-esteem ($p < 0.01$), and a higher score on a general scale of psychopathology, as measured by the Child Behaviour Checklist (CBCL).

Levine 2001 [803]	
Aim	To evaluate the acceptability and feasibility of a family-based intervention for severely obese children.
Participants	Children between the ages of 8 to 12 years, along with at least one parent or guardian. To be eligible, children had to be heavier than 160% of their IBW for their age, height, and gender according to WHO charts. Moreover, children who endorsed current psychiatric symptomatology and that were on a weight control programme were excluded. Twenty-four families completed initial assessment.
Intervention	Children completed the Child Depression Inventory, the State Trait Anxiety Inventory for Children (STAIC) (at pre-treatment, post-treatment and follow-up) and the ChEAT (at pre-treatment and follow-up session). The ChEAT is designed to assess respondents' attitudes toward their eating and dieting behaviour. The ChEAT measures perceived body image, obsessions/concerns with food, and dieting practices. Before initiating the group intervention, all children completed self-report questionnaires about depression, anxiety and eating attitudes and behaviours. Families participated in a 10–12-session behavioural group intervention targeted to increase healthy eating behaviours and PA. Focus on peer teasing using role-plays and problem-solving techniques were also given. At the beginning of each session, children and parents reviewed with group leaders their self-monitoring books for both eating and exercise. Initial sessions focused on self-monitoring of eating and activity and understanding the stoplight diet. Children were given energy intake goals for the week, based on the child's initial body weight and were set at 1200–1500 kcal (5.02–6.28 MJ)/day. They were also given exercise goals and worked toward 30 min of activity 5 days per week. Goals to decrease sedentary activity were also provided.
Control	Only one cohort.
Length of follow-up	Follow-up meeting occurred between 4 and 13 months after the final week of the treatment programme.
Results	Children lost and average of 2.5 ± 3.5 kg during the brief intervention programme. BMI changed from 34.5 (SD 5.2) to 32.8 (SD 5.7) kg/m^2. Weight losses were not maintained over the follow-up period. Children gained an average of 8.6 ± 5.2 kg between the end of treatment and their follow-up visit, although as children grew an average of 1.6 ± 0.7 in this period, these changes do not reliably reflect degree of obesity.
Quality and	Overall limited quality study. Observational study

comments

Epstein et al. 1994 [805]	
Aim	Main aim of the study was the presentation of 10-year outcomes for obese children treated in four randomised studies. The secondary aim of this study was to identify variables associated with long-term weight regulation and to extend the research on predictors of 5-year changes in percentage overweight.
Participants	At baseline participants' percentage overweight was not different across groups ($p > 0.05$). Significant differences were observed in age ($p = 0.001$), height ($p < 0.001$) and weight ($p = 0.004$).
Intervention	In study 1, children were randomised to one of three groups: both the parent and child were targeted for weight loss, only the child was targeted for losing weight, or a non-specific target. Targeting included contingency management for habit and weight change, with contingencies for the parent and child group arranged so that both the parent and child had to change habits and lose weight. Study 2 randomised families to regimens of diet and lifestyle exercise or diet alone or to a no-treatment control. The exercise programme increased energy expenditure by the equivalent of 6.4 km of walking per day, or 2800 kcal (11.72 MJ) per week for a 150 lb (68.0 kg) person. The diet-alone group was given information on low expenditure and stretching but were not reinforced for any exercise changes. Study 3 assessed the effects of parental weight status and child self-control on child weight loss. Contingencies were directed toward child weight change, with no requirement for joint parent and child behaviour or weight change. In the study 4, children were randomised to one of three groups: aerobic exercise, lifestyle exercise and callisthenics control group. The groups were similar in exercise time, goal setting and feedback, but the control group required considerably less energy expenditure than the isoenergetic aerobic or lifestyle groups.
Control	Not applicable for this study.
Length of follow-up	This was a 10-year follow-up
Results	For study 1, the parent and child group had significantly greater changes than the non-specific control at both 5 and 10 years ($p = 0.009$). The parent and child group was significantly different from the child-only group at 5 years ($p = 0.025$), but not at 10 years. Children in the parent and child group decreased their percentage overweight by 15.3% whilst children in the control group increased by 7.6%. No significant differences for change in percentage overweight were observed between groups in studies 2 and 3 after 5 or 10 years.

	In study 4, children in the lifestyle or aerobic exercise ($p < 0.05$) had a greater 10-year change from 5 to 10 years than the callisthenics group.
Quality and comments	10-year assessment of four randomised studies. Self-reported data was used in 18% of the cases, although height and weight were adjusted with sample-specific equations. No ITT was performed.

Epstein et al. 2001 [710]	
Aim	To assess the effects of behavioural, family-based treatment on disordered eating and child behaviour problems for obese 8- to 12-year-old children
Participants	Sixty-seven families were randomised to three groups (25 boys and 22 girls). Participants had a mean BMI of 27.4 ± 3.2 kg/m^2, a mean percentage overweight of 60.0 ± 16.5 and a mean age of 10.3 ± 1.1 years.
Intervention	Three groups: problem-solving taught to parent and child, problem-solving taught to child only, and no additional problem-solving. All participants were given similar information about diet, activity, and behaviour change techniques, with the problem-solving training being different across groups. The traffic light diet was given, and the lifestyle programme was based on increasing lifestyle PA. Parents and children were taught to praise increases in targeted eating and lifestyle activity behaviours and to use reciprocal contracts based on meeting the goal. The CBCL, the SCL-90 and the Kid's Eating Disorder Survey (KEDS) were used.
Control	No additional problem-solving
Length of follow-up	2 years.
Results	At 2 years follow-up, percentage overweight changed by –12.5 ± 13.5 ($p < 0.001$) and weight changed by 8.3 ± 6.4 kg ($p < 0.001$).
Quality and comments	Parents deposited US$75, which was returned contingent upon completion of 75% of the treatment sessions and attendance at the 6- and 12-month follow-up. Families were paid US$50 at the 24-month follow-up.

Other outcomes

Braet 2003	
Results	Eating behaviours showed no increase in eating psychopathology during the 10-month treatment. On the subscales of the EDI, a significant reduction on the drive for thinness (DT) subscale was

	reported ($p < 0.001$) and no change was reported on the bulimia subscale. The scores on the emotional eating and restrained eating showed an insignificant trend, whilst the scores on the subscale 'external eating' declined significantly, $p < 0.001$. The scores on the SPPC, the scores on three subscales increased significantly during the 10 months treatment: physical appearance $p < 0.001$; athletic competence $p < 0.05$; and social competence $p < 0.05$. On the subscales academic competence, behavioural conduct and global self-worth, no significant trends were found.
Quality and comments	–

Braet 2000	
Results	Paired *t* test on the subscales of the DEBQ revealed a significant reduction in external eating ($p < 0.001$), a significant increase in restrained eating ($p < 0.001$), and no difference between pre-testing and the 4.6 follow-up for emotional eating. Mean score on the drive for thinness (DT) subscale of the EDI was 5.6 (SD 5); for the body dissatisfaction (BD) subscale the mean score for the total sample was 13.2 (SD 7), and for the bulimia (B) subscale the mean score was 1.2 (SD 3).
Quality and comments	–

Levine 2001	
Results	Children reported significant improvement in psychosocial measures, as both self-reports of depressive symptoms and state anxiety declined from pre-treatment through the follow-up period ($p < 0.03$). These improvements in self-reported depression and anxiety were maintained despite the trend in regaining weight following end of treatment. An analysis between changes in weight between post-treatment and the follow-up period (co-varied) indicate similar decreases in self-reported depressive symptoms.
Quality and comments	–

Epstein 1994	
Results	Six girls reported that they were treated for eating disorders. One child had been treated for depression, and another had sought treatment for alcohol abuse. Nineteen other children developed major psychiatric disorders that required hospitalisation or long-term medication use. One child was treated for irritable bowel syndrome.
Quality and	–

comments	

Epstein 2001	
Results	The significant reductions for CBCL total behaviour problems and internalising behaviour problems were associated with a decrease in the percentage of children within the borderline clinical range. There were no significant overall change in total KEDS scores There were no significant changes for weight dissatisfaction or restricting/purging scales.
Quality and comments	–

Reported harms

Braet 2003	
Results	No harms were reported.
Quality and comments	–

Braet 2000	
Results	No harms were reported.
Quality and comments	–

Levine 2001	
Results	No harms were reported.
Quality and comments	–

Epstein 1994	
Results	No harms were reported.
Quality and comments	–

Epstein 2001	
Results	No harms were reported.
Quality and comments	–

Generalisability

Braet 2003	
Country and setting	Belgium. Inpatient treatment centre.
Participants (included/excluded)	See above
Recruitment	By referral from physicians for inpatient treatment due to obesity.
Intervention (mode and intensity)	
Duration of active intervention	10 months.
Control (mode and intensity)	For each 38 children, a case-control (based on age and gender) was selected from the waiting list of the centre.
Delivery of intervention/control (who)	Standardised treatment was developed and supervised by two behaviour therapists and two medical doctors. It was carried out with the help of one dietitian, one psychologist, one social worker, one medical doctor, one physiotherapist and six group leaders.
Dropout rates	Seven children left the programme during the study. At 6 months, data for three children could not be collected, and at 14 months one additional children could not be traced.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only from those who completed the study.

Braet 2000	
Country and setting	Belgium. Outpatient and inpatient.
Participants (included/excluded)	No specific inclusion/exclusion criteria
Recruitment	Majority of the subjects heard about the study from the media, and 15% were referred by physicians.
Intervention (mode and intensity)	Treatment consisted of 12 steps spread over 12 sessions of 60 min or six sessions of 90 min. For the outpatient groups, the programme consisted of six biweekly sessions of 90 min, spread over 3 to 4 months. In the summer camp the children followed the 12-session programme in the morning. They received balanced healthy food (1500 kcal [6.28 MJ]/day) and daily lifestyle exercises (5 hours/day). All children were asked to attend the monthly follow-up sessions. The children that were not able to participate in the treatment programme (*n* = 58, 43%) were assigned to an advice-in-one-session group. After the initial 3-hour intake session, these parents and their children received the same information during a

	90 min family session. The experimental groups consisted of 36 subjects spread over two summer camps, 26 subjects spread over six outpatient group programmes, and 16 subjects in the individual treatment programme.
Duration of active intervention	Not clear duration of treatment.
Control (mode and intensity)	See above
Delivery of intervention/control (who)	Standardised treatment was carried out by the authors and students in psychology, trained and supervised by the first author. Medical and dietary supervision was given at every session by the second author and a dietitian.
Dropout rates	19.9% at 4.6 years, which accounted for 27 children.
Treatment of dropouts (return to baseline, or last measurement?)	Analyses done with data from subjects who completed the follow-up.

Epstein 1994	
Country and setting	USA. University Research Centre
Participants (included/excluded)	Children had to be aged 6 to 12 years, 20 to 100% overweight for age, sex and height, no current psychiatric diagnosis or treatment, no learning disability, and one parent willing to participate in treatment with the child. Parents or children with current psychological problems were referred for treatment before entrance in the study. Parents or children could have had psychiatric problems that had been treated or were in remission when they entered treatment. Families that participated in study 1 were intact, and families who participated in the exercise studies could not have a medical problem that limited exercise.
Recruitment	Subjects were participants in one of four weight-control studies.
Intervention (mode and intensity)	Four different randomised studies.
Duration of active intervention	Four different randomised studies.
Control (mode and intensity)	Four different randomised studies.
Delivery of intervention/control (who)	Not reported.

Dropout rates	25% dropouts registered at the 10-year follow-up
Treatment of dropouts (return to baseline, or last measurement?)	No ITT performed.

Epstein 2001	
Country and setting	USA. University research centre
Participants (included/excluded)	Children between 8 and 12 years; between 20 and 100% overweight based on comparisons of the BMI to the 50th percentile BMI for age and sex; neither parent over 100% overweight; one parent willing to attend treatment meetings; no family member participating in an alternative weight-control programme; no parent or child with current psychiatric problems as assessed by health history questionnaire and standardised interview; no restrictions on the participating parent or child that prevent exercise; and child able to read at the third-grade level.
Recruitment	Not clear.
Intervention (mode and intensity)	The treatment included 16 weekly meetings, followed by two biweekly meetings and two monthly meetings during the 6 month treatment
Duration of active intervention	6 months.
Control (mode and intensity)	Same as treatment.
Delivery of intervention/control (who)	Individual therapist.
Dropout rates	24% at 2 years follow-up.
Treatment of dropouts (return to baseline, or last measurement?)	No ITT was performed.

Levine 2001	
Country and setting	USA. University research centre
Participants (included/excluded)	See above
Recruitment	Participants were recruited through advertisements in local newspapers and letters distributed to local paediatricians and family physicians.
Intervention (mode and	See above

intensity)	
Duration of active intervention	Follow-up meeting occurred between 4 and 13 months after the final week of the treatment programme.
Control (mode and intensity)	Only one cohort.
Delivery of intervention/control (who)	Not reported
Dropout rates	33.3%
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who finished treatment programme.

1.7.2 Effects of professionally prescribed weight loss programmes on child/adolescent growth

Weight loss

Dao 2004 [280]	
Aim	To determine if a multidisciplinary weight loss programme in adolescents with severe obesity allows adequate growth and development and avoids lean mass loss.
Participants	Fifty-five (33 girls and 22 boys) adolescents aged 9 to 17 years.
Intervention	Patients were housed at the therapeutic unit except during the weekends that were spent at home, for 9 ± 3 (range 6–12) months where they participated on a voluntary basis in a weight reduction programme. Participants were given specific dietary and PA advice.
Control	Only one cohort.
Length of follow-up	Up to 12 months
Results	The mean BMI dropped in boys from 34.5 ± 3.2 to 25.5 ± 2.3 kg/m^2 and in girls from 38.4 ± 4.1 to 28.4 ± 4.1 kg/m^2. At baseline, the mean total fat mass content and percentage body fat were marginally higher in girls and boys ($p = 0.06$). After weight loss, both differences reached significance ($p < 0.01$). The total fat mass decreased by 42.7 ± 7.6% in girls and 51.9 ± 11.4% in boys ($p < 0.0001$). At baseline, percentage fat contents of the upper limbs and trunk were significantly higher in girls than in boys ($p = 0.05$). After weight loss, percentage fat mass in all regions was higher in girls than in boys ($p < 0.05$), whilst in absolute value fat mass contents were higher in the trunk and lower limbs only ($p < 0.02$). Trunk to legs fat mass ratio decreased in both sexes ($p < 0.0001$) and remained higher in girls than in boys either before (1.14 ± 0.21 vs.

	1.02 ± 0.16, $p = 0.01$) or after weight loss (0.89 ± 0.24 vs. 0.68 ± 0.17, $p = 0.001$). In the upper limbs, lean mass decreased slightly in boys ($p = 0.06$) and girls ($p = 0.06$) and was correlated with the corresponding local decrease of fat mass in both sexes ($p = 0.06$ and $p = 0.037$). Lean mass increased with increasing Tanner stage either before of after weight loss in girls ($F = 18.7$, $p = 0.0001$; $F = 4.6$, $p = 0.01$) and boys ($F = 9.1$, $p = 0.007$; $F = 22.8$, $p = 0.0001$).
Quality and comments	Overall poor quality study.
Sponsor details	Not applicable.

Dietz 1985 [806]	
Aim	To retrospectively compare height velocity before and during weight reduction in a cohort
Participants	Fourteen girls and 5 boys treated in the weight control programme.
Intervention	The energy intake in all cases was about two-thirds of the usual daily intake, estimated from either a 24-hour dietary recall or a 7-day dietary diary. During weight reduction, protein intakes were maintained at 1.5 to 2.0 g/kg of IBW per day. During weight reduction period, children were seen every 2 to 4 weeks. Annual rates of height velocity were calculated by extrapolating the rate for the period measured to a 1-year interval,
Control	No control.
Length of follow-up	Mean duration of treatment was 9.7 months.
Results	The mean weight losses were 4.5 ± 5.3 kg, resulting in a mean decrease of 29% IBW. Height velocity before weight reduction was calculated over a mean period of 20 months. The mean z-score for height velocity before weight reduction was 2.32 (SD 2.47) units. During weight reduction, the mean z-score for height velocity decreased significantly to 0.62 (SD 2.37) units ($p < 0.01$). A high correlation between the change in z-scores of height velocity prior to and during weight reduction and the change in weight was observed ($p < 0.01$).
Quality and comments	Retrospective case series.

Other outcomes

Dao 2004	
Results	Not reported.
Quality and comments	–

Dietz 1985	
Results	Not reported.
Quality and comments	–

Reported harms

Dao 2004	
Results	No harms were reported.
Quality and comments	–

Dietz 1985	
Results	No adverse effects were reported in any patient.
Quality and comments	–

Generalisability

Dao 2004	
Country and setting	France. Inpatient research centres.
Participants (included/excluded)	Children/adolescents with severe primary obesity; agreement of the child and its family to participate on a voluntary basis in a weight reduction programme. The exclusion criteria were as follows: identified genetic, metabolic or endocrine disease, obesity secondary to a brain tumour.
Recruitment	Not reported.
Intervention (mode and intensity)	Participants were advised to restrict energy intake to 1600–1800 kcal (6.70–7.53 MJ)/day during weight reduction phase. An increase of up to 1800–2200 kcal (7.53–9.1 MJ)/day was required during the stabilisation phase in order to stop weight loss and achieve a stable body weight. This was reached, on an individual basis, by increasing caloric intake by steps of 200 kcal (0.84 MJ)/day until a stable weight was reached. Nutrition training was also addressed to the parent. Parents were provided the same documents as their children in addition to which meetings took place every 6 weeks and

	phone calls were made by the dietitian and the parents were encouraged to call of they needed extra information. PA training session took place three times a week, with 90 min and included alternatively swimming, gymnastics, walking and recreational team sports
Duration of active intervention	6 to 12 months.
Control (mode and intensity)	No control.
Delivery of intervention/control (who)	Phone calls were made by the dietitian and the parents were encouraged to call of they needed extra information.
Dropout rates	Not reported.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only with data of those who completed.

Dietz 1985	
Country and setting	USA. University research centre.
Participants (included/excluded)	To be included, participants had to have: use of a balanced energy-deficit diet, height measurements recorded at least 1 year before and on at least one 4-month interval during weight reduction, and weight change of maintenance to achieve a reduction of 10% or more in IBW for height (%IBW).
Recruitment	Appears to be from children who were attending a weight control programme at the Boston’s Children’s Hospital from 1981 to 1983.
Intervention (mode and intensity)	The energy intake in all cases was about two-thirds of the usual daily intake, estimated from either a 24-hour dietary recall or a 7-day dietary diary. During weight reduction, protein intakes were maintained at 1.5 to 2.0 g/kg of IBW per day. During weight reduction period, children were seen every 2 to 4 weeks. Annual rates of height velocity were calculated by extrapolating the rate for the period measured to a 1-year interval
Duration of active intervention	Mean 9.7 months.
Control (mode and intensity)	N/A

Delivery of intervention/control (who)	Not clear.
Dropout rates	Not clear.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to have been only from those who finished treatment. No dropouts seem to have occurred, or were not reported.

Appendix 14

2 Excluded studies

2.1 Measures other than body mass index

References were excluded from this review because they did not evaluate the utility of the measure of interest compared with body mass index (BMI), but compared with some other measure of overweight or obesity. For a full list of excluded references, please contact the Methods Team.

2.2 Measures and morbidity in ethnic populations

2.3 Lifestyle interventions

Study	Reason for exclusion
Bailes JR, Strow MT, Werthammer J, McGinnis RA, Elitsur Y (2003) Effect of low-carbohydrate, unlimited calorie diet on the treatment of childhood obesity: a prospective controlled study. *Metabolic Syndrome and Related Disorders* 1:221–225.	Less than 6 months study.
Balagopal P, Bayne E, Sager B, Russell L, Patton N, George D (2003) Effect of lifestyle changes on whole-body protein turnover in obese adolescents. *International Journal of Obesity and Related Metabolic Disorders* 27:1250–7.	Not only obese children as participants.
Ball SD, Keller KR, Moyer-Mileur LJ, Ding YW, Donaldson D, Jackson WD (2003) Prolongation of satiety after low versus moderately high glycemic index meals in obese adolescents. *Pediatrics* 111:488–94.	No weight outcomes reported.
Barbeau P, Gutin B, Litaker MS et al. (2003) Influence of physical training on plasma leptin in obese youths. *Canadian Journal of Applied Physiology* 28:382–96.	Weight outcomes were only reported at baseline.
Barbeau P, Litaker MS, Woods KF et al. (2002) Hemostatic and inflammatory markers in obese youths: effects of exercise and adiposity. *Journal of Pediatrics* 141:415–20	Only body fat percentage was reported.
Barbeau P (2002) Hemostatic and inflammatory markers in obese youths: effects of exercise and adiposity. *Journal of Pediatrics* 141(3)	No weight outcomes reported such as BMI, percentage overweight, or weight.
Becque MD, Katch VL, Rocchini AP, Marks CR, Moorehead C (1988) Coronary risk incidence of obese adolescents: reduction by exercise plus diet intervention. *Pediatrics* 81:605–12.	Less than 6 months (treatment and follow-up).
Berg-Smith SM, Stevens VJ, Brown KM et al. (1999) A brief motivational intervention to improve dietary adherence in adolescents. ***Health Education Research, Vol. 14, No. 3, 399-***	Participants were not

Study	Reason for exclusion
410, June 1999	overweight/obese.
Bhargava A, Sachdev HS, Fall C et al. (2004) Relation of serial changes in childhood body-mass index to impaired glucose tolerance in young adulthood. *New England Journal of Medicine* 350.	Not children or adolescents.
Braet C, Mervielde I, Vandereycken W (1997) Psychological aspects of childhood obesity: a controlled study in a clinical and nonclinical sample. *Journal of Pediatric Psychology* 22 (1):59–71	No weight outcomes such as BMI, percentage overweight or weight were reported.
Braet C, Wydhooge K (2000) Dietary restraint in normal weight and overweight children. A cross-sectional study. *International Journal of Obesity*;24: 314–318.	Not controlled study.
Brandou F, Dumortier M, Garandeau P, Mercier J, Brun JF (2003) Effects of a two-month rehabilitation program on substrate utilization during exercise in obese adolescents. *Diabetes and Metabolism* 29:20–7.	Less than 6 months duration (treatment and follow-up).
Cairella M (1991***). Overweight and obesity: significance of diet therapy. Clinica Terapeutica; 136 (6): 211-6.***	Language other than English.
Davis K, Christoffel KK, Vespa H, Pierleoni MP, Papanastassiou R (1993) Obesity in preschool and school-age children. *Clinical Nutrition* 23:000	Only IBW measures.
Deforche B, Bourdeaudhuij I, Tanghe A, Debode P, Hills AP, Bouckaert J (2005) Post-treatment phone contact: a weight maintenance strategy in obese youngsters. *International Journal of Obesity* 29:543–6.	Less than 6 months study.
Deforche B, Bourdeaudhuij I, Tanghe A et al. (2003) Changes in fat mass, fat-free mass and aerobic fitness in severly obese children and adolescents following a residential treatment programme. *European Journal of Pediatrics* 162: 616–622.	Not controlled study.
Deforche B, Bourdeaudhuij I, Tanghe A, Debode P, Hills AP (2004) Changes in physical activity and psychosocial determinants of physical activity in children and adolescents treated for obesity. *Patient Education and Couseling* 55:407–415.	Not controlled study.
Dietz WH, Gortmaker SL (1985) Do we fatten our children at the TV set? Television viewing and obesity in children and adolescents. *Pediatrics* 75:000.	Cohort study.
Disc collaborative research group (1995). Dietary intervention study in children (DISC) with elevated low-density-lipoprotein cholesterol. JAMA. May 10;273(18):1429-35	Participants were not overweight/obese.

Study	**Reason for exclusion**
Ebbeling CB, Leidig MM, Sinclair KB, Hangen JP, Ludwig DS (2003) A reduced-glycemic load diet in the treatment of adolescent obesity. *Archives of Pediatrics and Adolescent Medicine* 157:773–9.	No age stratification for the participants.
Effective Public Health Practice Project (2004) Effective Public health Practice project 2004. http://library.umassmed.edu/ebpph/	Participants were not overweight/obese.
Emes C, Velde B (1990) An activity based weight control program. *Adapted Physical Activity Quarterly* 7.	Less than 6 months duration (treatment and follow-up).
Endo H, Tagaki Y, Nozue T, Kuwahata K, Uemasu F, Kobayashi A (1992) Beneficial effects of dietary interventions on serum lipid and apolipoprotein levels in obese children. *American Journal of Diseases of Children* 146:000.	Less than 6 months duration and no weight outcomes.
Epstein LH, McCurly J, Wing RR, Valoski A (1986). Family-based behavioral weight control in obese young children. Journal of the American Dietetic Association. Apr;86(4):481-4.	Not controlled study
Epstein (1996) Family-based behavioural intervention for obese children. International Jourbal of Obesity Related Metabolic Disorders. 1996 Feb;20 Suppl 1:S14-21	Narrative review.
Epstein LH, McCurly J, Wing RR, Valoski A (1990) Five-year follow-up of family-based behavioral treatments for childhood obesity. *Journal of Consulting and Clinical Psychology* 58(5):661–664.	No precise figures of changes in percentage overweight were reported.
Ewart CK, Young DR, Hagberg JM (1998) Effects of school-based aerobic exercise on blood pressure in adolescent girls at risk for hypertension. *American Journal of Public Health* 88:000.	Participants were not overweight/obese.
Faith MS, Berman N, Heo M et al. (2001) Effects of contingent television on physical activity and television viewing in obese children. *Pediatrics* 107:1043–8.	Less than 6 months duration (treatment and follow-up).
Fanaria P, Somazzi R, Nasrawi F et al. (1993) Haemorheological changes in obese adolescents after short-term diet. *International Journal of Obesity* 17:487.	Less than 6 months duration (treatment and follow-up).
Fernandez Paredes F, Sumano- Avendado S (1986). Obesity in childhood and adolescence: evaluation after 1 year of integrated treatment**.** *Boletin Medico del Hospital Infantil de Mexico. 43(9):555-557.*	Language other than English.
Foreyt J (1991) Cuidando El Corazon – a weight reduction intervention for Mexican Americans. *American Journal of Clinical Nutrition* 53:000.	No weight outcomes reported such as BMI, percentage

Study	Reason for exclusion
	overweight or weight.
Foster GD, Wadden TA, Brownell KD (1985) Peer-led program for the treatment and prevention of obesity in the schools. *Journal of Consulting and Clinical Psychology* 53:538–40.	Intervention delivered by non clinical professionals in non-clinical setting.
Frenn M, Malin S, Bansal NK (2003) Stage-based interventions for low-fat diet with middle school students. *Journal of Pediatric Nursing* 18:000.	Health promotion.
Gilbertson HR, Thorburn AW, Brand Miller JC, Chondros P, Werther GA (2003) Effect of low-glycemic-index dietary advice on dietary quality and food choice in children with type 1 diabetes. *American Journal of Clinical Nutrition* 77:000.	No weight outcomes reported.
Goldfield GS, Kalakanis LE, Ernst MM, Epstein LH (2000) Open-loop feedback to increase physical activity in obese children. *International Journal of Obesity and Related Metabolic Disorders* 24:888–92.	No weight outcomes reported.
Gortmaker SL (1999) Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Archives of Pediatrics and Adolescent Medicine* 153(4):000.	Non RCT with aim other then to treat childhood obesity.
Graf C, Sylvia VR, Benjamin K et al. (2005) Data from the StEP TWO programme showing the effect on blood pressure and different parameters for obesity in overweight and obese primary school children. *Cardiology in the Young* 15:291–8.	Not controlled study.
Gutin B (2002) Effects of exercise intensity on cardiovascular fitness, total body composition, and visceral adiposity of obese adolescents. *American Journal of Clinical Nutrition* 75(5):000.	Only body mass composition and fat mass were reported.
Hartmuller VW (1994) Creative approaches to cholesterol lowering used in the dietary intervention study in children. *Topics of Clinical Nutrition* 10:71.	Participants were not overweight/obese.
Hills AP, Parker AW (1988) Obesity managemeny via diet and exercise intervention. *Child: Care, Health and Development* 14:409.	Less than 6 months duration (treatment and follow-up).
Hoerr SL, Nelson RA, Essex-Sorlie D (1988) Treatment and follow-up of obesity in adolescent girls. J Adolesc Health Care. 1988 Jan;9(1):28-37.	No comparison. No control group reported.
Hopper CA, Gruber MB, Munoz KD, Herb RA (1992) Effect of including parents in a school-based exercise and nutrition program for children. *Research Quarterly for Exercise and Sport* 63:000.	Intervention delivered by non-clinical professionals in non-clinical setting

Study	Reason for exclusion
Hunter GR, Weinsier RL, Bamman MM, Larson DE (1998) A role for high intensity exercise on energy balance and weight control. *International Journal of Obesity* 22:489.	Narrative review.
Isnard P, Michel G, Frelut ML et al. (2003) Binge eating and psychopathology in severely obese adolescents. *International Journal of Eating Disorders* 34:000.	Non-RCT with aim other than treatment of childhood obesity.
Johnson WG (1997) Dietary and exercise interventions for juvenile obesity: long-term effect of behavioral and public health models. *Obesity Research* 5: 257–261.	Less than 6 months duration intervention. Five year follow-up weight data was self-reported.
Lappe JM, Rafferty KA, Davies M, Lypaczewski G (2004) Girls on a high-calcium diet gain weight at the same rate as girls on a normal diet: a pilot study. *Journal of the American Dietetic Association* 104:1361.	Participants were not overweight or obese.
Lauer RM, Obarzanek E, Hunsberger S, Horn S (2000) Efficacy and safety of lowering dietary intake of total fat, saturated fat, and cholesterol in children with elevated LDL cholesterol. *American Journal of Clinical Nutrition* 72:000.	Participants were not overweight/obese.
Lazzer S, Boirie Y, Poissonier C et al. (2005) Longitudinal changes in activity patterns, physical capacities, energy expenditure, and body composition in severely obese adolescents during a multidisciplinary weight-reduction program. *International Journal of Obesity* 29:37–46.	Not controlled study.
Ludwig DS, Majzoub JA, Al Zahrani A, Dallal GE, Blanco I, Roberts SB (1999) High glycemic index foods, overeating, and obesity. *Pediatrics* 103:E26.	No weight outcomes reported.
Maffeis C. Schutz Y. Chini L. Grezzani A. Piccoli R. Tato L. Effects of dinner composition on postprandial macronutrient oxidation in prepubertal girls. *Obesity Research 2004. 12(7):1128-35.*	Weight outcomes only reported at baseline.
Matheson DM (2004) Children's food consumption during television viewing. *American Journal of Clinical Nutrition* 79(6):000.	Non-randomised trial with aim other than to treat childhood obesity.
Moon YI (2004) Effects of behavior modification on body image, depression and body fat in obese Korean elementary school children. *Yonsei Medical Journal* 45:61–67.	Only 8 weeks duration.
Mo-suwan L, Pongprapai S, Junjana C, Puetpaiboon A (1998) Effects of a controlled trial of a school-based exercise program on the obesity indexes of preschool children. *American Journal*	Intervention delivered by non-clinical

Study	Reason for exclusion
of Clinical Nutrition 68:1006.	professionals in non-clinical setting.
Nelson G. Evaluation of a social problem-solving skills program for third and fourth grade students (1988) *American Journal of Community Psychology* 16(1):000.	Participants were not obese.
Nuutinen O (1991) Long-term effects of dietary counselling on nutrient intake and weight loss in obese children. *European Journal of Clinical Nutrition* 45:287. Nuutinen O, Knip M (1992) Long-term weight control in obese children: persistence of treatment outcome and metabolic chnages. *International Journal of Obesity* 16:000. Nuutinen O, Knip M (1992) Predictors of weight reduction in obese children. *European Journal of Clinical Nutrition* 46:785–94.	Results from each group were combined. No clear conclusions can be drawn.
Obarzanek E (2001) Long-term safety and efficacy of a cholesterol-lowering diet in children with elevated low-density lipoprotein cholesterol: seven year results of the dietary intervention study in children (DISC). *Pediatrics* 107:256.	Participants were not overweight/obese.
Owens S, Gutin B, Allison J et al. (1999) Effect of physical training on total and visceral fat in obese children. *Medicine and Science in Sports and Exercise* 31:143–8.	Less than 6 months duration (treatment and follow-up).
Patrick K, James MS, Sallis JF et al. (2001) A multicomponent program for nutrition and physical activity change in primary care. *Archives of Pediatrics and and Adolescent Medicine* 155:000.	Weight loss or reduction of BMI not reported.
Patrick K, Norman GJ, Calfas KJ et al. (2004) Diet, physical activity, and sedentary behaviors as risk factors for overweight in adolescence. *Archives of Pediatrics and and Adolescent Medicine* 158:385–90.	Participants were not overweight/obese.
Pena M, Bacallao J, Barta L, Amador M, Johnston FE (1987) Fiber and exercise in the treatment of obese adolescents. *Journal of Adolescent Health Care* 10:30.	Less than 6 months duration (treatment and follow-up).
Robinson TN (1999) Behavioral treatment of childhood and adolescent obesity. *International Journal of Obesity* 23(2):000.	Narrative review.
Rocchini AP, Katch V, Anderson J et al. (1988) Blood pressure in obese adolescents: effect of weight loss. *Pediatrics* 82:16–23.	Less than 6 months duration (treatment and follow-up).
Rocchini AP, Katch V, Schork A, Kelch RP (1987) Insulin and blood pressure during weight loss in obese adolescents. *Hypertension* 10:267–73.	Less than 6 months duration (treatment and follow-up).
Rudolf MCJ, Greenwood DC, Cole TJ et al. (2004) Rising obesity and expanding wasitlines in schoolchildren: a cohort	Cohort study.

Study	Reason for exclusion
study. *Archives of Disease in Childhood* 89:235.	
Sahota, P (2001) Evaluation of implementation and effect of primary school based intervention to reduce risk factors for obesity. *British Medical Journal* 323:000.	Health promotion programme.
Sahota, P (2001) Randomised controlled trial of primary school based intervention to reduce risk factors for obesity. *British Medical Journal* 323:000.	Health promotion programme.
Sallis JF, McKenzie TL, Alcaraz JE, Kolody B, Hovell MF, Nader PR (1993) Project SPARK. Effects of physical education on adiposity in children. *Annals of the New York Academy of Sciences* 699:127–36.	Intervention delivered by non-clinical professionals in non-clinical setting.
Sasaki J, Shindo M, Tanaka H, Ando M, Arakawa K (1987) A long-term aerobic exercise program decreases the obesity index and increases the high density lipoprotein cholesterol concentration in obese children. *International Journal of Obesity* 11:339.	Intervention delivered by non-clinical professionals in non-clinical setting.
Sondike SB, Copperman N, Jacobson MS (2003) Effects of a low-carbohydrate diet on weight loss and cardiovascular risk factor in overweight adolescents.[see comment]. *Journal of Pediatrics* 142:253–8.	Less than 6 months (treatment and follow-up).
Sothern MS (1993) An effective multidisciplinary approach to weight reduction in youth. *Annals of the New York Academy of Sciences* 699:000.	No details of interventions.
Sothern MS, Hunter S, Suskind RM, Brown R, Udall JR, Blecker U (1999) Motivating the obese child to move: the role of structured exercise in pediatric weight management. *Southern Medical Journal* 92:000.	Not comparing to any other intervention.
Sothern MS, Udall JR, Suskind RM, Vargas A, Blecker U (2000) Weight loss and growth velocity in obese children after very low calorie diet, exercise, and behaviour modification. *Acta Paediatrica* 89:000.	Before and after study.
Stallings VA, Archibald EH, Pencharz PB, Harrison JE, Bell LE (1988) One-year follow-up of weight, total body potassium, and total body nitrogen in obese adolescents treated with the protein-sparing modified fast. *American Journal of Clinical Nutrition* 48:91–4.	Before and after study.
Sung RY, Yu CW, Chang SK, Mo SW, Woo KS, Lam CW (2002) Effects of dietary intervention and strength training on blood lipid level in obese children. *Archives of Disease in Childhood* 86:407–10.	Less than 6 months duration (treatment and follow-up).
Suskind RM, Sothern MS, Farris P et al. (1993) Recent advances in the treatment of childhood obesity. *Annals of the New York*	Cohort study.

Study	Reason for exclusion
Academy of Sciences 699:181.	
Suttapreyasri D, Kanpoem J, Suthontan N, Krainam J, Boonsuya C (1990) Weight-control training models for obese pupils in Bangkok. *Journal of the Medical Association of Thailand* 73:000.	Intervention delivered by non-clinical professionals in non-clinical setting.
Tucker LA (1986) The relationship of television viewing to physical fitness and obesity. *Adolescence* 21:000.	Non RCT with aim other then to treat childhood obesity.
Vandongen R, Jenner DA, Thompson C et al. (1995) A controlled evaluation of a fitness and nutrition intervention program on cardiovascular health in 10 to 12 year old children. *Preventive Medicine* 24:9.	Not overweight/obese children.
Warren JM, Henry CJ, Lightowler HJ, Bradshaw SM, Perwaiz S (2003) Evaluation of a pilot school programme aimed at the prevention of obesity in children. *Health Promotion International* 18:287–96.	Prevention of obesity in children.
Warren JM, Henry JK, Simonite V. Low-glycemic index breakfasts and reduced food intake in preadolescent children (2003) *Pediatrics* 112:414.	No weight outcomes reported.
Watts K, Beye P, Siafarikas A et al. (2004) Exercise training normalizes vascular dysfunction and improves central adiposity in obese adolescents. *Journal of the American College of Cardiology* 43:1823–7.	Less than 6 months duration.
Watts K, Beye P, Siafarikas A et al. (2004) Effects of exercise training on vascular function in obese children. *Journal of Pediatrics* 144:620–5.	Less than 6 months duration.
Zametkin XXX (2004) Psychiatric aspects of child and adolescent obesity: a review of the past 10 years. *Journal of the American Academy of Child and Adolescent Psychiatry* 43(2):000.	Narrative review.

2.4 Pharmacological interventions

We also scanned reference lists of other guidelines and reviews for additional studies and recommendations on both orlistat and sibutramine. These are listed below for completeness.

Study	Source	Reason
Barlow SE. Dietz WH (1998) Obesity evaluation and treatment: Expert Committee recommendations. The Maternal and Child Health Bureau, Health Resources and Services Administration and the Department of Health and	Searches	Drug treatment not mentioned.

Study	Source	Reason
Human Services. *Pediatrics* 102(3):E29.		
Batch JA, Baur LA (2005) Management and prevention of obesity and its complications in children and adolescents. *Medical Journal of Australia* 182(3):130–5.	Searches	No additional references.
Daniels, S (2001) Pharmacological treatment of obesity in paediatric patients. [Review] [33 refs]. *Paediatric Drugs* 3(6):405–410.	Searches	No additional references.
Daniels S (2005) Regulation of body mass and management of childhood overweight. *Pediatric Blood and Cancer* 44(7):15.	Searches	No additional references.
Daniels SDK, Arnett RH, Eckel SS et al. (2005) Overweight in children and adolescents: Pathophysiology, consequences, prevention, and treatment. *Circulation* 111(15):19.	Searches	No additional references.
Cuttler LJL, Whittaker XXX, Kodish ED (2005) The overweight adolescent: Clinical and ethical issues in intensive treatments for pediatric obesity. *Jouranal of Pediatrics* 146(4):2005.	Searches	No additional references.
Hayman LL. Hughes S (2004) Obesity: focus on prevention and policy**.** *Journal of Cardiovascular Nursing*19(3):217–8.	Searches	No additional references.
Kolagotla L, Adams W (2004) Ambulatory management of childhood obesity. *Obesity Research* 12(2):275–83.	Searches	Drug treatment not mentioned.
Michaud PA, Suris JC, Viner R (2004) The adolescent with a chronic condition. Part II: healthcare provision. *Archives of Disease in Childhhood* 89(10):943–9.	Searches	General healthcare for adolescents, not obesity.
Rudolf MCJ, Greenwood DC, Cole TJ et al. (2004) Rising obesity and expanding waistlines in schoolchildren: a cohort study. *Archives of Disease in Childhood* 89(3):235–7.	Searches	No additional references.
Speiser PW (2005) Childhood obesity. Consensus Development Conference. Guideline. Journal Article. Practice Guideline***].*** *Journal of Clinical Endocrinology and Metabolism* 90(3):1871–87.	Searches	No additional references.
Suris JC, Michaud PA, Viner R. The adolescent with a chronic condition. Part I: developmental issues. *Archives of Disease in Childhood* 2004; 89 (10):938–942.	Searches	General healthcare for adolescents, not obesity.
Trent ME, Laufer MR (2000) Obesity in adolescent girls – Emerging role of reproductive	Searches	No additional references.

Study	Source	Reason
health professionals. *Journal of Reproductive Medicine* 45(6):445–53.		
Vieweg WV (2005) Newer antipsychotic drugs and obesity in children and adolescents. How should we assess drug-associated weight gain? *Acta Psychiatrica Scandinavica* 111(3):177–84.	Searches	Not treatment of obesity, but link between antipsychotic drug treatment and weight gain.
Viner R (2005) Managing obesity in secondary care: a personal practice. *Archives of Disease in Childhood* 90; 385–90.	Searches	No additional references.
Yanovski JA (2003) Treatment of pediatric and adolescent obesity. *Journal of the American Medical Association* 9; 289(14):1851–3.	Searches	No additional references.

2.5 Surgery [reorder alphabetically?]

Study	Source	Reason
Yanovski A, Yanovski JA (2001) Intensive therapies for pediatric obesity. [Review] [62 refs] *Pediatric Clinics of North America* 48:1041–53.	Searches	Narrative review. No additional references.
Albanese CT (2005) The ‘skinny’ on adolescent bariatric surgery. *Journal of Laparoendoscopic and Advanced Surgical Techniques* Part A:15.	Searches	Narrative review. No additional references.
Alvarez-Leite JL (2004) Nutrient deficiencies secondary to bariatric surgery. [Review] [93 refs] *Current Opinion in Clinical Nutrition and Metabolic Care* 7:569–75.	Searches	Narrative review. No additional references.
Strauss BJ (2002) Gastric bypass surgery in adolescents with morbid obesity. *Nutrition in Clinical Practice* 17:43.	Searches	See Strauss 2001.
Rothschild B, Masheb R, Brody M, Toth C, Burke-Martindale C, Grilo C (2004) Childhood maltreatment in severely obese male and female bariatric surgery candidates. *Obesity Research* 12:A75.	Searches	Abstract only. See Grilo 2005.
Barlow SE (2004) Bariatric surgery in adolescents: for treatment failures or health care system failures? *Pediatrics* 114:252–3.	Searches	Narrative review. No additional references.
Grilo CM, Masheb RM, Brody M, Toth C, Burke Martindale CH, Rothschild RS (2005) Childhood maltreatment in extremely obese male and female bariatric surgery candidates. *Obesity Research* 13:123–30.	Searches	Participants were not children or adolescents.

Study	Source	Reason
Daviglus ML, Pirzada A (2005) In the long run, healthcare costs appear to be related to overweight and obesity at younger ages. *Expert Review of Pharmacoeconomics and Outcomes Research* 000:5.	Searches	Not relevant to topic.
Fielding G (2004) Laparoscopic adjustable gastric banding as surgical treatment for severely obese adolescents – Initial experience with 44 children.	Searches	Abstract only. See Dolan 2004/2003.
Flodmark FE (2004) New insights into the field of children and adolescents' obesity: The European perspective. *International Journal of Obesity* 28:000.	Searches	Narrative review. Checked references. Added Hayr 2003 for assessment.
Garcia VF, Langford L, Inge TH. Application of laparoscopy for bariatric surgery in adolescents. [Review] [125 refs], *Current Opinion in Pediatrics* 2003;15:248–55.	Searches	Narrative review.
Greenstein RJ, Rabner JG (1995) Is adolescent gastric-restrictive antiobesity surgery warranted? *Obesity Surgery* 5:000.	Searches	Not clear when BMI and weight were measured in the follow-up period.
Haynes B (1959) Creation of a bariatric surgery program for adolescents at a major teaching hospital. *Pediatric Nursing* 31:21–22.	Searches	Case-study with no reports on weight loss values.
Hayr T, Widhalm K. Laparoscopic gastric banding in morbidly obese adolescents. Ann Nutr Metab 2003; 47: 427.	Searches	Abstract only. No published references found July 2005.
Ippisch H (2004) Does gastric bypass surgery decrease cardiac risk factors in morbidly obese young patients? Abstract of the Section on Cardiology and Cardiac Surgery of the American Academy of Pediatrics National Conference and Exhibition	Searches	Abstract only.
Kaur H (2003) Childhood overweight: an expanding problem. *Treatments in Endocrinology* 2:000.	Searches	Narrative review. No additional references.
Klish WJ, Brandt ML, Helmrath MA (2004) Obesity surgery in pediatrics. *Journal of Pediatric Gastroenterology and Nutrition* 39:2–4.	Searches	Narrative review.
Yap N, Frydenberg H (2004) Obesity in adolescence – Is surgery a good option. *Obesity Surgery* 14:931.	Searches	Abstract only.
Reichard K (2004) Bariatric surgery in morbidly	Searches	Narrative review. No

Study	Source	Reason
obese adolescents. *Maryland Medicine* 5:16–18.		additional references.
Rigg CA (1975) Proceedings: Jejunoileal bypass by morbidly obese adolescent. *Acta Paediatrica Scandinavica* Suppl:62–4.	Searches	Comment.
Rodgers BM (2004) Bariatric surgery for adolescents: a view from the American Pediatric Surgical Association. *Pediatrics*114:255–6.	Searches	No clear values on weight loss.
Sugerman HJ, Sugerman EL, DeMaria EJ et al. (2003) Bariatric surgery for severely obese adolescents. *Journal of Gastrointestinal Surgery* 7:102–107.	Searches	Gastroplasty, distal gastric bypass, and long-limb gastric bypass.
Inge TH, Donnelly LF, Vierra M, Cohen AP, Daniels SR, Garcia VF (2005) Managing bariatric patients in a children's hospital: Radiologic considerations and limitations, *Journal of Pediatric Surgery* 40:000.	Searches	Narrative review.
White J, Cheek D, Haller AJ (1974) Small bowel bypass is applicable for adolescents with morbid obesity. *American Surgeon* 40:000.	Searches	Small bowel bypass procedure.

2.6 Harms

Study	Reason for exclusion
Daee A, Robinson P, Lawson M, Turpin JA, Gregory B, Tobias JA (2002). Psychologic and physiologic effects of dieting in adolescents". Southern Medical Journal, Sep;95(9):1032-41	Not professionally delivered weight loss program
Faith MS, Scanlon KS, Birch LL, Francis LA and Sherry B(2004). Parent-Child Feeding Strategies and Their Relationships to Child Eating and Weight Status". Obesity Research. Nov; 12(11):1711-22.	Not professionally delivered weight loss program
Field AE, Camargo CA Jr, Taylor CB, Berkley CS and Colditz GA (1999). Relation of peer and media influences to the development of purging behaviours among preadolescent and adolescent girls. Archives of Pediatric and Adolescent Medicine, Nov; 153(11):1184-9.	Not professionally delivered weight loss program

Study	Reason for exclusion
Field AE, Austin SB, Taylor CB, Malspeis S, Rosner B, Rockett, HR, Gillman, MW and Colditz GA (2003). Relation between dieting and weight change among preadolescents and adolescents. Pediatrics. Oct; 112(4):900-6.	Not professionally delivered weight loss program
Hill AJ (2004). Does dieting make you fat? British Journal of Nutrition. 2004 Aug; 92 Suppl 1:S15-8.	Review. References checked
Irving LM and Neumark-Sztainer D(2002). Integrating the prevention of eating disorders and obesity: feasible or futile? Preventive Medicine. 2002 Mar; 34(3):299-309.	Narrative review on prevention of eating disorders.
Keller C and Stevens SR (1996). Assessment, etiology, and intervention in obesity in children. Nurse Practitioner, Sep; 21(9):31-6, 38, 41-2.	Narrative review.
Lowe MR and Timko CA (2004). Dieting: really harmful, merely ineffective or actually helpful? British Journal Nutrition. 2004 Aug; 92 Suppl 1:S19-22.	Review. References checked
Neumark-sztainer D, Wall M, Story M, Fulkerson JA (2004). Are family meal patterns associated with disordered eating behaviors among adolescents? Journal of Adolescent Health, Nov; 35(5):350-9.	Not professionally delivered weight loss program
Neumark-Sztainer D, Wall M, Story M, Fulkerson JA (2002).Weight-related concerns and behaviors among overweight and non-overweight adolescents: implications for preventing weight-related disorders. Archives of pediatrics and Adolescent Medicine, 156.	Not relevant
Patton et al (1999). Onset of adolescent eating disorders in overweight and obese adults: population based cohort study over 3 years. BMJ, 318.	Not professionally delivered weight loss program
Pesa J (1999). Psychosocial factors associated with dieting behaviors among female adolescents". Journal of School Health, May; 69(5):196-201.	Not professionally delivered weight loss program
Pugliese MT, Lifshitz F, Grad G, Fort P, Marks-Katz M(1983). Fear of obesity. A cause of short stature and delayed puberty. New England Journal of Medicine. Sep 1; 309(9):513-8.	Not effect of weight management programme – underweight children with fear of obesity as a cause of short stature or delayed puberty.

Study	Reason for exclusion
Reilly JJ (2003). Health consequences of obesity. Archives of Disease in Childhood, Sep; 88(9):748-52.	Not relevant systematic review. References checked.
Stice E, Cameron RP, Killen JD, Hayward C, Taylor CB (1999). Naturalistic weight-reduction efforts prospectively predict growth in relative weight and onset of obesity among female adolescents. Journal of consulting and clinical psychology, Dec;67(6):967-74	Not professionally delivered weight loss program
Stice E, Presnell K, Groesz L, Shaw H (2005). Effects of a weight maintenance diet on bulimic symptoms in adolescent girls: an experimental test of the dietary restraint theory. Health Psychology, Jul; 24(4):402-12.	Participants were not overweight or obese.
White JH (2000). Eating disorders in elementary and middle school children: risk factors, early detection, and prevention". Journal of School Nursing, Apr;16(2):28-35; quiz 36	Literature review. References checked.

2.7 Update searches excluded studies

Study	Reason for exclusion
Anderson ZJ, Anderson ZJ. Childhood obesity: assessing the cost. [Review] [6 refs]. J Okla State Med Assoc 2004; 97(10):418-421.	Narrative review
Bacchini D, Duval M, Valerio P, Pasanisi F, Bacchini D, Duval M et al. Eating disorder variables and self image in Italian girls attending a weight control clinic. Eat Weight Disord 2005; 10(2):125-132.	Less than 6 months
Barton SB, Walker LL, Lambert G, Gately PJ, Hill AJ, Barton SB et al. Cognitive change in obese adolescents losing weight. Obes Res 2004; 12(2):313-319.	Non-clinical setting
Berkel LA, Poston WS, Reeves RS, Foreyt JP, Berkel LA, Poston WSC et al. Behavioral interventions for obesity. [Review] [29 refs]. J Am Diet Assoc 2005; 105(5 Suppl 1):S35-S43	Narrative review. References checked.
Berry D, Galasso P, Melkus G, Grey M, Berry D, Galasso P et al. Obesity in	Narrative review. References checked.

youth: implications for the advanced practice nurse in primary care. [Review] [84 refs]. J Am Acad Nurse Pract 2004; 16(8):326-334.	
Berry D, Sheehan R, Heschel R, Knafl K, Melkus G, Grey M. Family-Based Interventions for Childhood Obesity: A Review. Journal of Family Nursing, Nov 2004, vol 10, no 4, p 429 449 , ISSN : 1074 8407 Publisher : Sage Publications , US, http ://www sagepublications com / 2004.	Narrative review
Boyd GS, Koenigsberg J, Falkner B, Gidding S, Hassink S. Effect of obesity and high blood pressure on plasma lipid levels in children and adolescents. Pediatrics 2005; 116(2 Part 1):442-446.	Retrospective case-control.
Brownell KD. Fast Food and Obesity in Children. Pediatrics 2004; 113(1 I):132	Narrative review
Chartier K, Chartier K. The economic impact of childhood obesity. Nephrol News Issues 2004; 18(11):40-41	Narrative review
Clemmens D, Hayman LL, Clemmens D, Hayman LL. Increasing activity to reduce obesity in adolescent girls: a research review. [Review] [39 refs]. J Obstet Gynecol Neonatal Nurs 2004; 33(6):801-808.	Not overweight/ obese participants
Deforche B, Bourdeaudhuij ID, Tanghe A, Hills AP, Bode PD. Changes in physical activity and psychosocial determinants of physical activity in children and adolescents treated for obesity. Patient Education & Counseling 2004; 55(3):407-415.	Not controlled study.
Deforche B, Bourdeaudhuij I, Tanghe A, Debode P, Hills AP, and Bouckaert J. Post-treatment phone contact: a weight maintenance strategy in obese youngsters. International Journal of Obesity 2005, 29 (5): 543-6.	Non-clinical setting.
Deforche B, Bourdeaudhiuj ID, Tanghe A, Debode P, Hills AP, Bouckaert J. Role of physical activity and eating behaviour in weight control after treatment in severly obese children and adolescents. Acta paediatrica 2005; 94: 464-470.	Different groups based on perceptions of the participants towards physical activity and diet, and not actually different treatment procedures.
Denzer C, Reithofer E, Wabitsch M, Widhalm K, Denzer C, Reithofer E et al. The outcome of childhood obesity	Not controlled study

management depends highly upon patient compliance. Eur J Pediatr 2004; 163(2):99-104	
Diettrich S, Widhalm K. A multidisciplinary therapy program for morbidly obese children and teenagers: results after 7 months. International Pediatrics 2004; 19 (2): 83- 88.	Not controlled study
Dorsey KB, Wells C, Krumholz HM, Concato JC, Dorsey KB, Wells C et al. Diagnosis, evaluation, and treatment of childhood obesity in pediatric practice. Arch Pediatr Adolesc Med 2005; 159(7):632-638.	Medical records review
Durant N, Cox J. Current treatment approaches to overweight in adolescents. Current Opinion in Pediatrics 2005; 17(4):454-459.	Narrative review
Faith MS, Berkowitz RI, Stallings VA, Kerns J, Storey M, Stunkard AJ. Parental feeding attitudes and styles and child body mass index: Prospective analysis of a gene-environment interaction. Pediatrics 2004; 114(4):e429-e436.	Not controlled study
Flodmark CE, Lissau I, Moreno LA, Pietrobelli A, Widhalm K, Flodmark CE et al. New insights into the field of children and adolescents' obesity: the European perspective. [Review] [65 refs]. Int J Obes Relat Metab Disord 2004; 28(10):1189-1196	Narrative Review.
Gately PJ, Barth JH, Radley D, Cooke CB. Acute physiological outcomes of a children's weight-loss camp using exercise and dietary therapy. American Journal of Recreation Therapy 2005; 4(2):13-20.	Less than 6 months.
Gelbrich G, Reich A, Muller G, Kiess W, Gelbrich G, Reich A et al. Knowing more by fewer measurements: about the (In)ability of bioelectric impedance to enhance obesity research in children. J Pediatr Endocrinol 2005; 18(3):265-273.	Did not modify any of the recommendations.
Gillis L, McDowell M, Bar-Or O. Relationship between summer vacation weight gain and lack of success in a pediatric weight control program. Eating Behaviors 2005; 6(2):137-143.	Retrospective study
Graf C, Rost SV, Koch B, Heinen S,	Not relevant to KCQs'

Falkowski G, Dordel S et al. Data from the StEP TWO programme showing the effect on blood pressure and different parameters for obesity in overweight and obese primary school children. Cardiol Young 2005; 15(3):291-298.	
Herrera EA, Johnston CA, Steele RG. A comparison of cognitive and behavioral treatments for pediatric obesity. Children's Health Care 2004; 33(2):151-167.	Narrative review. References checked.
Horn LV, Obarzanek E, Friedman LA, Gernhofer N, Barton B. Children's adaptions to a fat-reduced diet: The Dietary Interventions Study in Children (DISC). Pediatrics 2005; 115: 1723-1733.	Children no overweight/obese
Hydrie MZI, Basit A, Hakeem R, Ahmadani MY, Masood MQ. Comparison of fasting glucose, insulin levels and lipid profile in normal and overweight children. Journal of Postgraduate Medical Institute 2001;(1):8-13	Participants did not undergo weight management programme.
Janssen I, Katzmarzyk PT, Srinivasan SR, Chen W, Malina RM, Bouchard C et al. Combined influence of body mass index and waist circumference on coronary artery disease risk factors among children and adolescents. Pediatrics 2005; 115(6):1623-1630.	Not controlled study
Kanda A, Kamiyama Y, Kawaguchi T, Kanda A, Kamiyama Y, Kawaguchi T. Association of reduction in parental overweight with reduction in children's overweight with a 3-year follow-up. Prev Med 2004; 39(2):369-372.	Not controlled study
Kirk S, Zeller M, Claytor R, Santangelo M, Khoury PR, Daniels SR et al. The relationship of health outcomes to improvement in BMI in children and adolescents. Obes Res 2005; 13(5):876-882.	Not controlled study
Kolagotla L, Adams W, Kolagotla L, Adams W. Ambulatory management of childhood obesity. Obes Res 2004; 12(2):275-283.	Not controlled study
Lau PWC, Yu CW, Lee A, Sung RYT. The physiological and psychological effects of resistance training on Chinese obese adolescents. Journal of Exercise	Less than 6 months duration

Science and Fitness 2004; 2(2):115-120.	
Lazzer S, Boirie Y, Montaurier C, Vernet J, Meyer M, Vermorel M et al. A weight reduction program preserves fat-free mass but not metabolic rate in obese adolescents. Obes Res 2004; 12(2):233-240.	Not controlled study
Lazzer S, Boirie Y, Poissonnier C, Petit I, Duche P, Taillardat M et al. Longitudinal changes in activity patterns, physical capacities, energy expenditure, and body composition in severely obese adolescents during a multidisciplinary weight-reduction program. International Journal of Obesity 2005; 29(1):37-46.	Not controlled study
Lazzer S, Boirie Y, Bitar A, Petit I, Meyer M, Vermorel M. Relationship between percentage of VO2max and type of physical activity in obese and non-obese adolescents. J Sports Med Phys Fitness 2005; 45(1):13-19. (40) Li S, Liu X, Okada T, Iwata F, Hara M, Harada K et al. Serum lipid profile in obese children in China. Pediatr Int 2004; 46(4):425-428	Less than 6 months duration
Luke A, Philpott J, Brett K, Cruz L, Lun V, Prasad N et al. Physical inactivity in children and adolescents. Clin J Sport Med 2004; 14(5):261-266.	Narrative review
Macey L, Sternberg A, and Muzumbar H. The Downstart Program: A Hospital-based weight-loss program. Ethnicity and disease 2005, volume 15, 58-59.	Less than 6 months
Maffeis C, Zaffanello M, Pellegrino M, Banzato C, Bogoni G, Viviani E et al. Nutrient oxidation during moderately intense exercise in obese prepubertal boys. Journal of Clinical Endocrinology & Metabolism 2005; 90(1):231-236.	Not controlled study
Malecka-Tendera E, Klimek K, Matusik P, Olszanecka-Glinianowicz M, Lehingue Y, the Polish Childhood Obesity Study Group. et al. Obesity and overweight prevalence in Polish 7- to 9-year-old children. Obes Res 2005; 13(6):964-968.	Not controlled study.
Marshall SJ, Biddle SJ, Gorely T, Cameron N, Murdey I, Marshall SJ et al. Relationships between media use, body fatness and physical activity in children	Not only overweight/ obese participants. No group stratification.

and youth: a meta-analysis. [Review] [76 refs]. Int J Obes Relat Metab Disord 2004; 28(10):1238-1246.	
McElroy SL, Kotwal R, Malhotra S, Nelson EB, Keck-Paul-E-Jr, Nemeroff CB. Are Mood Disorders and Obesity Related? A Review for the Mental Health Professional. Journal of Clinical Psychiatry, May 2004, vol 65 , no 5, p 634 651 , ISSN : 0160 6689 Publisher : Physicians Postgraduate Press, US, http ://www psychiatrist com / 2004	Did not undertake weight management programme.
McGarvey E, Keller A, Forrester M, Williams E, Seward D, Suttle DE. Feasibility and benefits of a parent-focused preschool child obesity intervention. American Journal of Public Health 2004; 94 (9): 1490- 1495.	Participants were not overweight.
Mohn A, Catino M, Capanna R, Giannini C, Marcovecchio M, Chiarelli F. Increased oxidative stress in prepubertal severly obese children: effect of a dietary restriction-weight loss program. The Journal of Clinical Endocrinology and Metabolism 2005; 90 (5): 2653-2658.	Control group does not report weight parameters at follow-up.
Nagai N, Moritani T, Nagai N, Moritani T. Effect of physical activity on autonomic nervous system function in lean and obese children. Int J Obes Relat Metab Disord 2004; 28(1):27-33.	Less than 6 months duration
Norman AC, Drinkard B, Mcduffie JR, Ghorbani S, Yanoff LB, Yanovski JA. Influence of excess adiposity on exercise fitness and performance in overweight children and adolescents. Pediatrics 2005; 115: 690-696.	Did not report changes in regard to weight parameters.
Ramos dM, V, Almeida RM, Pereira RA, Azevedo Barros MB, Ramos de Marins VM, Almeida RMVR et al. The relationship between parental nutritional status and overweight children/adolescents in Rio de Janeiro, Brazil. Public Health 2004; 118(1):43-49.	Not controlled study.
Reinehr T, Kiess W, Andler W. Insulin sensitivity indices of glucose and free fatty acid metabolism in obese children and adolescents in relation to serum	Participants did not undertake weight management programme.

lipids. Metabolism: Clinical & Experimental 2005; 54(3):397-402.	
Reybrouck T, Vinckx J, Gewillig M. Assessment of oxygen deficit during exercise in obese children and adolescents. Pediatric Exercise Science 2005; 17(3):291-300.	Less than 6 months duration
Rooney BL, Gritt LR, Havens SJ, Mathiason MA, Clough EA. Growing Healthy Families: family use of pedometers to increase physical activity and slow the rate of obesity. Wisconsin Medical Journal 2005; 104 (5): 54- 60.	Non-clinical setting.
Ribeiro MM, Silva AG, Santos NS, Guazzelle I, Matos LNJ, Trombetta IC et al. Diet and exercise training restore blood pressure and vasodilatory responses during physiological maneuvers in obese children. Circulation 1915; 111(15):15-1923.	Less than 6 months duration
Rudolf MCJ, Hochberg Z, Speiser P. Perspectives on the development of an international consensus on childhood obesity. Archives of Disease in Childhood 2005; 90(10):994-996.	Narrative review. References checked.
Sabia, RV, Santos JE and Ribeiro RPPR. Effect of physical associated with nutritional orientation for obese adolescents: comparison between aerobic and anaerobic exercise. Revista Brasileira de Medicina do Esporte 2004; 10 (5): 356 – 360.	Less than 6 months
Sung RYT, Yu CW, So RCH, Lam PKW, and Hau KT. Self-perception of physical competences in preadolescent overweight Chinese children. European Journal of Clinical Nutrition 2005; 59: 101-106.	Not controlled study.
Tennefors C, Forsum E, Tennefors C, Forsum E. Assessment of body fatness in young children using the skinfold technique and BMI vs body water dilution. Eur J Clin Nutr 2004; 58(3):541-547.	Less than 2 year olds.
Tudor-Locke C, Pangrazi RP, Corbin CB, Rutherford WJ, Vincent SD, Raustorp A et al. BMI-referenced standards for recommended pedometer-determined	Secondary analysis of cross sectional data.

steps/day in children. Prev Med 2004; 38(6):857-864.	
Vila G, Zipper E, Dabbas M, Bertrand C, Robert JJ, Ricour C et al. Mental disorders in obese children and adolescents. Psychosom Med 2004; 66(3):387-394.	Did not undertake weight management program.
White MA, Martin PD, Newton RL, Walden HM, York-Crowe EE, Gordon ST et al. Mediators of weight loss in a family-based intervention presented over the internet. Obes Res 2004; 12(7):1050-1059	Not clinical approach
Williamson DA, Davis MP, White MA, Newton R, Walden H, York CE et al. Efficacy of an internet-based behavioral weight loss program for overweight adolescent African-American girls. Eating and Weight Disorders 2005; vol. 10, no. 3, p. 193-203,.ISSN: 1590-1262..Publisher: Editrice Kurtis, Italy, http://www.kurtis.it.:193-203.	Not clinical approach
Yin TJ WFLYY. Effects of a weight-loss program for obese children: a "mix of attributes" approach. The journal of nursing research: JNR 2005; 13(1):21-30.	School-based study
Yoshinaga M, Sameshima K, Miyata K, Hashiguchi J, Imamura M, Yoshinaga M et al. Prevention of mildly overweight children from development of more overweight condition. Prev Med 2004; 38(2):172-174	Not clear length of study
Young KL. Treating overweight children and adolescents in the clinic. Clinical Pediatrics 2005; 44(8):647-653.	Narrative review

Appendix 15

NOTE: all text in italic is taken from the source documents as acknowledged.

Abbreviations

BEDD	Balanced energy-deficient diet
BMI	Body mass index
BP	Blood pressure
BT	Behavioural therapy
CAD	Coronary artery disease
CHD	Coronary heart disease
CI	Confidence interval
CON	Control
CRP	C-reactive protein
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
DEXA	Dual-energy X-ray absorptiometry
DS-BPD	Duodenal switch-bileopancreatic diversion
EE	Energy expenditure
EWL	Excess weight loss
FEV	Forced expiratory volume
FFM	Fat-free mass
FPG	Fasting plasma glucose
FVC	Forced vital capacity
GBP	Gastric bypass
GI	Gastrointestinal
GP	General practitioner
GRP	Group
HP	High protein
HRQL	Health-related quality of life
ICAM	Intracellular adhesion molecule
IGT	Impaired glucose tolerance
IND	Individual treatment
INT	Intermittent
ITT	Intention to treat
KPWMP	Kaiser Permanente Weight Management Program
LAGB	Laparoscopic (adjustable) gastric banding
LB	Long bout
LED	Low-energy diet
LGBP	Laparoscopic Roux en Y gastric bypass
LGBY	Laparoscopic gastric bypass
LOCF	Last observation carried forward
LTPA	Leisure time physical activity
METS	Metabolic equivalent tasks
MI	Myocardial infarction
MP	Medium protein
NGT	Normal glucose tolerance
NIDDM	Non-insulin-dependent diabetes mellitus
NS	Not significant
OA	Osteoarthritis
OGTT	Oral glucose tolerance test
OR	Odds ratio
PEF	Peak expiratory flow
PS	Problem-solving
PSMF	Protein-sparing modified fast
RCT	Randomised controlled trial
RDA	Recommended daily allowance
ROC	Received operator characteristic

RP	Relapse prevention
RR	Relative risk
SB	Short bout
SBEQ	Short bout plus home treadmill
SBP	Systolic blood pressure
SBT	Standard behavioural therapy
SP	Standard protein
TAG	Triacylglycerol
TC	Total cholesterol
VLED	Very-low-energy diet
WC	Waist circumference
WHO	World Health Organization
WHR	Waist:hip ratio

Evidence tables

Comparison of guidelines included in the syntheses

COMPARISON OF SCOPE AND CONTENT	
Objective and Scope	
ACP (2005)	To provide recommendations based on a review of the evidence on pharmacological and surgical treatments of obesity To complement the guidelines on screening for obesity developed by the US Preventive Services Task Force
ACPM (2001)	To present a practice policy statement on weight management counselling of overweight adults
AGA (2002)	To provide gastroenterologists with a comprehensive evaluation of the important clinical issues in adult obesity, including prevalence, aetiology, physiology, pathophysiology, medical complications, metabolic and medical effects of weight loss, treatment options and treatment guidelines
BWH (2003)	To provide physicians with clear clinical pathways to identify and treat obesity
SINGAPORE MOH (2004)	To assist healthcare professionals who have a role in managing overweight or obese patients To provide current evidence-based clinical practice recommendations on various aspects of obesity management found across various medical disciplines To provide a framework to assist doctors in the management of overweight and obesity without restricting the physician's individual judgement To provide a review of the various medical, surgical, and ancillary intervention modalities in the management of obesity To aid primary care physicians in basic management of obesity and subsequent referrals to specialists for more resistant cases
USPSTF (2003)	To summarise the USPSTF recommendations on screening for obesity in adults based on the USPSTF's examination of evidence specific to obesity and overweight in adults To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, Second Edition
Target Population	
ACP (2005)	USA Patients with a body mass index (BMI) ≥30 kg/m^2 Note: The target patient populations vary according to the intervention under consideration, since pharmacological and surgical trials have used different selection criteria with differing BMIs and comorbid conditions. This guideline does not apply to patients with BMIs <30 kg/m^2
ACPM (2001)	USA General adult population (Counselling/Prevention) Overweight and obese adults (Management)
AGA	USA

(2002)	Overweight and obese adults
BWH (2003)	USA Women who are overweight or obese Women who are at risk of becoming overweight or obese
SINGAPORE MOH (2004)	Singapore Adults in Singapore who are obese or overweight, or who are at risk of obesity Note: Children and adolescents are also considered in this guideline; recommendations concerning these younger age groups are covered in a separate synthesis.
USPSTF (2003)	USA Adults seen in primary care settings
Intended Users	
ACP (2005)	Advanced Practice Nurses; Allied Health Personnel; Nurses; Physician Assistants; Physicians
ACPM (2001)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physical Therapists; Physician Assistants; Physicians
AGA (2002)	Physicians
BWH (2003)	Advanced Practice Nurses; Healthcare Providers; Physician Assistants; Physicians
SINGAPORE MOH (2004)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physician Assistants; Psychologists/Non-Physician Behavioural Health Clinicians; Public Health Departments; Respiratory Care Practitioners
USPSTF (2003)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physician Assistants; Physicians; Psychologists/Non-physician Behavioural Health Clinicians
Interventions and Practices Considered	
ACP (2005)	Counselling Dietary and physical activity counselling Management/Treatment Determination of weight loss and other therapeutic goals (for BMI ≥30 kg/m^2) Pharmacotherapy (drugs considered: sibutramine, orlistat, phentermine, diethylpropion, fluoxetine, bupropion) (for BMI ≥30 kg/m^2) Lifestyle modifications such as diet and exercise Surgery (for BMI ≥40 kg/m^2)
ACPM (2001)	Assessment and Preventive Counselling BMI Weight monitoring Dietary and physical activity counselling Management/Treatment Moderate physical activity Dietary interventions (e.g., energy-reduced or low-energy diet [LED]) Pharmacotherapy, such as sibutramine and orlistat (considered but not specifically recommended) Behaviour therapy Surgery (e.g., surgical gastroplasty and gastric bypass (GBP)

AGA (2002)	Assessment Medical evaluation, including a careful history, physical examination (including determination of BMI), and laboratory tests Assessment of weight loss readiness Management/Treatment Determination of therapeutic goals, considering patient readiness for obesity treatment and obesity-related health risk Dietary interventions (e.g., reduction of energy through strategies such as portion-controlled servings, pre-packaged prepared meals and liquid formula meal replacements) Physical activity at varying intensities Behaviour modification (e.g., self-monitoring activities, consultation with local professionals, group behaviour therapy) Pharmacotherapy (e.g., sibutramine hydrochloride [Meridia] and orlistat [Xenical]) Surgery Procedures primarily for gastric restriction (e.g., GBP and vertical banded gastroplasty) Procedures primarily for maldigestion/malabsorption (e.g., biliopancreatic diversion, biliopancreatic diversion with duodenal switch, distal GBP)
BWH (2003)	Assessment BMI Waist circumference Evaluation of risk factors and associated overweight and obesity health risks Identification of potential triggers (e.g., medications, injuries and/or medical conditions, smoking status, or behavioural, cultural, and economic issues that impact food choices or exercise options) Treatment/Management/Prevention Goal setting Dietary therapy (including changes in dietary composition and LED or very-low-energy diets [VLED}) Physical activity and exercise Behaviour therapy Pharmacotherapy (including, appetite suppressants [phentermine], serotonergic agonists [sibutramine], and fat malabsorption agents [orlistat]) Avoidance of medications that may contribute to weight gain Surgery (including GBP, vertical banded gastroplasty, and laparoscopic banding) Weight loss maintenance Referrals Psychiatric and nutrition referrals for binge eating or bulimia
SINGAPORE MOH (2004)	Assessment BMI Waist circumference Evaluation of risk factors for, and secondary causes of, obesity Screening for comorbid conditions Evaluation of patient motivation Management/Treatment Goal setting Dietary therapy (decrease in energy intake, macronutrient composition, meal size and distribution of food intake during day, LED and VLED) Physical activity and exercise Behaviour therapy Pharmacotherapy (e.g., orlistat, sibutramine, phentermine, mazindol, metformin) Non-prescription and off-label weight loss supplements Surgery (including, GBP, vertical banded gastroplasty, or laparoscopic banding) Weight loss maintenance Referrals Evaluation for depression and binge-eating disorders with referrals Note: Interventions for assessment and treatment of overweight and obesity in adolescents and children were also considered in this guideline. These

	interventions are addressed in a separate synthesis.
USPSTF (2003)	Assessment/Screening BMI Waist circumference Management *Combined counselling and behavioural interventions including*: Low-, moderate- and high-intensity counselling Nutritional education Behavioural strategies including the 5-A framework (Assess, Advise, Agree, Assist and Arrange) Note: Treatment interventions such as medications (orlistat and sibutramine) and surgery (GBP, vertical banded gastroplasty and adjustable gastric banding) were considered.

1.1 Measures other than BMI

<table>
<tr><th colspan="2">Dasgupta 1999</th></tr>
<tr><td>Country</td><td>India</td></tr>
<tr><td>Setting</td><td>Outpatient clinic</td></tr>
<tr><td>Aim or objective</td><td>To assess the correlation between waist circumference and waist:hip ratio (WHR) and BMI. Also to assess if a simple measurement such as waist circumference (WC) can be used as an independent indicator for detecting health risk and management</td></tr>
<tr><td>Adults or children</td><td>Assumed to be adults</td></tr>
<tr><td>No. of participants</td><td>1000. 500 male (M) and 500 female (F)</td></tr>
<tr><td>Prevalence</td><td>Only 7% of the males and 16% of the females had BMI ≥25 kg/m^2</td></tr>
<tr><td>Included participants</td><td>Mean age 47 years M and 46 years F. People attending clinics</td></tr>
<tr><td>Excluded participants</td><td>People with disease such as ascites, Cushings or oedema</td></tr>
<tr><td>Self-referred or not</td><td>Nor reported (N/R)</td></tr>
<tr><td>Definitions</td><td>Defined as low WC <80 for men, <72 cm for women. Low BMI <25 kg/m^2</td></tr>
<tr><td>Reference standard</td><td>BMI</td></tr>
<tr><td>Source of funding</td><td>N/R</td></tr>
<tr><td>Results</td><td>About 50% of both males and females had WHR above the desirable range (0.80 for females and 0.95 for males). About 99% of females with WC ≥72 cm had either BMI ≥25 kg/m^2 or high WHR ≥0.80 or both. Similarly, 99% of males with WC ≥80 cm had either high BMI ≥25 kg/m^2 or high WHR ≥0.90 or both.
For men with WC ≥80 cm and women with WC ≥72 cm
<table>
<tr><th></th><th>M</th><th>F</th></tr>
<tr><td>**Total**</td><td>293</td><td>**355**</td></tr>
<tr><td>**With low WHR**</td><td>224
44.8%</td><td>**223**
44.5%</td></tr>
<tr><td>**With high WHR**</td><td>69</td><td>**132**</td></tr>
<tr><td>**With high WHR but BMI <25 kg/m^2**</td><td>66
13.2%</td><td>**126**
25.2%</td></tr>
<tr><td>**With high WHR and high BMI ≥25 kg/m^2**</td><td>**3**
0.6%</td><td>**6**
1.2%</td></tr>
</table>
WC showed a high specificity (98.4% in men and 99.4% in women) and a high sensitivity (98.5% in men and 95.9% in women).</td></tr>
<tr><td>Authors’ conclusions</td><td>WC is simple to assess and can be used as an independent measure to identify those at risk from either increased body weight or central fat distribution or both.</td></tr>
<tr><td>Quality and notes</td><td>–
Lack of reporting of methods. Not sure if population is</td></tr>
</table>

	generalisable.

Gill 2003	
Country	Australia
Setting	Community
Aim or objective	To determine the proportion of a representative population sample of adults who have a BMI classified as normal or underweight, but who also have a WC or WHR that indicates obesity
Adults or children	Adults
No. of participants	2523
Prevalence	Overall prevalence of overweight by BMI over 25 kg/m^2 was 35.2%. For BMI over 30 kg/m^2, prevalence of obesity was 28.5%.
Included participants	Randomly recruited participants. Age range 18 to >60 years.
Excluded participants	…
Self-referred or not	N/R
Definitions	Defined as Action level 1. Low WC <95 cm for men, <80 cm for women. Low BMI <25 kg/m^2 Defined as Action level 2. Low WC <100 cm for men, <90 cm for women. Low BMI <30 kg/m^2
Reference standard	BMI
Source of funding	None reported, but collaboration between Health Services and universities
Results	Among women with a normal BMI, 19.0% had a high WC (≥80 cm) and 8.5% had a high WHR (>0.85). Among males with a normal BMI, 3.4% had a high WC (≥95 cm) and 0.1% had a high WHR (>1.0)
Authors' conclusions	The authors concluded that BMI, WHR and WC all have a role in the identification of those who are obese or overweight
Quality and notes	+ No blinding

Goodman-Gruen 1996	
Country	USA
Setting	Community
Aim or objective	To describe sex differences in obesity and body fat distribution using commonly used assessment methods in men and women age 65–96 years.
Adults or children	Adults
No. of participants	385 older people. 140 M and 245 F
Prevalence	…
Included participants	First 385 participants. Mean age 80 (range 65 to 96) years
Excluded participants	…
Self-referred or not	N/R
Definitions	…
Reference standard	…
Source of funding	National Institute of Diabetes and Digestive and Kidney Diseases. Weight Watchers Foundation
Results	WHR was more strongly correlated with the truncal fat:leg fat ratio in women than in men. WHR correlated significantly with the subscapular:triceps skinfold thickness ratio in women only. In both sexes, WC was more strongly correlated with BMI and the % body fat by bioelectric impedance analysis and dual-energy X-ray absorptiometry (DEXA) than with the WHR. In those aged >80 years, age stratification showed that the WHR was not correlated with any other measurement of obesity or fat distribution in men and correlated only with subscapular skinfold thickness in women. WC correlated significantly with almost all other measures of central obesity in older and younger men and women.

Authors' conclusions	Estimates of upper body (central) fat distribution appear to be age specific. After age 80 years, the WHR is a poor method of assessing central or visceral adiposity, and WC is a better measure of body fat distribution. But suggest that several measures should be done.
Quality and notes	– Possible some blinding as several tests were done that may have required different operators (e.g. DEXA and bioimpedance). Study not designed to evaluate the validity of different measures but to compare the concordance.

Han 1997	
Country	UK and Netherlands
Setting	Not clear – samples from World Health Organization study 1989.
Aim or objective	To assess the influences of height and age on the differences in waist circumference between individuals of different stature
Adults or children	Adults (assumed)
No. of participants	Four samples; 4881 and 384 from the Netherlands, and 1918 and 494 from Scotland. Overall 3319 M and 4358 F
Prevalence	Overall, mean (SD) BMI (kg/m^2) 25.8 (3.6) for men and 25.7 (4.9) for women.
Included participants	Samples from four previous anthropometric studies.
Excluded participants	…
Self-referred or not	Not clear.
Definitions	…
Reference standard	N/R?
Source of funding	N/R
Results	Analysis of the samples found that height had a very limited influence on the differences in WC between individuals. Without adjusting for age, height accounted for 0.3 to 3.5% of variance in WC in men and 0.1 to 2.5% in women. When age was adjusted for, this became 0.4 to 7.5% for men and 0.0 to 2.6% in women.
Authors' conclusions	Height and weight had limited influences on the differences in WC between white people of difference stature. WC alone may be used to indicate adiposity or to reflect metabolic risk factors. In contrast, the effect of height on body weight is important.
Quality and notes	+

Lean 1995	
Country	UK
Setting	Community
Aim or objective	To test the hypothesis that a single measurement, waist circumference, might be used to identify people at health risk both from being overweight and from having a central fat distribution
Adults or children	Adults
No. of participants	904 M and 1014 F in determination sample. 86 M and 202 F in validation sample. Total 2206.
Prevalence	52.13% for Action level 1 and 18.64% for Action level 2
Included participants	Randomly recruited participants. Age range 25 to 74 years.
Excluded participants	People who were chair-bound
Self-referred or not	N/R
Definitions	Defined as Action level 1. Low WC <94 cm for men, <80 cm for women. Low BMI <25 kg/m^2. Defined as Action level 2. Low WC<102 cm for men, <88 cm for women. Low BMI <30 kg/m^2.
Reference standard	BMI
Source of funding	Scottish Home and Health Department. University.
Results	WC ≥94 cm for men and ≥ 80 cm for women identified

	participants with high BMI ≥25 kg/m^2) and those with lower BMI but high WHR (≥0.95 for men, ≥0.80 women) with a sensitivity of >96% and specificity >97.5%. WC ≥102 cm for men or ≥88 cm for women identified participants with BMI ≥30 kg/m^2 and those with lower BMI but high WHR with a sensitivity of >96% and specificity >98%, with only about 2% of the sample being misclassified.
Authors' conclusions	WC could be used in health promotion programmes to identify individuals who should seek and be offered weight management. Men with WC ≥94 cm and women with waist circumference ≥80 cm should gain no further weight; men with waist circumference ≥102 cm and women with waist circumference ≥88 cm should reduce their weight.
Quality and notes	+ No blinding, some validation.

Logue 1995	
Country	USA
Setting	Family practice community
Aim or objective	To describe the prevalence of general and central obesity, and to compare different measurements
Adults or children	Adults
No. of participants	414. 130 M and 284 F
Prevalence	56.2% M and 57.6% F had BMI (kg/m^2) >27.8 for men and >27.3 for women)
Included participants	Adults aged ≥45 years who attended family practice centres.
Excluded participants	…
Self-referred or not	N/R
Definitions	Men with BMI >27.8 kg/m^2 and women with BMI >27.3 kg/m^2 classified as having some degree of obesity. Men with WHR >0.95 and women with WHR >0.80 classified as having some degree of central obesity.
Reference standard	BMI
Source of funding	Summa Heath System Foundation and the family practice centres
Results	57% of patients had an elevated BMI. 50% of men (95% CI 46 to 55) and 78% of women (95% CI 75 to 80) had central obesity based on elevated WHRs. Using an elevated WHR as the standard for central obesity, elevated WHR as the standard for central obesity, elevated BMI had a positive predictive value of only 64% and a negative predictive value of 68% in men. For women, the corresponding positive and negative predictive values were 84% and 31%, respectively.
Authors' conclusions	The data indicate that the practice of using only scales to identify 'overweight' patients should be re-evaluated since doing so will miss patients at risk. In primary care patients, particularly those ≥50 years of age, weight-for-height indices such as BMI result in under-diagnosis of central obesity.
Quality and notes	– No blinding

Molarius 1999	
Country	Various, including UK
Setting	Community
Aim or objective	To examine the sensitivity and specificity of WC cut-off points when applied to 19 populations with widely different prevalences of overweight.
Adults or children	Adults
No. of participants	>32,000 men and women aged 25–64 years from 19 (18 in women) populations participating in the second MONItoring trends and determinants in CArdiovascular disease (MONICA)

	survey from 1987–92
Prevalence	54.87% for Action level 1 and 31.74% for Action level 2
Included participants	Aged 25–64 years from 19 (18 in women) populations.
Excluded participants	…
Self-referred or not	N/R
Definitions	Defined as Action level 1. Low WC <94 cm for men, <80 cm for women. Low BMI <25 kg/m^2. Defined as Action level 2. Low WC<102 cm for men, <88 cm for women. Low BMI <30 kg/m^2.
Reference standard	BMI
Source of funding	Governments, research councils and charities. Also the World Health Organization (WHO).
Results	At waist action level 1 (WC ≥94 cm in men and ≥ 80 cm in women), sensitivity varied between 40% and 80% in men and between 51% and 86% in women between populations when compared with the cut-off points based on BMI (≥25 kg/m^2) and WHR (≥0.95 for men, ≥0.80 for women). Specificity was high (≥90%) in all populations. At waist action level 2 (WC ≥102 cm and ≥88 cm in men and women, respectively, BMI ≥30 kg/m^2), sensitivity varied from 22% to 64% in men and from 26% to 67% in women, whereas specificity was >95% in all populations. Sensitivity was in general lowest in populations in which overweight was relatively uncommon, whereas it was highest in populations with relatively high prevalence of overweight.
Authors' conclusions	Cut-off points based on WC as a replacement for cut-off points based on BMI and WHR should be viewed with caution. Based on the proposed waist action levels, very few people would unnecessarily be advised to have weight management, but a varying proportion of those who would need it might be missed. The optimal screening cut-off points for WC may be population specific.
Quality and notes	+ Used UNK-GLA data only. Action level 1 from files on internet. No blinding.

Molarius 1999	
Country	Various, including UK
Setting	Community
Aim or objective	To assess differences in waist and hip circumferences and WHR measured using a standard protocol among populations with different prevalences of overweight. In addition, to quantify the associations of these anthropometric measures with age and degree of overweight.
Adults or children	Adults
No. of participants	>32,000 men and women aged 25–64 years from 19 (18 in women) populations participating in the second MONItoring trends and determinants in CArdiovascular disease (MONICA) survey from 1987–1992
Prevalence	…
Included participants	Aged 25–64 years from 19 (18 in women) populations
Excluded participants	…
Self-referred or not	…
Definitions	Defined as Action level 1. Low WC <94 cm for men, <80 cm for women. Low BMI <25 kg/m^2. Defined as Action level 2. Low WC<102 cm for men, <88 cm for women. Low BMI <30 kg/m^2.
Reference standard	N/R
Source of funding	Governments, research councils and charities. Also WHO.
Results	Age-standardised mean WC range between populations 83–98 cm in men and 78–91 cm in women. Mean hip circumference range 94–105 cm and 97–108 cm in men and women, respectively, and mean WHR 0.87–0.99 and 0.76–0.84,

	respectively. Together, height, BMI, age group and population explained about 80% of the variance in WC. BMI was the predominant determinant (77% in men, 75% women). Similar results were obtained for hip circumference. However, height, BMI, age group and population, accounted only for 49% (men) and 30% (women) the variation in WHR.
Authors' conclusions	Considerable variation in waist and hip circumferences and WHR were observed among the study populations. WC and WHR, both of which are used as indicators of abdominal obesity, seem to measure different aspects of the human body: WC reflects mainly the degree of overweight whereas WHR does not
Quality and notes	+

Molarius 2000	
Country	The Netherlands
Setting	Community
Aim or objective	To examine the applicability of the suggested waist action levels in an older population
Adults or children	Adults
No. of participants	Total 6423 men and women aged ≥55 years. 2640 M and 3783 F.
Prevalence	61.09% for Action level 1 and 14.56% for Action level 2
Included participants	Aged between 55 and >85 years. Nursing home residents accounted for approx 11% of sample.
Excluded participants	…
Self-referred or not	N/R
Definitions	Defined as Action level 1. Low WC <94 cm for men, <80 cm for women. Low BMI <25 kg/m^2. Defined as Action level 2. Low WC <102 cm for men, <88 cm for women. Low BMI <30 kg/m^2.
Reference standard	BMI
Source of funding	N/R
Results	At waist action level 1 (WC ≥94 cm in men, ≥80 cm in women), sensitivity was 71% in men and 86% in women for detecting those with high BMI (≥25 kg/m^2) and/or WHR (≥0.95 in men, or ≥0.80 in women). At waist action level 2 (WC ≥102 cm in men, ≥88 cm in women in comparison with BMI ≥30 kg/m^2 and/or WHR ≥0.95 in men, ≥0.80 in women), sensitivity was considerably lower: 35% in men and 59% in women. This was mainly due to a large proportion of participants with low waist and BMI but high WHR. Specificity was high (>90%) at both action levels. Cardiovascular disease (CVD) risk factors, except smoking, tended to increase with increasing WC, WHR and BMI.
Authors' conclusions	The suggested cut-off points for WC were only to a limited degree useful in identifying participants with overweight and obesity and/or central fat distribution in an older population. This concerned especially the upper cut-off point (waist action level 2) and was mainly due to the increased central distribution of fat with advancing age
Quality and notes	+

Sonmez 2003	
Country	Turkey
Setting	Clinic?
Aim or objective	To determine BMI, WC and WHR in cases with angiographically established coronary artery disease (CAD) and to compare the obesity degrees established according to the ranges determined by the International Guidelines Committees for BMI, waist circumference and WHR

Adults or children	Adults
No. of participants	617. 516 M and 101 F
Prevalence	46.99% for Action level 1 and 17.99% for Action level 2
Included participants	Consecutive cases undergoing first coronary angiography with at least 50% narrowing of at least one artery. Mean age 57.2±10.8 years
Excluded participants	…
Self-referred or not	…
Definitions	Defined as Action level 1. Low WC <94 cm for men, <80 cm for women. Low BMI <25 kg/m^2. Defined as Action level 2. Low WC <102 cm for men, <88 cm for women. Low BMI <30 kg/m^2.
Reference standard	BMI
Source of funding	None reported
Results	Overweight cases comprised approximately half of the patients in both sexes. In males, the percentage of obese cases with regard to BMI was 15%, while males with action level 2 WC were 20%. Obese male patients whose WHRs were ≥0.95 were 51%. In female cases, corresponding percentages of obesity were estimated to be 32, 72 and 86%, respectively.
Authors' conclusions	In the same patient groups, the prevalence of obesity, defined by BMI, WC and WHR, could vary threefold.
Quality and notes	– Not blinded to anthropometric measures

Taylor 1998	
Country	New Zealand
Setting	Community
Aim or objective	To construct receiver operating characteristic (ROC) curves to assess the value of BMI as a screening measure for total adiposity and to examine WHR and WC as measures of central fat distribution.
Adults or children	Adults
No. of participants	96 F
Prevalence	…
Included participants	Recruited women by advertisement. Aged 16 to 80 years.
Excluded participants	…
Self-referred or not	N/R
Definitions	…
Reference standard	…
Source of funding	N/R
Results	BMI (75th percentile=27.3) performed well as a screening measure of total adiposity, correctly identifying 83% of participants with a high body fat mass while misclassifying only eight participants (four false-negatives [participants with high fat mass who were in the low BMI category] and four false-positives [participants with a low fat mass who were in the high BMI category]). The screening performance of WHR (75th percentile=0.81) was lower, accurately categorising 58% of participants while misclassifying 28 participants. By contrast, WC (75th percentile=86.9 cm) was significantly better than WHR at screening for regional fat distribution, accurately classifying 83% of participants and misclassifying eight participants (*p*<0.05).
Authors' conclusions	BMI and WC provide simple yet sensitive methods for the estimation of total and central adiposity in groups of adult women.
Quality and notes	+ Did not use BMI as the reference standard

1.2 Measures and morbidity in ethnic populations[*]

Bose 1995 and Bose 1996	
Country	UK
Setting	GP practice
Aim or objective	To compare the anatomical distribution of subcutaneous fat in adult White and Pakistani migrant males
Adults or children	Adults
No. of participants	Letters sent to 400 Asian males and 1000 randomly selected white males. 25% response rate. Participants=362 (100 Pakistani, 262 white males)
Included participants	Adult males
Excluded participants	Adult females
Self-referred or not	Letter invitation
Measures	BMI and skinfold thickness tests (subscapular, suprailiac, abdomen, midaxillary, forearm)
Results	There were no significant differences in the distribution of BMI between the two groups. However, Pakistani groups had significantly higher truncal adiposity and total subcutaneous adiposity. Upper extremity adiposity was significantly lower. For a given level of generalised obesity, the amount and distribution of fat is significantly different in these two ethnic groups.
Authors' conclusions	These preliminary results clearly indicate that there is a tendency for accumulation of truncal adiposity in the abdominal region in Asian men of Pakistani origin compared with White men irrespective of the level of generalised (BMI) adiposity.
Quality and notes	– Consistent with previous UK-based study by MeKeigue et al 1991. Note that white group significantly older than Pakistani group.

Lovegrove 2003	
Country	UK
Setting	Community
Aim or objective	To determine whether the positive statistical associations between measures of total and regional adiposity and measures of glucose, insulin and TAG (TAG) metabolism reported in white men, are also observed in UK Sikhs.
Adults or children	Adults
No. of participants	55 healthy white and 55 healthy UK Sikh men
Included participants	Included if non-smoker, not on any hypolipidaemic medication, or any other medication known to affect lipoprotein metabolism.
Excluded participants	Excluded if had diabetes, liver or endocrine dysfunction, malabsorption syndrome, anaemia, or had previously had a coronary event. Also excluded if BMI <20 or >37 kg/m^2, if aged <27 or >68 years, had total cholesterol (TC) >8 mmol/l, TAG >4 mmol/l, glucose >8 mmol/l, gamma-glutamyltransferase >80 IU/l, haemoglobin <12.5 g/dl, activity levels exceeded more than two 20 min sessions of aerobic exercise per week. Sikh men had to be resident in UK for at least 2 years prior to inclusion.
Self-referred or not	Recruited through posters, leaflets, advertisements, letters, interviews on radio and television, and word of mouth.
Measures	BMI, WC, sum of skinfold thicknesses, subscapular skinfold thickness, suprailiac skinfold thickness
Results	Sikh men had significantly higher body fat, with the sum of the

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[*] Evidence tables only done for UK studies.

	four skinfold thickness measurements (*p*=0.0001) and subscapular skinfold thickness value (*p*=0.009) higher compared with the white men. Sikh volunteers also had characteristics of the metabolic syndrome: lower HDL-cholesterol (*p*=0.07), higher TAG (*p*=0.004), higher % LDL_3 (*p*=0.0001) and insulin resistance (*p*=0.05). Both ethnic groups demonstrated positive correlations between insulin and WC (white: *r*=0.661, *p*=0.0001; Sikh: *r*=0.477, *p*=0.0001). White men demonstrated significant positive correlations between central adiposity (*r*=0.275, *p*=0.04), other measures of adiposity (BMI and suprailiac skinfold thickness) and plasma TAG, whereas Sikh men showed no correlation for central adiposity (*r*=0.019, NS) and TAG with a trend to a negative relationship between other measures (Ssk and suprailiac) which reached near significance for subscapular skinfold thickness and TAG (*r*=–0.246, *p*=0.007). The expected positive association between insulin and TAG was observed in white men (*r*=0.318, *p*=0.04) but not in Sikh men (*r*=0.011, NS).
Authors' conclusions	In white men, expected positive association between plasma TAG and centralised body fat was observed. However, a lack of association between centralised, or any other measure of adiposity, and plasma TAG was observed in matched Sikh men, although both groups showed a positive association between centralised body fat and insulin resistance,(less strong for Sikhs). These findings in the Sikh men were not consistent with the hypothesis that there is a clear causal relationship between body fat and its distribution, insulin resistance, and lipid abnormalities associated with the metabolic syndrome, in this ethnic group.
Quality and notes	+ Seem to be very restrictive inclusion/exclusion criteria, so not sure how generalisable

McKeigue 1991	
Country	UK
Setting	Recruitment from GP practices and factories
Aim or objective	To compare the relation of central obesity with diabetes and cardiovascular risk between Europeans, South Asians and Afro-Caribbeans
Adults or children	Adults
No. of participants	Males: European 1515, South Asian 1421, Afro-Caribbean 209. Females: European 246, South Asian 291
Included participants	Factory sample – males >40 years old (of 1141 men, 808 took part)/GP sample 16 GP practices – males 40–64 years (for three practices women included) 63% response rate.
Excluded participants	GP sample – all those already included in industrial sample. Patients with cancer, renal failure, severe disability or severe psychiatric disturbance.
Self-referred or not	Invitation by letter
Measures	Skinfold thickness, BMI, WHR
Results	The key findings were that ethnicity differences were not found in the correlation of WHR with HDL, TAG and blood pressure (BP). However, controlling for WHR did not explain South Asian–European differences in diabetes prevalence and serum insulin
Authors' conclusions	These results confirm the existence of an insulin resistance syndrome, prevalent in South Asian populations and associated with a pronounced tendency to central obesity in this group.
Quality and notes	+ A potential implication of this study is that WHR cut-offs for obesity as a predictor of diabetes may need to be lower for South Asian

Patel 1999	
Country	UK
Setting	Recruitment from community (conducted in research centre)
Aim or objective	To assess how four proxy measures of abdominal obesity (WC, WHR, waist:height ratio, C index) were associated with features of metabolic syndrome in three ethnic groups
Adults or children	Adults
No. of participants	629 Europeans (320 men, 309 women), 380 Chinese (183 men, 197 women), 597 South Asians (275 men, 322 women) aged 25–64 years
Included participants	Aged 25 to 64 years (further details in additional publications)
Excluded participants	…
Self-referred or not	Recruited from name analysis, and invited to participate.
Measures	WC, WHR, waist to height ratio, C index
Results	Most proxy measures of abdominal obesity were associated with features of metabolic syndrome. However, across ethnic groups, WC and waist-to-height ratio were the most consistent and WHR and C index were least.
Authors' conclusions	Not all the proxy measures of abdominal obesity were consistently related to features of the metabolic syndrome across the ethnic groups studied. However, WC and waist:height ratio were the most consistent and WHR the least when comparing across the ethnic groups.
Quality and notes	+ Implication of this study is that some measures of abdominal obesity are more consistently associated with metabolic syndrome than others. It is suggested that the problems with WHR are due to genetic differences in pelvic dimensions.

1.3 Dietary interventions

1.3.1 2.51 MJ (600 kcal)/day deficit or low-fat diet[†] compared with control

Weight loss

Cohen 1991 (in HTA) cluster RCT	
Aim	To test the feasibility of a low-technology office-based approach to weight reduction in obese hypertensive patients
Participants	People aged 20 to 75 years who were overweight (BMI [kg/m^2] ≥27.8 men, 27.3 women) with hypertension *30 total – 22 F, 8 M. Mean age 59.3 years intervention (n=15), 59.7 years control (n=15). Mean BMI (kg/m^2) 34.2 intervention, 34.0 control.*

[†] Due to lack of reporting, healthy eating advice and diets where the fat or energy restriction was not estimable are included in this category.

Intervention (including details of diet)	Physicians received special instruction and materials in weight reduction methods; reviewed diet of participant using questionnaire and suggested dietary changes, gave participant diet history sheet, information and advice sheet; advised participants to reduce energy content of diet and set short-term goals; used methods of encouragement such as reinforcement, each month reviewed participants previous days food intake. *Goal of diet to reduce energy content without radically changing patients' lifestyle. Given instruction sheet on low-energy alternatives to high-energy foods.*
Control	*Participants received usual care, physicians free to refer patients for dietary advice or provide themselves but did not receive any special weight reduction instructions or materials.*
Length of follow-up	12 months
Results	*At 6 months, mean (SD) weight change in kg was –1.80 (3.4) in the diet group, and 0.56 (2.5) in the control group. The difference was statistically significant (p=0.04).* At 12 months, mean (SD) weight change in kg was –0.88 (4.0) in the diet group, and 1.3 (3.0) in the control group. The difference was not statistically significant.
Quality and comments	Possible intention to treat (ITT) analysis. Blinded assessment not reported. Random allocation but no description of concealment. *Mean BMI noted as highest mean BMI in HTA. No details of accounting for cluster effect.*

DISH 1985 (in HTA) RCT	
Aim	To determine whether dietary modification can increase the number of patients who remain normotensive after drug withdrawal
Participants	Hypertension Detection and Follow-up Program Stepped Care participants (*n*=496 in study overall) who had greater than 5 years antihypertensive therapy and stratified by weight (120% or more of ideal body weight [IBW]) to no dietary intervention, sodium control, or weight control diets. 176 total – *116 F, 60 M. Mean age 56.1 years intervention (*n*=87), 57.2 years no intervention (*n*=89). Mean weight (SD) 86.0 (17.3) kg intervention, 89.9 (17.8) kg no dietary intervention.*[‡]
Intervention (including details of diet)	Standardised stepped withdrawal of antihypertensives medication during weeks 2 to 8. Medication restarted if diastolic blood pressure DBP 95–99 mmHg three times in 3 months, 100–104 mmHg twice in a month, or 105 mmHg at any time. Dietary intervention began at 1 to 2 weeks post baseline with the aim of desirable weight according to the Metropolitan Life Insurance standards. Diet involved decreasing energy, with relatively little emphasis on physical activity and keeping electrolytes constant. Little emphasis on physical activity.
Control	*As above, but no dietary intervention.*
Length of follow-up	56 weeks
Results	At 12 months (*56 weeks*), mean (SD) weight change in kg was –4.00 (5.00) in the intervention group, and –0.46 (3.60) in the no dietary intervention group. Mean weight change in the intervention group compared to no dietary intervention was –3.54 (95% CI –4.98 to –2.10). No significant differences were seen in weight loss between men and women.
Quality and comments	Study also included continued medication control, and no medication sodium restriction group. Possible ITT analysis. Blinded assessment not done. Random allocation but no description given. *Only reported weight control results.*

Frey-Hewitt 1990 (in HTA) RCT	
Aim	To determine the effect of energy restriction and exercise training on weight loss and resting metabolic rate

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[‡] Text in italics taken from either evidence tables or text published in the original review.

Participants	Sedentary men (age 30–59) who were overweight (120–160% of IBW) *155 total – all men. Mean (SD) weight 93.63 (9.16) kg in diet group (n=51), 94.14 (8.8) kg in physical activity group (n=52), 94.99 (10.63) kg in control group (n=52) (weight for completers only).*
Intervention (including details of diet)	Energy requirements for individuals determined at baseline by 7-day food records. Diet designed to reduce total body fat by one-third. Advised to reduce food quantity without changing proportions of fat, carbohydrate, protein, alcohol. Individual weigh loss goals determined by amount of body fat; 300–500 kcal/day deficit to produce 0.3–0.6 kg fat loss per week. Instruction and behavioural strategies to for weight loss for first 9 months, then weight maintenance for about 2 months. Monthly activity and 24 h energy intake monitored, and if changed activity for more then 3 months, counselled to return to baseline habits. (See physical activity review for detail of physical activity intervention)
Control	*Energy requirements determined at baseline by 7-day food records. Advised to keep weight stable with no added energy restriction or physical activity.*
Length of follow-up	12 months
Results (3, 6 and 12 months, control and intervention results)	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –6.68 (3.94) in the diet group, and 0.38 (3.66) in the control group. Mean weight change in the intervention group compared to control was –7.06 (95% CI –8.77 to –5.35).
Quality and comments	Not ITT analysis. Blinded assessment not done. Random allocation but no description of concealment. Not in BT review, as no detail of techniques used. Also results for diet-only group reported here.

Hankey 2001 (in HTA) RCT (pilot)	
Aim	To determine the effectiveness of comprehensive dietary counselling, including weight management advice, in people post MI.
Participants	Survivors of myocardial infarction (MI) participating in cardiac rehabilitation programmes. (Results reported for people BMI >25 kg/m^2 only.) *54 total – 10 F, 44 M. Mean age 57 (range 41 to 72) years in the intervention group (n=28), and 57 (range 40 to 75) years in the control group (n=26). Mean BMI (SD) (kg/m^2) 28.6 (2.8) intervention group, and 30.4 (3.9) in control group.*
Intervention (including details of diet)	Cardiac rehabilitation; one group session of 30–60 min with a dietitian and 12 practical physical activity sessions of about 30 min each. Four 1 h sessions of individual dietary counselling during the initial 12 weeks, including weight management advice, individualised 2.51 MJ (600 kcal)/day deficit, and following Scottish dietary targets *(minimum five portions of fruits and vegetables daily, two to three portions of oily fish weekly, reduction in saturated fat to <10% dietary energy).*
Control	*As above for cardiac rehabilitation, but no specific weight management advice.*
Length of follow-up	52 weeks
Results	*Only 12 month outcomes reported.* At 12 months, mean (SD) weight change in kg was –0.60 (5.30) in the diet group, and 2.40 (5.00) in the control group. Mean weight change in the intervention group compared to control was –3.00 (95% CI –5.86 to –0.14) kg.
Quality and comments	Baseline BMI appears different between groups. ITT analysis done. Results from contact with the author, and refer only to those individuals with BMI >25 kg/m^2. Blinded assessment not done. Random allocation but no description of concealment.

HOT 1999 (in HTA) RCT	
Aim	To determine whether a dietary behavioural intervention resulting in weight loss would allow fewer medications or lower doses of medication to achieve goal BP in very obese, older people with hypertension

Participants	Older people with a BMI ≥27 kg/m^2, who met the HOT study criteria Patients were randomised to reach a target diastolic BP (DBP): ≤90, ≤85 or ≤80 mmHg by taking a five-step drug treatment. *102 total – 53 F, 49 M. Mean (SD) age, 57 (9) years in the diet group (n=55), 59 (7) years in the control group (n=56) (data for completers only). Mean (SD) BMI (kg/m^2) 34 (6) in the diet group and 34 (6) in the control.*
Intervention (including details of diet)	Weight loss counselling (food selection and preparation, establishing weight reduction goals, energy and fat restriction) by weight loss dietitian with 10 days of randomisation. *Not counselled to exercise.* Counselled again at 2–4 weeks, and attended group support sessions twice monthly for first 3 months, then every 3–6 months, weight measured at 6-monthly intervals.
Control	*Research nurses told participants to lose weight, but no formal diet counselling or group support given. Weight measured only at 6-monthly intervals.*
Length of follow-up	30 months.
Results	*At 3 months, mean weight change (SD) was –2.7 (3.4) kg in the weight loss group compared with –1.7 (2.3) kg in the control group. But the difference was not significant (p=0.09).* *At six months, mean weight change (SD) was –3.2 (4.3) kg in the weight loss group compared with –1.8 (2.7) kg in the control group. The difference was significant (p=0.05).* *After 6 months, the weight loss group showed a gradual, continuous return to baseline, but the control group showed a tendency towards weight loss.* At 12 months, mean weight change (SD) was –1.70 (6.40) kg in the weight loss group compared with –1.30 (6.28) kg in the control group. Mean weight change in the intervention group compared with control was –0.40 (95% CI –2.86 to 2.06). At 18 months, mean weight change (SD) was –1.80 (6.42) kg in the weight loss group compared with –1.40 (6.31) kg in the control group. Mean weight change in the intervention group compared with control was –0.40 (95% CI –2.87 to 2.07). At 24 months, mean weight change (SD) was –1.70 (6.40) kg in the weight loss group compared with –1.90 (6.45) kg in the control group. Mean weight change in the intervention group compared with control was 0.20 (95% CI –2.29 to 2.69). At 30 months, mean weight change (SD) was –1.30 (6.28) kg in the weight loss group compared with –2.00 (6.48) kg in the control group. Mean weight change in the intervention group compared with control was 0.70 (95% CI –1.78 to 3.18).
Quality and comments	Diet (weight loss) group were considerably taller than control (*p*=0.05). Possible ITT analysis. Blinded assessment not done. Author contacted for results by treatment group. Random allocation but no description of concealment.

HPT 1990 (in HTA) RCT	
Aim	To assess the effect of dietary counselling and dietary changes on BP in healthy people
Participants	In reduced energy counselling group, *healthy adults aged 25 to 49 years with 'high-normal' BP* who were overweight (BMI [kg/m^2] >25 men, >23 for women). In other groups (control, other counselling), participants did not have to be overweight. *251 total – 82 F, 169 M. Mean age 38 years intervention (n=126), 39.4 control (n=126). Mean BMI (kg/m^2) 29.0 intervention, 28.0 control.*
Intervention (including details of diet)	Energy restriction dietary counselling where individual goal was for participants to attain IBW and group goal was to reduce mean body weight by 5%. Participants recommended to include daily servings of low-fat milk and dairy products, choose fish, poultry or lean cuts of meat, decrease fats in cooking and at the table. Decrease high-energy desserts, snacks and drinks. Limit alcohol and increase fruit and vegetable intake. Dietary change counselling related to meal planning and rationing, food purchase, label reading. Included didactic presentation and demonstrations, token incentives, bimonthly newsletters, telephone calls if missed session, daily food records.
Control	*No dietary counselling.*
Length of follow-up	3 years

Results	*At 6 months, mean (SD) weight change (kg) was –5.58 (2.86) in the diet group, and 0.18 (2.95) in the control group. Mean weight change in the intervention group compared with control was –5.76 (95% CI –6.51 to –5.01).* At 36 months, mean (SD) weight change in kg was –1.63 (4.43) in the diet group, and 1.86 (4.36) in the control group. Mean weight change in the intervention group compared with control was –3.49 (95% CI –4.63 to –2.35).
Quality and comments	Baseline unequal for genders. 24.8% in intervention group vs 40.5% control. ITT analysis done. Blinded assessment done. Random allocation but no description of concealment.

ODES 1995 (in HTA) RCT	
Aim	The primary aim of the trial was to compare the isolated and combined effects of the diet and exercise on the variables fibrinogen, fibrinolytic capacity, coagulation factor VII, and platelet volume. Secondary aims were the effects on other coagulation and fibrinolytic components and activities; lipids and lipoproteins; fatty acids; glucose and insulin response to a glucose load; clinical, physiological, and anthropometric variables; and quality of life
Participants	*Men and women aged 41 to 50 years who were overweight (BMI >24 kg/m^2) and sedentary.* *219 total – 21 F, 198 M. Mean (SD) age 44.9 (2.5) years. Mean (SD) BMI (kg/m^2) 29.54 (3.89) diet group (n=55), 28.56 (3.22) exercise group (n=54), 28.57 (3.47) diet and exercise group (n=67), 28.30 (3.15) control group (n=43).*
Intervention (including details of diet)	Dietary counselling with spouse at baseline then individually at 3- and 9-month follow-up sessions. Diet adapted to individual's risk profile with main focus on energy restriction in those overweight, increase in fish and vegetables, decrease in saturated fat, cholesterol, sugar, and salt restriction for those with elevated BP. Weight targets agreed and set. 180 food-frequency questionnaire at baseline and 12 months. Advised to stop smoking. (See physical activity review for details of exercise intervention)
Control	*Told not to change lifestyle and that after 12 months would receive dietary advice and supervised physical training. Advised to stop smoking.*
Length of follow-up	12 months
Results	*Only 12 month outcomes reported.* At 12 months, mean (SD) weight change in kg was –4.00 (5.05) in the diet group, and 1.10 (2.62) in the control group. Mean weight change in the intervention group compared with control was –5.10 (95% CI –6.68 to –3.52).
Quality and comments	TC and LDL levels significantly lower in the exercise and the diet and exercise groups ($p<0.05$). ITT not done. Only blood analyses blinded. Discrepancy between results in published papers. Good concealment of allocation.

Pritchard 1997 (in HTA) RCT	
Aim	To compare the effects of two weight loss interventions, diet or exercise, on changes in bone, fat and lean tissue
Participants	*Healthy men aged 35 to 55 years who were overweight (BMI 26 to 35 kg/m^2).* *66 total – all men. Mean age (SD) 43.6 (6.0) years in the diet group (n=24), 42.3 (4.5) years in the control group (n=20). Mean BMI (SD) (kg/m^2) 29.0 (2.8) in the diet group, 28.6 (2.8) in the control. Data for 12-month completers only (n=58 overall).*
Intervention (including details of diet)	Advised to follow low-fat intake of *20 to 22*% energy as fat per day, to avoid foods rich in fat, discouraged from eating more than one sweet per day and more than two alcoholic drinks per day. Personalised diet plan to meet recommended daily intakes for use in Australia, given in *The Weight Loss Guide* by the Australian Heart Foundation. Exercise restricted to pre-study level. Completion of daily adherence calendar. At 13 months, exercise intervention was added. (See physical activity review for detail of exercise intervention)
Control	*Attended monthly weight monitoring sessions where counselled to follow usual food and exercise habits. Told participants that they would be able to enter the weight loss study at the end of the study. Both diet and physical activity interventions were added at 13 months.*

Length of follow-up	18 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –6.40 (3.30) in the diet group, and 0.30 (2.40) in the control group. Mean weight change in the intervention group compared with control was –6.70 (95% CI –8.57 to –4.83).
Quality and comments	ITT analysis done. Blinded assessment not done. Real possibility of disclosure of allocation, although some attempt made at concealment. Author provided unpublished report. Data up to 12 months only used. Discrepancy in data between reports.

Pritchard 1999 (in HTA) RCT	
Aim	To study the clinical and cost outcomes of providing nutritional counselling to people with one or more of the following conditions: overweight, hypertension, type 2 diabetes.
Participants	*Men and women aged between 25 and 65 years with either hypertension, type 2 diabetes or were overweight (BMI >25 kg/m^2).* *273 total – 198 F, 75 M. 199 participants were aged <50 years. Mean weight (kg) 91.7 in the dietitian led intervention group (n=92), 85.5 in the doctor and dietitian led intervention group (n=88), 89.1 in the control group (n=90).* Majority were from disadvantaged socioeconomic groups (58% most disadvantaged quartile and 20% more disadvantaged quartile).
Intervention (including details of diet)	Counselling focused on principles of good nutrition and exercise and addressed problem areas in lifestyle and dietary patterns. Counselled on food, shopping, cooking, food selection, meal planning, exercise programmes. Advised to complete food records and diet history. Advised to reduce total energy intake and to reduce % energy from fat to ≤30% (carbohydrate ≥50% and protein 20%). Discouraged from smoking and to have two or more alcohol-free days per week, with two or fewer alcoholic standard drinks for women and four for men. In the doctor and dietitian group, as well as counselling above, participants were seen by the GP at baseline and saw same GP on two other occasions during the 12 months for 5 min each time to encourage and monitor the participant.
Control	*Received results of initial screening and advised to discuss queries with the GP at appointment. Received usual care from GP but no dietitian counselling. Mailed to re-attend at 12 months.*
Length of follow-up	12 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –5.10 (7.36) in the dietitian group and 0.60 (6.08) in the control group. Mean weight change in the intervention group compared with control was –5.70 (95% CI –8.05 to –3.35). At 12 months, mean (SD) weight change in kg was –6.20 (7.67) in the dietitian and doctor group, and 0.60 (6.08) in the control group. Mean weight change in the intervention group compared with control was –6.80 (95% CI –9.17 to –4.43).
Quality and comments	*Control groups halved.* ITT analysis done. Blinded assessment not done. Real possibility of disclosure of allocation, although some attempt made at concealment. *Results only for overweight group.*

TAIM 1992 (in HTA) RCT	
Aim	To determine the relative efficacy of drug and dietary measures in mild hypertension.
Participants	*People aged 21 to 65 years, who were overweight (110 to 160% IBW) and with mild hypertension.* *179 total at 6 months – 'significantly more men than women' – no details. Mean age 48.6 years intervention (n=100), 46.8 years control (n=100). Mean BMI (kg/m^2) 30.45 intervention and 30.14 control.*

Intervention (including details of diet)	Diet counselling and nutrition education aimed at behaviour change, related activities (exercise) aimed at weight loss to achieve BP control, given individual goal of energy intake and weight loss of 10% baseline weight or 4.5 kg (whichever is the larger). Also given placebo. Participants given step-up medication if necessary to control BP, administered in double blind fashion; if DBP ≥99 mmHg or 90 to 94 mmHg at two visits with 3 month interval or 95 to 99 mmHg at two visits with 2 week interval then 25 mg chlorthalidone or 50 mg atenolol prescribed, if still not controlled then open-label therapy used (known antihypertensive medication).
Control	*No change in diet and given placebo. As above for drug treatment of BP.*
Length of follow-up	2.5 years minimum
Results	*At 6 months, mean (SD) weight change in kg was –4.40 (6.60) in the diet group, and –0.70 (3.79) in the control group. Mean weight change in the intervention group compared with control was –3.70 (95% CI –5.28 to –2.12).* At 12 months, mean (SD) weight change in kg was –3.70 (6.79) in the diet group, and –0.50 (3.12) in the control group. Mean weight change in the intervention group compared with control was –3.20 (95% CI –5.13 to –1.27). At 18 months, mean (SD) weight change in kg was –2.70 (7.55) in the diet group, and –1.00 (3.12) in the control group. Mean weight change in the intervention group compared with control was –1.70 (95% CI –3.81 to 0.41). At 24 months, mean (SD) weight change in kg was –1.90 (7.55) in the diet group, and –0.40 (3.91) in the control group. Mean weight change in the intervention group compared with control was –1.50 (95% CI –3.69 to 0.69). *Gender was not associated with weight loss at 6 months.*
Quality and comments	Significantly more men than women in the intervention group. Assessors blinded to drug status only. ITT not done. Good concealment of allocation. *Results for 12 months onwards for 24-month completers only.*

Wood 1988 (in HTA) RCT	
Aim	To determine the influence of two methods for losing fat weight on the levels of plasma lipids and lipoproteins in overweight sedentary men – decreasing energy intake without increasing exercise (diet), and increasing energy expenditure without altering energy intake (exercise, primarily running)
Participants	*Men aged 30 to 59 years, overweight (120 to 160% IBW) and no regular exercise for past 3 months.* *155 M. Mean (SD) age 44.2 (8.2) years diet group (*n*=51), 44.1 (7.8) years exercise group (*n*=52), 45.2 (7.2) years control (*n*=52). Mean (SD) weight 93.0 (8.8) kg diet group, 94.1 (8.6) exercise group, and 95.4 (10.6) control (results for 131 assessed participants).* Noted in HTA as highest mean reported weight (kg)
Intervention (including details of diet)	Diet group 1: baseline 7-day diet recall and body fat mass used to provide individual counselling including behavioural strategies, to reduce energy intake to produce gradual weight loss and to lose one-third of body fat (assumed a reduction of 7762 kcal for loss of 1 kg adipose tissue). No change in nutrient composition, requested to remain sedentary, included weight stabilisation for last 6 weeks. (See PA review for details of exercise group)
Control	*Advised not to make any changes in diet, including composition, exercise or body weight, offered weight loss programme of diet and exercise at end of study.*
Length of follow-up	12 months *(24 months follow-up for other groups not relevant to this review)*
Results	*At 7 months, mean (SD) weight change in kg was –7.60 (3.90) in the diet group and 0.20 (2.50) in the control group. Mean weight change in the intervention group compared with control was –7.80 (95% CI –9.20 to –6.40).* At 12 months, mean (SD) weight change in kg was –7.20 (3.70) in the diet group, and 0.60 (3.70) in the control group. Mean weight change in the intervention group compared with control was –7.80 (95% CI –9.38 to –6.22).
Quality and comments	ITT analysis not done. Blinded assessment only in year 2. Random allocation but no description of concealment. Only 12-month outcomes reported in published papers.

Wood 1991 (in HTA) RCT	
Aim	To test the hypothesis that exercise (walking or jogging) will increase HDL-cholesterol levels in moderately overweight, sedentary people who adopt a hypoenergetic National Cholesterol Education Programme (NCEP) diet
Participants	*Sedentary people (exercise less than twice per week) who were moderately overweight (BMI 28 to 34 kg/m^2 for men, 24 to 20 for women).* *264 total – 132 F, 132 M. Mean (SD) age 39.1 (6.4) years women, 40.3 (6.3) years men. Mean BMI (SD) (kg/m^2) 27.9 (2.2) women, 30.7 (2.2) men.* (Noted as lowest mean BMI in HTA.) *Eighty-seven allocated to diet, 90 to diet and exercise, and 87 to control.*
Intervention (including details of diet)	*NCEP step 1 diet consisting of 55% energy as carbohydrate, 30% as fat (saturated fat ≤10%), dietary cholesterol <300 mg/day, energy reduction, no change in exercise* *(See physical activity review for details of exercise)*
Control	Instructed to maintain usual diet and exercise patterns.
Length of follow-up	*12 months*
Results	*Only 12 months outcomes reported.* Women: At 12 months, mean (SD) weight change in kg was –4.10 (5.50) in the diet group, and 1.30 (5.20) in the control group. Mean weight change in the intervention group compared with control was –5.40 (95% CI –7.93 to –2.87). Men: At 12 months, mean (SD) weight change in kg was –5.10 (5.80) in the diet group, and 1.70 (4.80) in the control group. Mean weight change in the intervention group compared with control was –6.80 (95% CI –9.13 to –4.47).
Quality and comments	Significant differences between men in both intervention groups vs control for DBP (*p*<0.001), TC for women in diet group vs control (*p*≤0.01), and diet and exercise group vs control (*p*≤0.05), and LDL levels in women in both intervention groups vs control (*p*≤0.05). Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment.

Other outcomes

Cohen 1991 (in HTA) cluster RCT	
Results	*At 6 and 12 months, there was no difference between groups in mean arterial pressure change from baseline (*p*>0.10).* *At 6 months, there was a change in the number of antihypertensive medications from baseline of –0.6 (SD 1.0) in the diet group compared with 0 (SD 0.5) in the control group. This was significantly different (*p*=0.04) but this was not maintained at 12 months (–0.3 vs –0.2,* p*>0.10).* *After 12 months, subjects who lost weight had more physician visits (*p*=0.006) and took fewer antihypertensive medications (*p*=0.01) but had no significant change in BP (*p*>0.10) than those who gained weight.*
Quality and comments	…

DISH 1985 (in HTA) RCT	
Results	At 12 months, 59.5% of people allocated to dietary intervention remained off antihypertensive medication compared with 35.5% of those with no dietary intervention (p=0.0015). *Dietary estimates, obtained by analysis of 3-day food records, showed that the overweight participants were more likely to underestimate than the non-overweight participants.*
Quality and comments	…

Frey-Hewitt 1990 (in HTA) RCT	
Results	*At 12 months, mean change (SD) in energy intake (kcal/day) in the diet group was –335.39 (412.55) from a baseline of 2489.56 (474.36) in the diet group compared with –121.70 (514.83) from a baseline of 2517.24 (557.40) in the control group. The difference was not significant.* *Also reported were changes in fat free mass, fat mass, % body fat,* VO_{2max} *and resting metabolic rate at 12 months, which were all significant (*p*≤0.01) in the diet group compared with control.*
Quality and comments	Energy intake estimated from participants' 7-day food diaries and recall checks periodically from trained interviewers by telephone.

Hankey 2001 (in HTA) RCT (pilot)	
Results	*At 52 weeks anthropometric measurements were unchanged in the 25 overweight patients provided with weight management advice, but increased significantly in overweight control patients, but the difference between the groups was not significant (WC +0.7 vs +2.6 cm,* p*=0.10, and % body fat –1.1 vs 0.6,* p*=0.16).*
Quality and comments	…

HOT 1999 (in HTA) RCT	
Results	*No difference was found between the proportions of people who reached their target DBP at any time point in either the weight loss group or the control.* *Stratified analysis showed no difference between DBP in weight loss compared with control.* People in the weight loss group required fewer medications between 6 months and 30 months (difference consistently statistically significant). The weight loss group tended to regain weight after the first 6 months of the study.
Quality and comments	…

HPT 1990 (in HTA) RCT	
Results	*At 6 months, mean (SD) DBP change in mmHg was –5.30 (7.41) in the diet group, and –2.50 (7.70) in the control group. Mean DBP change in the intervention group compared with control was –2.80 (95% CI –4.74 to –0.86).* *At 6 months, mean (SD) SBP change in mmHg was –6.90 (7.41) in the diet group, and –1.80 (7.70) in the control group. Mean SBP change in the intervention group compared with control was –5.10 (95% CI –7.04 to –3.16).* At 36 months, mean (SD) DBP change in mmHg was –4.20 (8.65) in the diet group, and –2.40 (8.58) in the control group. Mean DBP change in the intervention group compared with control was –1.80 (95% CI –4.02 to 0.42). At 36 months, mean (SD) SBP change in mmHg was –5.00 (9.73) in the diet group, and –2.69 (9.65) in the control group. Mean SBP change in the intervention group compared with control was –2.31 (95% CI –4.80 to 0.18). 9% in the intervention and control groups needed drug treatment for hypertension during the 3-year study. *Energy restriction alone did not affect sodium and potassium excretion rates.*
Quality and comments	…

ODES 1995 (in HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.23 (0.65) in the diet group, and –0.16 (0.59) in the control group. Mean TC change in the intervention group compared with control was –0.07 (95% CI –0.32 to 0.18). At 12 months, mean (SD) LDL change in mmol/l was –0.18 (0.72) in the diet group, and –0.22 (0.59) in the control group. Mean LDL change in the intervention group compared with control was 0.04 (95% CI –0.22 to 0.30). At 12 months, mean (SD) HDL change in mmol/l was 0.05 (0.12) in the diet group, and 0.02 (0.10) in the control group. Mean HDL change in the intervention group compared with control was 0.03 (95% CI –0.01 to 0.07). At 12 months, mean (SD) TAG change in mmol/l was –0.23 (1.01) in the diet group, and 0.17 (0.92) in the control group. Mean TAG change in the intervention group compared with control was –0.04 (95% CI –0.79 to 0.01). At 12 months, mean (SD) DBP change in mmHg was –3.40 (7.21) in the diet group, and –0.70 (8.52) in the control group. Mean DBP change in the intervention group compared with control was –2.70 (95% CI –5.91 to 0.51). At 12 months, mean (SD) systolic BP (SBP) change in mmHg was –6.40 (10.10) in the diet group, and –0.50 (11.15) in the control group. Mean SBP change in the intervention group compared with control was –5.90 (95% CI –10.22 to –1.58). At 12 months, mean (SD) fasting plasma glucose (FPG) change in mmol/l was –0.21 (0.50) in the diet group, and 0.07 (0.46) in the control group. Mean FPG change in the intervention group compared with control was –0.28 (95% CI –0.47 to –0.09). *The diet group had a mean (SD) change in total energy intake of –1679 (3245) kJ/day, which was significantly different compared with control (p<0.05). No values were reported for the control group.* *The diet group had a mean (SD) change in energy from fat of –4.9 (7.93)%, which was significantly different compared with control (p<0.05). No values were reported for the control group.* *At 12 months, significant changes from baseline were seen in the diet group for energy intake (–550 kcal), protein (–13.4 g), fat (–32.5 g), % energy as fat (–5.1%), carbohydrate (–42.3 g), sugar (–16.8 g), alcohol (–2.5 g), cholesterol (–121 mg), saturated fatty acids (–13.6 g), monounsaturated fatty acids (–12.3 g) and polyunsaturated fatty acids (–4.9 g).* *Within the upper tertile of baseline BP, the decline in blood pressure in the diet group were almost comparable with those obtained with drug treatment.* *The 1-year diet intervention gave a significant decrease in the calculated insulin resistance from 4.6 to 4.2 and a positive correlation between the changes in insulin resistance and changes in BMI (r=0.40).*

Quality and comments	Dietary intake assessed through a validated food-frequency questionnaire.

Pritchard 1997 (in HTA) RCT	
Results	*At 12 months, significant differences from baseline were seen in the diet group compared with control for energy intake (–30.4 vs +4.0%), % energy as fat (–32.0 vs +1.7%) ($p<0.001$) and % energy protein (+23.3 vs –1.1%) ($p<0.05$).* *No significant differences were seen between diet and control for dietary calcium or index of activity (used to calculate daily energy expenditure).* *Also at 12 months, significant differences were seen from baseline between diet and control in bone mineral density (–1.5 vs +0.4%) ($p<0.05$), bone mass (–1.4 vs –0.1%) ($p<0.01$), fat mass (–19.4 vs +0.4%) and lean mass (–3.9 vs +0.1%) ($p<0.001$).* *DEXA scans revealed that 40% of dieters' weight loss was lean tissue.*
Quality and comments	Dietary intake estimated from participants' 3-day food diaries

Pritchard 1999 (in HTA) RCT	
Results	*No other results reported for overweight participants only.* The cost of an additional kg weight loss was A$9.76 in the doctor and dietitian group compared with A$7.30 in the dietitian group.
Quality and comments	…

TAIM 1992 (in HTA) RCT	
Results	*At 6 months, the weight loss group showed a change (SD) in pulse beats per min of –4.9 (9.43) vs control of –1.8 (11.4), and a change in dietary intake of –442.5 kcal vs –122.6. No p values were reported.*
Quality and comments	Energy intake calculated from participants' diet diaries.

Wood 1988 (in HTA) RCT	
Results	*At 7 months, changes in TAG, TC, HDL and HDL$_2$ levels were significantly different to controls (–0.40 vs –0.01 $p\leq0.01$, –0.40 vs –0.21 $p\leq0.05$, 0.06 vs 0.00 $p\leq0.01$, 0.06 vs 0.00 $p\leq0.001$ respectively). Changes in LDL and HDL$_3$ levels were not significantly different between groups.* At 12 months, mean (SD) TC change in mmol/l was –0.36 (0.56) in the diet group, and –0.23(0.65) in the control group. Mean TC change in the intervention group compared with control was –0.13 (95% CI –0.39 to 0.13). At 12 months, mean (SD) LDL change in mmol/l was –0.31 (0.64) in the diet group, and –0.21 (0.67) in the control group. Mean LDL change in the intervention group compared with control was –0.10 (95% CI –0.38 to 0.18). At 12 months, mean (SD) HDL change in mmol/l was 0.12 (0.16) in the diet group, and –0.02 (0.11) in the control group. Mean HDL change in the intervention group compared with control was 0.14 (95% CI 0.08 to 0.20). At 12 months, mean (SD) TAG change in mmol/l was –0.27 (0.72) in the diet group, and 0.08 (0.60) in the control group. Mean TAG change in the intervention group compared with control was –0.35 (95% CI –0.63 to –0.07). At 12 months, mean (SD) DBP change in mmHg was –5.60 (7.30) in the diet group, and –2.60 (8.10) in the control group. Mean DBP change in the intervention group compared with control was –3.00 (95% CI –6.55 to 0.55). At 12 months, mean (SD) SBP change in mmHg was –5.70 (7.90) in the diet group, and –4.10 (8.00) in the control group. Mean SBP change in the intervention group compared with control was –1.60 (95% CI –5.25 to 2.05). *TC/HDL-cholesterol ratios were significantly lower in the diet group compared with control at both 7 and 12 months ($p\leq0.01$).* *At 12 months, the diet group showed significant changes from baseline compared with control for body fat (–4.6% vs –0.9%) ($p<0.01$), energy intake per day (–306*

	vs –112) and g of fat per day (2.0 vs 1.4) (p*<0.05). No other changes in outcomes were significant (saturated fat, poly- and monounsaturated fat, alcohol, calcium, potassium, sodium levels).* *At 12 months,* VO_{2max} *and treadmill test duration decreased significantly less in the diet group compared with control (p≤0.001) (0.0 vs –2.4* VO_{2max}*, and –0.8 vs –1.6 treadmill test duration in min).*
Quality and comments	Dietary intake estimated from participants' 7-day food diaries.

Wood 1991 (in HTA) RCT	
Results	Women: At 12 months, mean (SD) TC change in mmol/l was –0.39 (0.61) in the diet group, and –0.03 (0.47) in the control group. Mean TC change in the intervention group compared with control was –0.36 (95% CI –0.62 to –0.10). Women: At 12 months, mean (SD) LDL change in mmol/l was –0.28 (0.63) in the diet group, and –0.03 (0.41) in the control group. Mean LDL change in the intervention group compared with control was –0.25 (95% CI –0.51 to 0.01). Women: At 12 months, mean (SD) HDL change in mmol/l was –0.15 (0.26) in the diet group, and –0.05 (0.24) in the control group. Mean HDL change in the intervention group compared with control was –0.10 (95% CI –0.22 to 0.02). Women: At 12 months, mean (SD) TAG change in mmol/l was 0.09 (0.36) in the diet group, and 0.13 (0.37) in the control group. Mean TAG change in the intervention group compared with control was –0.04 (95% CI –0.79 to 0.01). Women: At 12 months, mean (SD) DBP change in mmHg was –2.20 (5.10) in the diet group, and 0.90 (5.30) in the control group. Mean DBP change in the intervention group compared with control was –3.10 (95% CI –5.55 to –0.65). Women: At 12 months, mean (SD) SBP change in mmHg was –4.10 (6.00) in the diet group, and –0.20 (6.60) in the control group. Mean SBP change in the intervention group compared with control was –3.90 (95% CI –6.86 to –0.94). Men: At 12 months, mean (SD) TC change in mmol/l was –0.42 (0.51) in the diet group, and –0.14 (0.64) in the control group. Mean TC change in the intervention group compared with control was –0.28 (95% CI –0.53 to –0.03). Men: At 12 months, mean (SD) LDL change in mmol/l was –0.39 (0.48) in the diet group, and –0.20 (0.59) in the control group. Mean LDL change in the intervention group compared with control was –0.19 (95% CI –0.43 to 0.05). Men: At 12 months, mean (SD) HDL change in mmol/l was 0.02 (0.17) in the diet group, and –0.05 (0.15) in the control group. Mean HDL change in the intervention group compared with control was 0.07 (95% CI 0.00 to 0.14). Men: At 12 months, mean (SD) TAG change in mmol/l was –0.12 (0.59) in the diet group, and 0.18 (0.67) in the control group. Mean TAG change in the intervention group compared with control was –0.30 (95% CI –0.58 to –0.02). Men: At 12 months, mean (SD) DBP change in mmHg was –2.40 (6.60) in the diet group, and 2.10 (5.00) in the control group. Mean DBP change in the intervention group compared with control was –4.50 (95% CI –7.70 to –1.93). Men: At 12 months, mean (SD) SBP change in mmHg was –4.10 (8.10) in the diet group, and 0.10 (7.70) in the control group. Mean SBP change in the intervention group compared with control was –4.20 (95% CI –7.66 to –0.74). *Women: at 12 months, significant changes in baseline were seen in the diet group compared with the control groups for total energy intake (–2180 vs 60 kJ/day* p*≤0.001), total fat intake (–7.8% vs –0.9%,* p*≤0.001), saturated fat (–3.7 vs –0.4%* p*≤0.001) and cholesterol intake (–123 vs –5 mg/day,* p*≤0.001). No significant difference was seen for aerobic capacity. Also, the estimated 12 year CHD risk decreased by 1.0 events/1000 persons in the diet group compared with an increase of 1.3 in the control group, but the difference was not significant between groups.* *Men: at 12 months, significant changes in baseline were seen in the diet group compared with the control groups for total energy intake (–2915 vs 155 kJ/day,* p*≤0.001), total fat intake (–6.0 vs 0.8%,* p*≤0.001), saturated fat (–3.2 vs –0.2%,* p*≤0.001) and cholesterol intake (–159 vs 7 mg/day,* p*≤0.001). No significant difference was seen for aerobic capacity. Also, the estimated 12 year CHD risk*

Quality and comments	*decreased by 12.9 events/1000 persons in the diet group compared with an increase of 0.6 in the control group (p≤0.01).* *Men and women in the weight-loss (diet only) programme reported greater restraint, less disinhibition, and less hunger at 1 year than those in no programme. Significant differences between men in both intervention groups vs control for DBP (p<0.001), TC for women in diet group vs control (p≤0.01), and diet and exercise group vs control (p≤0.05), and LDL levels in women in both intervention groups vs control (p≤0.05).* Dietary intake estimated from participants' 7-day food diaries, with further probing for more detail by trained interviewers when collecting the data by telephone.

Reported harms

Cohen 1991 (in HTA) cluster RCT	
Harms	None reported
Quality and comments	…

DISH 1985 (in HTA) RCT	
Harms	None reported
Quality and comments	

Frey-Hewitt 1990 (in HTA) RCT	
Harms	None reported
Quality and comments	…

Hankey 2001 (in HTA) RCT (pilot)	
Harms	Two deaths occurred in the intervention group and one in the control group.
Quality and comments	Participants by definition at high risk of death. Serious illness was also reported, but not by overweight group only.

HOT 1999 (in HTA) RCT	
Harms	Of the participants who dropped out, thee died and one had a serious illness. No details of group allocation were given.
Quality and comments	…

HPT 1990 (in HTA) RCT	
Harms	*One death occurred in the control group.*
Quality and comments	…

ODES 1995 (in HTA) RCT	
Harms	*One death and two cancers (allocation not known).*
Quality and comments	…

Pritchard 1997 (in HTA) RCT	
Harms	Two participants withdrew before completion due to ill health unrelated to the study.
Quality and comments	…

Pritchard 1999 (in HTA) RCT	
Harms	None reported
Quality and comments	…

TAIM 1992 (in HTA) RCT	
Harms	*Two deaths reported in the intervention group (Phase I study)*
Quality and comments	…

Wood 1988 (in HTA) RCT	
Harms	*One diagnosis of cancer reported in year 2.*
Quality and comments	…

Wood 1991 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Cohen 1991 (in HTA) cluster RCT	
Country and setting	USA. Family health centre – primary care.
Participants (included/excluded)	*Included if aged 20–75 years, BMI (kg/m^2) 27.8 for men and ≥27.3 for women; average SBP 140 mmHg or more on two or more readings, or average DBP more than 90 mmHg on two or more readings.* *No details of exclusion given.*
Recruitment	Patients who attended the health centre who met the eligibility criteria – no further details.
Intervention (mode and intensity)	12 months intervention, contacted 13 times (baseline then monthly)
Control (mode and intensity)	*Assessed three times (baseline, 6 and 12 months)*
Delivery of intervention/control (who)	Physicians were taught by a behavioural psychologist with a special interest in weight reduction The 'trained' physician then reviewed individual patient's diet using a questionnaire. Management of hypertension was the responsibility of the treating physician.
Dropout rates	*0% intervention and 0% control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	No dropouts

DISH 1985 (in HTA) RCT	
Country and setting	*USA. Multicentred.*
Participants (included/excluded)	*Included if no SBP >180 mmHg in past year, average DBP <95mmHg, average of last two DBP ≤90 mmHg and neither >95 mmHg.* *Excluded if congestive cardiac failure, ECG evidence of MI, stroke, transient ischaemic attacks, creatinine ≥2.5 mg/dl on at least two occasions, personal problems, compliance with diet difficult, severe alcoholism, pregnancy, □-blockers for angina, glucocorticosteroids.*
Recruitment	Recruited from Stopped Care clinic populations in the Hypertension Detection and Follow-up programme (initially found by population screening).
Intervention (mode and intensity)	Intervention lasted 56 weeks. Participants contacted about 38 times, (baseline then every 2 weeks for initial 16 weeks, monthly to week 56, plus eight initial weekly nutritional visits, then monthly to week 56).
Control (mode and intensity)	*No dietary intervention for 56 weeks. Contacted 20 times, (baseline then every 2 weeks for initial 16 weeks, then monthly to week 56).*

Delivery of intervention/control (who)	N/R
Dropout rates	*23% in intervention group, 13% in no dietary intervention group at 56 weeks.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Frey-Hewitt 1990 (in HTA) RCT	
Country and setting	*USA. University.* No further details.
Participants (included/excluded)	*Included men aged 30 to 59 years, 120–160% IBW, non-smokers, weight-stable (±2.27 kg during previous year).* *Excluded if BP >160/100, medications known to affect lipids, plasma TC >7.76 mmol/l or TAG >5.65 mmol/l, exercising more than three times per week.*
Recruitment	Volunteers – no further details.
Intervention (mode and intensity)	Dietary and physical activity groups were contacted 25 times (every 2 weeks) over the 12-month intervention period.
Control (mode and intensity)	*Over the 12 months, contact was unclear (possibly twice – baseline and 12 months).*
Delivery of intervention/control (who)	Dietitian met participants in the diet group every 2 weeks.
Dropout rates	4% in diet group, (2% in physical activity group), 6% in control at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Hankey 2001 (in HTA) RCT (pilot)	
Country and setting	UK. Cardiac rehabilitation programme. *Glasgow Royal Infirmary.*
Participants (included/excluded)	People attending cardiac rehab at two study hospitals, aged 35 to 75 years, survived acute MI about 3 months before study. No exclusion criteria stated.
Recruitment	Participants (assumed to be) recruited from cardiac rehabilitation programmes. No further details reported in published paper.
Intervention (mode and intensity)	Intervention for 12 weeks, with follow-up at 52 weeks. *Not clear about number of contacts, but routine cardiac rehabilitation plus four 1 h sessions of nutritional counselling.*
Control (mode and intensity)	*Assessed at baseline, 12 weeks and 52 weeks* with one 30–60 min group session
Delivery of intervention/control (who)	Nutrition counselling – assume dietitian? Routine cardiac rehabilitation – no details
Dropout rates	11% in diet group and 4% in control group at 52 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

HOT 1999 (in HTA) RCT	
Country and setting	Multicentre trial conducted in 26 countries (Europe, North and South America and Asia). No further details.
Participants (included/excluded)	*People with a BMI or ≥27 kg/m^2 from the HOT study.* (Inclusion for the HOT study was male or female patients aged 50–80 years with hypertension and office average sitting DBP between 100 and 115 mmHg at three consecutive measurements taken on two occasions, at least 1 week apart.) *Excluded for this sub-study if BMI <27 kg/m^2.*
Recruitment	N/R

Intervention (mode and intensity)	Intervention lasted 30 months, with maximum 24 contacts (baseline, at 2–4 weeks, twice per month to 3 months, every 3–6 months to 30 months).
Control (mode and intensity)	*30 months of control, with six contacts (baseline, 6, 12, 18, 24, 30 months).*
Delivery of intervention/control (who)	*Counselling in the intervention group was by the dietitian. Research nurses gave information to the control group.*
Dropout rates	7% in the weight loss group and 9% in the control group at 30 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

HPT 1990 (in HTA) RCT	
Country and setting	USA. Four *university?* clinics and four resource centres. No further details.
Participants (included/excluded)	*Included men and women aged 25 to 49 years, BMI <35 kg/m^2 or <150% IBW (Metropolitan Life Insurance tables), DBP ≥76mmHg or <99 mmHg at first baseline visit and DBP ≤89mmHg at second visit (7 to 30 days later).* *Excluded if antihypertensive medications or medication that may affect sodium metabolism, major chronic disease, BMI ≥35 kg/m^2, dietary requirements incompatible with dietary regimens, 21 or more alcoholic drinks per week, perceived unable to comply with study.*
Recruitment	No details in the papers reporting results.
Intervention (mode and intensity)	Dietary change counselling included didactic presentation and demonstrations, token incentives, bimonthly newsletters, telephone calls if missed session, daily food records. 3 years of intervention. About 38 contacts (three times at baseline, then at clinic sessions other than those of treatment sessions, six times at 6 monthly intervals, treatment group sessions weekly for 10 weeks, then every other month to 3 years. Also individual counselling sessions.)
Control (mode and intensity)	*3 years of control. Contacted ten times (assessed three times at baseline, then at 3, 6, 12, 18, 24, 30, 36 months).*
Delivery of intervention/control (who)	Counselling was provided by 'personnel trained and experienced in effecting behaviour changes related to shopping, cooking, and eating practices'.
Dropout rates	*6% in diet group and 10% in control at 36 months.*
Treatment of dropouts (return to baseline, or last measurement?)	People with missing follow-up data were excluded from the analysis of change for that time point. For BP, values were imputed for all follow-up visits after the initiation of antihypertensive therapy to avoid distortion of results by including BP lowered by such therapy. For DBP, 95 mmHg was used if observed DBP 95 mmHg or less, if not observed value used. For SBP, value imputed was value at last visit before initiation of therapy or current observed value, whichever was higher.

ODES 1995 (in HTA) RCT	
Country and setting	Norway. Community-based?
Participants (included/excluded)	*Included if aged 41 to 50 years, sedentary (exercise no more than once per week), BMI >24 kg/m^2, DBP 86 to 99 mmHg, TC 5.2 to 7.74 mmol/l, HDL <1.2 mmol/l, fasting serum TAG >1.4mmol/l.* *Excluded if overt diabetes or CVD, other disease or drugs that could interfere with test results, treatment with antihypertensive drugs, acetylsalicylic acid, lipid-lowering diet, personal traits unsuitable for inclusion.*
Recruitment	Participants recruited from continuous screening programme of 40-year old men and women in Oslo. No further details reported.
Intervention (mode and intensity)	Dietary intervention lasted 12 months. Four contacts (baseline, 3, 9, 12 months).

Control (mode and intensity)	*12-month control. Contacted at baseline and 12 months.*
Delivery of intervention/control (who)	N/R
Dropout rates	5% in diet group and 0% in control at 12 months (includes five excluded)
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pritchard 1997 (in HTA) RCT	
Country and setting	Australia. Work-based.
Participants (included/excluded)	*Included men aged 35 to 55 years of age, satisfactory cardiovascular fitness test, BMI 26–35 kg/m^2, 110 to 130% of IBW, otherwise healthy. No details of exclusion criteria given.*
Recruitment	Volunteers recruited from a national business corporation, previously screened as being overweight in a corporate health programme.
Intervention (mode and intensity)	18 months of intervention. Contacted 19 times (baseline then monthly. Also encouraged to attend bimonthly motivational group breakfasts or lunch meetings with guest speakers or videos relevant to diet, exercise and health issues).
Control (mode and intensity)	12 months of control. 6 months of diet and exercise. Contacted at baseline and weight monitored monthly
Delivery of intervention/control (who)	N/R
Dropout rates	*25% in the diet group and 5% in the control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Pritchard 1999 (in HTA) RCT	
Country and setting	Australia. University group general practice.
Participants (included/excluded)	*Included if aged between 25 and 65 years. Also if BMI >25 kg/m^2, or screened BP >140/90 mmHg and recorded BP >140/90 mmHg at least twice in medical records, history of type 2 diabetes.* *Excluded if mentally ill, intellectually disabled, terminally ill, acutely ill, pregnant, or participating in other health education programmes.*
Recruitment	Participants were screened opportunistically when attending the GP. People with recorded diagnosis of overweight, hypertension or type 2 diabetes in their patient notes were invited to participate. People who appeared to be overweight on presentation at reception were also invited to participate.
Intervention (mode and intensity)	Intervention lasted 12 months. Contacted seven times (baseline then six times by dietitian over 12 months). *Also supplemented with baseline contact with GP and 25 min sessions with the GP in the doctor and dietitian group.*
Control (mode and intensity)	*Contacted twice (baseline and 12 months).*
Delivery of intervention/control (who)	*Initial screening and counselling done by dietitian. Dietitian invited those allocated to the dietitian group to participate. GP invited those allocated to the doctor and dietitian group, after screening by the dietitian. Mailed invite to attend for final measurement in control group.*
Dropout rates	*45% dietitian group, 29% doctor and dietitian group, and 29% control at 12 months (as reported in original paper, not HTA.) Dropouts were significantly higher in the dietitian group (p=0.022) than either the doctor and dietitian group or the control.*
Treatment of dropouts (return to baseline, or last measurement?)	If missing data, the last measurement recorded was taken to populate subsequent data values.

TAIM 1992 (in HTA) RCT	
Country and setting	USA. Multicentre (clinical centres), but no details given in the results paper.
Participants (included/excluded)	*Included if 21 to 65 years of age, 100 to 160% IBW, BP untreated or discontinued medication 2 weeks before start of study, one member per household treated DBP ≤99 mmHg or untreated DBP 90 to 104 mmHg at preliminary screening, 90 to 100 mmHg at first clinic visit, <115 mmHg at second visit (pre-randomisation).* *Excluded if MI during past year or history of MI, history or other evidence of stroke, bronchial asthma, diabetes mellitus requiring insulin, history or other evidence of allergy to thiazides or □-blockers, creatinine ≥180 µmol/l at baseline, other major disease (e.g. kidney disease, liver disease, cancer), pregnancy or likelihood of pregnancy during study, lifestyle or other conditions likely to affect compliance.*
Recruitment	N/R
Intervention (mode and intensity)	30 months intervention. Contacted at least 25 times (baseline, 10 weekly group sessions, monthly assessment in initial 6 months then every 6 to 12 weeks up to maximum of 30 months).
Control (mode and intensity)	*Contacted 5 times (baseline, 6, 12, 18, 24 months).*
Delivery of intervention/control (who)	N/R
Dropout rates	Not clear.
Treatment of dropouts (return to baseline, or last measurement?)	*Excluded from analysis if attendance not 100%.*

Wood 1988 (in HTA) RCT	
Country and setting	USA. University clinic.
Participants (included/excluded)	*Included men aged 30 to 59 years, 120 to 160% IBW, no regular exercise for past 3 months, non-smokers, clinically healthy, resting clinic BP <160/100 mmHg, plasma cholesterol <8.28 mmol/l, plasma TAG <5.65 mmol/l, average<4 alcoholic drinks per day, expected to reside in Stanford area for at least 12 months, normal ECG during grade treadmill test.* *Excluded if orthopaedic limitations, medications known to effect BP or plasma lipids.*
Recruitment	Potential participants invited to be screened via mass media. Interviewed by telephone, and scheduled for orientation session if criteria met and still interested.
Intervention (mode and intensity)	First 12 months, no details of frequency of contact. In year 2, monthly mailings, telephone contact of 5 to 10 min each during months 13, 14, 15, 18, 21, 24 (for contact groups). In year 2, contacted twice at 18 and 24 months (no contact groups).
Control (mode and intensity)	Contacted three times in year 1 – baseline and 7, 12 months.
Delivery of intervention/control (who)	Registered dietitian provided individual counselling.
Dropout rates	4% diet, 6% control in first 12 months. 17% diet 2 (contact) group, 20% in diet 3 (no contact) group at 24 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Wood 1991 (in HTA) RCT	
Country and setting	USA. University clinic?
Participants (included/excluded)	*Included if aged between 25 and 49 years, 120 to 150% IBW, BMI 28 to 34 kg/m^2 for men, BMI 24 to 30 kg/m^2 for women, non-smokers, sedentary (exercise less than twice per week, <30 min per time), resting BP <160/95 mmHg, plasma cholesterol <6.72 mmol/l, plasma TAG <5.65 mmol/l, average less than four alcoholic drinks per day, generally good health.* *Excluded if medication known to affect BP or lipid metabolism, pregnancy, lactating or taking oral contraception in past 6 months or planning pregnancy in subsequent 2 years.*
Recruitment	Potential participants were invited to be screened via mass media, followed with telephone interviews.
Intervention (mode and intensity)	12-month intervention. Contacted 25 times (baseline then weekly for first 3 months, then every other week for 3 months, then monthly)
Control (mode and intensity)	*Contacted twice (baseline and 12 months)*
Delivery of intervention/control (who)	Dietary recommendations were presented by a registered dietitian. Group sessions assumed to be dietitian?
Dropout rates	*10% in diet group and 10% in control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Analyses restricted to individuals with complete data only.

1.3.2 Low-energy diet (1000 to 1600 kcal/day) compared with control

Weight loss

de Waard 1993 (in HTA) RCT	
Aim	To assess the effect of weight reduction in obese postmenopausal breast cancer patients as an adjuvant to primary surgical and radiotherapeutic treatment (feasibility study)
Participants	*Postmenopausal women with breast cancer who were also obese (BMI ≥27 kg/m^2).* *107 total – all women (107 randomised, 102 participated). No details of age reported. Minimum mean BMI 29.3 kg/m^2 intervention (The Netherlands,* n=*30), 29.5 control (The Netherlands,* n=*24), 30.6 intervention (Poland,* n=*29), 32.2 control (Poland,* n=*19).*
Intervention (including details of diet)	Participants received dietary advice from a dietitian of 1500 kcal per day (reduced to 1000 kcal/day if insufficient weight loss was noted) and psychological support.
Control	*No details given.*
Length of follow-up	3 years – The Netherlands. 1 year – Poland.

Results	Other time points shown graphically but not able to determine exact numbers. Women in the Netherlands: at 12 months, mean (SD) weight change in kg was –5.50 (7.50) in the diet group, and 1.50 (6.30) in the control group. Mean weight change in the intervention group compared with control was –7.00 (95% CI –10.75 to –3.25). Women in Poland: at 12 months, mean (SD) weight change in kg was –5.90 (7.60) in the diet group, and –0.60 (6.10) in the control group. Mean weight change in the intervention group compared with control was –5.30 (95% CI –9.51 to –1.09). Women in the Netherlands: at 24 months, mean (SD) weight change in kg was –5.00 (7.30) in the diet group, and 2.00 (6.50) in the control group. Mean weight change in the intervention group compared with control was –7.00 (95% CI –10.99 to –3.01). Women in the Netherlands: at 36 months, mean (SD) weight change in kg was –5.00 (7.30) in the diet group, and 1.10 (6.20) in the control group. Mean weight change in the intervention group compared with control was –6.10 (95% CI –10.71 to –1.49).
Quality and comments	Control group in Poland had significantly fewer women with moderate overweight (*p*<0.02). Blinded assessment not done. ITT not done. Random allocation but no description of concealment. Some calculations needed on the data presented. Data presented as two trials – The Netherlands and Poland. Small study.

Other outcomes

de Waard 1993 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Reported harms

de Waard 1993 (in HTA) RCT	
Harms	*Three cases of breast cancers occurred in the intervention group and one in the control group. Three women died from breast cancer in the intervention group and five in the control group. Two deaths from other causes also occurred in both the intervention and the control group.*
Quality and comments	…

Generalisability

de Waard 1993 (in HTA) RCT	
Country and setting	*The Netherlands – three hospitals. Poland – two oncology hospitals.*
Participants (included/excluded)	*Included women who had had primary treatment for breast cancer, no signs of distant metastases, aged 50–69 years, postmenopausal (no menses for at least 1 year), overweight by ≥10 kg (according to Broca's 1st rule, equivalent to BMI of ≥27 kg/m^2).* *Excluded initially if tamoxifen use but this exclusion criterion was subsequently omitted.*
Recruitment	Screened for eligibility by treating physician.
Intervention (mode and intensity)	The Netherlands – 3 years. Poland – 1 year. No further details reported.
Control (mode and intensity)	*The Netherlands – 3 years. Poland – 1 year. No further details reported.*

Delivery of intervention/control (who)	*Dietary advice delivered by dietitian.*
Dropout rates	*The Netherlands: 40% intervention, 38% control at 36 months. Poland: 7% intervention, 21% control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.3.3 Very-low-energy diet (<1000 kcal/day) compared with control

Weight loss

Stenius-Aarniala 2000 (in HTA) RCT	
Aim	To determine whether weight loss affects lung function, morbidity, symptoms, or health status in obese people with asthma
Participants	People with asthma who were obese (BMI 30–42 kg/m^2). *38 total – 29 F, 9 M. Mean age (range) 49.7 (34–60) years intervention (*n=19*) 48.3 (23–60) years control (*n=19*). Mean BMI (range) 35.8 (31.3–39.4) kg/m^2 intervention, 36.7 (32.8–41.8) kg/m^2 control.*
Intervention (including details of diet)	2–3 weeks pre-treatment phase consisting of lung function tests and laboratory tests to fulfil exclusion and inclusion criteria then 2 weeks of baseline measurements. Then 14 weeks weight reduction programme consisting of 12 × 30 min group sessions and including 8 weeks VLED (Nutrilett) consisting of 420 kcal/day containing daily allowances of all essential nutrients; discussed same themes as controls but at a later date so that each group had the same amount of education about asthma and allergy at end of treatment. *Nutrilett was described as a 'dietary preparation', so assumed to be a meal replacement option?*
Control	*2–3 weeks pre-treatment phase consisting of lung function tests and laboratory tests to fulfil exclusion and inclusion criteria then 2 weeks of baseline measurements. Then 12 × 30 min group sessions during initial 14 weeks where themes chosen by participants were discussed freely.*
Length of follow-up	*52 weeks*
Results	*At 14 weeks, mean (SD) weight change in kg was –14.20 (9.93) in the diet group, and –0.30 (6.00) in the control group. Mean weight change in the intervention group compared with control was –13.40 (95% CI –19.11 to –8.69). At this point, nine participants had lost ≥15% of initial weight, eight had lost between 10 and 14.9%, and two between 5 and 9.9% of initial body weight.* At 12 months, mean (SD) weight change in kg was –11.10 (9.06) in the diet group, and 2.30 (6.57) in the control group. Mean weight change in the intervention group compared with control was –13.40 (95% CI –18.43 to –8.37).
Quality and comments	Some calculation needed for HTA analysis. Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. *Used HTA Appendix 13 for SD calculation.*

Other outcomes

Stenius-Aarniala 2000 (in HTA) RCT	
Results	*At 8 weeks, the difference in forced expiratory volume (FEV) in 1 s between diet and control groups was 7.2% (95% CI 1.9 to 12.5), forced vital capacity (FVC) 8.6% (95% CI 4.8 to 12.4) and peak expiratory flow (PEF) 4.8% (95% CI –0.3 to 9.8).*

	At 14 weeks, the difference in FEV in 1 s between diet and control groups was 6.7% (95% CI 2.1 to 11.4), FVC 7.4% (95% CI 2.8 to 12.1) and peak expiratory flow (PEF) 4.8% (95% CI –1.9 to 11.4). *At 6 months, the difference in FEV in 1 s between diet and control groups was 8.4% (95% CI 3.7 to 13.2), FVC 7.6% (95% CI 4.1 to 11.2) and PEF 4.7% (95% CI –2.5 to 11.9).* At 12 months, the difference in FEV in 1 s between diet and control groups was 7.6% (95% CI 1.5 to 13.8), FVC 7.6% (95% CI 3.5 to 11.8) and PEF 6.2% (95% CI –1.4 to 13.7). During the 12 months, overall reduction in rescue medication was 0.5 doses in the diet group compared with 0 doses in the control group (*p*=0.002). Ten of the intervention group needed a course of oral steroids compared with 13 in the control group (*p*=0.07). Overall median change in dyspnoea was –13 mm in the diet group and –2 mm in the control (*p*=0.03). No significant differences were seen in cough, *After 1 year the differences in the changes between the two groups were –12 for symptom scores (range –1 to –22,* p*=0.04) and –10 for total scores (–18 to –1,* p*=0.02). The median number of exacerbations in the treatment group was 1 (0–4) and in the controls 4 (0–7),* p*=0.001.*
Quality and comments	*Small study so wide CIs.* Not sure how cough, dyspnoea, medication use was measured – self-reported? From St George's questionnaire?

Reported harms

Stenius-Aarniala 2000 (in HTA) RCT	
Harms	*During the 12 months, 16 of 19 of the intervention group and 18 of the 19 control group had at least one exacerbation of asthma. Median exacerbations were 1 (range 0 to 4) in the intervention group and 1 (range 0 to 7) in the control group, which were significantly different (reported* p*=0.001).* *Two of the participants found the consistency or the taste of the dietary preparation intolerable but followed an LED (no details given).*
Quality and comments	Not sure how exacerbation was measured – self-reported? From St George's questionnaire?

Generalisability

Stenius-Aarniala 2000 (in HTA) RCT	
Country and setting	*Finland. Private outpatients clinic.*
Participants (included/excluded)	*Included if aged 18–60 years, BMI 30–42 kg/m*^{2}*, diagnosis of asthma with spontaneous diurnal variation or a bronchodilator response of 15% or more; non-smoker or having stopped smoking for 2 years or more and before age 50 years.* *Excluded if pregnant, history of bulimia or anorexia, unstable angina or arrhythmia, untreated thyroid disease, symptomatic liver or gall bladder disorder, any other severe disease, insulin treatment, systemic steroid treatment, history of food allergy or intolerance to any component of the study VLED preparation (Nutrilett) such as soya, fish, chocolate or lactose; history of adverse reactions to peas, beans or peanuts; poor motivation.*
Recruitment	Participants were recruited by advertisements in two daily newspapers, then interviewed by telephone.
Intervention (mode and intensity)	12 months, contacted 16 times (12 half hour group sessions during initial 14 weeks then at week 14, month 6 and month 12).
Control (mode and intensity)	*As for intervention group.*

Delivery of intervention/control (who)	N/R explicitly, but cost of trained nurse supervision noted in the Discussion section, so assume trained nurse?
Dropout rates	0% for intervention and 0% control at 52 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	*N/R*

1.3.4 Low-energy diet compared with 600 kcal/day deficit or low-fat diet

Weight loss

Shah 1996 (in HTA) RCT	
Aim	To compare a energy-restricted diet with a fat-restricted diet (categorised as LED vs low-fat)
Participants	Healthy women who were overweight (20 to 40% above IBW). *122 total – all women. Age range 25 to 45 years, mean age 36 years. Mean (SD) weight 79.92 (4.45) kg, LED (n=61), 79.70 (4.40) kg low fat (*n=61*).*
Intervention (including details of diet)	Participants counselled on diet, exercise, menu planning, eating out, stimulus control, problem-solving, social assertion, goal setting, relapse prevention; cooking demonstrations given, all participants advised to walk for 30 min, 5 days per week, all participants advised to keep a daily record of food intake and physical activity. LED was 1000–1200 kcal/day, fat intake no more than 30% of total energy intake, no more than 170 g (6 oz) meat each day (only poultry, fish and lean red meat), limit fats, oils, eggs and high-fat desserts, snacks and dairy produce and replace with low fat alternatives, increase complex carbohydrates and limit simple sugars.
Control	*Participants counselled on diet, exercise, menu planning, eating out, stimulus control, problem-solving, social assertion, goal setting, relapse prevention; cooking demonstrations given, all participants advised to walk for 30 min, 5 days per week, all participants advised to keep a daily record of food intake and physical activity.* *Also to reduce fat intake to 20 g per day, unlimited complex carbohydrate, limit meat, fish and poultry to 60 g (2 oz) per day or less, (categorised as low fat) specific food recommendations, otherwise the same as LED.*
Length of follow-up	12 months
Results	*At 6 months, changes in BMI, % body fat, WHR were not significantly different between groups.* *At 6 months, mean (SD) weight change in kg was –3.70 (6.96) in the LED group and –4.60 (7.22) in the low-fat group. Mean weight change in the LED group compared with low-fat was 0.90 (95% CI –2.33 to 4.13).* *A*t 12 months, mean (SD) weight change in kg was –0.82 (6.15) in the LED group, and –2.45 (6.61) in the low-fat group. Mean weight change in the LED group compared with low-fat was 1.63 (95% CI –1.26 to 4.52). *A*t 18 months, mean (SD) weight change in kg was 1.80 (5.00) in the LED group and 0.40 (5.00) in the low-fat group, and. Mean weight change in the LED group compared with low-fat was 1.40 (95% CI –0.88 to 3.68).
Quality and comments	Some calculation needed for HTA analysis. Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. *Used 6-month data from Shah paper and HTA formula.*

Dansinger 2005 RCT	
Aim	To assess adherence rates and the realistic clinical effectiveness of four popular diets (Atkins, Zone, Weight Watchers and Ornish) for weight loss and cardiac risk factor reduction. Dietary components only of the programmes were used (see details of intervention later).
Participants	People who were overweight (BMI between 27 and 24 kg/m^2) who also had at least one metabolic cardiac risk factor. 160 total – 81 F, 79 M. Mean (SD) age 49 (10) years LED (*n*=40), 51 (9) years low fat (*n*=40). Mean (SD) BMI 35 (3.8) kg/m^2 LED, 34 (4.5) low fat.
Intervention (including details of diet)	*LED: number of daily points determined by current weight. Each point was roughly 50 kcal, and most participants aimed for 24 to 32 points daily (1200 to 1500 kcal). Lists provided by Weight Watchers determined point values of common foods.* *Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence.* *Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also encouraged to follow the assigned diet to the best of their ability until the 2 month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.*
Control	Low fat: aimed for a 40–30–30 balance of percentage energy from carbohydrate, fat and protein respectively. No further details reported. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also encouraged to follow the assigned diet to the best of their ability until the 2 month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.
Length of follow-up	*12 months*
Results	*At 2 months, mean (SD) weight change in kg was –3.50 (3.80) in the LED group and –3.80 (3.60) in the low-fat group. Mean weight change in the LED group compared with low-fat was 0.30 (95% CI –1.32 to 1.92).* *At 6 months, mean (SD) weight change in kg was –3.50 (5.60) in the LED group and –3.40 (5.70) in the low-fat group. Mean weight change in the LED group compared with low-fat was –0.10 (95% CI –2.58 to 2.38).* *At 12 months, mean (SD) weight change in kg was –3.00 (4.90) in the LED group and –3.20 (6.00) in the low-fat group. Mean weight change in the LED group compared with low-fat was 0.20 (95% CI –2.20 to 2.60).* *Weight and BMI were significantly lower than baseline for both groups (*p≤*0.05) but there was no statistically significant difference between the groups.* *Greater effects were observed in study completers.*
Quality and comments	*Weight Watchers categorised as LED (1200–1600 kcal/day). Zone diet categorised as low fat (not able to determine energy intake).* *Blinded assessment done. ITT analysis done. Randomisation done by computer-generated sequence, and good allocation concealment.* *See other sections for comparisons of protein-sparing modified fast (PSMF), LED, low-fat, and very-low-fat (Atkins, Weight Watchers, Zone and Ornish respectively).*

Other outcomes

Shah 1996 (in HTA) RCT	
Results	*Significant differences were seen between the groups over time for changes in energy from fat (–3.4 vs –8.9%, p=0.0002) and energy from carbohydrate (2.6 vs 7.3%, p=0.015). No differences were seen for changes in energy from protein or alcohol, overall protein, palatability, satiety, quality of life or physical activity.* *Significant differences were seen between the groups over time for changes in intake of vitamin C (–28% recommended daily allowance [RDA] vs 19% RDA, p=0.043), calcium (–27% RDA vs –4% RDA, p=0.009) and phosphorus (–36 vs –10% RDA, p=0.02). No differences were seen for the changes of intake of vitamins A, D, E and C, thiamine, riboflavin, niacin, folacin, B_6, B_{12}, iron, magnesium, zinc or dietary fibre.* *Data on compliance suggested that the low-fat diet may have been more attractive to participants (attendance, completion of diaries, days achieving dietary goals were all higher in this group). Compliance was associated with weight loss at 6 months, but not 12 months.*
Quality and comments	Dietary intake assessed by daily food diary and three random telephone recalls (unannounced).

Dansinger 2005 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was –0.21 (0.62) in the LED group, and –0.26 (0.90) in the low-fat group. Mean TC change in the LED group compared with low-fat was 0.05 (95% CI –0.29 to 0.39).* *At 12 months, mean (SD) LDL change in mmol/l was –0.24 (0.69) in the LED group, and –0.30 (0.87) in the low-fat group. Mean LDL change in the LED group compared with low-fat was 0.06 (95% CI –0.28 to 0.40).* *At 12 months, mean (SD) HDL change in mmol/l was 0.09 (0.25) in the LED group, and 0.08 (0.26) in the low-fat group. Mean HDL change in the LED group compared with low-fat was 0.01 (95% CI –0.10 to 0.12).* *At 12 months, mean (SD) TAG change in mmol/l was –0.14 (0.69) in the LED group, and 0.03 (1.65) in the low-fat group. Mean TAG change in the LED group compared with low-fat was –0.17 (95% CI –0.72 to 0.38).* *At 12 months, mean (SD) DBP change in mmHg was –1.70 (6.40) in the LED group, and –1.20 (9.50) in the low-fat group. Mean DBP change in the LED group compared with low-fat was –0.50 (95% CI –4.05 to 3.05).* *At 12 months, mean (SD) SBP change in mmHg was –2.70 (13.00) in the LED group, and 1.40 (15.00) in the low-fat group. Mean SBP change in the LED group compared with low-fat was -4.10 (95% CI –10.25 to 2.05).* *At 12 months, mean (SD) FPG change in mmol/l was –0.26 (1.06) in the LED group, and –0.23 (1.00) in the low-fat group. Mean FPG change in the LED group compared with low-fat was –0.03 (95% CI –0.48 to 0.42).* *At 12 months, the mean energy reductions from baseline were 244 for LED and 251 for low fat (p≤0.05). These were not significantly different between groups.* *No significant differences were seen in macronutrient content between any of the groups* *In each group, about 25% of participants lost 5% or more of initial body weight, and about 10% lost 10% or more at 12 months.* *Group mean adherence scores according to diet records and self-assessment decreased over time, and to a similar extent in all groups. About 25% of each group sustained a mean adherence level of at least 6/10, which 'appeared to delineate a clinically meaningful adherence level'.* *Amount of weight loss was associated with self-reported dietary adherence level (r=0.60; p<0.001) but not with diet type (r=0.07; p=0.40).*
Quality and	Converted mg/dl to mmol/l (see paper for conversion rates and values used).

comments	Dietary intake was assessed from 3-day diet records at 1, 2, 6 and 12 months.

Reported harms

Shah 1996 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Dansinger 2005 RCT	
Harms	Common reasons for discontinuation were that the assigned diet was too hard to follow, or not yielding enough weight loss. No diet-related or adverse events or serious adverse effects were found.
Quality and comments	Reasons for discontinuation not reported by group but overall only.

Generalisability

Shah 1996 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if healthy, non-smoking, women, aged 25–45 years, 20–40% above IBW.* *Excluded if smokers, consumed more than 20 alcoholic drinks per week, pregnant or lactating, suffered from chronic disease or psychiatric problems.*
Recruitment	Recruited through newspaper advertisements.
Intervention (mode and intensity)	26 weeks plus follow-up visit at 12 months, contacted 18 times (baseline, then 16 times in first 26 weeks then at 12 months).
Control (mode and intensity)	*As for intervention.*
Delivery of intervention/control (who)	A dietitian and health educator delivered counselling to participants.
Dropout rates	39% overall at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for participants with no missing data only.

Dansinger 2005 RCT	
Country and setting	USA. Enrolled at an academic medical centre.
Participants (included/excluded)	Included if adults of any age who were overweight (BMI between 27 and 42 kg/m^2) and having at least one of the following metabolic cardiac risk factors: FPG ≥6.1 mmol/l, TC ≥5.2 mmol/l, LDL ≥3.4 mmol/l, HDL ≤1.0 mmol/l, TAG ≥1.7 mmol/l, SBP ≥145 mmHg, DBP ≥90 mmHg, or current use of oral medication to treat hypertension, diabetes, dyslipidaemia. Excluded if unstable chronic illness, insulin therapy, urinary microalbumin of more than two times normal, serum creatinine ≥123.8 µmol/l, clinically significant abnormalities of liver or thyroid test results, weight loss medication or pregnancy.
Recruitment	Newspaper advertisements and TV publicity (local news coverage).
Intervention (mode and intensity)	*Four classes lasting 1 h during the first 2 months. Assessed at baseline, 2, 6 and 12 months (additional dietary assessment at 1 month).*
Control (mode and intensity)	As above

Delivery of intervention/control (who)	Team consisted of dietitian and physician who facilitated the meetings.
Dropout rates	*35% LED and 35% low-fat at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Weight and cardiac risk factors, baseline values carried forward. Dietary intake, baseline or subsequent values used.

1.3.5 Very-low energy diet compared with 600 kcal/day deficit or low-fat diet

Weight loss

Simonen 2000 (in HTA) RCT	
Aim	To investigate whether cholesterol and lipoprotein metabolism are related to serum variables of glucose metabolism at baseline, and to study the effects of weight reduction on glucose, cholesterol and lipoprotein metabolism during a prolonged follow-up in obese people with type 2 diabetes
Participants	People who were obese (BMI >30 kg/m^2) and who had type 2 diabetes. 1*6 total – 3 F, 13 M. Mean (SD) age 51.1 (8.8) years VLED (*n*=6), 54.3 (3.4) years low-fat (*n*=10). Mean BMI 31.94* kg/m^2 *VLED, 32.32* kg/m^2 *low-fat.*
Intervention (including details of diet)	6 week pre-treatment phase consisting of ad libitum diet at home whilst metabolic tests carried out. Hypoglycaemia treatment discontinued; VLED diet consisted of three daily servings of 140 kcal per serving (Cambridge diet – meal replacement), one serving=14.2 g protein, 15 g carbohydrate, 2.7 g fat, essential minerals, trace nutrients and vitamins for 3 months. From month 4 until month 24 diets individually tailored by dietitian to provide daily energy balance of zero.
Control	*6 week pre-treatment phase consisting of ad libitum diet at home whilst metabolic tests carried out.* *Participants' dose of glibenclamide adjusted so that plasma glucose <7.0 mmol/l and biguanides discontinued; LED where participants advised to consume low-fat, low-cholesterol diet for 3 months.* *From month 4 until month 24 diets individually tailored by dietitian to provide daily energy balance of zero*.
Length of follow-up	24 months
Results	*A*t 24 months, mean (SD) weight change in kg was –6.70 (7.81) in the *VLED* group, and –2.00 (6.48) in the low-fat group. Mean weight change in the *VLED* group compared with low fat was –4.70 (95% CI –11.79 to 2.39).
Quality and comments	Fasting plasma glucose and HbA$_{1c}$ differed significantly between groups (*p*<0.05). Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. All 16 participants analysed in aggregate, author replied, only weight data outcome used as treatment by hypoglycaemic medications differed between groups.

Other outcomes

Simonen 2000 (in HTA) RCT	
Results	Only weight data outcome used as treatment by hypoglycaemic medications differed between groups. *Other published outcomes not reported by treatment group (VLED or low-fat).*
Quality and	…

comments

Reported harms

Simonen 2000 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Simonen 2000 (in HTA) RCT	
Country and setting	Finland. No further details.
Participants (included/excluded)	*Included if diagnosis of type 2 diabetes in last 2 years (fasting plasma glucose ≥7.0 mmol/l).* (All women were postmenopausal and none had received hormone replacement therapy – but this appeared to be more a coincidence rather than a defined inclusion criteria) *Excluded if on insulin therapy, diabetic microangiopathy, hepatic or thyroid disease; unstable angina pectoris or MI; or invasive coronary artery disease (CAD) treatment in previous year.*
Recruitment	N/R.
Intervention (mode and intensity)	3 months plus follow-up at 2 years.
Control (mode and intensity)	*3 months plus follow-up at 2 years.*
Delivery of intervention/control (who)	Dietitian calculated individual energy intakes in the weight maintenance phase (months 4 to 24).
Dropout rates	0% overall.
Treatment of dropouts (return to baseline, or last measurement?)	No missing values reported.

1.3.6 Very-low energy diet compared with low-energy diet

Weight loss

Viegener 1990 (in HTA) RCT	
Aim	To determine whether the efficacy of behaviour therapy for obesity might be improved by the use of an intermittent, low-fat, LED.
Participants	Women who were obese (25 to 99% overweight based on the Metropolitan Life Insurance Company tables). *85 total – all women. Mean (SD) age 47.10 (7.49) years VLED (*n=42*), 47.13 (8.86) years LED (*n=43*). Mean (SD) weight 94.58 (12.64) kg VLED, 98.57 (15.91) kg LED.*

Intervention (including details of diet)	All participants received behaviour therapy which included self-monitoring, stimulus control, self-reinforcement, cognitive modification and problem-solving; all participants were advised to follow a regimen of programmed aerobic exercise with a target goal of 30 min a day for 6 days per week; all participants required to purchase a nutrition guide book and to complete daily food diary and daily exercise diary. Diet *(classified as VLED)* was 800 kcal/day diet for 4 days per week and 1200 kcal/day for 3 days per week consisting of 15% or less intake from fat on VLED days and 25% or less fat on LED days; each treatment session included significant focus on nutrition education with sample meals and practical guidance regarding low fat and low energy foods.
Control	*All participants received behaviour therapy which included self-monitoring, stimulus control, self-reinforcement, cognitive modification and problem-solving; all participants were advised to follow a regimen of programmed aerobic exercise with a target goal of 30 min per day for 6 days per week; all participants required to purchase a nutrition guide book and to complete daily food diary and daily exercise diary.* *Diet* (classified as LED) *was 1200 kcal/day balanced deficit diet with 55% energy as carbohydrate, 30% as fat and 15% as protein.*
Length of follow-up	52 weeks
Results	At 1 month, mean (SD) weight change in kg was –3.72 (1.65) in the VLED group, and –2.37 (2.00) in the LED group. Mean weight change in the VLED group compared with LED was –1.35 (95% CI –2.25 to –0.45). At 2 months, mean (SD) weight change in kg was –5.91 (2.88) in the VLED group, and –3.91 (3.19) in the LED group. Mean weight change in the VLED group compared with LED was –2.00 (95% CI –3.50 to –0.50). At 3 months, mean (SD) weight change in kg was –7.88 (3.17) in the VLED group, and –5.51 (4.12) in the LED group. Mean weight change in the VLED group compared with LED was –2.37 (95% CI –4.18 to –0.56). At 4 months, mean (SD) weight change in kg was –8.89 (3.78) in the VLED group, and –6.98 (4.67) in the LED group. Mean weight change in the VLED group compared with LED was –1.91 (95% CI –4.00 to 0.18). At 5 months, mean (SD) weight change in kg was –9.63 (4.44) in the VLED group, and –8.02 (5.23) in the LED group. Mean weight change in the VLED group compared with LED was –1.61 (95% CI –4.00 to 0.78). At 6 months, mean (SD) weight change in kg was –10.19 (5.06) in the VLED group, and –8.87 (5.56) in the LED group. Mean weight change in the VLED group compared with LED was –1.32 (95% CI –3.94 to 1.30). *At 12 months, mean (SD) weight change in kg was –8.97 (6.72) in the VLED group, and –8.95 (7.26) in the LED group. Mean weight change in the VLED group compared with LED was –0.02 (95% CI –3.56 to 3.52).*
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment.

Wing 1984 (in HTA) RCT	
Aim	To compare two weight control strategies: intermittent LED and intermittent booster sessions.
Participants	People who were overweight (≥20% greater than IBW] *48 total – 42 F, 6 M. Mean (SEM) age 44.79 (1.56) years overall. Mean BMI 36.45 kg/m^2 overall. Allocated 25 to VLED and 23 to LED.*

Kg/m2)Intervention (including details of diet)	All participants underwent 10 days pre-treatment assessment prior to randomisation, first 4 days involved food and exercise records, days 5–7 involved individual energy deficit (initial weight in pounds × 12 – 1000 kcal) using Slender breakfast bars and liquid, days 8–10 participants returned to conventional foods but still maintaining same prescribed energy deficit. Post randomisation for initial 10 weeks participants received 60–90 min weekly sessions involving individual weight-in, review, food diaries, presentation of a behavioural lesson (energy balance, strategies for increasing exercise, stimulus control, cognitive restructuring, self-reinforcement and relapse prevention) To maintain weight, individually prescribed energy goal (initial weight in pounds × 12 – 1000 kcal) for 5 days per week and <750 kcal/day for 2 days each week (chosen by participant) for initial 10 weeks, could use low energy menu or return to using Slender bars and liquid *(classified as VLED).* Further randomised by weight loss to maintenance by either massed booster session at weeks 14, 23, 24, 25, 26 and 34 which included problem-solving techniques, coping strategies, nutrition and exercise topics or spaced booster sessions with the same content as the massed booster sessions.
Control	*All participants underwent 10 days pre-treatment assessment prior to randomisation, first 4 days involved food and exercise records, days 5–7 involved individual energy deficit (initial weight in pounds × 12 – 1000 kcal) using Slender breakfast bars and liquid, days 8–10 participants returned to conventional foods but still maintaining same prescribed energy deficit.* *Post randomisation for initial 10 weeks participants received 60–90 min weekly sessions involving individual weight-in, review, food diaries, presentation of a behavioural lesson (energy balance, strategies for increasing exercise, stimulus control, cognitive restructuring, self-reinforcement and relapse prevention)* *To maintain weight, individually prescribed energy goal (initial weight in pounds × 12 – 1000 kcal) for 7 days per week* (classified as LED). *Further randomised by weight loss to maintenance by either massed booster session at weeks 14, 23, 24, 25, 26 and 34 which included problem-solving techniques, coping strategies, nutrition and exercise topics or spaced booster sessions with the same content as the massed booster sessions.*
Length of follow-up	52 weeks
Results	Concentrated sessions: at 6 months, mean (SD) weight change in kg was –4.05 (7.06) in the VLED group, and –1.47 (6.33) in the LED group. Mean weight change in the VLED group compared with LED was –2.58 (95% CI –8.08 to 2.92). Spaced sessions: at 6 months, mean (SD) weight change in kg was –1.31 (6.29) in the VLED group, and –3.12 (6.80) in the LED group. Mean weight change in the VLED group compared with LED was 1.81 (95% CI –3.88 to 7.50). *Concentrated sessions: at 12 months, mean (SD) weight change in kg was –1.95 (6.47) in the VLED group, and 0.38 (6.02) in the LED group. Mean weight change in the VLED group compared with LED was –2.33 (95% CI –7.45 to 2.79).* *Spaced sessions: at 12 months, mean (SD) weight change in kg was –0.58 (6.08) in the VLED group, and –2.69 (6.68) in the LED group. Mean weight change in the VLED group compared with LED was 2.11 (95% CI –3.45 to 7.67).*

Quality and comments	Baseline comparability not stated. Blinded assessment done. ITT analysis done. Random allocation but no description of concealment. Mean change in weight calculated by subtracting pre-randomisation weight loss from weight change at 12 months, SDs calculated. *HTA reported results comparing VLED and LED for two groups: concentrated booster sessions (Wing 1984a) and spaced booster sessions (Wing 1984b).*

Pavlou 1989 1 (in HTA) RCT	
Aim	To determine the role of exercise in relation to the type of diet, rate of weight loss and defined exercise experience on long-term maintenance
Participants	Healthy men. *160 total (for complete study) – all men. Mean (SD) age 46.1 (9.33) years VLED, 41.5 (7.59) years LED (Pavlou 1ga). Mean (SD) age 44.5 (9.60) years VLED, 42.9 (6.63) years LED (Pavlou 1hb). Mean BMI (kg/m^2) 31.89 VLED, 32.54 LED (Pavlou 1ga). Mean BMI 33.78 VLED, 32.4 LED (Pavlou 1hb).* *Data for completers only (18 VLED, 10 LED, 16 VLED, 11 LED respectively completed at 18 months post-treatment). No details of allocation to each group.*
Intervention (including details of diet)	All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts. VLED: DPC 800; assumed VLED 800 kcal/day diet provided in powdered form to be consumed similarly to DPC-70, provided a complete mixture of nutrients and similar nutritionally to balanced energy-deficit diet (BEDD) except for less energy. For groups allocated to exercise (Pavlou 1ga) 90 min supervised exercise programme three times per week from baseline to week 8 which consisted of 35–60 min of aerobic activity, e.g. walk-jog-run (70–85% maximum heart rate), callisthenics and relaxation techniques. For groups allocated to no exercise (Pavlou 1hb) participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks.
Control	*All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts.* *LED: BEDD, where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements.* *For groups allocated to exercise (Pavlou 1ga) 90 min supervised exercise programme three times/week from baseline to week 8 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques.* *For groups allocated to no exercise (Pavlou 1hb) participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks.*
Length of follow-up	*86 weeks.*
Results	Only 18-month outcomes reported. Published values showed results over the initial 12 weeks, but difficult to determine the numbers exactly. Supervised exercise: at 18 months, mean (SD) weight change in kg was –12.40 (9.42) in the VLED group, and –9.19 (8.52) in the LED group. Mean weight change in the VLED group compared with LED was –3.21 (95% CI –10.05 to 3.63). No additional exercise: at 18 months, mean (SD) weight change in kg was –3.45 (6.89) in the VLED group, and –3.57 (6.93) in the LED group. Mean weight change in the VLED group compared with LED was 0.12 (95% CI –5.19 to 5.43).

Quality and comments	*HTA reported results for two groups. Pavlou 1ga – VLED (800 kcal) and exercise vs LED and exercise, and Pavlou 1hb – VLED (800 kcal) vs LED.* Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Weight data derived from graph and SDs calculated.

Other outcomes

Viegener 1990 (in HTA) RCT	
Results	*At months 1, 2, 4 and 6 the VLED group were consuming significantly less energy per day than the LED group (*p*<0.05). Energy intake at months 3 and 5 were not significantly different.* *At 12 months, mean (SD) energy intake (kcal/day) in the diet group was 1283 (391) in the VLED group compared with 1293 (473) in the LED group. The difference was not significant.* *For the first 5 months, the VLED group was consuming significantly less energy from fat per day than the LED group (*p*<0.05). Energy intake from fat at month 6 was not significantly different.* *At 12 months, there was not enough data in the diaries to calculate the energy intake from fat* *No difference was seen between groups in attendance rates, self-reported diet adherence, and self-reported physical activity.*
Quality and comments	Dietary intake calculated from participants' 7-day eating diaries.

Wing 1984 (in HTA) RCT	
Results	*During the 10-week treatment programme, participants in the VLED group reported significantly more days where the energy intake was <750 kcal compared with the LED group (13.4 days vs 5.9 days,* p*<0.001). But the total energy intake was no different between the groups (1106 vs 1199 kcal).* *Significant improvements in eating habits (assessed by the Eating Behaviour Inventory) were seen at 10 weeks and 6 months (*p*<0.01). Significant reductions in the amount of high-energy food stored in the home were also seen (*p*<0.01).*
Quality and comments	Self-reported dietary intake from diaries.

Pavlou 1989 1 (in HTA) RCT	
Results	*No other outcomes by different diet groups were reported.*
Quality and comments	…

Reported harms

Viegener 1990 (in HTA) RCT	
Harms	*None reported.*
Quality and comments	…

Wing 1984 (in HTA) RCT T	
Harms	None reported.
Quality and comments	…

Pavlou 1989 1 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Viegener 1990 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included women aged 21–59 years, 25–99% overweight, with physicians approval, $125 deposit (with return based on attendance and completion of food diaries).* *Excluded if had obesity related disorders.*
Recruitment	Newspaper advertisements
Intervention (mode and intensity)	12 months, contacted maximum of 39 times (baseline, weekly 2 h group and individual sessions for first 26 weeks then opportunity to attend group maintenance sessions twice monthly for 26 weeks).
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Clinical psychology graduate students facilitated the behavioural treatment groups.
Dropout rates	29% in VLED and 30% in LED at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	Missing data was imputed by assuming that dropouts relapsed to pre-treatment weight.

Wing 1984 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if aged 20–65 years, 20% or more overweight, $85 deposit, $35 non-refundable, $50 refunded at attendance.* *Excluded if currently involved in other weight control programme.*
Recruitment	Recruited via newspaper articles and physician referrals. Interested people were then invited to an orientation meeting.
Intervention (mode and intensity)	Massed booster sessions: 12 months, contacted 18 times (baseline, weekly for first 10 weeks then at weeks 14, 23, 24, 25, 26, 34 and 52) Concentrated booster sessions: 12 months, contacted 18 times (baseline, weekly for first 10 weeks then at weeks 14, 18, 22, 26, 34 and 52
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.
Dropout rates	*8% overall*
Treatment of dropouts (return to baseline, or last measurement?)	Dropouts were assumed to have lost no weight.

Pavlou 1989 1 (in HTA) RCT	
Country and setting	USA. Workplace.
Participants (included/excluded)	*Included men, aged 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment.* *Exclusion criteria not stated.*
Recruitment	Men were recruited from the Boston Police Department and the Metropolitan District Commission. No further details reported.
Intervention (mode and intensity)	8 weeks plus 18 months post-treatment follow-up (weekly from baseline to week 8 then at 8 months and 18 months post-treatment)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.

Dropout rates	31% overall at 18 months post-treatment.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.3.7 Low-fat diet compared with another weight-reducing diet

Weight loss

Baron 1986 (in CR Pirozzo) RCT	
Aim	To compare the effects of low-carbohydrate and low-fat/low-fibre diets on weight and metabolic outcomes
Participants	*People who were overweight (above upper limit of acceptable weight for medium framed person from the Metropolitan Life Insurance tables)* *135 total – 115 F, 20 M.* Mean (SE) age 39.7 (1.5) years low-fat, 39.5 (1.3) years other diet. Mean (SE) BMI (kg/m^2) 28.5 (0.5) low-fat, 29.1 (0.6) other diet. *Low-fat group (n=69) and other control group (n=66).*
Intervention (including details of diet)	Diet: 1000–1200 kcal/day; low fat//high fibre; fat not >30 g/day. General orientation to dieting and limited discussion of behavioural techniques and value of exercise. Given diet instruction sheets and verbal advice. Weekly meetings with group (at diet club) for 3 months.
Control	*Control: 1000–1200 kcal/day; low-carbohydrate/low-fibre; carbohydrate no t>50 g/day.* *General orientation to dieting and limited discussion of behavioural techniques and value of exercise. Given diet instruction sheets and verbal advice. Weekly meetings with group (at diet club) for 3 months.*
Length of follow-up	12 months.
Results	*At 1 month, mean (SD) weight change in kg was –2.80 (6.71) in the low-fat diet group, and –3.9 (7.02) in the other diet group. Mean weight change in the low-fat diet group compared with the other diet group was 1.1 (95% CI –1.26 to 3.46).* *At 3 months, mean (SD) weight change in kg was –3.70 (6.96) in the low-fat diet group, and –5.00 (7.33) in the other diet group. Mean weight change in the low-fat diet group compared with the other diet group was 1.30 (95% CI –0.26 to 2.86).* At 12 months, mean (SD) weight change in kg was –1.60 (5.20) in the low-fat diet group, and –2.30 (5.20) in the other diet group. Mean weight change in the low-fat diet group compared with the other diet group was 0.70 (95% CI –1.16 to 2.56). *Dieters given low-carbohydrate/low-fibre dietary advice tended to lose more weight than those given a higher-carbohydrate/higher-fibre regimen. This pattern was particularly marked among women, and among participants who were under age 40 years or of lower social class. There were no differences between the diet groups in the proportion complaining of hunger but, in general, members of the low-carbohydrate group complained of more problems in dieting.*
Quality and comments	Blinded assessment not done. No details of randomisation or concealment. *Used HTA calculation for 1 and 3 month SDs (so slightly different CIs to those reported in the paper).*

Harvey-Berino 1998 (in CR Pirozzo) RCT	
Aim	To assess whether an energy-restricted diet or fat-restricted diet was more effective at promoting weight loss, improving eating behaviours and reducing barriers to dietary adherence.

Participants	People who were overweight (20 to 40% overweight as defined by the Metropolitan Life Insurance tables). *80 total – 65 F, 15 M. Mean age 38 years (range 25 to 45 years), not reported by group. Mean (SD) BMI (kg/m^2) 29.5 (1.8) for 28 completers low-fat, 29.9 (1.5) for 29 completers low-energy. Numbers allocated to each group not reported.*
Intervention (including details of diet)	Low-fat diet: 22–26 g/day; unrestricted carbohydrates. Given advice on how to follow diet; given counselling on behavioural modification strategies *(stimulus control, problem-solving, social skills, relapse prevention)* and self-management skills and how to increase physical activity; completed exercise and food diary daily; weekly meetings with group for 6 months.
Control	*LED – 1000–1200 kcal/day. Given advice on how to follow diet; given counselling on behavioural modification strategies* (as above) *and self-management skills and how to increase physical activity; completed exercise and food diary daily; weekly meetings with group for 6 months.*
Length of follow-up	18 months
Results	*A*t 6 months, mean (SD) weight change in kg was –5.20 (4.60) in the low-fat group, and –11.80 (4.90) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was 6.60 (95% CI 4.13 to 9.07). *A*t 12 months, mean (SD) weight change in kg was –3.00 (5.00) in the low-fat group, and –8.70 (5.00) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was 5.70 (95% CI 2.86 to 8.54). *A*t 18 months, mean (SD) weight change in kg was –1.80 (5.00) in the low-fat group, and –7.50 (5.00) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was 5.70 (95% CI 2.86 to 8.54). *At 6 months, 21% of the low-fat group and 75% of the low energy group had lost 10% or more of initial bodyweight. This was statistically significant* (p*<0.0001).*
Quality and comments	Blinded assessment unclear. No details of randomisation or concealment. ITT analysis not done.

McManus 2001 (in CR Pirozzo) RCT	
Aim	To evaluate a diet moderate in fat based on the Mediterranean diet compared with a standard low-fat diet for weight loss (both controlled for energy).
Participants	Healthy people who were overweight (BMI between 26.5 and 46 kg/m^2). *101 total – 91 F, 10 M. Mean (SD) age 44 (10) years in the low-fat diet (*n*=51) and 44 (10) years in the other (moderate fat) diet (*n*=50). Mean BMI (SD) in the low-fat diet group 34 (5) and 33 (3) kg/m^2 in the other group.*
Intervention (including details of diet)	Low-fat: 1200–1500 kcal – carbohydrate (60–65% of energy), fat (20% of energy), protein (15–20% of energy) Dietitian gave advice on how to follow diets and specific food recommendations; provided with meal plans and sample menus; teaching modules addressed behavioural modification skills and physical activity; completed daily food diary; weekly meetings with group for 18 months
Control	*Moderate fat: 1200–1500 kcal – carbohydrate 45–50% of energy, fat 35% of energy, protein 15–20% of energy.* *Dietitian gave advice on how to follow diets and specific food recommendations; provided with meal plans and sample menus; teaching modules addressed behavioural modification skills and physical activity; completed daily food diary; weekly meetings with group for 18 months*
Length of follow-up	18 months.

Results	*A*t 6 months, mean (SD) weight change in kg was –5.10 (4.60) in the low-fat group, and –4.90 (4.30) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was –0.20 (95% CI –2.61 to 2.21). *A*t 12 months, mean (SD) weight change in kg was –5.00 (7.30) in the low-fat group, and –4.80 (5.20) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was –0.20 (95% CI –4.63 to 4.23). *A*t 18 months, mean (SD) weight change in kg was 2.90 (7.70) in the low-fat group, and –4.10 (6.50) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was 7.00 (95% CI 3.42 to 10.58). *At 6 months, mean (SD) in WHR was –0.01 (0.04) in the low-fat group, and –0.02 (0.05) in the other diet group. Mean WHR change in the low-fat group compared with the other diet group was 0.01 (95% CI –0.01 to 0.03) (named wrongly in CR).*
Quality and comments	Blinded assessment unclear. No details of concealment. ITT analysis done. *Results at 6 and 12 months for active participants only – at 18 months, for all available participants.*

Pascale 1995 (in CR Pirozzo) RCT	
Aim	To compare the effects of a behavioural intervention focusing on either energy restriction alone or energy plus fat restriction on weight, lipids, and glycaemic control on people with non-insulin-dependent diabetes mellitus (NIDDM) or a family history of diabetes. (Results reported only for people with family history. Exclusion criterion for the review was no serious medical condition, so assumed to exclude those participants with NIDDM?)
Participants	Women who were overweight (20% or more above IBW by Metropolitan Life Insurance tables) with NIDDM or a family history of diabetes. *46 total – all women. Age range 34 to 51 years. Mean (SD) BMI 36.1 (5.6) kg/m^2 low fat, 35.0 (4.4) kg/m^2 other diet (results for completers only). Low-fat group (n=23) and other control group (n=23).*
Intervention (including details of diet)	Low fat: 1000–1500 kcal/day; low fat (20% total energy) Given advice on how to follow diet; given counselling on behavioural modification strategies and self-management skills and how to increase physical activity; completed exercise and food diary daily; weekly meetings with group for 4 months.
Control	*Other diet: 1000–1500 kcal/day* *Given advice on how to follow diet; given counselling on behavioural modification strategies and self-management skills and how to increase physical activity; completed exercise and food diary daily; weekly meetings with group for 4 months.*
Length of follow-up	12 months.
Results	*NIDDM: At 16 weeks, mean (SD) weight change in kg was –7.70 (3.60) in the low-fat group, and –4.70 (3.90) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was –3.00 (95% CI –5.64 to –0.36).* *NIDDM: A*t 12 months, mean (SD) weight change in kg was –5.20 (7.30) in the low-fat group, and –0.96 (3.70) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was –4.24 (95% CI –8.36 to –0.12). *Family history: At 16 weeks, mean (SD) weight change in kg was –7.40 (4.0) in the low-fat group, and –6.90 (4.70) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was –0.50 (95% CI –3.72 to 2.72).* *Family history: A*t 12 months, mean (SD) weight change in kg was –3.00 (8.40) in the low-fat group, and –3.50 (7.40) in the other diet group. Mean weight change in the low-fat group compared with the other diet group was 0.50 (95% CI –5.26 to 6.26).
Quality and comments	Blinded assessment unclear. No details of concealment. ITT analysis not done.

Other outcomes

Baron 1986 (in CR Pirozzo) RCT	
Results	*No significant differences between groups for changes from baseline were seen at either 1 or 3 months for TC, HDL, LDL, VLDL, TAG, HDL:LDL ratio, or glucose levels.* *The low-fat group decreased whole milk and red meat intake (servings per week) more than the low-carbohydrate group, but this was not significant at 12 months.* *The low-carbohydrate group decreased white bread intake (slices per week) more than the low-fat group, but this was not significant at 12 months. However, both groups increased consumption of brown bread, with the low-fat group eating significantly more (11.1 vs 8.3 slices per week) at 12 months than the low-carbohydrate groups. Similarly, potato intake decreased in both groups, with the low-carbohydrate group eating significantly less (2.6 vs 4.0 servings per week) at 12 months.* *Total cereal fibre increased in the low-fat group and decreased in the low-carbohydrate group, but the difference was not significant at 12 months.* *Total dietary fibre (g per day) also increased in the low-fat group but decreased in the low-carbohydrate group, and the difference was significant at 1, 3 and 12 months.* *Weight loss differed significantly between participating diet clubs, and club membership was a better predictor of weight loss than diet allocation (results not reported).*
Quality and comments	Dietary intake from self-completed questionnaires.

Harvey-Berino 1998 (in CR Pirozzo) RCT	
Results	*At 6 months in both groups, levels of physical activity increased, and % energy as protein intake increased from baseline, but the differences between groups were not statistically significant. However, energy intake decreased more in the low-energy group (*p*<0.05), % carbohydrate intake increased more in the low-fat group (*p*<0.01), and % fat intake decreased more in the low-fat group (*p*<0.01).* *At 6 months in both groups, measures of wellness improved more in the low-energy group (*p*=0.03), but inconvenience of eating outside the home was significantly higher for this group from baseline, whereas the low-fat group reported a lower inconvenience than at baseline. The difference was statistically significant (*p*=0.01). Other measures (distaste for fat, cost, deprivation of favourite foods and family issues) did not differ between the groups.* *Participants in the low-energy group reported a significantly greater positive change in eating behaviours (measured by Eating Behaviour Inventory) than did those in the low-fat group (*p*<0.001).* *People in the low-carbohydrate group consumed significantly less energy, less carbohydrate and the same amount of fat as those in the low fat condition; however, energy and carbohydrate intake were decreasing for low-fat participants by the 12- and 18-month assessments. There were no long-term differences in most measured predictors of dietary adherence.*
Quality and comments	Dietary intake was from 3-day food diaries, which were then reviewed for accuracy and completeness by a nutritionist who was blind to the treatment allocation of the participant. Other factors relating to dietary adherence (wellness, distaste, cost, inconvenience, deprivation and family) were measured using a scale previously developed for the Women's Health Trial.

McManus 2001 (in CR Pirozzo) RCT	
Results	*Total energy intake (kcal) was similar at 6 and 12 months, but at 18 months, the low-fat group consumed less energy than the moderate fat group (1697 vs 1877,* $p=0.08$*).* *% Energy intake from both total fat and monounsaturated fat was consistently lower in the low-fat diet at 6, 12 and 18 months (*$p<0.05$*). Although % intake from polyunsaturated fat was significantly lower in the low-fat group at 6 and 12 months (*$p<0.05$*), the groups were not significantly different at 18 months (*$p=0.06$*).* *% Energy intake from saturated fatty acids did not differ between the groups at any time (*$p>0.05$*).* *At 6 months, % energy intake from carbohydrate was lower in the low-fat group (*$p=0.02$*) but this difference was not maintained at 12 and 18 months (*$p<0.05$*).* *No differences were seen in the % energy intake from protein between the groups at any time point (*$p>0.05$*).* *Dietary fibre did not differ between groups except at 18 months, where the low-fat group reported consuming significantly less fibre (g) than the moderate fat group (*$p=0.03$*).* *Dietary cholesterol did not differ between groups except at 12 months, where the low-fat group reported consuming significantly more cholesterol (mg/1000 kcal) than the moderate fat group (*$p=0.008$*).* *Only 20% (10/51) of those in the low-fat group were actively participating in the weight loss programme after 18 months compared with 54% (27/50) in the moderate-fat group, (*$p<0.002$*).*
Quality and comments	Dietary intake assessed by validated questionnaire.

Pascale 1995 (in CR Pirozzo) RCT	
Results	*Significant decreases in glucose, HDL-cholesterol and TC were seen after 16 weeks of treatment among NIDDM participants; these changes were similar in CAL and CAL+FAT groups, but a greater proportion of participants in CAL condition required oral hypoglycaemic medication. At the 1-year follow-up, all parameters had returned to baseline. No significant differences in weight loss or physiological changes were seen between diets for women with a family history of diabetes.*
Quality and comments	Data for people with family history of diabetes only. Dietary intake assessed from 3-day food diaries.

Reported harms

Baron 1986 (in CR Pirozzo) RCT	
Harms	The participants in the low-fat group tended to voice fewer complaints. At 3 months, 6% of the low-carbohydrate group complained about how much the diet was costing compared with 0% of the low-fat group. 23% of the low-carbohydrate group complained of constipation compared with only 3% of the low-fat group. 81% of the low-carbohydrate group thought they would use the diet again compared with 92% of the low-fat group. 22% of all participants complained of fatigue at 3 months, and 31% found dieting difficult due to emotional stress.
Quality and comments	…

Harvey-Berino 1998 (in CR Pirozzo) RCT	
Harms	None reported.
Quality and comments	…

McManus 2001 (in CR Pirozzo) RCT	
Harms	None of those who dropped out cited the diet as the reasons. No other harms reported.
Quality and comments	…

Pascale 1995 (in CR Pirozzo) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Baron 1986 (in CR Pirozzo) RCT	
Country and setting	*UK.* Diet clubs and work places.
Participants (included/excluded)	*Included if weight greater than upper limit of acceptable weight for a medium framed person (Metropolitan Life Insurance tables). Excluded if dieted in last 3 months, within 6 months of childbirth, or still breast-feeding.*
Recruitment	Recruited from diet clubs and employee groups in one geographical area.
Intervention (mode and intensity)	3-month intervention. Contact at baseline, weekly for 3 months, and then at 12 months (14 contacts).
Control (mode and intensity)	*3-month control. As above.*
Delivery of intervention/control (who)	Diet group leaders
Dropout rates	11% overall.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Harvey-Berino 1998 (in CR Pirozzo) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if aged 25–45 years, 20–40% above IBW. Excluded if smokers, pregnant or lactating, history of chronic disease or psychosis.*
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	6 months. *24 weeks of group treatment sessions.*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	*A trained therapist reviewed the diaries and gave advice on strategies for dietary adherence.*
Dropout rates	40% overall.
Treatment of dropouts (return to baseline, or last measurement?)	Analysis of data for completers only – no missing data

McManus 2001 (in CR Pirozzo) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included if aged 18 to 70 years, BMI 26.5 to 46 kg/m^2, non-smokers, free from chronic disease, and willing to attend weekly classes for the study duration.
Recruitment	Letters sent to primary care physicians at a women's hospital. Also announcements posted.
Intervention (mode and intensity)	*18 months – weekly meetings for 18 months (about 78 contacts)*
Control (mode and intensity)	As above

Delivery of intervention/control (who)	One dietitian per group recorded body weight, provided sample menus, ran the weekly meetings, taught behaviour modification techniques. They also ensured that the intensity of the programmes was similar between groups.
Dropout rates	*At 18 months, 80% in the low-fat diet and 50% in the control group.*
Treatment of dropouts (return to baseline, or last measurement?)	Dropouts contacted at the end of the study for measurements. Also last observation carried forward for ITT analysis.

Pascale 1995 (in CR Pirozzo) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if women whose weight 20% or more above IBW, and who had at least one biological parent with type 2 diabetes.* *No details of exclusions.*
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	4 months intervention with weekly meetings (about 16 contacts), plus baseline and 12 month follow-up.
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	*Trained therapists reviewed food diaries and offered advice on strategies for dietary adherence.*
Dropout rates	33% overall at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.3.8 Protein-sparing modified fast compared with 600 kcal/deficit or low-fat diet

Weight loss

Dansinger 2005 RCT	
Aim	To assess adherence rates and the realistic clinical effectiveness of four popular diets (Atkins, Zone, Weight Watchers and Ornish) for weight loss and cardiac risk factor reduction. Dietary components only of the programmes were used (see details of intervention later).
Participants	People who were overweight (BMI between 27 and 24 kg/m^2) who also had at least one metabolic cardiac risk factor. 160 total – 81 F, 79 M. Mean (SD) age 47 (12) years PSMF (*n*=40), 51 (9) years low-fat (*n*=40). Mean (SD) BMI 35 (3.5) kg/m^2 PSMF, 34 (4.5) kg/m^2 low-fat.
Intervention (including details of diet)	*PSMF: aimed for less than 20 g of carbohydrate daily, with a gradual increase to 50 g/day.* *Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.*

Control	Low fat: aimed for a 40–30–30 balance of percentage energy from carbohydrate, fat and protein, respectively. No further details reported. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also encouraged to follow the assigned diet to the best of their ability until the 2 month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.
Length of follow-up	*12 months*
Results	*At 2 months, mean (SD) weight change in kg was –3.60 (3.30) in the PSMF group and –3.80 (3.60) in the low-fat group. Mean weight change in the PSMF group compared with low fat was 0.20 (95% CI –1.31 to 1.71).* *At 6 months, mean (SD) weight change in kg was –3.20 (4.90) in the PSMF group and –3.40 (5.70) in the low-fat group. Mean weight change in the PSMF group compared with low fat was 0.20 (95% CI –2.13 to 2.53).* *At 12 months, mean (SD) weight change in kg was –2.10 (4.80) in the PSMF group and –3.20 (6.00) in the low-fat group. Mean weight change in the PSMF group compared with low fat was 1.10 (95% CI –1.28 to 3.48).* *Weight and BMI were significantly lower than baseline for both groups ($p \leq 0.05$) but there was no statistically significant difference between the groups.* *In each group, about 25% of participants lost 5% or more of initial body weight, and about 10% lost 10% or more at 12 months.*
Quality and comments	*Atkins categorised as PSMF. Zone diet categorised as low fat (not able to determine energy intake).* *Blinded assessment done. ITT analysis done. Randomisation done by computer-generated sequence, and good allocation concealment.* *See other sections for comparisons of PSMF, LED, low-fat and very-low-fat (Atkins, Weight Watchers, Zone and Ornish respectively).*

Stern 2004 (and Samaha 2003) RCT	
Aim	To compare the effectiveness of a low-carbohydrate diet (categorised as PSMF) and a conventional diet (categorised as low fat) in people who were obese.
Participants	People who were obese (BMI of ≥35 kg/m^2). 132 total – 23 F, 109 M. Mean (SD) 53 (9) years PSMF (*n*=64), 54 (9) years low-fat (*n*=68). Mean (SD) BMI 42.9 (6.6) kg/m^2 PSMF, 42.9 (7.7) kg/m^2 low fat.
Intervention (including details of diet)	*PSMF: instructed to reduce carbohydrate intake to <30 g per day. No instruction on total fat intake was provided. Vegetables and fruit with high ratios of fibre:carbohydrate were recommended.* *Weekly counselling sessions (2 h long) for 4 weeks, followed by 11 (1 h) monthly sessions. Participants received diet overview handout, instructional nutritional labels, sample, menus and recipes, book on 'counting calories' and carbohydrate. No specific exercise was recommended.*
Control	Low fat: instructed to reduce energy intake by 500 kcal per day, with <30% of energy from fat (guidelines of the National Heart, Lung, and Blood Institute). Weekly counselling sessions (2 h long) for 4 weeks, followed by 11 (1 h) monthly sessions. Participants received diet overview handout, instructional nutritional labels, sample, menus and recipes, book on 'counting calories' and carbohydrate. No specific exercise was recommended.
Length of follow-up	*12 months.*

Results	*At 6 months, mean (SD) weight change in kg was –5.70 (8.60) in the PSMF group and –1.80 (3.90) in the low-fat group. Mean weight change in the PSMF group compared with low-fat was –3.90 (95% CI –6.20 to –1.60).* *At 12 months, mean (SD) weight change in kg was –5.10 (8.70) in the PSMF group and –3.10 (8.40) in the low-fat group. Mean weight change in the PSMF group compared with low-fat was –2.00 (95% CI –4.99 to 0.99).* *At 6 months, 14% of the PSMF group lost 10% or more of initial body weight compared with 3% of the low-fat group (*p=0.02*).*
Quality and comments	*Higher prevalence of hypertension in the PSMF group (72 vs 57%,* p=*0.082, NS).* *ITT analysis done. Blinded assessment not clear. Random allocation but no details of concealment.*

Foster 2003 RCT	
Aim	To evaluate the effects of a low-carbohydrate, high-protein, high-fat diet (categorised as PSMF) compared with a high-carbohydrate, low-fat, energy-deficit conventional diet (categorised as low fat) on weight loss and coronary risk factors in people who were obese.
Participants	People who were obese (no definition reported). 63 total – 43 F, 20 M. Mean (SD) age 44.0 (9.4) years PSMF (*n*=33), 44.2 (7.0) years low-fat (*n*=30). Mean (SD) BMI 33.9 (3.8) kg/m^2 PSMF, 34.4 (3.1) kg/m^2 low-fat.
Intervention (including details of diet)	*PSMF: limiting carbohydrate intake without restriction of fat or protein. For first 2 weeks, carbohydrate intake is limited to 20 g/day, but is then gradually increased until a stable and desirable weight is reached.* *Met with registered dietitian to review central components of the diet. Also given copy of Atkins diet programme book. Participants instructed to read the book and follow the diet as described.*
Control	Low fat: 1200 to 1500 kcal/day for women, 1500 to 1800 kcal/day for men, about 60% of energy from carbohydrate, 25% from fat and 15% from protein. Met with registered dietitian to review central components of the diet, and received information on 'calorie counting'. Also given copy of LEARN programme for weight management. Participants instructed to read the manual and follow the diet as described.
Length of follow-up	*12 months*
Results	*At 3 months, mean (SD) weight change in kg was –6.71 (4.94) in the PSMF group and –2.65 (3.64) in the low-fat group. Mean weight change in the PSMF group compared with low fat was –4.06 (95% CI –6.19 to –1.93).* *At 6 months, mean (SD) weight change in kg was –6.91 (6.42) in the PSMF group and –3.15 (5.50) in the low-fat group. Mean weight change in the PSMF group compared with low fat was –3.76 (95% CI –6.70 to –0.82).* *At 12 months, mean (SD) weight change in kg was –4.34 (6.61) in the PSMF group and –2.46 (6.19) in the low-fat group. Mean weight change in the PSMF group compared with low fat was –1.88 (95% CI –5.04 to 1.28).*
Quality and comments	*Used percentages to calculate actual weight losses and other outcomes.* *ITT analysis done. Blinded assessment not reported. Randomisation done but no details of concealment of allocation.*

Other outcomes

Dansinger 2005 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was –0.11 (0.59) in the PSMF group, and –0.26 (0.90) in the low-fat group. Mean TC change in the PSMF group compared with low fat was 0.15 (95% CI –0.18 to 0.48).* *At 12 months, mean (SD) LDL change in mmol/l was –0.18 (0.62) in the PSMF*

	group, and –0.30 (0.87) in the low-fat group. Mean LDL change in the PSMF group compared with low fat was 0.12 (95% CI –0.21 to 0.45). *At 12 months, mean (SD) HDL change in mmol/l was 0.09 (0.18) in the PSMF group, and 0.08 (0.26) in the low-fat group. Mean HDL change in the PSMF group compared with low fat was 0.01 (95% CI –0.09 to 0.11).* *At 12 months, mean (SD) TAG change in mmol/l was –0.02 (0.94) in the PSMF group, and 0.03 (1.65) in the low-fat group. Mean TAG change in the PSMF group compared with low fat was –0.05 (95% CI –0.64 to 0.54).* *At 12 months, mean (SD) DBP change in mmHg was –1.40 (7.50) in the PSMF group, and –1.20 (9.50) in the low-fat group. Mean DBP change in the PSMF group compared with low fat was –0.20 (95% CI –3.95 to 3.55).* *At 12 months, mean (SD) SBP change in mmHg was 0.20 (12.00) in the PSMF group, and 1.40 (15.00) in the low-fat group. Mean SBP change in the PSMF group compared with low fat was –1.20 (95% CI –7.15 to 4.75).* *At 12 months, mean (SD) FPG change in mmol/l was 0.08 (0.77) in the PSMF group, and –0.23 (1.00) in the low-fat group. Mean FPG change in the PSMF group compared with low fat was 0.31 (95% CI –0.08 to 0.70).* *At 12 months, the mean energy reductions from baseline (p≤0.05) were 138 for PSMF and 251 for low fat. These were not significantly different between groups.* *Group mean adherence scores according to diet records and self-assessment decreased over time, and to a similar extent in all groups. About 25% of each group sustained a mean adherence level of at least 6/10, which 'appeared to delineate a clinically meaningful adherence level'.* *Amount of weight loss was associated with self-reported dietary adherence level (r=0.60; p<0.001) but not with diet type (r=0.07; p=0.40).*
Quality and comments	Converted mg/dl to mmol/l (see paper for conversion rates and values used). Dietary intake was assessed from 3-day diet records at 1, 2, 6 and 12 months.

Stern 2004 (and Samaha 2003) RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was 0.16 (1.11) in the PSMF group, and –0.21 (0.91) in the low-fat group. Mean TC change in the PSMF group compared with low fat was 0.37 (95% CI –0.06 to 0.80).* *At 12 months, mean (SD) LDL change in mmol/l was 0.18 (0.91) in the PSMF group, and –0.10 (0.75) in the low-fat group. Mean LDL change in the PSMF group compared with low fat was 0.28 (95% CI –0.07 to 0.63).* *At 12 months, mean (SD) HDL change in mmol/l was –0.03 (0.18) in the PSMF group, and –0.13 (0.16) in the low-fat group. Mean HDL change in the PSMF group compared with low fat was 0.10 (95% CI 0.03 to 0.17).* *At 12 months, mean (SD) TAG change in mmol/l was –0.65 (1.78) in the PSMF group, and 0.05 (0.96) in the low-fat group. Mean TAG change in the PSMF group compared with low fat was –0.70 (95% CI –1.30 to –0.10).* *At 12 months, mean (SD) DBP change in mmHg was 3.00 (15.00) in the PSMF group, and 1.00 (10.00) in the low-fat group. Mean DBP change in the PSMF group compared with low fat was 2.00 (95% CI –3.35 to 7.35).* *At 12 months, mean (SD) SBP change in mmHg was 1.00 (19.00) in the PSMF group, and 2.00 (15.00) in the low-fat group. Mean SBP change in the PSMF group compared with low-fat was –1.00 (95% CI –8.18 to 6.18).* *FPG was not reported for the group as a whole, but for people with or without diabetes. There were no significant changes for either population between each group.* *No significant differences were seen between groups at 12 months for changes in intake of energy, protein, fat, fibre, saturated fat or dietary cholesterol.* *No significant differences were seen in macronutrient content between any of the groups.* *Dietary intake of carbohydrate decreased significantly more in PSMF group (–131 vs –22 g, p=0.011) as did dietary sodium (–633 vs 451 mg, p=0.05).*
Quality and	Dietary intake from 24 h dietary recall assessed using a previously validated

comments	instrument (Karvetti 1985).

Foster 2003 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was 0.01 (0.50) in the PSMF group, and –0.14 (0.40) in the low-fat group. Mean TC change in the PSMF group compared with low-fat was 0.15 (95% CI –0.07 to 0.37).* *At 12 months, mean (SD) LDL change in mmol/l was 0.01 (0.55) in the PSMF group, and –0.10 (0.37) in the low-fat group. Mean LDL change in the PSMF group compared with low-fat was 0.11 (95% CI –0.12 to 0.34).* *At 12 months, mean (SD) HDL change in mmol/l was 0.13 (0.23) in the PSMF group, and 0.02 (0.14) in the low-fat group. Mean HDL change in the PSMF group compared with low-fat was 0.11 (95% CI 0.02 to 0.20).* *At 12 months, mean (SD) TAG change in mmol/l was –0.25 (0.34) in the PSMF group, and 0.01 (0.52) in the low-fat group. Mean TAG change in the PSMF group compared with low-fat was –0.26 (95% CI –0.48 to –0.04).* *At 12 months, mean (SD) DBP change in mmHg was –2.76 (9.25) in the PSMF group, and –2.95 (10.24) in the low-fat group. Mean DBP change in the PSMF group compared with low-fat was 0.19 (95% CI –4.65 to 5.03).* *At 12 months, mean (SD) SBP change in mmHg was –1.21 (11.33) in the PSMF group, and 2.10 (14.55) in the low-fat group. Mean SBP change in the PSMF group compared with low-fat was –3.31 (95% CI –9.79 to 3.17).*
Quality and comments	…

Reported harms

Dansinger 2005 RCT	
Harms	Common reasons for discontinuation were that the assigned diet was too hard to follow, or not yielding enough weight loss. No diet-related or adverse events or serious adverse effects were found.
Quality and comments	Reasons for discontinuation not reported by group but overall only.

Stern 2004 (and Samaha 2003) RCT	
Harms	Changes in serum creatinine concentration did not differ significantly between groups. Blood urea nitrogen increased more in the PSMF group (0.4 vs –0.5 mmol/l, *p*=0.007). Changes in uric acid levels were not clinically significant but were statistically significant (17 vs –12 mmol/l, *p*=0.05). One participant in the PSMF group was hospitalised with non-cardiac chest pain during the study. Two participants died in the PSMF group (complications of hyperosmolar coma, severe ischaemic cardiomyopathy).
Quality and comments	…

Foster 2003 RCT	
Harms	In the first 3 months, there was a higher percentage of people in the PSMG group who tested positive for urinary ketones (at 3 months, about 43% PSMF vs 4% low-fat, *p*>0.003). After 3 months, no significant difference was seen between the groups.
Quality and comments	…

Generalisability

Dansinger 2005 RCT	
Country and setting	USA. Enrolled at an academic medical centre.
Participants (included/excluded)	Included if adults of any age who were overweight (BMI between 27 and 42 kg/m^2) and having at least one of the following metabolic cardiac risk factors: FPG ≥6.1 mmol/l, TC ≥5.2 mmol/l, LDL ≥3.4 mmol/l, HDL ≤1.0 mmol/l, TAG ≥1.7 mmol/l, SBP ≥145 mmHg, DBP ≥90 mmHg, or current use of oral medication to treat hypertension, diabetes, dyslipidaemia. Excluded if unstable chronic illness, insulin therapy, urinary microalbumin of more than two times normal, serum creatinine ≥123.8 µmol/l, clinically significant abnormalities of liver or thyroid test results, weight loss medication or pregnancy.
Recruitment	Newspaper advertisements and TV publicity (local news coverage).
Intervention (mode and intensity)	*Four classes lasting 1 h during the first 2 months. Assessed at baseline, 2, 6 and 12 months (additional dietary assessment at 1 month).*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Team consisted of dietitian and physician who facilitated the meetings.
Dropout rates	*48% PSMF and 35% low-fat at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Weight and cardiac risk factors, baseline values carried forward. Dietary intake, baseline or subsequent values used.

Stern 2004 (and Samaha 2003) RCT	
Country and setting	USA. Outpatient practices of a Veterans Affairs Medical Centre.
Participants (included/excluded)	Included if aged ≥18 years, BMI >35 kg/m^2. Excluded if serum creatinine >133 µmol/l, hepatic disease, severe life-limiting medical illness, inability to self monitor glucose levels, active use of weight loss programme or weight loss medication.
Recruitment	No details.
Intervention (mode and intensity)	*Weekly counselling sessions (2 h long) for 4 weeks, followed by 11 (1 h) monthly sessions.*
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	*Sessions led by experts in nutritional counselling.*
Dropout rates	*31% PSMF and 37% low-fat at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Missing weight data was collected from medical records. In the ITT analysis, baseline data was carried forward.

Foster 2003 RCT	
Country and setting	USA (assumed). No details reported.
Participants (included/excluded)	No inclusion criteria reported, other than ‘obese persons’. Excluded if clinically significant illness (including type 2 diabetes), taking lipid-lowering drugs, pregnant or lactating, taking medications that affected body weight.
Recruitment	No details.
Intervention (mode and intensity)	*Met with dietitian before study started. Assessed at weeks 2, 4, 8, 12, 16, 20, 26, 34, 24 and 52.*
Control (mode and intensity)	As above.

Delivery of intervention/control (who)	Dietitian instructed on diet.
Dropout rates	*39% PSMF and 43% low-fat at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Baseline values carried forward in cases of missing data.

1.3.9 Protein-sparing modified fast compared with low-energy diet

Weight loss

Wadden 1989 (in HTA) RCT	
Aim	To compare the effectiveness of VLED alone, behaviour therapy (BT) alone, and VLED plus BT on weight control.
Participants	People who were overweight (25 kg or more above IBW from the Metropolitan Life Insurance tables) *76 total – all women (completers only – men excluded from analysis due to small numbers). Mean age (SE) 42.1 (1.1) years. Mean (SE) BMI 39.4 (0.8) kg/m^2. Numbers allocated to each group unclear.*
Intervention (including details of diet)	1000–1200 kcal/day for month 1, months 2 + 3 400–500 kcal/day PSMF consisting of three servings of lean meat, fish or fowl and to avoid all other food with the exception of non-energy beverages and bouillon, requested to drink at least 1.5 litres water per day, daily supplements 3 g each of potassium, sodium chloride and 800 mg calcium; month 4 refeeding to conventional foods, firstly fruit and vegetables then bread and cereal then fats. Participants were encouraged to increase physical activity by walking and using the stairs; diet records kept throughout active treatment; paid US$40 which was refunded after the 1-year follow-up visit.
Control	*1000–1200 kcal/day diet of participants choosing for 25 weeks, taught traditional behavioural methods of weight control which included recording eating behaviour, controlling stimuli related to eating, slowing rate of consumption, increasing lifestyle activity, nutrition education, modifying self-defeating thoughts and emotions, social support, reinforcing changes in eating and exercise behaviour.* I*n months 5 + 6 an additional group was prescribed 1000–1200 kcal/day diet, extensive training in behaviour therapy throughout months 4, 5 + 6 addressed weight maintenance and included relapse prevention training and strategies for handling weight regain.* *Both groups were encouraged to increase physical activity by walking and using the stairs; diet records kept throughout active treatment; paid $10 for each visit and deposited $40 which was refunded after the 1 year follow-up visit.*
Length of follow-up	64 to 66 months

Results	*At 6 months, mean (SD) weight change in kg was –16.80 (6.68) in the PSMF group, and –13.00 (6.57) in the LED group. Mean weight change in the PSMF group compared with LED was –3.80 (95% CI –7.41 to –0.19).* At 12 months, mean (SD) weight change in kg was –10.60 (8.00) in the PSMF group, and –6.60 (8.91) in the LED group. Mean weight change in the PSMF group compared with LED was –4.00 (95% CI –8.87 to 0.87). At 36 months, mean (SD) weight change in kg was –5.11 (8.28) in the PSMF group, and –3.54 (6.26) in the LED group. Mean weight change in the PSMF group compared with LED was –1.57 (95% CI –6.79 to 3.65). At 60 months, mean (SD) weight change in kg was 2.90 (11.26) in the PSMF group, and 2.70 (6.97) in the LED group. Mean weight change in the PSMF group compared with LED was 0.20 (95% CI –5.68 to 6.08). *At the end of the active treatment (6 months), 96.8% of the PSMF and 95.5% of the LED group had lost 5 kg or more, and 90.3% and 63.5% respectively had lost 10 kg or more.* *At 12 months, 72.0% of the PSMF and 54.5% of the LED group had lost 5 kg or more, and 52.0% and 22.7% respectively had lost ≥10 kg.* *At 60 months, 27.3% of the PSMF and 13.3% of the LED group had lost 5 kg or more, and 9.1% and 0.0% respectively had lost ≥10 kg.*
Quality and comments	Two cohorts differed significantly in age at baseline (43.9 vs 39.5 years). 2 kg added to all self-reported weights, 3 and 5 year weight outcomes recalculated for participants who had additional weight loss treatment in years 1–5 post-treatment, self-reported weight at time of seeking additional therapy was subtracted from pre-treatment weights, significant difference in whole sample from uncorrected changes (*p*<0.002 at 3 years, *p*<0.005 at 5 years post-treatment). Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. *More than 90% of participants reported a chronic history of obesity and multiple cycles of weight loss and regain.*

Wadden 1994 (in HTA) RCT	
Aim	To determine the effect of maintenance therapy in maintaining an initial weight loss achieved by a VLED (based on PSMF) compared with initial weight loss using a LED
Participants	Women who were overweight (25 kg or more above IBW from the Metropolitan Life Insurance tables) 49 total – all women. Mean (SD) age 36.82 (8.87) years PSMF group (*n*=28), 42.86 (10.12) years LED group (n=21). Mean (SD) BMI 40.01 (5.73) kg/m^2 PSMF, 38.80 (5.39) LED.
Intervention (including details of diet)	Week 1 advised regarding 1200 kcal/day, weeks 2–17 420 kcal/day liquid formula PSMF (70 g protein, 30 g carbohydrate, 2 g fat) and 2 litres non-energy fluids daily and avoidance of all other foods; week 18 conventional foods gradually reintroduced to 100 kcal/day by week 23, weeks 24–78 1200 kcal/day. All participants received behaviour therapy consisting of keeping an eating record, stimulus control, modifying cognitions, eliciting social support (materials presented in different order for group b for initial 52 weeks); then during weeks 53–78 ‘upkeep’ skills such as weight graphing and biography, preparing low fat meals, continuing to exercise, relapse prevention, risk avoidance and reversing small weight gains; all participants received same exercise programme consisting of 10–20 min three times per week at 40–60% maximum heart rate gradually increased to 20–40 min three to five times per week at 60–70% maximum heart rate by week 52.

Control	*1200 kcal/day BEDD for first 52 weeks, 15–20% protein, 30% fat and remainder carbohydrate, energy intake then adjusted for weeks 53–78 depending on participants desired weight change (minimum 1200 kcal/day).* *All participants received behaviour therapy consisting of keeping an eating record, stimulus control, modifying cognitions, eliciting social support (materials presented in different order for group b for initial 52 weeks); then during weeks 53–78 'upkeep' skills such as weight graphing and biography, preparing low-fat meals, continuing to exercise, relapse prevention, risk avoidance and reversing small weight gains; all participants received same exercise programme consisting of 10–20 min three times per week at 40–60% maximum heart rate gradually increased to 20–40 min three to five times per week at 60–70% maximum heart rate by week 52*
Length of follow-up	78 weeks
Results	*At 1 week, mean (SD) weight change in kg was –0.67 (1.54) in the PSMF group, and –1.45 (1.05) in the LED group. Mean weight change in the PSMF group compared with LED was 0.78 (95% CI 0.05 to 1.51).* *At 5 weeks, mean (SD) weight change in kg was –8.51 (2.37) in the PSMF group, and –4.05 (2.47) in the LED group. Mean weight change in the PSMF group compared with LED was –4.46 (95% CI –5.83 to –3.09).* *At 9 weeks, mean (SD) weight change in kg was –13.29 (4.02) in the PSMF group, and –5.44 (3.61) in the LED group. Mean weight change in the PSMF group compared with LED was –7.85 (95% CI –10.00 to –5.71).* *(Not able to calculate for weeks 13 and 17 as no details of numbers of participants)* *At 6 months, mean (SD) weight change in kg was –21.45 (9.63) in the PSMF group, and –11.86 (7.89) in the LED group. Mean weight change in the PSMF group compared with LED was –9.59 (95% CI –14.86 to –4.32).* At 12 months, mean (SD) weight change in kg was –17.33 (9.86) in the PSMF group, and –14.43 (9.46) in the LED group. Mean weight change in the PSMF group compared with LED was –2.90 (95% CI –8.94 to 3.14). At 18 months, mean (SD) weight change in kg was –10.94 (9.97) in the PSMF group, and –12.18 (8.23) in the LED group. Mean weight change in the PSMF group compared with LED was 1.24 (95% CI –4.63 to 7.11). *At 6 months, 96% of the PSMF group lost ≥5 kg, 85% ≥10 kg and 58% ≥20 kg.* *At 12 months, 87% of the PSMF group lost ≥5 kg, 78% ≥10 kg and 35% ≥20 kg.* *At 18 months, 71% of the PSMF group lost ≥5 kg, 52% ≥10 kg and 19% ≥20 kg.* *At 6 months, 82% of the LED group lost ≥5 kg, 59% ≥10 kg and 18% ≥20 kg.* *At 12 months, 88% of the LED group lost ≥5 kg, 59% ≥10 kg and 18% ≥20 kg.* *At 18 months, 94% of the LED group lost ≥5 kg, 44% ≥10 kg and 19% ≥20 kg.* *At week 17, the PSMF group had lost significantly more fat free mass than the LED group (*p *0.001), but this difference was not maintained at week 48.*
Quality and comments	Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. VLED group over selected to allow for greater attrition.

Pavlou 1989 1 (in HTA) RCT	
Aim	To determine the role of exercise in relation to the type of diet, rate of weight loss and defined exercise experience on long-term maintenance

Participants	Healthy men (no weight inclusion criteria). *160 total (for complete study) – all men. Mean (SD) age 45.1 (10.00) years PSMF, 41.5 (7.59) years LED (Pavlou 1ca). Mean (SD) age 49.6 (8.40) years PSMF, 42.9 (6.63) years LED (Pavlou 1db). Mean (SD) age 41.8 (10.44) years PSMF, 41.5 (7.59) years LED (Pavlou 1ea). Mean (SD) age 41.8 (7.57) years PSMF, 42.9 (6.63) years LED (Pavlou 1fb).* *Mean BMI (kg/m^2) 32.07 PSMF, 32.54 LED (Pavlou 1ca). Mean BMI 31.5 PSMF, 32.4 LED (Pavlou 1db). Mean BMI 30.13 PSMF, 32.54 LED (Pavlou 1ea). Mean BMI 34.82 PSMF, 32.4 LED (Pavlou 1fb).* *Data for completers only (16 PSMF vs 10 LED, 16 PSMF vs 11 LED, 10 PSMF vs 10 LED, 13 PSMF vs 11 LED respectively completed at 18 months post-treatment). No details of allocation to each group.*
Intervention (including details of diet)	All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts. PSMF (groups c and d): ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat, fish and fowl; 2.8 g potassium chloride daily. PSMF (groups e and f): DPC-70; assumed PSMF 420 kcal/day diet of powdered protein–carbohydrate mix derived from calcium caseinate, egg albumin and fructose dissolved in water or other non-energy liquid, fat content zero, fortified with vitamins and minerals to meet US Recommended Daily Allowance, mix five packets per day in 850 g (30 oz) of non-energy liquid and consume no other nutrients; 2.8 g potassium chloride daily. For groups allocated to exercise (Pavlou 1ca, Pavlou 1ea) 90 min supervised exercise programme three times per week from baseline to week 8 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques For groups allocated to no exercise (Pavlou 1db, Pavlou 1fb) participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks.
Control	*All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts.* *LED: BEDD where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements* *For groups allocated to exercise (Pavlou 1ca, Pavlou 1ea) 90 min supervised exercise programme three times per week from baseline to week 8 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques.* *For groups allocated to no exercise (Pavlou 1db, Pavlou 1fb) participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks.*
Length of follow-up	*86 weeks.*

Results	Only 18-month outcomes reported. Published figures showed results over the initial 12 weeks, but difficult to determine exact numbers from graphs. *Food-based PSMF and supervised exercise: at 18 months, mean (SD) weight change in kg was –8.64 (8.36) in the PSMF group, and –9.19 (8.52) in the LED group. Mean weight change in the PSMF group compared with LED was 0.55 (95% CI –7.97 to 9.07).* *Food-based PSMF and no additional exercise: at 18 months, mean (SD) weight change in kg was –1.13 (6.23) in the PSMF group, and –3.57 (6.93) in the LED group. Mean weight change in the PSMF group compared with LED was 2.44 (95% CI –4.36 to 9.24).* *Meal replacement PSMF and supervised exercise: at 18 months, mean (SD) weight change in kg was –9.68 (8.65) in the PSMF group, and –9.19 (8.52) in the LED group. Mean weight change in the PSMF group compared with LED was –0.49 (95% CI –9.31 to 8.33).* *Meal replacement PSMF and no additional exercise: at 18 months, mean (SD) weight change in kg was –0.93 (6.18) in the PSMF group, and –3.57 (6.93) in the LED group. Mean weight change in the PSMF group compared with LED was 2.64 (95% CI –4.10 to 9.38).*
Quality and comments	*HTA reported results for four groups. Pavlou 1ca – PSMF (food) and exercise vs LED and exercise, Pavlou 1db – PSMF (food) vs LED, Pavlou 1ea – PSMF (meal replacement) and exercise vs LED and exercise, and Pavlou 1fb – PSMF (meal replacement) vs LED.* Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Weight data derived from graph and SDs calculated. *Have recalculated using halved sample size…*

Pavlou 1989 2 (in HTA) RCT	
Aim	To determine the role of exercise in relation to the type of diet, rate of weight loss and defined exercise experience on long-term maintenance
Participants	Healthy men (no weight inclusion criteria). *24 total – all men. Mean (SD) age 48.1 (4.65) years PSMF no exercise, 44.8 (7.84) years LED no exercise, 46.1 (5.14) years PSMF with exercise, 49.2 (6.48) years LED with exercise. Mean BMI (kg/m^2) 30.4 PSMF no exercise, 31.92 LED no exercise, 31.11 PSMF with exercise, 31.75 LED with exercise. Data for completers only. No details of numbers allocated.*
Intervention (including details of diet)	All participants attended weekly educational sessions up to week 12 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 12, non-energy liquids including coffee were allowed in unrestricted amounts. PSMF: ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat fish and fowl; 2.8 g potassium chloride daily Exercise: 90 min supervised exercise programme three times per week from baseline to week 12 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques
Control	*All participants attended weekly educational sessions up to week 12 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 12, non-energy liquids including coffee were allowed in unrestricted amounts.* *BEDD where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements.* *No exercise: participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks*
Length of follow-up	168 weeks

Results	*Only 18- and 36-month outcomes reported. Published values showed results over the initial 12 weeks, but difficult to determine exact numbers from graphs.* Food-based PSMF and supervised exercise: at 18 months, mean (SD) weight change in kg was –14.04 (9.89) in the PSMF group, and –11.83 (9.26) in the LED group. Mean weight change in the PSMF group compared with LED was –2.21 (95% CI –14.09 to 9.67). Food-based PSMF and no additional exercise: at 18 months, mean (SD) weight change in kg was –7.29 (7.98) in the PSMF group, and –5.75 (7.54) in the LED group. Mean weight change in the PSMF group compared with LED was –1.54 (95% CI –10.78 to 7.70). Food-based PSMF and supervised exercise: at 36 months, mean (SD) weight change in kg was –13.00 (3.83) in the PSMF group, and –10.67 (8.93) in the LED group. Mean weight change in the PSMF group compared with LED was –2.33 (95% CI –10.85 to 6.19). Food-based PSMF and no additional exercise: at 36 months, mean (SD) weight change in kg was –3.83 (7.10) in the PSMF group, and –3.25 (6.83) in the LED group. Mean weight change in the PSMF group compared with LED was –0.58 (95% CI –8.86 to 7.70).
Quality and comments	*HTA reported results for two groups. Pavlou 2a – PSMF (food) vs LED, Pavlou 2b – PSMF (food) and exercise vs LED and exercise.* Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Weight data derived from graph and SDs calculated.

Wing 1991 (in HTA) RCT	
Aim	To determine whether a combination of VLED (categorised as PSMF in HTA) plus behaviour modification would promote better short-term and long-term glycaemic control in people who were obese and had type 2 diabetes than behaviour modification alone.
Participants	People with type 2 diabetes who were overweight (30% or more above IBW from Metropolitan Life Insurance tables). *36 total – 26 F, 10 M. Mean (SD) age 50.6 (7.7) years PSMF, 51.9 (9.9) years LED. Mean (SD) BMI (kg/m^2) 37.34 (4.7) PSMF, 38.1 (5.7) LED. Data for completers only – initial allocation 17 to PSMF and 19 to LED.*
Intervention (including details of diet)	PSMF (food-based with option of meal replacement): month 1 same as LED then weeks 5–12 given 400 kcal/day PSMF consisting of lean meat, fish, fowl and choice of Optifast 70 for occasional meals, week 9 other foods gradually reintroduced and kcal increased so by week 17=1000–1500 kcal/day diet until week 72, participants on insulin started VLED in hospital where insulin withdrawn or sharply reduced; vitamin and mineral daily supplements. All participants given instructions to diet, exercise and behaviour modification emphasised in particular; advised to increase walking and given weekly exercise goals starting at 50 kcal/week (the equivalent of 0.5 mile walk for a 67.5 kg person) increased to 1000 kcal/week (approximately 10 miles walking per week); participants self-monitored their energy intake and exercise daily throughout the programme, stimulus control techniques, including strategies for removing food cues from the environment, slowing the rate of eating, and separating eating from other activities; also taught techniques for modifying cognitions, for relapse prevention and for self-reinforcement; all participants deposited $150 at start which was earned back weekly for meeting homework goals.

Control	*LED: 1000–1500 kcal/day (depending on initial weight) until week 72 unless IBW achieved; information regarding energy content of protein, carbohydrate and fat given and participants advised to increase complex carbohydrate and decrease fat intake, food choices unlimited, in line with American Diabetic Association recommendation* *All participants given instructions to diet, exercise and behaviour modification emphasised in particular; advised to increase walking and given weekly exercise goals starting at 50 kcal/week (the equivalent of 0.5 mile walk for a 67.5 kg person) increased to 1000 kcal/week (approximately 10 miles walking per week); participants self-monitored their energy intake and exercise daily throughout the programme, stimulus control techniques, including strategies for removing food cues from the environment, slowing the rate of eating, and separating eating from other activities; also taught techniques for modifying cognitions, for relapse prevention and for self-reinforcement; all participants deposited $150 at start which was earned back weekly for meeting homework goals.*
Length of follow-up	72 weeks
Results	At 5 months, mean (SD) weight change in kg was –18.60 (11.18) in the PSMF group, and –10.10 (8.77) in the LED group. Mean weight change in the PSMF group compared with LED was –8.50 (95% CI –15.33 to –1.67). *At 18 months, mean (SD) weight change in kg was –8.60 (9.20) in the PSMF group, and –6.80 (6.90) in the LED group. Mean weight change in the PSMF group compared with LED was –1.80 (95% CI –7.33 to 3.73).*
Quality and comments	Author confirmed main study and sub-study publications, mean change in risk outcomes at 72 weeks calculated from actual values, SDs also calculated. Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Used HTA SD calculation.

Torgerson 1997 (in HTA) and Lantz 2003 RCT	
Aim	To determine whether 12 initial weeks on a VLED (categorised as PSMF) included in a 2-year support programme is associated with better long-term weight loss maintenance than a dietary and behavioural support programmes alone.
Participants	People who were obese (BMI >32 kg/m^2) *113 total – 74 F, 39 M. Mean (SD) age 47.3 (6.7) years PSMF (n=58), 46.9 (5.8) years LED (n=55). Mean (SD) BMI (kg/m^2) 40.2 (3.3) PSMF, 40.5 (4.3) LED.*
Intervention (including details of diet)	PSMF: Modifast PSMF 456–608 kcal/day for 12 weeks then individualised hypoenergetic diet of 1200–1400 kcal/day (women) or 1400–1800 kcal/day (men) consisting of 55% energy as carbohydrate, 15–20% protein, 25–30% fat up to 2 years. All participants were asked to complete food records before each 6 monthly visit, all received behavioural support programme which included nutrition education and lifestyle advice, risk avoidance and coping strategies, cooking groups, physical activity groups offered such as swimming and physical training.
Control	*LED: individualised hypoenergetic diet of 1200–1400 kcal/day (women) or 1400–1800 kcal/day (men) consisting of 55% energy as carbohydrate, 15–20% protein, 25–30% fat, for 2 years* *All participants were asked to complete food records before each 6 monthly visit, all received behavioural support programme which included nutrition education and lifestyle advice, risk avoidance and coping strategies, cooking groups, physical activity groups offered such as swimming and physical training.*
Length of follow-up	*4 years*

Results	Only 24- and 48-month outcomes reported. *At 24 months, mean (SD) weight change in kg was –9.20 (13.00) in the PSMF group, and –6.20 (8.70) in the LED group. Mean weight change in the PSMF group compared with LED was –3.00 (95% CI –7.06 to 1.06).* At 48 months, mean (SD) weight change in kg was –7.60 (12.20) in the PSMF group, and –6.30 (8.50) in the LED group. Mean weight change in the PSMF group compared with LED was –1.30 (95% CI –6.81 to 4.21). Examination of selected demographic, psychosocial and dietary characteristics showed that the VLED-approach was more effective than the supportive strategy alone in men and possibly in individuals sharing household with only one person.

Weight loss at 24 months (about from graph)	**<5%**		**5–10%**		**>10%**	
Completers only	PSMF	LED	PSMF	LED	PSMF	**LED**
Women	55%	53%	26%	15%	17%	**28%**
Men	**26%**	**61%**	**38%**	**17%**	**32%**	**17%**

Quality and comments	Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. *PSMF only for 12 weeks of 24-month intervention. 48-month results for completers only.*

Wing 1994 (in HTA) RCT	
Aim	To evaluate a year-long behavioural weight control programme used with and without an intermittent VLED in the treatment of type 2 diabetes
Participants	People with NIDDM who were overweight (>30% or >18 kg above IBW, Metropolitan Life Insurance tables). *93 total – 60 F, 33 (kg/m^2) 37.9 (6.3). 38 allocated to PSMF and 41 to LED.*
Intervention (including details of diet)	PSMF (food or meal replacement): PSMF 500 kcal/day either as liquid supplement (Optifast) or lean meat, fish or fowl for weeks 0–12 and weeks 24–36; other foods gradually reintroduced over following 4 weeks to consume 1000–1200 kcal/d at weeks 13–23 and weeks 37–50. All participants kept self-monitoring records which were reviewed at weekly group meetings along with detailed discussion on nutrition which included focusing on reducing fat content and increasing intake of complex carbohydrate and fibre; exercise which stressed walking or behavioural techniques which included stimulus control, goal setting and self-monitoring of intake and exercise, preplanning, relapse prevention and modifying cognitions; included role playing and individual discussion and questions; all participants encouraged to increase walking to 2 miles per day 5 days per week; all participants kept 3 day food diaries at baseline, 6 months and 12 months; all diabetes medications discontinued at start and algorithm used to determine if and when to restart medication; all participants given vitamin/mineral supplements throughout study; all participants deposited $150 which was refunded in full for reaching behavioural goals and attending assessments at baseline, 6 months and 50 weeks.

Control	*LED: 1000–1200 kcal/day consisting of <30% energy intake from fat from baseline to week 50.* *All participants kept self-monitoring records which were reviewed at weekly group meetings along with detailed discussion on nutrition which included focusing on reducing fat content and increasing intake of complex carbohydrate and fibre; exercise which stressed walking or behavioural techniques which included stimulus control, goal setting and self-monitoring of intake and exercise, preplanning, relapse prevention and modifying cognitions; included role playing and individual discussion and questions; all participants encouraged to increase walking to 2 miles per day 5 days per week; all participants kept 3 day food diaries at baseline, 6 months and 12 months; all diabetes medications discontinued at start and algorithm used to determine if and when to restart medication; all participants given vitamin/mineral supplements throughout study; all participants deposited $150 which was refunded in full for reaching behavioural goals and attending assessments at baseline, 6 months and 50 weeks.*
Length of follow-up	102 weeks.
Results	*Shorter time periods reported graphically only.* *At 12 months, mean (SD) weight change in kg was –14.20 (10.30) in the PSMF group, and –10.5 (11.60) in the LED group. Mean weight change in the PSMF group compared with LED was –3.70 (95% CI –8.55 to 1.15).* *At 12 months 47% of the PSMF lost ≥15 kg compared with 22% of the LED group (*p*<0.05). 32% of the PSMF lost ≥20 kg compared with 15% of the LED group (*p*=0.07).* *Women in the PSMG group lost significantly more weight at 12 months than did the LED participants (14.1 vs 8.6 kg,* p*<0.023). Men had comparable losses between the groups (15.4 and 15.5kg). The percentage of women losing ≥15 kg or at least 5 BMI units was significantly greater in the PSMF group (*p*<0.01 for both comparisons). The proportion of men achieving these two goals was similar in each group.* At 24 months, mean (SD) weight change in kg was –7.20 (8.00) in the PSMF group, and –5.70 (7.90) in the LED group. Mean weight change in the PSMF group compared with LED was –1.50 (95% CI –5.15 to 2.15).
Quality and comments	Blinded assessment not reported. ITT analysis not done. Random allocation but no description of concealment. Author confirmed study and sub study reports. *Added 12 month outcomes*

Dansinger 2005 RCT	
Aim	To assess adherence rates and the realistic clinical effectiveness of four popular diets (Atkins, Zone, Weight Watchers and Ornish) for weight loss and cardiac risk factor reduction. Dietary components only of the programmes were used (see details of intervention later).
Participants	People who were overweight (BMI between 27 and 24 kg/m^2) who also had at least one metabolic cardiac risk factor. 160 total – 81 F, 79 M. Mean (SD) age 47 (12) years PSMF (*n*=40), 49 (10) years low-fat (*n*=40). Mean (SD) BMI (kg/m^2) 35 (3.5) PSMF, 35 (3.8) low-fat.

Intervention (including details of diet)	*PSMF: aimed for <20 g of carbohydrate daily, with a gradual increase to 50 g/day. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.*
Control	LED: number of daily points determined by current weight. Each point was roughly 50 kcal, and most participants aimed for 24 to 32 points daily (1200 to 1500 kcal). Lists provided by Weight Watchers determined point values of common foods. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.
Length of follow-up	*12 months*
Results	*At 2 months, mean (SD) weight change in kg was –3.60 (3.30) in the PSMF group and –3.50 (3.80) in the LED group. Mean weight change in the PSMF group compared with LED was –0.10 (95% CI –1.66 to 1.46).* *At 6 months, mean (SD) weight change in kg was –3.20 (4.90) in the PSMF group and –3.50 (5.60) in the LED group. Mean weight change in the PSMF group compared with LED was 0.30 (95% CI –2.01 to 2.61).* *At 12 months, mean (SD) weight change in kg was –2.10 (4.80) in the PSMF group and –3.00 (4.90) in the LED group. Mean weight change in the PSMF group compared with LED was 0.90 (95% CI –1.23 to 3.03).* *Weight and BMI were significantly lower than baseline for both groups (p≤0.05) but there was no statistically significant difference between the groups.* *In each group, about 25% of participants lost 5% or more of initial body weight, and about 10% lost 10% or more at 12 months.*
Quality and comments	*Atkins categorised as PSMF. Weight Watchers diet categorised as LED.* *Blinded assessment done. ITT analysis done. Randomisation done by computer generated sequence, and good allocation concealment.* *See other sections for comparisons of PSMF, LED, low-fat, and very-low-fat (Atkins, Weight Watchers, Zone and Ornish respectively).*

Other outcomes

Wadden 1989 (in HTA) RCT	
Results	*No other outcomes reported.*
Quality and comments	…

Wadden 1994 (in HTA) RCT	
Results	*Participants in both groups scored lower (p<0.03) on the Beck Depression*

	Inventory over time (i.e. improved) but there was no significant difference between the two groups. *Also, participants in both groups scored lower (p<0.01) on the Binge Eating Scale over time (i.e. improved at weeks 26 and 52) and change from baseline was significantly different for participants in the LED compared with those in the PSMF week 52 (p<0.02) but not at week 26.*
Quality and comments	…

Pavlou 1989 1 (in HTA) RCT	
Results	*Only* VO_{2max} *reported by different diet groups.*
Quality and comments	…

Pavlou 1989 2 (in HTA) RCT	
Results	*Only* VO_{2max} *at 8 weeks reported by different diet groups.*
Quality and comments	…

Wing 1991 (in HTA) RCT	
Results	*At 18 months, mean (SD) TC change in mmol/l was 0.29 (1.08) in the PSMF group and 0.31 (1.08) in the LED group. Mean TC change in the intervention group compared with control was –0.02 (95% CI –0.76 to 0.72).* *At 18 months, mean (SD) HDL change in mmol/l was 0.22 (0.29) in the PSMF group and 0.13 (0.29) in the LED group. Mean HDL change in the intervention group compared with control was 0.09 (95% CI –0.11 to 0.29).* *At 18 months, mean (SD) TAG change in mmol/l was –0.13 (0.96) in the PSMF group and –0.29 (0.96) in the LED group. Mean TAG change in the intervention group compared with control was 0.16 (95% CI –0.50 to 0.82).* *At 18 months, mean (SD)* HbA_{1c} *% change was –1.20 (2.58) in the PSMF group and 1.40 (2.58) in the LED group. Mean* HbA_{1c} *% change in the intervention group compared with control was –2.60 (95% CI –4.36 to –0.84).* *At 18 months, mean (SD) FPG change in mmol/l was –3.80 (3.77) in the PSMF group and 0.70 (3.77) in the LED group. Mean FPG change in the intervention group compared with control was –4.50 (95% CI –7.07 to –1.93).* The PSMF group reported consuming significantly less energy from baseline than the LED group through the treatment period (*p*<0.001), but these data were not available for the 18 month follow-up. The PSMG group increased levels of physical activity significantly from pre- to post-treatment (*p*<0.02) compared with the LD group but these were not maintained at the 18 month point. From the Eating Behaviour Inventory, both groups reported increased use of behaviour modification strategies from pre- to post-treatment (*p*<0.0001) but these were not maintained at the 18 month follow-up.
Quality and comments	Data on dietary intake from daily diaries throughout the study.

Torgerson 1997 (in HTA) and Lantz 2003 RCT	
Results	*High initial hunger-score was associated with attrition, irrespective of treatment.*
Quality and comments	…

Wing 1994 (in HTA) RCT	
Results	*At 12 months, the PSMF group showed an increase in levels of TC compared with a decrease in the LED group (p=0.058).* *Other lipid changes were similar in the two groups at 12 months, with significant increases in HDL (p<0.001) and decreases in TAG (p<0.001).* *Both SBP and DBP decreased significantly in both groups (p<0.001), but the*

	decrease in DBP in the PSMF group was greater (p=0.03). *Also, both groups showed similar decreases in levels of HbA$_1$, FPG and fasting insulin at 12 months (p<0.001).* At 24 months, mean (SD) HbA$_{1c}$ % change was 0.07 (2.22) in the PSMF group, and 0.24 (2.40) in the LED group. Mean HbA$_{1c}$ % change in the intervention group compared with control was –0.17 (95% CI –1.23 to 0.89). At 24 months, mean (SD) FPG change in mmol/l was –1.22 (4.56) in the PSMF group, and 0.39 (4.67) in the LED group. Mean FPG change in the intervention group compared with control was –1.61 (95% CI –3.73 to 0.51). *Attendance rates decreased similarly over time in both groups, but was highly related to weight loss (p<0.0001 for both groups).*
Quality and comments	…

Dansinger 2005 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was –0.11 (0.59) in the PSMF group and –0.21 (0.62) in the LED group. Mean TC change in the PSMF group compared with LED was 0.10 (95% CI –0.17 to 0.37).* *At 12 months, mean (SD) LDL change in mmol/l was –0.18 (0.62) in the PSMF group and –0.24 (0.69) in the LED group. Mean LDL change in the PSMF group compared with LED was 0.06 (95% CI –0.23 to 0.35).* *At 12 months, mean (SD) HDL change in mmol/l was 0.09 (0.18) in the PSMF group and 0.09 (0.25) in the LED group. Mean HDL change in the PSMF group compared with LED was 0.00 (95% CI –0.10 to 0.10).* *At 12 months, mean (SD) TAG change in mmol/l was –0.02 (0.94) in the PSMF group and –0.14 (0.69) in the LED group. Mean TAG change in the PSMF group compared with LED was 0.12 (95% CI –0.24 to 0.48).* *At 12 months, mean (SD) DBP change in mmHg was –1.40 (7.50) in the PSMF group and –1.70 (6.40) in the LED group. Mean DBP change in the PSMF group compared with LED was 0.30 (95% CI –2.76 to 3.36).* *At 12 months, mean (SD) SBP change in mmHg was 0.20 (12.00) in the PSMF group and –2.70 (13.00) in the LED group. Mean SBP change in the PSMF group compared with LED was 2.90 (95% CI –2.58 to 8.38).* *At 12 months, mean (SD) FPG change in mmol/l was 0.08 (0.77) in the PSMF group and –0.26 (1.06) in the LED group. Mean FPG change in the PSMF group compared with LED was 0.34 (95% CI –0.07 to 0.75).* *At 12 months, the mean energy reductions from baseline (p≤0.05) were 138 for PSMF and 244 for LED. These were not significantly different between groups.* *No significant differences were seen in macronutrient content between any of the groups.* *Group mean adherence scores according to diet records and self-assessment decreased over time, and to a similar extent in all groups. About 25% of each group sustained a mean adherence level of at least 6/10, which 'appeared to delineate a clinically meaningful adherence level'.*
Quality and comments	Converted mg/dl to mmol/l (see paper for conversion rates and values used). Dietary intake was assessed from 3-day diet records at 1, 2, 6 and 12 months.

Reported harms

Wadden 1989 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wadden 1994 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Pavlou 1989 1 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Pavlou 1989 2 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wing 1991 (in HTA) RCT	
Harms	During the first 4 months of the treatment, both groups were asked about difficulties with coldness, constipation, dry skin, diarrhoea, dizziness, vomiting or weakness. There were no differences between the groups or over time for any participant reporting these (as either mild, moderate, or severe symptoms). No values were reported. ECGs showed no negative effects of the PSMF – in two participants, non-specific ST-T wave changes noted at baseline resolved over the study period. Increased levels of uric acid were seen in the PSMF group ($p<0.007$), but clinical symptoms of gout did not develop. One participant experienced levels of uric acid <594 µmol/l, which responded to treatment. In addition, levels of alkaline phosphatase decreased ($p<0.002$) in the PSMF group but no other changes were significant.
Quality and comments	…

Torgerson 1997 (in HTA) and Lantz 2003 RCT	
Harms	No serious adverse effects of a VLED were seen and no serious or unexpected laboratory aberrations in the blood chemistry profiles or ECGs appeared.
Quality and comments	…

Wing 1994 (in HTA) RCT	
Harms	Commonly reported side effects of the PSMF were cold intolerance, constipation, and hair loss. These all resolved when the PSMF was stopped. No numbers were reported. Both groups reported significant improvements in depressive symptomatology (Beck Depression Inventory) over the 12 months ($p<0.001$), but there was no difference between the groups.
Quality and comments	…

Dansinger 2005 RCT	
Harms	Common reasons for discontinuation were that the assigned diet was too hard to follow, or not yielding enough weight loss. No diet-related or adverse events or serious adverse effects were found.
Quality and comments	Reasons for discontinuation not reported by group but overall only.

Generalisability

Wadden 1989 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if 25 kg or more above IBW (Metropolitan Life Insurance tables).* *Excluded if recent MI or evidence of cardiac abnormalities; history of cerebrovascular, kidney or liver disease; cancer, type 1 diabetes, severe psychiatric illness, pregnancy, contraindications to treatment by VLED (assessed at screening), participants agreed not to participate in additional weight loss treatment before follow-up at 1 year post-treatment.*
Recruitment	N/R.
Intervention (mode and intensity)	16 weeks, contacted 25 times (90 min each week for 16 weeks then months 1, 2, 3, 6, 9 and 12 post-treatment, 3 years and 5 years post-treatment)
Control (mode and intensity)	*25 weeks, contacted 39 times (90 min each week for 25 weeks then 11 post-treatment visits every other week for first 2 months then once a month for next 4 months then every other month for last 6 months, 3 years and 5 years post-treatment)*
Delivery of intervention/control (who)	All participants were treated by doctoral level clinical psychologists.
Dropout rates	Unclear, but 68/76 were assessed at 12 months, 50/76 at 36 months, and 55/76 at 60 months.
Treatment of dropouts (return to baseline, or last measurement?)	Data for completers only.

Wadden 1994 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included women who were overweight (BMI ≥25 kg/m^2). $300 refunded at 6 monthly intervals.* *Excluded if myocardial infarction, cardiac problems, cerebrovascular disease, kidney or liver disease, cancer, type 1 diabetes, bulimia nervosa, psychiatric illness.*
Recruitment	Newspaper advertisements, then medical examination for eligibility.
Intervention (mode and intensity)	18 months, contacted 66 times (baseline then 90 min small group sessions weekly for first 52 weeks, then biweekly for weeks 53–78)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	*Behavioural sessions conducted by either a doctoral-level clinical psychologist or a psychology graduate student. Food and nutrition education delivered by a dietitian.*
Dropout rates	25% PSMF and 24% LED at 78 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	N/R – only complete data used?

Pavlou 1989 1 (in HTA) RCT	
Country and setting	USA. Workplace.
Participants (included/excluded)	*Included men, aged 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment.* *Exclusion criteria not stated.*
Recruitment	Men were recruited from the Boston Police Department and the Metropolitan District Commission. No further details reported.

Intervention (mode and intensity)	8 weeks plus 18 months post-treatment follow-up (weekly from baseline to week 8 then at 8 months and 18 months post-treatment)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.
Dropout rates	31% overall at 18 months post-treatment.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pavlou 1989 2 (in HTA) RCT	
Country and setting	USA. Workplace
Participants (included/excluded)	*Included men aged 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment.* *No details of exclusion.*
Recruitment	Men were recruited from the Boston Police Department and the Metropolitan District Commission. No further details reported.
Intervention (mode and intensity)	12 weeks plus 36 months post-treatment follow-up, contacted 16 times (weekly from baseline to week 12 then at 6, 8 and 18 months post-treatment)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.
Dropout rates	13% overall at 36 months post-treatment
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Wing 1991 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if aged 35–70 years, 30% or more IBW (Metropolitan Life Insurance tables), type 2 diabetes* *Excluded if liver disease, renal disease, heart disease.*
Recruitment	N/R
Intervention (mode and intensity)	72 weeks, contacted 25 times (weekly from baseline to week 20 then at weeks 24, 28, 46 and 72)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Groups led by team of therapists. Medication changes were made by the project physician.
Dropout rates	0% PSMF and 16% LED at 72 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Torgerson 1997 (in HTA) and Lantz 2003 RCT	
Country and setting	*Sweden. Outpatient clinics of two county hospitals.*
Participants (included/excluded)	*Recruited if aged 37–60 years, obese (non-surgery arm of SOS study) Exclusion criteria not stated.*
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	2 years, contacted 31 times (baseline then at 1, 2, 4, 6, 8, 12, 13, 14, 16, 18 and 20 weeks then monthly). *After 4 years, averaged 38 visits.*
Control (mode and intensity)	*2 years, contacted 28 times (baseline then at 1, 2, 4, 6 and 8 weeks then monthly).* After 4 years, averaged 38 visits.
Delivery of intervention/control (who)	Individual nutritional counselling, support, and further education on nutrition and lifestyle were delivered by a dietitian. The physician performed the physical examination and evaluation of risk factors and counselling.

Dropout rates	50% PSMF and 53% LED at 4 years.
Treatment of dropouts (return to baseline, or last measurement?)	LOCF.

Wing 1994 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if aged 30–70 years, >30% or >18 kg IBW (based on Metropolitan Life Insurance Tables) and NIDDM (criteria according to National Diabetes Data Group).* *Excluded if had health problems that would interfere with the use of VLCDs.*
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	50 weeks plus follow-up at 1 year later (102 weeks in total), contacted 5two times (weekly in groups of approximately 15)
Control (mode and intensity)	*As above.*
Delivery of intervention/control (who)	Meetings conducted by a multi-disciplinary team of therapists (behavioural therapist, health educator, nutritionist, physician). Also seen by project physician every other week.
Dropout rates	20% PSMF and 21% LED at 102 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	N/R.

Dansinger 2005 RCT	
Country and setting	USA. Enrolled at an academic medical centre.
Participants (included/excluded)	Included if adults of any age who were overweight (BMI between 27 and 42 kg/m^2) and having at least one of the following metabolic cardiac risk factors: FPG ≥6.1 mmol/l, TC ≥5.2 mmol/l, LDL ≥3.4 mmol/l, HDL ≤1.0 mmol/l, TAG ≥1.7 mmol/l, SBP ≥145 mmHg, DBP ≥90 mmHg, or current use of oral medication to treat hypertension, diabetes, dyslipidaemia. Excluded if unstable chronic illness, insulin therapy, urinary microalbumin of more than two times normal, serum creatinine ≥123.8 µmol/l, clinically significant abnormalities of liver or thyroid test results, weight loss medication or pregnancy.
Recruitment	Newspaper advertisements and TV publicity (local news coverage).
Intervention (mode and intensity)	*Four classes lasting 1 h during the first 2 months. Assessed at baseline, 2, 6 and 12 months (additional dietary assessment at 1 month).*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Team consisted of dietitian and physician who facilitated the meetings.
Dropout rates	*48% PSMF and 35% LED at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Weight and cardiac risk factors, baseline values carried forward. Dietary intake, baseline or subsequent values used.

1.3.10 Protein-sparing modified fast compared with very-low-energy diet

Weight loss

Pavlou 1989 1 (in HTA) RCT	
Aim	To determine the role of exercise in relation to the type of diet, rate of weight loss and defined exercise experience on long-term maintenance
Participants	Healthy men (no weight inclusion criteria). *160 total (for complete study) – all men. Mean (SD) age 45.1 (10.00) years PSMF, 41.8 (10.44) years VLED (Pavlou 1ce). Mean (SD) age 49.6 (8.40) years PSMF, 41.8 (7.57) years VLED (Pavlou 1df). Mean (SD) age 45.1 (10.00) years PSMF, 46.1 (9.33) years VLED (Pavlou 1cg). Mean (SD) age 49.6 (8.40) years PSMF, 44.5 (9.6) years VLED (Pavlou 1dh)..* *Mean BMI (kg/m^2) 32.07 PSMF, 30.13 VLED (Pavlou 1ce). Mean BMI 31.5 PSMF, 34.82 VLED (Pavlou 1df). Mean BMI 32.07 PSMF, 31.89 VLED (Pavlou 1cg). Mean BMI 31.5 PSMF, 33.78 VLED (Pavlou 1dh).* *Data for completers only (16 PSMF vs 10 VLED, 16 PSMF vs 13 VLED, 16 PSMF vs 18 VLED, 16 PSMF vs 16 VLED respectively completed at 18 months post-treatment). No details of allocation to each group.*
Intervention (including details of diet)	All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts. PSMF (groups c and d): ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat, fish and fowl; 2.8 g potassium chloride daily For groups allocated to exercise (Pavlou 1ce, Pavlou 1cg) 90 min supervised exercise programme three times per week from baseline to week 8 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques For groups allocated to no exercise (Pavlou 1df, Pavlou 1dh) participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks
Control	*All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts.* *VLED using PSMF (groups e and f): DPC-70; assumed PSMF 420 kcal/day diet of powdered protein–carbohydrate mix derived from calcium caseinate, egg albumin and fructose dissolved in water or other non-energy liquid, fat content zero, fortified with vitamins and minerals to meet US Recommended Daily Allowance, mix five packets per day in 850 g (30oz) of non-energy liquid and consume no other nutrients; 2.8 g potassium chloride daily.* *VLED (groups g and h): DPC 800; assumed VLED 800 kcal/day diet provided in powdered form to be consumed similarly to DPC-70, provided a complete mixture of nutrients and similar nutritionally to BEDD except for less energy.* *For groups allocated to exercise (Pavlou 1ce, Pavlou 1cg) 90 min supervised exercise programme three times per week from baseline to week 8 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques* *For groups allocated to no exercise (Pavlou 1df, Pavlou 1dh) participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks*
Length of follow-up	86 weeks.

Results	Only 18-month outcomes reported. Published values showed results over the initial 12 weeks, but difficult to determine exact numbers from graphs. PSMF vs 420 kcal VLED and supervised exercise: at 18 months, mean (SD) weight change in kg was –8.64 (8.36) in the PSMF group, and –9.68 (8.65) in the VLED group. Mean weight change in the PSMF group compared with VLED was 1.04 (95% CI –6.85 to 8.93). PSMF vs 420 kcal VLED and no additional exercise: at 18 months, mean (SD) weight change in kg was –1.13 (6.23) in the PSMF group, and –0.93 (6.18) in the VLED group. Mean weight change in the PSMF group compared with VLED was 3.76 (95% CI –3.97 to 11.49). PSMF vs 800 kcal VLED and supervised exercise: at 18 months, mean (SD) weight change in kg was –8.64 (8.36) in the PSMF group, and –12.40 (9.42) in the VLED group. Mean weight change in the PSMF group compared with VLED was –0.20 (95% CI –5.38 to 4.98). PSMF vs 800 kcal VLED and no additional exercise: at 18 months, mean (SD) weight change in kg was –1.13 (6.23) in the PSMF group, and –3.45 (6.89) in the VLED group. Mean weight change in the PSMF group compared with VLED was 2.32 (95% CI –3.16 to 7.80).
Quality and comments	*HTA reported results for four groups. Pavlou 1ce – PSMF (food) and exercise vs VLED (420 kcal) and exercise, Pavlou 1df – PSMF (food) vs VLED (420 kcal), Pavlou 1cg – PSMF and exercise vs VLED (800 kcal) and exercise, and Pavlou 1dh - PSMF vs VLED (800 kcal).* Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Weight data derived from graph and SDs calculated. *Recalculated values presented.*

Other outcomes

Pavlou 1989 1 (in HTA) RCT	
Results	*No other outcomes by different diet groups were reported.*
Quality and comments	…

Reported harms

Pavlou 1989 1 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Pavlou 1989 1 (in HTA) RCT	
Country and setting	USA. Workplace.
Participants (included/excluded)	*Included men, aged 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment.* *Exclusion criteria not stated.*
Recruitment	Men were recruited from the Boston Police Department and the Metropolitan District Commission. No further details reported.
Intervention (mode and intensity)	8 weeks plus 18 months post-treatment follow-up (weekly from baseline to week 8 then at 8 months and 18 months post-treatment)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.
Dropout rates	31% overall at 18 months post-treatment.

Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.3.11 Low-fat diet compared with very-low-fat diet

Weight loss

Dansinger 2005 RCT	
Aim	To assess adherence rates and the realistic clinical effectiveness of four popular diets (Atkins, Zone, Weight Watchers and Ornish) for weight loss and cardiac risk factor reduction. Dietary components only of the programmes were used (see details of intervention later).
Participants	People who were overweight (BMI between 27 and 24 kg/m^2) who also had at least one metabolic cardiac risk factor. 160 total – 81 F, 79 M. Mean (SD) age 51 (9) years low-fat (*n*=40), 49 (12) years very-low-fat (*n*=40). Mean (SD) BMI (kg/m^2) 34 (4.5) low-fat, 35 (3.9) very-low-fat.
Intervention (including details of diet)	*Low fat: aimed for a 40–30–30 balance of % energy from carbohydrate, fat and protein respectively. No further details reported.* *Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.*
Control	Very low fat: aimed for a vegetarian diet containing 10% of energy from fat. No further details reported. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.
Length of follow-up	*12 months*

Results	*At 2 months, mean (SD) weight change in kg was –3.80 (3.60) in the low-fat group and –3.60 (3.40) in the very-low-fat group. Mean weight change in the low-fat group compared with very-low-fat was –0.20 (95% CI –1.73 to 1.33).* *At 6 months, mean (SD) weight change in kg was –3.40 (5.70) in the low-fat group and –3.60 (6.70) in the very low-fat group. Mean weight change in the low-fat group compared with very-low-fat was 0.20 (95% CI –2.53 to 2.93).* *At 12 months, mean (SD) weight change in kg was –3.20 (6.00) in the low-fat group and –3.30 (7.30) in the very-low-fat group. Mean weight change in the low-fat group compared with very-low-fat was 0.10 (95% CI –2.83 to 3.03).* *Weight and BMI were significantly lower than baseline for both groups (*p*≤0.05) but there was no statistically significant difference between the groups.* *In each group, about 25% of participants lost 5% or more of initial body weight, and about 10% lost 10% or more at 12 months.*
Quality and comments	*Zone categorised as low-fat. Ornish diet categorised as very-low-fat.* *Blinded assessment done. ITT analysis done. Randomisation done by computer generated sequence, and good allocation concealment.* *See other sections for comparisons of PSMF, LED, low-fat and very-low-fat (Atkins, Weight Watchers, Zone and Ornish respectively).*

Other outcomes

Dansinger 2005 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was –0.26 (0.90) in the low-fat group, and –0.28 (0.54) in the very-low-fat group. Mean TC change in the low-fat group compared with very-low-fat was 0.02 (95% CI –0.31 to 0.35).* *At 12 months, mean (SD) LDL change in mmol/l was –0.30 (0.87) in the low-fat group, and –0.32 (0.49) in the very-low-fat group. Mean LDL change in the low-fat group compared with very-low-fat was 0.02 (95% CI –0.29 to 0.33).* *At 12 months, mean (SD) HDL change in mmol/l was 0.08 (0.26) in the low-fat group, and –0.01 (0.17) in the very-low-fat group. Mean HDL change in the low-fat group compared with very-low-fat was 0.09 (95% CI –0.01 to 0.19).* *At 12 months, mean (SD) TAG change in mmol/l was 0.03 (1.65) in the low-fat group, and 0.06 (0.40) in the very-low-fat group. Mean TAG change in the low-fat group compared with very-low-fat was –0.30 (95% CI –0.56 to 0.50).* *At 12 months, mean (SD) DBP change in mmHg was –1.20 (9.50) in the low-fat group, and 0.20 (4.60) in the very-low-fat group. Mean DBP change in the low-fat group compared with very-low-fat was –1.40 (95% CI –4.67 to 1.87).* *At 12 months, mean (SD) SBP change in mmHg was 1.40 (15.00) in the low-fat group, and 0.50 (7.70) in the very-low-fat group. Mean SBP change in the low-fat group compared with very-low-fat was 0.90 (95% CI –4.33 to 6.13).* *At 12 months, mean (SD) FPG change in mmol/l was –0.23 (1.00) in the low-fat group, and –0.23 (1.67) in the very-low-fat group. Mean FPG change in the low-fat group compared with very-low-fat was 0.00 (95% CI –0.60 to 0.60).* *At 12 months, the mean energy reductions from baseline (*p*≤0.05) were 251 for low-fat and 192 for very-low-fat. These were not significantly different between groups.* *No significant differences were seen in macronutrient content between any of the groups.* *Group mean adherence scores according to diet records and self-assessment decreased over time, and to a similar extent in all groups. About 25% of each group sustained a mean adherence level of at least 6/10, which 'appeared to delineate a clinically meaningful adherence level'.*
Quality and comments	Converted mg/dl to mmol/l (see paper for conversion rates and values used). Dietary intake was assessed from 3-day diet records at 1, 2, 6 and 12 months.

Reported harms

Dansinger 2005 RCT	
Harms	Common reasons for discontinuation were that the assigned diet was too hard to follow, or not yielding enough weight loss. No diet-related or adverse events or serious adverse effects were found.
Quality and comments	Reasons for discontinuation not reported by group but overall only.

Generalisability

Dansinger 2005 RCT	
Country and setting	USA. Enrolled at an academic medical centre.
Participants (included/excluded)	Included if adults of any age who were overweight (BMI between 27 and 42 kg/m^2) and having at least one of the following metabolic cardiac risk factors: FPG ≥6.1 mmol/l, TC ≥5.2 mmol/l, LDL ≥3.4 mmol/l, HDL ≤1.0 mmol/l, TAG ≥1.7 mmol/l, SBP ≥145 mmHg, DBP ≥90 mmHg, or current use of oral medication to treat hypertension, diabetes, dyslipidaemia. Excluded if unstable chronic illness, insulin therapy, urinary microalbumin of more than two times normal, serum creatinine ≥123.8 μmol/l, clinically significant abnormalities of liver or thyroid test results, weight loss medication or pregnancy.
Recruitment	Newspaper advertisements and TV publicity (local news coverage).
Intervention (mode and intensity)	*Four classes lasting 1 h during the first 2 months. Assessed at baseline, 2, 6 and 12 months (additional dietary assessment at 1 month).*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Team consisted of dietitian and physician who facilitated the meetings.
Dropout rates	*35% low-fat and 50% very-low-fat at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Weight and cardiac risk factors, baseline values carried forward. Dietary intake, baseline or subsequent values used.

1.3.12 Low-energy-diet compared with very-low-fat diet

Weight loss

Dansinger 2005 RCT	
Aim	To assess adherence rates and the realistic clinical effectiveness of four popular diets (Atkins, Zone, Weight Watchers and Ornish) for weight loss and cardiac risk factor reduction. Dietary components only of the programmes were used (see details of intervention later).
Participants	People who were overweight (BMI between 27 and 24 kg/m^2) who also had at least one metabolic cardiac risk factor. 160 total – 81 F, 79 M. Mean (SD) age 49 (10) years LED (*n*=40), 49 (12) years very-low-fat (*n*=40). Mean (SD) BMI (kg/m^2) 35 (3.8) LED, 35 (3.9) very-low-fat.

Intervention (including details of diet)	*LED: number of daily points determined by current weight. Each point was about 50 kcal, and most participants aimed for 24 to 32 points daily (1200 to 1500 kcal). Lists provided by Weight Watchers determined point values of common foods.* *Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.*
Control	Very-low-fat: aimed for a vegetarian diet containing 10% of energy from fat. No further details reported. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2-month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.
Length of follow-up	*12 months*
Results	*At 2 months, mean (SD) weight change in kg was –3.50 (3.80) in the LED group and –3.60 (3.40) in the very-low-fat group. Mean weight change in the LED group compared with very low-fat was 0.10 (95% CI –1.48 to 1.68).* *At 6 months, mean (SD) weight change in kg was –3.50 (5.60) in the LED group and –3.60 (6.70) in the very-low-fat group. Mean weight change in the LED group compared with very low-fat was 0.10 (95% CI –2.61 to 2.81).* *At 12 months, mean (SD) weight change in kg was –3.00 (4.90) in the LED group and –3.30 (7.30) in the very-low-fat group. Mean weight change in the LED group compared with very low-fat was 0.30 (95% CI –2.42 to 3.02).* *Weight and BMI were significantly lower than baseline for both groups (p≤0.05) but there was no statistically significant difference between the groups.* *In each group, about 25% of participants lost 5% or more of initial body weight, and about 10% lost 10% or more at 12 months.*
Quality and comments	*Weight Watchers categorised as LED. Ornish diet categorised as very-low-fat. Blinded assessment done. ITT analysis done. Randomisation done by computer generated sequence, and good allocation concealment.* *See other sections for comparisons of PSMF, LED, low-fat, and very-low-fat (Atkins, Weight Watchers, Zone and Ornish respectively).*

Other outcomes

Dansinger 2005 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was –0.21 (0.62) in the LED group, and –0.28 (0.54) in the very-low-fat group. Mean TC change in the LED group compared with very-low-fat was 0.07 (95% CI –0.18 to 0.32).*

	At 12 months, mean (SD) LDL change in mmol/l was –0.24 (0.69) in the LED group, and –0.32 (0.49) in the very low-fat group. Mean LDL change in the LED group compared with very-low-fat was 0.08 (95% CI –0.18 to 0.34). *At 12 months, mean (SD) HDL change in mmol/l was 0.09 (0.25) in the LED group, and –0.01 (0.17) in the very low-fat group. Mean HDL change in the LED group compared with very-low-fat was 0.10 (95% CI 0.01 to 0.19).* *At 12 months, mean (SD) TAG change in mmol/l was –0.14 (0.69) in the LED group, and 0.06 (0.40) in the very low-fat group. Mean TAG change in the LED group compared with very-low-fat was –0.20 (95% CI –0.45 to 0.05).* *At 12 months, mean (SD) DBP change in mmHg was –1.70 (6.40) in the LED group, and 0.20 (4.60) in the very low-fat group. Mean DBP change in the LED group compared with very-low-fat was –1.90 (95% CI –4.34 to 0.54).* *At 12 months, mean (SD) SBP change in mmHg was –2.70 (13.00) in the LED group, and 0.50 (7.70) in the very low-fat group. Mean SBP change in the LED group compared with very-low-fat was –3.20 (95% CI –7.88 to 1.48).* *At 12 months, mean (SD) FPG change in mmol/l was –0.26 (1.06) in the LED group, and –0.23 (1.67) in the very-low-fat group. Mean FPG change in the LED group compared with very-low-fat was –0.03 (95% CI –0.64 to 0.48).* *At 12 months, the mean energy reductions from baseline (p≤0.05) were 244 for LED and 192 for very-low-fat. These were not significantly different between groups.* *No significant differences were seen in macronutrient content between any of the groups.* *Group mean adherence scores according to diet records and self-assessment decreased over time, and to a similar extent in all groups. About 25% of each group sustained a mean adherence level of at least 6/10, which 'appeared to delineate a clinically meaningful adherence level'.*
Quality and comments	Converted mg/dl to mmol/l (see paper for conversion rates and values used). Dietary intake was assessed from 3-day diet records at 1, 2, 6 and 12 months.

Reported harms

Dansinger 2005 RCT	
Harms	Common reasons for discontinuation were that the assigned diet was too hard to follow, or not yielding enough weight loss. No diet-related or adverse events or serious adverse effects were found.
Quality and comments	Reasons for discontinuation not reported by group but overall only.

Generalisability

Dansinger 2005 RCT	
Country and setting	USA. Enrolled at an academic medical centre.
Participants (included/excluded)	Included if adults of any age who were overweight (BMI between 27 and 42 kg/m^2) and having at least one of the following metabolic cardiac risk factors: FPG ≥6.1 mmol/l, TC ≥5.2 mmol/l, LDL ≥3.4 mmol/l, HDL ≤1.0 mmol/l, TAG ≥1.7 mmol/l, SBP ≥145 mmHg, DBP ≥90 mmHg, or current use of oral medication to treat hypertension, diabetes, dyslipidaemia. Excluded if unstable chronic illness, insulin therapy, urinary microalbumin of more than two times normal, serum creatinine ≥123.8 µmol/l, clinically significant abnormalities of liver or thyroid test results, weight loss medication or pregnancy.
Recruitment	Newspaper advertisements and TV publicity (local news coverage).
Intervention (mode and intensity)	*Four classes lasting 1 h during the first 2 months. Assessed at baseline, 2, 6, and 12 months (additional dietary assessment at 1 month).*

Control (mode and intensity)	As above
Delivery of intervention/control (who)	Team consisted of dietitian and physician who facilitated the meetings.
Dropout rates	*35% LED and 50% very-low-fat diet at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Weight and cardiac risk factors, baseline values carried forward. Dietary intake, baseline or subsequent values used.

1.3.13 Protein-sparing modified fast compared with very-low-fat diet

Weight loss

Dansinger 2005 RCT	
Aim	To assess adherence rates and the realistic clinical effectiveness of four popular diets (Atkins, Zone, Weight Watchers, and Ornish) for weight loss and cardiac risk factor reduction. Dietary components only of the programmes were used (see details of intervention later).
Participants	People who were overweight (BMI between 27 and 24) who also had at least one metabolic cardiac risk factor. 160 total – 81F, 79M. Mean (SD) age 47 (12) years PSMF (*n*=40), 49 (12) years very-low-fat (*n*=40). Mean (SD) BMI 35 (3.5) PSMF, 35 (3.9) very-low-fat.
Intervention (including details of diet)	*PSMF: aimed for less than 20 g of carbohydrate daily, with a gradual increase to 50 g/day.* *Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also, encouraged to follow the assigned diet to the best of their ability until the 2 month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.*
Control	Very-low-fat: aimed for a vegetarian diet containing 10% of energy from fat. No further details reported. Participants met in groups of about ten people, where a dietitian and physician administered diet-specific advice. Meetings were held on four occasions for 1 h during the first 2 months of the study. At the first meeting, the diet assignment was revealed and corresponding rationale, written materials, and official diet cookbook. Subsequent meetings aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Recommendations on supplements, exercise and external support were standardised across all groups. All participants were encouraged to take a daily multivitamin, do at least 60 min exercise per week, and to avoid commercial support services. Also encouraged to follow the assigned diet to the best of their ability until the 2 month assessment, after which encouraged to follow assigned diet according to own self-determined interest level.
Length of follow-up	*12 months*

Results	*At 2 months, mean (SD) weight change in kg was –3.60 (3.30) in the PSMF group and –3.60 (3.40) in the very low-fat group. Mean weight change in the PSMF group compared with very-low-fat was 0.00 (95% CI –1.47 to 1.47).* *At 6 months, mean (SD) weight change in kg was –3.20 (4.90) in the PSMF group and –3.60 (6.70) in the very low-fat group. Mean weight change in the PSMF group compared with very-low-fat was 0.40 (95% CI –2.17 to 2.97).* *At 12 months, mean (SD) weight change in kg was –2.10 (4.80) in the PSMF group and –3.30 (7.30) in the very low-fat group. Mean weight change in the PSMF group compared with very-low-fat was 1.20 (95% CI –1.51 to 3.91).* *Weight and BMI were significantly lower than baseline for both groups (p≤0.05) but there was no statistically significant difference between the groups.* *In each group, about 25% of participants lost 5% or more of initial body weight, and about 10% lost 10% or more at 12 months.*
Quality and comments	*Atkins categorised as PSMF. Ornish diet categorised as very-low-fat.* *Blinded assessment done. ITT analysis done. Randomisation done by computer-generated sequence, and good allocation concealment.* *See other sections for comparisons of PSMF, LED, low fat, and very-low-fat (Atkins, Weight Watchers, Zone and Ornish respectively).*

Other outcomes

Dansinger 2005 RCT	
Results	*Only reported values at 12 months.* *At 12 months, mean (SD) TC change in mmol/l was –0.11 (0.59) in the PSMF group, and –0.28 (0.54) in the very-low-fat group. Mean TC change in the PSMF group compared with very-low-fat was 0.17 (95% CI –0.08 to 0.42).* *At 12 months, mean (SD) LDL change in mmol/l was –0.18 (0.62) in the PSMF group, and –0.32 (0.49) in the very low-fat group. Mean LDL change in the PSMF group compared with very-low-fat was 0.14 (95% CI –0.10 to 0.38).* *At 12 months, mean (SD) HDL change in mmol/l was 0.09 (0.18) in the PSMF group, and –0.01 (0.17) in the very low-fat group. Mean HDL change in the PSMF group compared with very-low-fat was 0.10 (95% CI 0.02 to 0.18).* *At 12 months, mean (SD) TAG change in mmol/l was 0.02 (0.94) in the PSMF group, and 0.06 (0.40) in the very-low-fat group. Mean TAG change in the PSMF group compared with very-low-fat was –0.08 (95% CI –0.40 to 0.24).* *At 12 months, mean (SD) DBP change in mmHg was –1.40 (7.50) in the PSMF group, and 0.20 (4.60) in the very low-fat group. Mean DBP change in the PSMF group compared with very-low-fat was –1.60 (95% CI –4.33 to 1.33).* *At 12 months, mean (SD) SBP change in mmHg was 0.20 (12.00) in the PSMF group, and 0.50 (7.70) in the very low-fat group. Mean SBP change in the PSMF group compared with very-low-fat was –0.30 (95% CI –4.72 to 4.12).* *At 12 months, mean (SD) FPG change in mmol/l was 0.08 (0.77) in the PSMF group, and –0.23 (1.67) in the very low-fat group. Mean FPG change in the PSMF group compared with very-low-fat was 0.31 (95% CI –0.26 to 0.88).* *At 12 months, the mean energy reductions from baseline (*p≤0.05*) were 138 for PSMF and 192 for very-low-fat. These were not significantly different between groups.* *No significant differences were seen in macronutrient content between any of the groups.* *Group mean adherence scores according to diet records and self-assessment decreased over time, and to a similar extent in all groups. About 25% of each group sustained a mean adherence level of at least 6/10, which 'appeared to delineate a clinically meaningful adherence level'.*
Quality and comments	Converted mg/dl to mmol/l (see paper for conversion rates and figures used). Dietary intake was assessed from 3-day diet records at 1, 2, 6 and 12 months.

Reported harms

Dansinger 2005 RCT	
Harms	Common reasons for discontinuation were that the assigned diet was too hard to follow, or not yielding enough weight loss. No diet-related or adverse events or serious adverse effects were found.
Quality and comments	Reasons for discontinuation not reported by group but overall only.

Generalisability

Dansinger 2005 RCT	
Country and setting	USA. Enrolled at an academic medical centre.
Participants (included/excluded)	Included if adults of any age who were overweight (BMI between 27 and 42 kg/m^2) and having at least one of the following metabolic cardiac risk factors: FPG ≥6.1 mmol/l, TC ≥5.2 mmol/l, LD L≥3.4 mmol/l, HDL ≤1.0 mmol/l, TAG ≥1.7 mmol/l, SBP ≥145 mmHg, DBP ≥90 mmHg, or current use of oral medication to treat hypertension, diabetes, dyslipidaemia. Excluded if unstable chronic illness, insulin therapy, urinary microalbumin of more than two times normal, serum creatinine ≥123.8 μmol/l, clinically significant abnormalities of liver or thyroid test results, weight loss medication or pregnancy.
Recruitment	Newspaper advertisements and TV publicity (local news coverage).
Intervention (mode and intensity)	*Four classes lasting 1 h during the first 2 months. Assessed at baseline, 2, 6 and 12 months (additional dietary assessment at 1 month).*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Team consisted of dietitian and physician who facilitated the meetings.
Dropout rates	*48% PSMF and 50% very-low-fat at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Weight and cardiac risk factors, baseline values carried forward. Dietary intake, baseline or subsequent values used.

1.3.14 Low-glycaemic-index (high-protein) diet compared with high-glycaemic-index (standard-protein) diet

Weight loss

Brinkworth 2004 RCT	
Aim	To compare the long-term compliance and effects of two low-fat diets differing in carbohydrate:protein ratio on body composition and biomarkers of CVD in obese people with hyperinsulinaemia.
Participants	People who were overweight (27<BMI (kg/m^2)<43) with a fasting serum insulin >12 mU/l. Total 58 – 45 F, 13 M. Mean age (SD) 52.0 (2.6) years high-protein (HP) (*n*=21), 51.5 (1.6) years standard-protein (SP) (*n*=22). Mean (SD) BMI (kg/m^2) 34.6 (0.9) HP, 33.6 (0.8) SP. Results for completers only.

Intervention (including details of diet)	*HP: 30% energy from protein (about 110 g/ day), 40% of energy from carbohydrate (about 140 g/day) and 30% from fat (about 50 g/day) in the energy restriction phase (about 1500 kcal/day for 12 weeks). During the next 4 weeks, the energy balance phase energy intake was increased to about 2000 kcal/day with the same macronutrient balance (extra 21 g protein).* *Met with a dietitian prior to the study and every 2 weeks up to week 16 for 15–30 min to discuss dietary issues.* *During the following 12 months, participants asked to continue the same dietary pattern, but were not provided with any foodstuffs or dietary counselling.*
Control	SP: 15% energy from protein (about 60 g/day), 55% of energy from carbohydrate (about 200 g/day) and 30% from fat (about 50 g/day) in the energy restriction phase (about 1500 kcal/day for 12 weeks). During the next 4 weeks, the energy balance phase energy intake was increased to about 2000 kcal/day with the same macronutrient balance (extra 7 g protein). Met with a dietitian prior to the study and every 2 weeks up to week 16 for 15–30 min to discuss dietary issues. During the following 12 months, participants asked to continue the same dietary pattern, but were not provided with any foodstuffs or dietary counselling.
Length of follow-up	*68 weeks (16 weeks plus 52)*
Results	*At 16 weeks, mean (SD) weight change in kg was –8.70 (3.21) in the HP group and –9.10 (3.28) in the SP group. Mean weight change in the HP group compared with SP was 0.40 (95% CI –1.54 to 2.34).* *At 68 weeks, mean (SD) weight change in kg was –4.10 (5.96) in the HP group and –2.90 (3.75) in the SP group. Mean weight change in the HP group compared with SP was –1.20 (95% CI –4.19 to 1.79).* *Other time points were shown graphically, but values were not reported.*
Quality and comments	*Blinded assessment not reported. ITT analysis done for completers.* *Randomisation done but no details of process or allocation concealment.*

Due 2004 RCT	
Aim	To evaluate the effects of a fat-reduced HP diet compared with a fat-reduced medium-protein (MP) diet.
Participants	Adults who were overweight (BMI 25–35). Total 50 – 38F 12M. Mean age 39.8 (95% CI 35.8 to 43.8) years HP (*n*=25), 39.4 (95% CI 35.3 to 43.6) years SP (*n*=25). Mean BMI (kg/m^2) 30.0 (95% CI 29.1 to 30.9) HP, 30.8 (95% CI 29.9 to 31.6) SP.
Intervention (including details of diet)	*Diet: HP (25% energy from protein). Energy from fat <30%. Macronutrient composition strictly controlled, but energy intake was ad libitum.* *Instructed not to change physical activity or smoking habits.* *For first 6 months, food provided from study shop only. Dietitian advised on items to ensure that diet adhered to.* *Counselling every 2 weeks from months 6 to 12. No details of content.*
Control	As above, except diet was MP (12% energy from protein).
Length of follow-up	*24 months*

Results	*At 6 months, mean (SD) weight change in kg was –9.40 (8.58) in the HP group and –5.90 (7.58) in the MP group. Mean weight change in the HP group compared with MP was –3.50 (95% CI –8.18 to 1.18).* *At 12 months, mean (SD) weight change in kg was –6.20 (7.67) in the HP group and –4.30 (7.13) in the MP group. Mean weight change in the HP group compared with MP was –1.90 (95% CI –6.45 to 2.65).* *At 24 months, mean (SD) weight change in kg was –6.40 (7.73) in the HP group and –3.20 (6.82) in the MP group. Mean weight change in the HP group compared with MP was –3.40 (95% CI –10.52 to 3.72).* *WC and WHR were significantly reduced in the HP group at 6 months and 12 months.*

	>5 kg		***>10 kg***	
	HP	***MP***	***HP***	***MP***
6 months	*78%*	*61% (NS)*	*39%*	***13% (p<0.05)***
12 months	*57%*	*50% (NS)*	*17%*	***0% (p=0.009)***
24 months	***55%***	***50% (NS)***	***18%***	***0% (NS)***

Quality and comments	*Blinded assessment not reported. ITT analysis unclear (last observation carried forwards [LOCF]) where done, and stated that results were similar).* *Randomisation done but no details of process or allocation concealment. Used HTA formula for weight SDs.*

Other outcomes

Brinkworth 2004 RCT	
Results	*Both diets significantly increased HDL-cholesterol concentrations (p<0.001) and decreased fasting insulin, insulin resistance, intracellular adhesion molecule-1 and C-reactive protein levels (p<0.05). Protein intake was significantly greater in HP during the initial 16 weeks (p<0.001), but decreased in HP and increased in SP during 52-week follow-up, with no difference between groups at week 68, indicating poor long-term dietary adherence behaviour to both dietary patterns.* *DBP fell significantly in the male participants from week 16 to 68, but not for females. However, at 68 weeks, there was no difference between men and women for DBP.*
Quality and comments	…

Due 2004 RCT	
Results	*No significant differences at baseline for dietary intake. Significantly higher % energy from protein was seen in the HP group from 6–12 months (p<0.0001). Conversely, % energy from carbohydrate was significantly lower in the HP group from 6–12 months (p≤0.0005).* *Only significant differences were seen in total energy intake at 6 months (lower in the HP group) and % energy from fat remained similar at all time points.* *No significant differences seen for lipids, glucose, TAG or insulin between the two groups.*
Quality and comments	Dietary records from 6 months onwards – up to 6 months, from shop records.

Reported harms

Brinkworth 2004 RCT	
Harms	The HP diet appeared to have no significant effect on either renal function or bone mineral content.
Quality and	…

comments

Due 2004 RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Brinkworth 2004 RCT	
Country and setting	Australia. Outpatient clinics.
Participants (included/excluded)	Included if aged between 20 and 65 years, Had a fasting serum insulin >12 μmol/l, and BMI between 27 and 43 kg/m^2. Excluded if type 2 diabetes, history of clinically significant illness (liver, unstable cardiovascular, respiratory, gastrointestinal (GI), malignancy), pregnant or lactating.
Recruitment	Advertisements
Intervention (mode and intensity)	*Seen every 2 weeks for 16 weeks*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Dietitian
Dropout rates	*28% HP, 24% SP at 68 weeks*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only. ITT used last-observation carried forward.

Due 2004 RCT	
Country and setting	Denmark. University department.
Participants (included/excluded)	Included if aged 18 to 65 years, BMI 25–35 kg/m^2. No exclusion criteria reported.
Recruitment	No details
Intervention (mode and intensity)	*After 6 months of food provision, seen every 2 weeks for counselling for months 6–12*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Dietitian assisted in food selection. Also dietitian involvement in BT sessions.
Dropout rates	*8% HP and 28% MP at 12 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only

1.4 Behavioural interventions (with or without diet)

1.4.1 Diet and behaviour therapy vs usual care

Weight loss

Munsch 2003 RCT	
Aim	To evaluate the effectiveness of a cognitive BT group therapy programme for the treatment of obesity

Participants	People who were overweight (BMI ≥30 kg/m^2). Total 70 – 52 F, 18 M. Mean age (SD) 49 (12) years F, 45 (14) years M diet+BT (*n*=53), 49 (10) years F, 49 (10) years M usual care (*n*=17). Mean (SD) BMI (kg/m^2) 35.7 (5.6) F, 36.8 (5.2) M diet+BT, 34.0 (3.0) F, 33.4 (2.5) M usual care.
Intervention	*Diet: no details other than 'long term change over to a balanced, fat-reduced nutrition'. Classified as 600 kcal/deficit or low fat.* *BT: self-monitoring, strategies to control eating behaviour, problem analysis and self-observation, alteration of cognitive patterns, social competence, relapse prevention. Adapted from LEARN manual.*
Comparison	Usual care: non-specific comments on weight loss.
Length of follow-up	*12 months*
Results	*At 16 weeks, mean weight change (SD) was –3.80 (6.99) kg in the diet and BT group compared with –0.70 (6.11) kg in the usual care group. Mean weight change in the intervention group compared with usual care was –3.10 (95% CI –7.17 to 0.97).* *At 12 months, mean weight change (SD) was –4.70 (7.25) kg in the diet and BT group compared with –0.40 (6.01) kg in the usual care group. Mean weight change in the intervention group compared with usual care was –4.30 (95% CI –9.02 to 0.42).*
Quality and comments	*Results for GP group only reported (clinic group not randomised). Used HTA formula for SDs.* *Blinded assessment not reported. ITT analysis not done. Random allocation but no description of concealment.* *Study reported significant differences between the two groups at 12 months – not seen in analysis?*

Other outcomes

Munsch 2003 RCT	
Results	*In regard to psychological factors the treatment group showed an increased sense of control over eating behaviour, and feelings of distractibility and hunger were reduced after treatment and at follow-up (*p*<0.05). The diet and BT group showed statistically relevant increases in feelings of attractiveness regarding their body and shape (*p*<0.05).*
Quality and comments	…

Harms

Munsch 2003 RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Munsch 2003 RCT	
Country and setting	Switzerland. GP surgeries
Participants (included/excluded)	Included if BMI ≥30 kg/m^2. Excluded if severe mental disorders, insulin dependent diabetes, hypothyroidism, terminal illness.
Recruitment	From patients and advertisements.
Randomisation	N/R.
Intervention (mode and intensity)	*16 weekly meetings (90 min)*
Duration of active intervention	16 weeks

Comparison (mode and intensity)	Usual care
Delivery of intervention/comparison (who)	Specially trained GPs and tutors.
Dropout rates	*23% diet and BT, 53% usual care at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.4.2 Diet and behaviour therapy vs information

Weight loss

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis (OA)
Participants	People with osteoarthritis, aged ≥60 years who were overweight (BMI ≥28 kg/m^2) Total 316 – 227 F, 89 M. Mean (SD) age years 68 (6.34) years diet+BT (*n*=82), 69 (0.88) years information (*n*=78). Mean (SD) BMI (kg/m^2) 34.5 (5.43) diet+BT, 34.2 (5.30) information.
Intervention	*Diet: to produce and maintain an average weight loss of 5% during the 18-month intervention period. Classified as a 600 kcal/day deficit/LED diet* *BT: self-monitoring, goal setting, cognitive restructuring, problem-solving, and environmental management*
Control	The group met monthly for 1 h for the first 3 months. A health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity and exercise, organised the healthy lifestyle programme. Patients were advised to follow the American College of Rheumatology and European League Against Rheumatism recommendations for weight loss and exercise as treatments for OA. Question-and-answer sessions followed each presentation. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18. During phone contact, information on pain, medication use, illnesses, and hospitalisation was obtained.
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –4.61 (7.22) in the diet and BT group, and –1.10 (6.23) in the information group. Mean weight change in the intervention group compared with information was –3.51 (95% CI –5.60 to –1.42).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated using HTA formula.*

Other outcomes

Messier 2004 RCT	
Results	*The diet and BT group was not significantly different from the healthy lifestyle group for any of the functional or mobility measures.*
Quality and comments	…

Reported harms

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant

Quality and comments	tripped and sustained a laceration to his head. No details of allocation. …

Generalisability

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	Included if aged ≥60 years, calculated BMI ≥28 kg/m^2, knee pain on most days of the month, sedentary activity pattern with <20 min of formal exercise once weekly for the past 6 months, self-reported difficulty in at least one of the following activities ascribed to knee pain: walking one-quarter of a mile (three to four city blocks), climbing stairs, bending, stooping, kneeling (e.g., to pick up clothes), shopping, house cleaning or other self-care activities, getting in and out of bed, standing up from a chair, lifting and carrying groceries, or getting in and out of the bath, radiographic evidence of grade I–III tibiofemoral or patellofemoral OA based on weight-bearing anteroposterior and sunrise view radiographs, and willingness to undergo testing and intervention procedures. Excluded if serious medical condition that prevented safe participation in an exercise programme, including symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, chronic obstructive pulmonary disease, severe insulin-dependent diabetes mellitus, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, and anaemia, a Mini-Mental State Examination score of <24, inability to finish the 18-month study or unlikely to be compliant, inability to walk without a cane or other assistive device, participation in another research study, reported alcohol consumption of >14 drinks per week, ST segment depression of at least 2 mm at an exercise level of 4 metabolic equivalent tasks (METS) or less, hypotension, or complex arrhythmias during a graded exercise test, inability to complete the protocol, in the opinion of the clinical staff, because of frailty, illness, or other reasons.
Recruitment	Mass mailings to age-eligible persons within the target area, targeted mailings to employees of the university and medical centre, presentations to various groups of older adults, mass media advertisements and placement of posters (with pull-off reply cards attached) in strategic locations. Also, strategies were developed to enhance recruitment among racial minorities, including advertisements and interviews on minority-run radio stations, newspaper ads in predominantly African American publications, letters to churches attended mainly by minorities, and inserts in these church bulletins. Initial screening for major eligibility criteria was via telephone.
Intervention (mode and intensity)	*One introductory individual session was followed by 16 weekly sessions (three group sessions and one individual session each month).*
Duration of active intervention	18 months
Control (mode and intensity)	Group met monthly for 1 h for the first 3 months. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18.
Delivery of intervention/control (who)	Diet and BT: N/R Information: health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity and exercise, organised the healthy lifestyle programme.
Dropout rates	*23% activity, 14% information at 24 months*

Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.4.3 Active diet, and behaviour therapy vs passive (information-based) diet and behaviour therapy

Weight loss

Cousins 1992 (in HTA) RCT	
Aim	To assess the effectiveness of a culturally sensitive, family-based weight-loss programme for cardiovascular risk reduction in obese Mexican American women
Participants	Women who were overweight (20 to 100% above IBW). *168 total – all women. Mean (SD) age 33.6 (6.4) years individual group (*n=32*), 33.8 (6.1) years family group (*n=27*), 33.8 (7.0) years control (*n=27*). Mean (SD) BMI* (kg/m^2) *31.7 (5.0) individual group, 30.3 (4.5) family group, 31.6 (4.9) control.*
Intervention	All participants received *Cuidando el Corazon*, a bilingual manual consisting of a low-fat eating plan and behaviour modification strategies; aimed at diet of 1200 kcal (women) 30% of energy from fat (10% unsaturated fat), 20% from protein, 50% from carbohydrate, <300 mg cholesterol/day, advised regarding moderate sodium intake, cookbook of recipes for fat-modified traditional Mexican foods, behaviour modification strategies such as maintaining weight loss, problem-solving and preventing relapse were described in simple terms and manual translated into Spanish. Individual group: individualised instruction by bilingual dietitian on nutrition, feedback on food records and behaviour modification techniques, group exercise, food tasting, cooking demonstrations; last 6 months group leaders focused on preventing or minimising relapse and emphasised problem-solving approach to problems of low-fat eating and exercise, where participants could enlist support of the group; taught using techniques specifically for adults with limited literacy skills. Family group: same sessions as individual group except that spouses encouraged to attend sessions (separate classes for children); manual modified to include information on partner support and to encourage family changes in eating and exercise behaviours.
Control	*All participants received* Cuidando el Corazon*, a bilingual manual consisting of a low-fat eating plan and behaviour modification strategies; aimed at diet of 1200 kcal (women) 30% energy as fat (10% unsaturated fat), 20% as protein, 50% as carbohydrate, <300 mg cholesterol/day, advised regarding moderate sodium intake, cookbook of recipes for fat-modified traditional Mexican foods, behaviour modification strategies such as maintaining weight loss, problem-solving and preventing relapse were described in simple terms and manual translated into Spanish.*
Length of follow-up	12 months

Results	*At 3 months, mean weight change (SD) was –2.60 (6.65) kg in the individual group compared with –0.90 (6.17) kg in the information group. Mean weight change in the individual group compared with the information group was –1.70 (95% CI –5.77 to 2.37).* *At 6 months, mean weight change (SD) was –3.30 (6.85) kg in the individual group compared with –0.20 (5.97) kg in the information group. Mean weight change in the individual group compared with the information group was –3.10 (95% CI –7.12 to 0.92).* *At 12 months, mean weight change (SD) was –2.10 (6.51) kg in the individual group compared with –0.70 (6.11) kg in the information group. Mean weight change in the individual group compared with the information group was –1.40 (95% CI –5.41 to 2.61).* *At 3 months, mean weight change (SD) was –3.00 (6.76) kg in the family group compared with –0.90 (6.17) kg in the information group. Mean weight change in the family group compared with the information group was –2.10 (95% CI –6.22 to 2.02).* *At 6 months, mean weight change (SD) was –4.50 (7.19) kg in the family group compared with –0.20 (5.97) kg in the information group. Mean weight change in the family group compared with the information group was –4.30 (95% CI –8.44 to –0.16).* *At 12 months, mean weight change (SD) was –3.80 (6.99) kg in the family group compared with–0.70 (6.11) kg in the information group. Mean weight change in the family group compared with the information group was –3.10 (95% CI –7.25 to 1.05).*
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Mean change in weight at 12 months calculated from actual values, and SDs also calculated. Halved control groups for analysis

Wing 1998 (in HTA) RCT	
Aim	To assess the effect of lifestyle intervention over 2 years on changes in weight, CHD risk factors, and incidence of diabetes in overweight adults with a parental history of diabetes
Participants	Adults aged 40 to 55 years who did not have diabetes, and were overweight (30 to 100% of IBW). *154 total – 122 F, 32 M. Mean (SD) age 45.0 (4.7) years diet (*n=37*), 45.3 (4.9) control (*n=40*). Mean (SD) BMI (kg/*m^2*) 36.1 (4.1) diet, 36.0 (5.4) control.*
Intervention	Diet: 800–1000 kcal/day weeks 1–8 then adjusted to 1200–1500 kcal/day by week 16, food diaries reviewed and feedback given, meal plans and shopping lists, behavioural or nutritional topic given at each session.
Control	*Participants received LEARN behavioural manual with information on healthy eating, exercise and behavioural strategies; participants encouraged to lose weight and exercise on their own, only participated in the assessments*
Length of follow-up	24 months
Results	*At 6 months, mean weight change (SD) was –9.10 (6.40) kg in the diet and BT group compared with –1.50 (2.70) kg in the control group. Mean weight change in the intervention group compared with control was –7.60 (95% CI –9.92 to –5.28).* At 12 months, mean weight change (SD) was –5.50 (6.90) kg in the diet and BT group compared with –0.30 (4.50) kg in the control group. Mean weight change in the intervention group compared with control was –5.20 (95% CI –8.07 to –2.33). At 24 months, mean weight change (SD) was –2.10 (7.60) kg in the diet and BT group compared with –0.30 (4.50) kg in the control group. Mean weight change in the intervention group compared with control was –1.80 (95% CI –4.77 to 1.17)
Quality and comments	Author confirmed main study and sub-study results. Blinded assessment done. ITT analysis done. Random allocation but no description of concealment.

Other outcomes

Cousins 1992 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Wing 1998 (in HTA) RCT	
Results	*At 6 months, mean (SD) TC change in mmol/l was –0.49 (0.71) in the diet group, and 0.12 (0.50) in the control group. Mean TC change in the diet group compared with control was –0.61 (95% CI –0.90 to –0.32).* *At 6 months, mean (SD) LDL change in mmol/l was –0.32 (0.60) in the diet group, and 0.08 (0.46) in the control group. Mean LDL change in the diet group compared with control was –0.40 (95% CI –0.65 to –0.15).* *At 6 months, mean (SD) HDL change in mmol/l was –0.10 (0.17) in the diet group, and –0.02 (0.11) in the control group. Mean HDL change in the diet group compared with control was –0.08 (95% CI –0.15 to –0.01).* *At 6 months, mean (SD) TAG change in mmol/l was –0.30 (1.45) in the diet group, and 0.29(0.32) in the control group. Mean TAG change in the diet group compared with control was –0.59 (95% CI –1.08 to –0.10).* *At 6 months, mean (SD) DBP change in mmHg was –6.20 (6.90) in the diet group, and –2.20 (8.00) in the control group. Mean DBP change in the diet group compared with control was –4.00 (95% CI –7.59 to –0.41).* *At 6 months, mean (SD) SBP change in mmHg was –10.20 (9.20) in the diet group, and –2.00 (10.50) in the control group. Mean SBP change in the diet group compared with control was –8.20 (95% CI –12.95 to –3.45).* *At 6 months, mean (SD) FPG change in mmol/l was –0.20 (0.40) in the diet group, and 0.10 (0.50) in the control group. Mean FPG change in the diet group compared with control was –0.30 (95% CI –0.52 to –0.08).* *At 6 months, mean (SD) change in %HbA_{1c} was 0.10 (0.50) in the diet group, and 0.20 (0.40) in the control group. Mean %HbA_{1c} change in the diet group compared with control was –0.10 (95% CI –0.32 to 0.12).* At 12 months, mean (SD) TC change in mmol/l was 0.26 (0.76) in the diet group, and 0.39 (0.70) in the control group. Mean TC change in the diet group compared with control was –0.13 (95% CI –0.49 to 0.23). At 12 months, mean (SD) LDL change in mmol/l was 0.12 (0.73) in the diet group, and 0.24 (0.66) in the control group. Mean LDL change in the diet group compared with control was –0.12 (95% CI –0.47 to 0.23). At 12 months, mean (SD) HDL change in mmol/l was 0.10 (0.16) in the diet group, and 0.08 (0.16) in the control group. Mean HDL change in the diet group compared with control was 0.02 (95% CI –0.06 to 0.10). At 12 months, mean (SD) TAG change in mmol/l was 0.55 (3.77) in the diet group, and 0.40 (1.25) in the control group. Mean TAG change in the diet group compared with control was 0.15 (95% CI –1.21 to 1.51). At 12 months, mean (SD) DBP change in mmHg was 3.40 (8.10) in the diet group, and 4.90 (8.20) in the control group. Mean DBP change in the diet group compared with control was –1.50 (95% CI –5.57 to 2.57). At 12 months, mean (SD) SBP change in mmHg was 1.30 (8.30) in the diet group, and 1.10 (9.60) in the control group. Mean SBP change in the diet group compared with control was 0.20 (95% CI –4.30 to 4.70). At 12 months, mean (SD) FPG change in mmol/l was 0.20 (0.80) in the diet group, and 0.00 (0.60) in the control group. Mean FPG change in the diet group compared with control was 0.20 (95% CI –0.15 to 0.55). At 24 months, mean (SD) TC change in mmol/l was –0.12 (0.61) in the diet group, and 0.18 (0.53) in the control group. Mean TC change in the diet group compared with control was –0.30 (95% CI –0.58 to –0.02). At 24 months, mean (SD) LDL change in mmol/l was –0.16 (0.63) in the diet

	group, and 0.03 (0.46) in the control group. Mean LDL change in the diet group compared with control was –0.19 (95% CI –0.45 to 0.07). At 24 months, mean (SD) HDL change in mmol/l was 0.02 (0.20) in the diet group, and 0.04 (0.24) in the control group. Mean HDL change in the diet group compared with control was –0.02 (95% CI –0.13 to 0.09). At 24 months, mean (SD) TAG change in mmol/l was 0.19 (2.42) in the diet group, and 0.52 (1.14) in the control group. Mean TAG change in the diet group compared with control was –0.33 (95% CI –1.23 to 0.57). At 24 months, mean (SD) DBP change in mmHg was 3.00 (7.80) in the diet group, and 2.00 (8.00) in the control group. Mean DBP change in the diet group compared with control was 1.00 (95% CI –2.82 to 4.82). At 24 months, mean (SD) SBP change in mmHg was –0.80 (9.40) in the diet group, and –1.50 (12.00) in the control group. Mean SBP change in the diet group compared with control was 0.70 (95% CI –4.55 to 5.95). At 24 months, mean (SD) FPG change in mmol/l was 0.30 (1.00) in the diet group, and 0.20 (0.40) in the control group. Mean FPG change in the diet group compared with control was 0.10 (95% CI –0.26 to 0.46). At 24 months, mean (SD) change in %HbA_{1c} was –0.10 (0.50) in the diet group, and –0.10 (0.30) in the control group. Mean %HbA_{1c} change in the diet group compared with control was 0.00 (95% CI –0.20 to 0.20). *At 6, 12 and 24 months, the diet group reported significant decreases from baseline in energy intake and percentage of energy from fat. Smaller, often non-significant decreases were also seen in the control group.* *At 24 months, the relative risk (of weight loss of 4.5 kg compared with no weight loss) of developing diabetes in the diet group was about 0.88 and about 0.89 in the control group. For people with impaired glucose tolerance (IGT), the relative risks were about 0.96 and 0.88 respectively.*
Quality and comments	Dietary intake assessed using self-completed questionnaires and 3-day food diaries.

Reported harms

Cousins 1992 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wing 1998 (in HTA) RCT	
Harms	7% in the control group and 30.3% of the diet group developed diabetes during the 24-month study. The development of diabetes was associated with increased initial IGT.
Quality and comments	…

Generalisability

Cousins 1992 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if Mexican American women, ?married, aged 18–45 years, 20–100% above IBW.* *Excluded if hypertension (DBP ≥115 mmHg), diabetes (fasting plasma glucose ≥140 mg/dl), chronic illness with diet or exercise recommendations different from those in the study.*
Recruitment	Media promotion, personal contacts in the local community (mainly churches and health agencies).

Intervention (mode and intensity)	12 months, contacted 37 times (baseline then weekly group sessions for initial 24 weeks then 6 monthly sessions up to month 12)
Control (mode and intensity)	*Unclear but presumed contacted only at baseline and at 12 months*
Delivery of intervention/control (who)	Classes taught by bilingual registered dietitians.
Dropout rates	49% overall at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	*Data for completers only.*

Wing 1998 (in HTA) RCT	
Country and setting	USA. No further details –university hospital?
Participants (included/excluded)	Included if aged 40–55 years, non-diabetic (confirmed by oral glucose tolerance test [OGTT]), 1 or 2 biological parents with type 2 diabetes, 30–100% above IBW. Excluded if diagnosis of diabetes.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*2 years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then 2 × 6 week course during second year).*
Control (mode and intensity)	Contacted at baseline, 6 months, 1 year and at 2 years.
Delivery of intervention/control (who)	Group meetings were led by a multidisciplinary team, including a behaviour therapist and a registered dietitian.
Dropout rates	*5% diet and 23% control at 24 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.4.4 Family vs individual treatment

Weight loss

Cousins 1992 (in HTA) RCT	
Aim	To assess the effectiveness of a culturally sensitive, family-based weight-loss programme for cardiovascular risk reduction in obese Mexican American women
Participants	Women who were overweight (20 to 100% above IBW). *168 total – all women. Mean (SD) age 33.6 (6.4) years individual group (n=32), 33.8 (6.1) years family group (n=27), 33.8 (7.0) years control (n=27). Mean (SD) BMI (kg/m^2) 31.7 (5.0) individual group, 30.3 (4.5) family group, 31.6 (4.9) control.*

Intervention	All participants received *Cuidando el Corazon*, a bilingual manual consisting of a low-fat eating plan and behaviour modification strategies; aimed at diet of 1200 kcal (women) 30% of energy from fat (10% unsaturated fat), 20% from protein, 50% from carbohydrate, <300 mg cholesterol/day, advised regarding moderate sodium intake, cookbook of recipes for fat-modified traditional Mexican foods, behaviour modification strategies such as maintaining weight loss, problem-solving and preventing relapse were described in simple terms and manual translated into Spanish. Individual group: individualised instruction by bilingual dietitian on nutrition, feedback on food records and behaviour modification techniques, group exercise, food tasting, cooking demonstrations; last 6 months group leaders focused on preventing or minimising relapse and emphasised problem-solving approach to problems of low-fat eating and exercise, where participants could enlist support of the group; taught using techniques specifically for adults with limited literacy skills. Family group: same sessions as individual group except that spouses encouraged to attend sessions (separate classes for children); manual modified to include information on partner support and to encourage family changes in eating and exercise behaviours.
Control	*All participants received* Cuidando el Corazon*, a bilingual manual consisting of a low-fat eating plan and behaviour modification strategies; aimed at diet of 1200 kcal (women) 30% of energy from fat (10% unsaturated fat), 20% from protein, 50% from carbohydrate, <300 mg cholesterol/day, advised regarding moderate sodium intake, cookbook of recipes for fat-modified traditional Mexican foods, behaviour modification strategies such as maintaining weight loss, problem-solving and preventing relapse were described in simple terms and manual translated into Spanish.*
Length of follow-up	12 months
Results	*At 3 months, mean weight change (SD) was –3.00 (6.76) kg in the family group compared with –2.60 (6.65) kg in the individual group. Mean weight change in the family group compared with the individual group was –0.40 (95% CI –3.84 to 3.04).* *At 6 months, mean weight change (SD) was –4.50 (7.19) kg in the family group compared with –3.30 (6.85) kg in the individual group. Mean weight change in the family group compared with the individual group was –2.40 (95% CI –6.00 to 1.20).* At 12 months, mean weight change (SD) was –3.80 (6.99) kg in the family group compared with –2.10 (6.51) kg in the individual group. Mean weight change in the family group compared with the individual group was –1.70 (95% CI –5.17 to 1.77).
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Mean change in weight at 12 months calculated from actual values, and SDs also calculated.

Black 1984 (in HTA) RCT	
Aim	To determine if spouse attendance at treatment sessions and participation in behavioural contracting would produce greater weight losses than other levels of spouse involvement.
Participants	Married women who were overweight (at least 10% overweight) and whose husband was willing to participate and provide support. *36 total – all women. Mean age 35.1 years overall. Mean weight (kg) 77.3 overall. Individual group (*n=12*), passive spouse involvement (*n=12*), active spouse involvement (*n=12*).*

Intervention	All participants received 90 min introductory meeting and signed contract to complete daily food record and record of non-routine physical activity for 2 weeks, 4 behavioural contracts written during 10 weeks focusing on changing eating and exercise habits. Passive spouse involvement: husbands attended as passive observers not encouraged to help their wives, counsellor negotiated and co-signed contracts. Active spouse involvement: husbands attended and actively participated in sessions and contracts specified ways husband could help their wives, spouse negotiated and co-signed contracts.
Control	*All participants received 90 min introductory meeting and signed contract to complete daily food record and record of non-routine physical activity for 2 weeks, 4 behavioural contracts written during 10 weeks focusing on changing eating and exercise habits.* *Individual group: participants attended alone, counsellor negotiated and co-signed contracts.*
Length of follow-up	4 years (only 12-month data reported due to exclusions and small numbers)
Results	*At 10 weeks, mean weight change (SD) was –4.61 (7.22) kg in the active family group compared with –3.71 (6.96) kg in the individual group. Mean weight change in the family group compared with the individual group was –0.90 (95% CI –6.83 to 5.03).* At 12 months, mean weight change (SD) was –7.04 (7.91) kg in the active family group compared with –7.42 (8.01) kg in the individual group. Mean weight change in the family group compared with the individual group was 0.38 (95% CI –6.27 to 7.03).
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. *SDs calculated using HTA formula. Slight differences in figures from HTA due to conversions and calculation roundings.*

Murphy 1982 (in HTA) RCT	
Aim	To assess the effect of spouse involvement on weight loss and maintenance
Participants	Couples, at least of whom was overweight (20 to 80% over IBW) 75 total – 50 F, 25 M. Mean age 35.3 years individual, one party contracts (*n*=13), 39.7 years individual, two party contracts (*n*=13), 42.3 years family, one party contracts (*n*=13), 47.5 years family, two party contracts (*n*=12), 42.0 years supportive group (*n*=11), 39.1 years waiting list control (*n*=13). Mean BMI 31.50, 32.03, 29.94, 30.49, 31.97, 29.89 kg/m^2 respectively.
Intervention	Individual, one party contracts: received treatment manual which focused on three meals per day and occasional snacks to reduce energy intake (minimum 1000 kcal/day) and increasing energy expenditure through walking; participants attended alone and entered into four contingency contracts regarding energy and nutrition, eating habits, exercise and problem behaviours; participants self-selected rewards and punishments. Individual, two party contracts: received same manual except for contingency contracts, attended alone, both participant and spouse agreed contingency contracts and spouse encouraged to actively participate in assisting with compliance and controlling rewards (mutually rewarding and/or punishing). Family, one party contracts: received identical manual as Individual, one party group, attended with spouse, participant alone responsible for contingency compliance, rewards and punishment Family, two party contracts: received identical manual to Individual, two party group, both participant and spouse attended sessions and both took part in contingency contracts. Supportive: attended alone, did not receive manual or enter into contingency contracts, group support format with therapist acting as facilitator, discussed possible strategies for successful weight loss.
Control	*Waiting list control for initial 10 weeks only, no treatment received, weight measured at week 1 and week 10.*

Length of follow-up	4 years
Results	*At 10 weeks, mean weight change (SD) was –8.16 (8.23) kg in the family, one party contracts group compared with –7.08 (7.92) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was–1.08 (95% CI –10.14 to 7.98).* *At 10 weeks, mean weight change (SD) was –7.62 (8.07) kg in the family, two party contracts group compared with –6.85 (7.85) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was –0.77 (95% CI –8.84 to 7.30).* *At 15 weeks, mean weight change (SD) was –9.43 (8.59) kg in the family, one party contracts group compared with –7.98 (8.17) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was –1.45 (95% CI –11.11 to 8.21).* *At 15 weeks, mean weight change (SD) was –9.66 (8.65) kg in the family, two party contracts group compared with –8.30 (8.26) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was –1.36 (95% CI –9.93 to 7.21).* *At 22 weeks, mean weight change (SD) was –10.34 (8.84) kg in the family, one party contracts group compared with –9.39 (8.57) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was –0.95 (95% CI –11.30 to 9.40).* *At 22 weeks, mean weight change (SD) was –10.89 (9.00) kg in the family, two party contracts group compared with –9.25 (8.53) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was –1.64 (95% CI –10.52 to 7.24).* *At 36 weeks, mean weight change (SD) was –6.89 (7.87) kg in the family, one party contracts group compared with –9.53 (8.61) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was 2.64 (95% CI –7.11 to 12.39).* *At 36 weeks, mean weight change (SD) was –8.21 (8.24) kg in the family, two party contracts group compared with –9.53 (8.61) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was1.32 (95% CI –8.39 to 11.03).* At 12 months, mean weight change (SD) was –5.44 (7.46) kg in the family, one party contracts group compared with –3.18 (6.81) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was –2.26 (95% CI –12.16 to 7.64). At 12 months, mean weight change (SD) was –8.75 (8.39) kg in the family, two party contracts group compared with –3.49 (6.90) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was –5.26 (95% CI –13.28 to 2.76). At 24 months, mean weight change (SD) was –3.36 (6.86) kg in the family, one party contracts group compared with –2.59 (6.65) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was –0.77 (95% CI –8.54 to 7.00). At 24 months, mean weight change (SD) was –7.21 (7.96) kg in the family, two party contracts group compared with 2.54 (6.63) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was –9.75 (95% CI –17.14 to –2.36). At 48 months, mean weight change (SD) was 0.73 (6.12) kg in the family, one party contracts group compared with –4.20 (7.10) kg in the individual, one party contracts group. Mean weight change in the family group compared with the individual group was 4.93 (95% CI –3.86 to 13.72). At 48 months, mean weight change (SD) was –2.87 (6.73) kg in the family, two party contracts group compared with 5.67 (7.52) kg in the individual, two party contracts group. Mean weight change in the family group compared with the individual group was –8.54 (95% CI –17.67 to 0.59).

Quality and comments	Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. SDs calculated. *HTA analysis compares ind-1 party vs family-1 party (Murphy 1982a) and ind-2 party vs family-2 party (Murphy 1982b). Again, some slight differences to HTA due to calculations.*

Pearce 1981 (in HTA) RCT	
Aim	To evaluate the effect of spouse training for long-term weight loss.
Participants	Married women who were overweight (at least 9 kg overweight or 20% above IBW Metropolitan Life Insurance norms) *68 total – all women. Mean age 39.0 years overall. Mean weight 87.43 kg overall. 14 women were allocated to the active spouse group and 13 to the individual group.*
Intervention	All participants advised to reduce energy intake to participants pre-treatment weight × 7 in pounds (1350 kcal/day), minimum 1000 kcal/day and advised to increase physical activity if weight not lost. Cooperative (active) spouse group: training in behavioural self-control including self-monitoring, imagery techniques, stimulus control and behaviour management methods. Spouses attended and actively helped wives to lose weight, spouses monitored each other's behaviour. Individual group: training in behavioural self-control including self-monitoring, imagery techniques, stimulus control and behaviour management methods. Spouses not involved and wives attended alone, wife unobtrusively monitored husbands behaviour. Non-participating spouse group: training in behavioural self-control including self-monitoring, imagery techniques, stimulus control and behaviour management methods. Spouse sent letter asking them to detach themselves from wife's weight losing efforts, wife attended alone and self-monitored and unobtrusively monitored husbands behaviour. Non-BT: focus directed at hypothetical and underlying causes of over eating, no training on behavioural techniques, attention diverted from current behaviours to past ones.
Control	*Waiting list control, participants received treatment after initial 10 weeks (therefore data not used for subsequent analyses)*
Length of follow-up	12 months
Results	*At 10 weeks, mean weight change (SD) was –6.50 (2.91) kg in the active spouse group compared with –4.32 (2.45) kg in the individual group. Mean weight change in the family group compared with the individual group was –2.18 (95% CI –4.20 to –0.16).* *At 22 weeks, mean weight change (SD) was –8.18 (4.74) kg in the active spouse group compared with –4.55 (4.31) kg in the individual group. Mean weight change in the family group compared with the individual group was –3.63 (95% CI –7.25 to –0.01).* *At 36 weeks, mean weight change (SD) was –7.47 (5.08) kg in the active spouse group compared with –3.42 (4.37) kg in the individual group. Mean weight change in the family group compared with the individual group was –4.05 (95% CI –7.84 to –0.26).* At 12 months, mean weight change (SD) was –8.25 (5.38) kg in the active spouse group compared with –2.16 (5.97) kg in the individual group. Mean weight change in the family group compared with the individual group was –6.09 (95% CI –10.64 to –1.54).
Quality and comments	Blinded assessment not reported. ITT analysis not done. Random allocation but no description of concealment. Only used active spouse group vs individual group for comparison.

Rosenthal 1980 (in HTA) RCT	
Aim	To compare the effectiveness of different degrees of husband involvement in the wives' weight loss effort.

Participants	Married women who were overweight (10% above IBW). *43 total – all women. Mean age 34.5 years overall. Mean BMI 27.56 kg/m*^{2} *spouse involved throughout (n=4 completed), 29.29 some spouse and some individual therapy (n=7 completed), 28.80 individual only (n=9 completed). Mean BMI for first two groups combined 28.43.*
Intervention	Spouse involved throughout: husband attended all eight session with wives, “Slim chance in a fat world” weight loss programme, husband assigned readings and informed of behavioural ways in which they could help their wives to lose weight; sessions 5 to 8 discussed couples specific situations. Spouse and individual: husband attended first four sessions to learn techniques for helping their wives to lose weight then wives attended alone for following sessions, identical weight loss programme as above.
Control	*Individual only: no husband involvement, identical weight loss programme as above.*
Length of follow-up	186 weeks (30 weeks treatments then 3 year follow-up).
Results	At 186 weeks, mean weight change (SD) was –4.37 (7.15) kg in the active spouse group compared with –3.62 (6.94) kg in the individual group. Mean weight change in the family group compared with the individual group was –0.75 (95% CI –6.95 to 5.45).
Quality and comments	Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. Combined results for spouse throughout and spouse and individual groups. SDs calculated.

Wing 1999 (in HTA) RCT	
Aim	To evaluate the effectiveness of a more comprehensive social support condition on the prevention of weight gain during a 6-month maintenance period.
Participants	Healthy people who were overweight (6.8 to 31.8 kg above IBW). *166 total – 84 F, 82 M. Mean (SD) age 41.8 (9.2) years individual (n=38), 43.5 (7.8) years assigned team (n=48), 40.6 (8.3) years non-encouraged friends (n=40), 43.8 (8.6) years encouraged friends (n=40). Mean (SD) BMI (kg/m*^{2} *) 30.6 (3.7) individual, 31.8 (3.1) assigned team, 32.1 (3.7) non-encouraged friends, 30.3 (4.0) encouraged friends.*
Intervention	All participants advised to eat no more than 1000 kcal/day with 22 g of fat if weighed less than 90.7 kg at baseline or no more than 1500 kcal/day with 33 g of fat if baseline weight more than 90.7 kg; given grocery lists and meals plans weekly during initial 16 weeks, exercise prescribed in gradual increments up to 100 kcal/week expenditure (equivalent to walking for 2 miles on 5 days per week), food and exercise diaries completed during 16 weeks, behavioural lessons focused on problem-solving, assertion, stimulus control, developing social support, dealing with high risk situations, cognitions and maintenance strategies. Non-encouraged friends: recruited with friends but relationships among and between teams not acknowledged, identical programme as Individual group. Encouraged friends: recruited with four friends whom became natural team and received same social support as assigned team.

Control	*All participants advised to eat no more than 1000 kcal/day with 22 g of fat if weighed less than 90.7 kg at baseline or no more than 1500 kcal/day with 33 g of fat if baseline weight more than 90.7 kg; given grocery lists and meals plans weekly during initial 16 weeks, exercise prescribed in gradual increments up to 100 kcal/week expenditure (equivalent to walking for 2 miles 5 days per week), food and exercise diaries completed during 16 weeks, behavioural lessons focused on problem-solving, assertion, stimulus control, developing social support, dealing with high risk situations, cognitions and maintenance strategies.* *Individual: recruited alone with no effort to increase communication in group, $25 deposit refunded for attending each follow-up at months 4 and 10.* *Assigned team: participants assigned to a team of four members and given social support intervention involving intra-group activities such as calling other members of their team to provide support, group assignments and an intra-group competition with team who had largest number of its members retaining their weight loss in full from months 4–7 and months 4–10, jackpot consisted of $25 of each participants deposit.*
Length of follow-up	16 months
Results	*At 4 months, mean weight change (SD) was –8.80 (8.41) kg in the intervention (friends) group compared with –6.70 (7.81) kg in the control (non-friends) group. Mean weight change in the friends group compared with the non-friends group was –2.10 (95% CI –4.57 to 0.37).* *At 10 months, mean weight change (SD) was –8.70 (8.38) kg in the intervention (friends) group compared with –5.80 (7.56) kg in the control (non-friends) group. Mean weight change in the friends group compared with the non-friends group was –2.90 (95% CI –5.33 to –0.47).* At 16 months, mean weight change (SD) was –4.70 (7.25) kg in the intervention (friends) group compared with –3.00 (6.76) kg in the control (non-friends) group. Mean weight change in the friends group compared with the non-friends group was –1.70 (95% CI –3.84 to 0.44).
Quality and comments	Assessed intervention groups and control groups together for analysis. Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. *Friends could include family members. No details of how many friends were family members were given. Also groups of four rather than couples in other trials.* *Added to 18 months summary – not sure why as only 16-month follow-up? SDs calculated using HTA formula.*

Wing 1991b (in HTA) RCT	
Aim	To test the effectiveness of a 'family-based' approach for weight loss in people with type 2 diabetes
Participants	*People with type 1 diabetes who were overweight (20% or more over IBW).* *43 total=25 F, 18 M. Mean (SD) age 53.6 (7.7) years spouse (*n=24*), 51.2 (7.3) years individual (*n=25*). Mean (SD) BMI (kg/m^2) 35.68 (5.76) spouse, 36.64 (5.77) individual.*
Intervention	All participants received behavioural weight loss programme consisting of stimulus control, problem-solving, assertion, goal setting and cognitive techniques; participants advised to monitor energy intake to between 1200–1500 kcal/day with a reduction in fat intake and simple carbohydrate and increase in fibre; stepwise goals for walking with final goal to expend 100 kcal/week; deposit refunded according to weight loss and attendance. Spouse participated in all aspects of programme and no distinction made in treatment between participant and spouse, half of therapy sessions focused on social support and behavioural marital therapy literature, e.g. mutual positive reinforcement

Control	*All participants received behavioural weight loss programme consisting of stimulus control, problem-solving, assertion, goal setting and cognitive techniques; participants advised to monitor energy intake to between 1200–1500 kcal/day with a reduction in fat intake and simple carbohydrate and increase in fibre; stepwise goals for walking with final goal to expend 100 kcal/week; deposit refunded according to weight loss and attendance.*
Length of follow-up	72 weeks
Results	*At 5 months (20 weeks), mean weight change (SD) was –8.66 (5.08) kg in the active spouse group compared with –9.03 (8.26) kg in the individual group. Mean weight change in the family group compared with the individual group was 0.37 (95% CI –3.67 to 4.41).* At 18 months (72 weeks), mean weight change (SD) was –3.18 (5.31) kg in the active spouse group compared with –5.26 (10.39) kg in the individual group. Mean weight change in the family group compared with the individual group was 2.08 (95% CI –2.76 to 6.92).
Quality and comments	Blinded assessment not done. ITT analysis possibly done. Random allocation but no description of concealment.

Other outcomes

Cousins 1992 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Black 1984 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Murphy 1982 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Pearce 1981 (in HTA) RCT	
Results	*There was no difference in the daily energy intake or compliance scores between the two groups.*
Quality and comments	Daily records of energy intake and self-reported compliance scores.

Rosenthal 1980 (in HTA) RCT	
Results	*Some outcomes related to the perceptions of the wives and the husbands were reported. These consistently showed that involving husbands in the treatment of women who were overweight enhanced weight loss, but that this effect may not be maintained over time.*
Quality and comments	…

Wing 1999 (in HTA) RCT	
Results	*There was a better attendance for people recruited with friends compared with the other group at 16 months (*p<0.008*).*
Quality and comments	…

Wing 1991b (in HTA) RCT	
Results	*At 20 weeks, mean (SD) %HbA$_{1c}$ change was –1.20 (1.90) in the family group, and –2.10 (2.10) in the individual group. Mean %HbA$_{1c}$ change in the family group compared with the individual group was 0.90 (95% CI –0.30 to 2.10).* At 72 weeks, mean (SD) %HbA$_{1c}$ change was –0.10 (1.90) in the family group, and –0.70 (2.70) in the individual group. Mean %HbA$_{1c}$ change in the family group compared with the individual group was 0.60 (95% CI –0.78 to 1.98). *At 20 weeks, mean (SD) FPG change in mmol/l was –2.78 (2.89) in the family group, and –3.56 (4.61) in the individual group. Mean FPG change in the family group compared with the individual group was 0.78 (95% CI –1.49 to 3.05).* At 72 weeks, mean (SD) FPG change in mmol/l was –0.61 (3.39) in the family group, and –2.00 (4.72) in the individual group. Mean FPG change in the family group compared with the individual group was 1.39 (95% CI –1.04 to 3.82). *Participants in both groups consumed significantly less energy over time, but those in the individual group had a significant greater decrease than those in the spouse group. Other outcomes such as % energy from fat, improved in both groups but were not significantly different between groups.* *There was a significant interaction of gender and treatment, such that women did better when treated with a spouse and men did better when treated individually.*
Quality and comments	Intake and exercise data were self-reported.

Reported harms

Cousins 1992 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Black 1984 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Murphy 1982 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Pearce 1981 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Rosenthal 1980 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wing 1999 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wing 1991b (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Cousins 1992 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if Mexican American women, married?, aged 18–45 years, 20–100% above IBW.* *Excluded if hypertension (DBP ≥115 mmHg), diabetes (fasting plasma glucose ≥140 mg/dl), chronic illness with diet or exercise recommendations different from those in the study.*
Recruitment	Media promotion, personal contacts in the local community (mainly churches and health agencies).
Intervention (mode and intensity)	12 months, contacted 37 times (baseline then weekly group sessions for initial 24 weeks then 6 monthly sessions up to month 12)
Control (mode and intensity)	*Unclear but presumed contacted only at baseline and at 12 months*
Delivery of intervention/control (who)	Classes taught by bilingual registered dietitians.
Dropout rates	49% overall at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	*Data for completers only.*

Black 1984 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if married women, 10% or greater overweight, husband signed statement if requested to attend, $11 deposit refunded on attendance.* *Excluded if physiological or medical problems that would inhibit weight loss.*
Recruitment	Advertisements in community and university newspaper. Referrals from colleagues.
Intervention (mode and intensity)	10 weeks with follow-up to 4 years, contacted 14 times (90 min introductory baseline visit then 10 weekly visits of 30–90 min duration then at 1, 3 and 4 years post-treatment (218 weeks in total)
Control (mode and intensity)	*As for spouse involvement.*
Delivery of intervention/control (who)	Counsellor was a doctoral candidate in clinical psychology (study author).
Dropout rates	*8% in active group, 17% in passive group, and 8% in individual group at 62 weeks.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Murphy 1982 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included married couples, 20–80% above IBW (US Department of Agriculture 1969), spouse willing to attend all treatment sessions, no contra-indications for restricting intake or increasing exercise (decided by physician). No details of exclusions.
Recruitment	Newspaper and radio advertisements, then personal interview.
Intervention (mode and intensity)	*All intervention groups. 10 weeks with follow-up to 4 years post-treatment, contacted 21 times (baseline then 11 × 1.5 h sessions in first 10 weeks then at 12, 15, 18, 22, 29 and 36 weeks, 1 year, 2 years and 4 years post-treatment)*
Control (mode and intensity)	10 weeks, contacted 12 times (baseline then 11 × 1.5 h sessions in first 10 weeks)

Delivery of intervention/control (who)	No details.
Dropout rates	*63% ind-1 party, 53% ind-2 party, 64% family-1 party, 50% family-2 party, 60% supportive at 4 years.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pearce 1981 (in HTA) RCT	
Country and setting	Canada. No further details.
Participants (included/excluded)	Included if women, aged 20–60 years, 9 kg or 20% overweight or more (Metropolitan Life Insurance tables), doctors permission, $50 deposit refunded on attendance of nine out of ten sessions and three follow-ups. Excluded if involvement in another weight control programme or psychotherapy, obesity related morbidity such as diabetes, thyroid problems, colitis, ulcers; taking medication which affected waters retention, appetite, metabolism; pregnant or planning pregnancy, unwilling to commit for 15 months or unwilling to pay $50 deposit, husbands unwilling to participate.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*12 months, contacted 14 times (baseline then weekly for initial 10 weeks then at 3, 6 and 12 months)*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	One male and one female graduate students in clinical psychology (neither of whom were obese) delivered the therapy. The male therapist was experienced (minimum 2 years with experience of BT for weight loss) compared with the female therapist who had just begun her graduate training and had no experience of delivering BT for weight loss. The therapists were trained before delivering the intervention to ensure uniformity of delivery. Also, therapists met each week to provide continued uniformity and resolve any differences or difficulties.
Dropout rates	*14% in the active group, and 8% in the individual group at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R. Results for completers only?

Rosenthal 1980 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included if women, ≥10% above IBW (Metropolitan Life Insurance tables 1970), husband and wife both willing to attend meetings every 2 weeks, willing to comply with demands of the weight loss programme, $10 commitment deposit (returned at first follow-up visit), signed medical release form certifying good health, signed form stating will not participate in concurrent obesity therapy. Exclusion criteria not stated.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*16 weeks active treatment, contacted 11 times (baseline then eight × 75 min group sessions twice monthly, follow-up at 6 weeks post-treatment and 3 years post-treatment)*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Sessions were conducted by two female therapists – no further details.
Dropout rates	*53% overall at 3 years post-treatment.*

Treatment of dropouts (return to baseline, or last measurement?)	N/R – completers only?

Wing 1999 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included if aged 25–55 years, 6.8–31.8 kg above IBW, generally good health. Exclusion criteria: not stated
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*16 weeks with follow-up at 16 months, contacted 18 times (baseline then weekly for initial 16 weeks then at 16 months).*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Meetings were led by a behaviour therapist, a nutritionist, or both.
Dropout rates	*46% overall at 16 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Dropouts assumed to return to baseline weight.

Wing 1991b (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included if aged 30–65 years, 20 % or more over IBW, FRG ≥140 mg/dl or ≥200 mg d/l at 2 h after oral glucose load and one other value 200mg/dl or more; spouses 15% or more above IBW and 30–70 years; $150 deposit per couple. Exclusion criteria: not stated
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*72 weeks, contacted 21 times (baseline then weekly for first 12 weeks then at weeks 14, 16, 18, 20, 24, 28, 40 and 72)*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	The programme was conducted by a multi-disciplinary team – no details.
Dropout rates	*17% in the spouse group, 23% individual group at 72 weeks.*
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

1.4.5 Group vs individual treatment

Weight loss

Hakala 1993 (in HTA) RCT	
Aim	To compare group and individual weight reduction programmes in the treatment of severe obesity
Participants	People who were severely overweight (at least 50% overweight according to the Finnish Social Insurance Institution. *60 total – 40 F, 20 M. Mean (SD) age 41 (8) years overall. Mean (SD) BMI (kg/m^2) 43 (5) overall. Thirty allocated to group and 30 to individual counselling arms.*

Intervention	Vitamin supplements recommended if weight loss >10 kg in first 3 months. Group: 2 week inpatient intensive group counselling treatment in groups of 10, consisting of 15 h of nutrition counselling, behaviour modification, 15 h physical activation and training, 12 h occupational therapy and 1 h individual nutrition counselling; also included a lecture and examination by a physician; participants provided with 1200 kcal/day diet of four low fat low sugar meals per day; nutrition education based on a mixed diet, group sessions after initial 2 weeks consisted of weight, group discussion, advice and motivation; participants also given individual appointments with physician and 4 month intervals.
Control	*Vitamin supplements recommended if weight loss >10 kg in first 3 months.* *Individual: counselling consisting of 20 min individual visits with same physician monthly for first 6 months, advised on weight reduction with 1200 kcal/day diet and physical activity, information given systematically in small portions, participants received information leaflets, counselling paid attention to personal characteristics, family relationships and working situation; after 6 months the sessions concentrated on follow-up of body weight changes and health status until end of year 2.*
Length of follow-up	5 years
Results	*Shorter terms results reported by gender only.* At 12 months, mean weight change (SD) was –14.80 (8.90) kg in the group arm compared with –17.00 (10.30) kg in the individual group. Mean weight change in the group arm compared with the individual group was 2.20 (95% CI –2.77 to 7.17). At 24 months, mean weight change (SD) was –4.20 (9.70) kg in the group arm compared with –12.30 (12.90) kg in the individual group. Mean weight change in the group arm compared with the individual group was 8.10 (95% CI 2.19 to 14.01). At 60 months, mean weight change (SD) was –2.40 (12.00) kg in the group arm compared with –6.80 (16.70) kg in the individual group. Mean weight change in the group arm compared with the individual group was 4.40 (95% CI –3.51 to 12.31).
Quality and comments	Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment. Author provided weight outcomes by group (reported by gender in paper). *Self reported weights, with some validation at 60 months.*

Jones 1986 (in HTA) RCT	
Aim	To evaluate the effect of introducing self-monitoring, cue avoidance and group treatment in a conventional NHS weight reduction clinic with no additional resources or staff training.
Participants	Women referred to a secondary care clinic who were judged as suitable by the responsible dietitian. *160 total – all women. Mean (SD) age 50.3 (13.5) years overall. Mean (SD) BMI (kg/m^2) 35.1 (9.2) overall. 17 allocated to group sessions and 21 to individual sessions.*
Intervention	All participants received individualised dietary advice at first session, recommended 1000 kcal/day below energy requirements but not less than 1000 kcal/day; (treatment was extended beyond 17 weeks if further involvement thought to be warranted). Group: four group treatment sessions in small groups of 5–7 for 60 min each
Control	*All participants received individualised dietary advice at first session, recommended 1000 kcal/day below energy requirements but not less than 1000 kcal/day; (treatment was extended beyond 17 weeks if further involvement thought to be warranted).* *Individual: participants seen individually for 10 min each session*
Length of follow-up	*68 weeks*

Results	*At 16 weeks, mean weight change (SD) was –3.95 (3.67) kg in the group arm compared with –4.79 (2.81) kg in the individual group. Mean weight change in the group arm compared with the individual group was 0.84 (95% CI –2.18 to 3.86).* At 18 months, mean weight change (SD) was –2.33 (5.06) kg in the group arm compared with –3.07 (5.34) kg in the individual group. Mean weight change in the group arm compared with the individual group was 0.74 (95% CI –4.21 to 5.69).
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Only used four (in total) of the eight intervention arms. *Other arms described in relevant sections/reviews.*

Long 1983 (in HTA) RCT	
Aim	To assess the effectiveness of combining behaviour modification with dietetic counselling in a hospital out-patient clinic.
Participants	Women who were overweight (BMI >25 kg/m^2) who were referred to an outpatient obesity clinic. *36 total – all women. Mean (range) age 36.8 (18 to 56) overall. Mean (range) BMI (kg/m^2) 33.5 (28.9 to 49.4) overall. Twelve each allocated to group or individual sessions.*
Intervention	All participants received same advice regarding obesity, health, nutrition and weight reduction, told successful weight loss depended on reducing energy intake and/or increasing physical activity. Group: 12 × 1 h group sessions plus four brief 30 min weigh-in sessions during initial 16 weeks; diet advice same as Individual group and also fostered high expectation of weight loss based on group support. Only average group weight loss reported to group not individual weights.
Control	*All participants received same advice regarding obesity, health, nutrition and weight reduction, told successful weight loss depended on reducing energy intake and/or increasing physical activity.* *Individual: advised regarding high-fibre diet tailored to give 1000–1200 kcal/day, seen individually by dietitian for 45 min initially then 15 × 15 minute sessions during initial 16 weeks, advised on weight reducing diets, nutrition, commercial slimming foods, seasonal topics and weight maintenance*
Length of follow-up	*68 weeks*
Results	*At 16 weeks, mean weight change (SD) was –4.60 (7.22) kg in the group arm compared with –8.30 (8.26) kg in the individual group. Mean weight change in the group arm compared with the individual group was3.70 (95% CI –3.57 to 10.97).* At 18 months (68 weeks), mean weight change (SD) was –0.90 (6.17) kg in the group arm compared with –8.10 (8.21) kg in the individual group. Mean weight change in the group arm compared with the individual group was 7.20 (95% CI –0.41 to 14.81).
Quality and comments	*Slight difference to HTA due to calculations.* Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Only used four (in total) of the eight intervention arms. Median weight change assumed to be similar to mean. SDs calculated.

Straw 1983 (in HTA) RCT	
Aim	To assess the efficacy of individualised behavioural obesity treatment and maintenance procedures.
Participants	Women who were overweight (≥35% body weight as fat). *45 total – all women. Mean age 39.99 (data completers only). Mean (SD) weight 85.16 (13.97) kg group arm (n=18), 86.73 (16.52) kg individual (n=15).*

Intervention	Participants required to purchase Ferguson's book *Learning to Eat* and to complete all assignments in it; topics included self-monitoring, stimulus control, eating style, problem-solving, activity management and social support. Participants seen in groups of 8–10. Also further randomised (at 10 weeks) to weight check each month where received encouragement or to individual problem-solving where topic determined by participant and discussed for 30 min twice a month then monthly to month 12.
Control	*Participants required to purchase Ferguson's book* Learning to Eat *and to complete all assignments in it; topics included self-monitoring, stimulus control, eating style, problem-solving, activity management and social support.* *Participants seen individually.* *Also further randomised (at 10 weeks) to weight check each month where received encouragement or to individual problem-solving where topic determined by participant and discussed for 30 min twice a month then monthly to month 12.*
Length of follow-up	12 months
Results	Weigh-in maintenance: At 10 weeks, mean weight change (SD) was –3.68 (2.90) kg in the group arm compared with –3.83 (3.14) kg in the individual group. Mean weight change in the group arm compared with the individual group was 0.15 (95% CI –2.74 to 3.04). Individual problem-solving maintenance: At 10 weeks, mean weight change (SD) was –2.59 (3.59) kg in the group arm compared with –4.76 (3.35) kg in the individual group. Mean weight change in the group arm compared with the individual group was 2.17 (95% CI –1.96 to 6.30). Weigh-in maintenance: At 12 months, mean weight change (SD) was –3.98 (7.04) kg in the group arm compared with 1.69 (6.39) kg in the individual group. Mean weight change in the group arm compared with the individual group was –5.67 (95% CI –13.28 to 1.94). Individual problem-solving maintenance: At 12 months, mean weight change (SD) was –4.99 (7.33) kg in the group arm compared with –6.94 (7.88) kg in the individual group. Mean weight change in the group arm compared with the individual group was 1.95 (95% CI –7.48 to 11.38).
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Mean change in weight calculated from change at week 10 plus change during weeks 11–52, SDs calculated, not all groups used in comparisons. Straw 1983a – weigh-in maintenance; Straw 1983b – individual problem-solving maintenance. *Have used Treatment values from Table 3 as 10-week outcomes?*

Other outcomes

Hakala 1993 (in HTA) RCT

Results

Mean participation rates in the group sessions (GRP) were 69% in the first 12 month follow-up period compared with 86% of appointments being kept in the individual group (IND), and 29% and 69% respectively in the second year.

	Increase or no change (%)	**1–10 kg loss (%)**	**11–20 kg loss (%)**	**21–30 kg loss (%)**	**>30 kg loss (%)**
3 months GRP (*n*=30)	0	12	78	10	0
3 months IND (*n*=28)	7	33	52	8	0
24 months GRP (*n*=30)	30	45	18	7	0
24 months IND	13	21	40	18	8

	(*n*=28)					
	60 months GRP (*n*=28)	43	33	17	7	0
	60 months IND (*n*=25)	37	37	12	12	2
Quality and comments	…					

Jones 1986 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Long 1983 (in HTA) RCT

Results

	>6.4 kg loss (%)	**>7.25 kg loss (%)**	**>10.88 kg loss (%)**
16 weeks GRP (*n*=10)	30	20	10
16 weeks IND (*n*=8)	75	50	25
68 weeks GRP (*n*=7)	14	14	14
68 weeks IND (*n*=7)	57	57	28

Quality and comments …

Straw 1983 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Reported harms

Hakala 1993 (in HTA) RCT	
Harms	None reported.
Quality and comments	

Jones 1986 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Long 1983 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Straw 1983 (in HTA) RCT	
Harms	Two women were seriously ill with cancer and dropped out. Group status was unclear.
Quality and comments	…

Generalisability

Hakala 1993 (in HTA) RCT	
Country and setting	Finland. Group intervention included a 2 week inpatient treatment period at the Rehabilitation Research Centre. Individual counselling assumed to be office-based but no details of setting.
Participants (included/excluded)	*Included if aged 22–54 years, >50% overweight (Finnish Adult Population 1980), no serious cardiovascular, metabolic or psychiatric disease.* *Excluded if presence of schizophrenia, hypothyroidism, cardiac failure*
Recruitment	Advertisements in local newspaper. The most overweight respondents were invited to participate (*n*=70).
Intervention (mode and intensity)	2 years, contacted 42 times (initial 2-week inpatient stay then weekly for 6 weeks, every other week for 10 months then once a month in year 2 then at 5 years)
Control (mode and intensity)	*2 years, contacted 17 times (baseline, once a month in year 1 and every 4 months in year 2 then at 5 years)*
Delivery of intervention/control (who)	Inpatient programme included nutrition counselling by a nutritionist, and a lecture and examination by a physician. Group sessions were conducted in turn by a nutritionist, a physiotherapist, and an occupational therapist. Individual appointments with a physician also. Individual group had appointments with the same physician throughout. The physician advised on weight reduction using diet and delivered counselling and information (using leaflets).
Dropout rates	0% group and 7% individual at 12 months, 7% group and 17% individual at 5 years.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Jones 1986 (in HTA) RCT	
Country and setting	UK. NHS outpatient weight reduction clinic (secondary care).
Participants (included/excluded)	*Included if women, aged 18 years or older, judged as suitable by dietitian.* *Excluded if diabetes, pregnancy*
Recruitment	Consecutive referrals to a district dietetic service from medical practitioners.
Intervention (mode and intensity)	17 weeks with follow-up 12 months later (69 weeks in total) contacted 7 times (baseline then week 1 then 4 more sessions at 4 week intervals then 12 months post-treatment)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Four dietitians, experienced in the dietary treatment of obesity but not behaviour therapy, carried out all the treatments. No additional resources or training were given.
Dropout rates	64% overall at 69 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

Long 1983 (in HTA) RCT	
Country and setting	UK. Outpatient clinic.

Participants (included/excluded)	*Included women, aged 18–60 years, BMI >25 kg/m^2* *Excluded if expectant mothers, diabetes, pre-operative patients, begun weight loss as inpatients, recent dramatic weight reduction.* *Fourteen indicated onset of weight gain in childhood or adolescence, and 15 attributed the weight gain to pregnancy. All had attempted at least one formal weight control method in addition to unsupervised dieting (Weight Watchers mentioned most frequently). Twenty-five reported having at least one overweight parent.*
Recruitment	Consecutive referrals deemed 'suitable' by the responsible dietitian.
Intervention (mode and intensity)	16 weeks with follow-up to 1 year post-treatment, contacted 20 times (baseline then weekly for 16 weeks then at 3, 6 and 12 months post-treatment)
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	Four qualified dietitians and one clinical psychologist served as therapists. No therapist had extensive experience of group therapy. Groups were run by a male/female therapist team, whilst individuals were seen by a female dietitian.
Dropout rates	42% in both groups at 68 weeks
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

Straw 1983 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included women, 35% or more of body weight as fat (skinfold thickness calliper)* *Excluded if serious physical or emotional problems, problems which required a special diet such as diabetes or hypoglycaemia, severely limited physical activity, endocrine disorder, Beck Depression Inventory score of ≥20, schedule did not allow random assignment*
Recruitment	Newspaper announcements.
Intervention (mode and intensity)	In treatment phase, 10 weeks, contacted 11 times (baseline then 1 h weekly for 10 weeks) Weigh-in maintenance: contacted 9 times (monthly from week 11 to 12 months) IPS: 42 weeks, contacted 12 times (30 min twice monthly from week 11 for 3 months then monthly to 12 months)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	All treatments administered by clinical psychology students under supervision (first author).
Dropout rates	18% overall at 12 months
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

1.4.6 Different levels of intensity of behaviour therapy and diet

Weight loss

Melin 2003 RCT	
Aim	To compare two group treatment programmes for people who were obese.
Participants	People who were obese (attending an obesity clinic – no cut-off defined). Total 43 – 39 F, 4 M. Mean (SD) age 40.7 years intervention group (*n*=22), 39.4 years standard group (*n*=21).
Intervention	*Intensive BT: continuous intensive treatment (self-monitoring, relapse situations, eating behaviour) with planned group meetings. Possibility to repeat self-monitoring, and obtain more information and education on nutrition, food habits and strategies to control eating behaviour.* *Diet: VLED 25 days total, 3 days over which reduced energy from 800 kcal to 200 kcal/day (liquid every 2 h – water, herbal tea, fruit/vegetable juice) for 19 days, then increased to 800 kcal/day over 3 days. Alternating with 600 kcal/day deficit diet.*
Comparison	Standard BT: as above, but met less often, had less contact, fewer repetitions of self-monitoring and less counselling. Diet: as above
Length of follow-up	*48 months*
Results	*At 3 months, mean weight change (SD) was –8.30 (2.64) kg in the intensive group compared with –10.00 (2.75) kg in the standard group. Mean weight change in the intensive group compared with the standard group was 1.70 (95% CI –0.17 to 3.57).* *At 6 months, mean weight change (SD) was –10.60 (2.64) kg in the intensive group compared with –12.30 (2.75) kg in the standard group. Mean weight change in the intensive group compared with the standard group was 1.70 (95% CI –0.17 to 3.57).* *At 12 months, mean weight change (SD) was –7.58 (4.04) kg in the intensive group compared with –6.40 (4.49) kg in the standard group. Mean weight change in the intensive group compared with the standard group was –1.18 (95% CI –4.16 to 1.80).* *At 24 months, mean weight change (SD) was –6.80 (5.77) kg in the intensive group compared with –8.60 (6.20) kg in the standard group. Mean weight change in the intensive group compared with the standard group was 1.80 (95% CI –2.37 to 5.97).* *No significant difference was seen for weight loss between high and low attenders.*
Quality and comments	*Calculated SDs from SEMs. Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Results for completers only.*

Other outcomes

Melin 2003 RCT	
Results	*At 3 months, mean (SD) FPG change in mmol/l was –0.35 (1.44) in the intensive group, and –0.90 (1.51) in the standard group. Mean FPG change in the intensive group compared with standard was 0.55 (95% CI –0.48 to 1.58).* *At 6 months, mean (SD) FPG change in mmol/l was –0.20 (0.87) in the intensive group, and –0.60 (0.93) in the standard group. Mean FPG change in the intensive group compared with standard was 0.40 (95% CI –0.23 to 1.03).* *At 12 months, mean (SD) FPG change in mmol/l was –0.20 (1.15) in the intensive group, and –0.90 (1.32) in the standard group. Mean FPG change in the intensive group compared with standard was 0.70 (95% CI –0.16 to 1.56).*

	At 24 months, mean (SD) FPG change in mmol/l was 0.08 (0.99) in the intensive group, and –0.50 (1.01) in the standard group. Mean FPG change in the intensive group compared with standard was 0.58 (95% CI –0.11 to 1.27). *At 3 months, mean (SD) SBP change in mmHg was –6.90 (27.42) in the intensive group, and -2.40 (37.88) in the standard group. Mean SBP change in the intensive group compared with standard was –4.50 (95% CI –27.68 to 18.68).* *At 6 months, mean (SD) SBP change in mmHg was –8.10 (10.72) in the intensive group, and –2.10 (11.23) in the standard group. Mean SBP change in the intensive group compared with standard was –6.00 (95% CI –13.63 to 1.63).* *At 12 months, mean (SD) SBP change in mmHg was –5.00 (12.37) in the intensive group, and –0.40 (13.94) in the standard group. Mean SBP change in the intensive group compared with standard was –4.60 (95% CI –13.78 to 4.58).* *At 24 months, mean (SD) SBP change in mmHg was –9.80 (17.11) in the intensive group, and 2.20 (15.10) in the standard group. Mean SBP change in the intensive group compared with standard was –12.00 (95% CI –23.16 to –0.84).* *At 3 months, mean (SD) DBP change in mmHg was –3.50 (13.19) in the intensive group, and –7.20 (18.20) in the standard group. Mean DBP change in the intensive group compared with standard was 3.70 (95% CI –7.44 to 14.84).* *At 6 months, mean (SD) DBP change in mmHg was –5.20 (8.04) in the intensive group, and –5.00 (8.40) in the standard group. Mean DBP change in the intensive group compared with standard was –0.20 (95% CI –5.92 to 5.52).* *At 12 months, mean (SD) DBP change in mmHg was –2.40 (8.25) in the intensive group, and –3.30 (8.91) in the standard group. Mean DBP change in the intensive group compared with standard was 0.90 (95% CI –5.08 to 6.88).* *At 24 months, mean (SD) DBP change in mmHg was –6.60 (8.25) in the intensive group, and 1.30 (8.44) in the standard group. Mean DBP change in the intensive group compared with standard was –7.90 (95% CI –13.70 to –2.10).*
Quality and comments	Only DBP at 24months noted as significantly different in published paper.

Harms

Melin 2003 RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Melin 2003 RCT	
Country and setting	Sweden. Secondary care obesity clinic.
Participants (included/excluded)	N/R, other than patients referred to the obesity clinic.
Recruitment	Referrals
Randomisation	N/R
Intervention (mode and intensity)	*Meetings every 2 weeks for 12 months, then 6 meetings during second year. During VLED period, meetings twice per week.*
Duration of active intervention	24 months
Comparison (mode and intensity)	Meetings every 3 months for 24 months. During VLED period, meetings twice per week.
Delivery of intervention/comparison (who)	Dietitian and psychologist.
Dropout rates	*23% intervention group, 29% standard group at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.4.7 Diet and behaviour therapy vs diet

Weight loss

Wadden 1989 (in HTA) RCT	
Aim	To compare the effectiveness of VLED alone, behaviour therapy alone, and VLED plus BT on weight control.
Participants	People who were overweight (≥25 kg above IBW from the Metropolitan Life Insurance tables) *76 total – all women (completers only – men excluded from analysis due to small numbers). Mean age (SE) 42.1 (1.1) years. Mean (SE) BMI (kg/m^2) 39.4 (0.8). Numbers allocated to each group unclear.*
Intervention (including details of diet)	1000–1200 kcal/day for month 1, months 2 + 3 400–500 kcal/day PSMF consisting of three servings of lean meat, fish or fowl and to avoid all other food with the exception of non-energy beverages and bouillon, requested to drink at least 1.5 l water per day, daily supplements 3 g each of potassium, sodium chloride and 800 mg calcium; month 4 refeeding to conventional foods, firstly fruit and vegetables then bread and cereal then fats. In addition months 5 + 6 prescribed 1000–1200 kcal/day diet, extensive training in behaviour therapy throughout (taught traditional behavioural methods of weight control which included recording eating behaviour, controlling stimuli related to eating, slowing rate of consumption, increasing lifestyle activity, nutrition education, modifying self-defeating thoughts and emotions, social support, reinforcing changes in eating and exercise behaviour;); months 4, 5 + 6 addressed weight maintenance and included relapse prevention training and strategies for handling weight regain. Also encouraged to increase physical activity by walking and using the stairs; diet records kept throughout active treatment; paid $10 for each visit and deposited $40 which was refunded after the 1-year follow-up visit.
Control	*1000–1200 kcal/day for month 1, months 2 + 3 400–500 kcal/day PSMF consisting of three servings of lean meat, fish or fowl and to avoid all other food with the exception of non-energy beverages and bouillon, requested to drink at least 1.5 litre of water per day, daily supplements 3 g each of potassium, sodium chloride and 800 mg calcium; month 4 refeeding to conventional foods, firstly fruit and vegetables then bread and cereal then fats.* *Also encouraged to increase physical activity by walking and using the stairs; diet records kept throughout active treatment; paid $10 for each visit and deposited $40 which was refunded after the 1 year follow-up visit.*
Length of follow-up	64 to 66 months
Results	*At 6 months, mean (SD) weight change in kg was –16.80 (6.68) in the diet and BT group, and –13.10 (4.80) in the diet group. Mean weight change in the diet and BT group compared with diet was –3.70 (95% CI –6.76 to –0.64).* At 12 months, mean (SD) weight change in kg was –12.89 (8.91) in the diet and BT group, and –4.70 (7.31) in the diet group. Mean weight change in the diet and BT group compared with diet was –8.19 (95% CI –13.64 to –2.74). At 36 months, mean (SD) weight change in kg was –5.11 (8.28) in the diet and BT group, and –2.20 (8.50) in the diet group. Mean weight change in the diet and BT group compared with diet was –2.91 (95% CI –8.60 to 2.78). At 60 months, mean (SD) weight change in kg was 2.90 (11.26) in the diet and BT group, and 1.00 (6.79) in the diet group. Mean weight change in the diet and BT group compared with diet was 1.90 (95% CI –3.75 to 7.55). *At the end of the active treatment (6 months), 96.8% of the diet and BT group and 95.6% of the diet group had lost 5kg or more, and 90.3% and 73.9% respectively had lost 10 kg or more.* *At 12 months, 72.0% of the diet and BT group and 52.4% of the diet group had lost 5 kg or more, and 52.0% and 14.3% respectively had lost 10 kg or more.* *At 60 months, 27.3% of the diet and BT group and 11.1% of the diet group had lost 5 kg or more, and 9.1% and 11.1% respectively had lost 10 kg or more.*

Quality and comments	Two cohorts differed significantly in age at baseline (43.9. vs 39.5 years). 2 kg added to all self-reported weights, 3 and 5 year weight outcomes recalculated for participants who had additional weight loss treatment in years 1–5 post-treatment, self-reported weight at time of seeking additional therapy was subtracted from pre-treatment weights, significant difference in whole sample from uncorrected changes (*p*<0.002 at 3 years, *p*<0.005 at 5 years post-treatment). Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. *More than 90% of participants reported a chronic history of obesity and multiple cycles of weight loss and regain.*

Jones 1986 (in HTA) RCT	
Aim	To evaluate the effect of introducing self-monitoring, cue avoidance, and group treatment in a conventional NHS weight reduction clinic with no additional resources or staff training.
Participants	Women referred to a secondary care clinic who were judged as suitable by the responsible dietitian. *160 total – all women. Mean (SD) age 50.3 (13.5) years overall. Mean (SD) BMI (kg/m^2) 35.1 (9.2) overall. 17 allocated to group sessions and 21 to individual sessions.*
Intervention	All participants received individualised dietary advice at first session, recommended 1000 kcal/day below energy requirements but not less than 1000 kcal/day (treatment was extended beyond 17 weeks if further involvement thought to be warranted). Diet and BT (group Jones 1986c): participants received leaflet at each four sessions regarding cue avoidance and food management, seen in group format. The recommendations and their implementation were discussed during visits with the dietitian. Diet and BT (individual Jones 1986d): participants received leaflet at each four sessions regarding cue avoidance and food management, seen individually. The recommendations and their implementation were discussed during visits with the dietitian.
Control	*All participants received individualised dietary advice at first session, recommended 1000 kcal/day below energy requirements but not less than 1000 kcal/day; (treatment was extended beyond 17 weeks if further involvement thought to be warranted).* *Four group treatment sessions in small groups of 5–7 for 60 min each or participants seen individually for 10 min each session.*
Length of follow-up	*68 weeks*
Results	*Group: At 16 weeks, mean weight change (SD) was –8.74 (2.35) kg in the diet and BT arm compared with –3.95 (3.67) kg in the diet group. Mean weight change in the diet and BT arm compared with the diet group was –4.79 (95% CI –7.75 to –1.83).* Group: At 12 months, mean weight change (SD) was –7.79 (5.21) kg in the diet and BT arm compared with –2.33 (5.06) kg in the diet group. Mean weight change in the diet and BT arm compared with the diet group was –5.46 (95% CI –10.67 to –0.25). *Individual: At 16 weeks, mean weight change (SD) was –4.52 (3.66) kg in the diet and BT arm compared with –4.79 (2.81) kg in the diet group. Mean weight change in the diet and BT arm compared with the diet group was 0.27 (95% CI –2.74 to 3.28).* Individual: At 12 months, mean weight change (SD) was –5.06 (7.91) kg in the diet and BT arm compared with –3.07 (5.34) kg in the diet group. Mean weight change in the diet and BT arm compared with the diet group was –4.18 (95% CI –8.32 to –0.04).

Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Only used four (in total) of the eight intervention arms. *Other arms described in relevant sections/reviews.*

Long 1983 (in HTA) RCT	
Aim	To assess the effectiveness of combining behaviour modification with dietetic counselling in a hospital outpatient clinic.
Participants	Women who were overweight (BMI >25 kg/m^2) who were referred to an outpatient obesity clinic. *36 total – all women. Mean (range) age 36.8 (18 to 56) overall. Mean (range) BMI (kg/m^2) 33.5 (28.9 to 49.4) overall. Twelve each allocated to group or individual sessions.*
Intervention	All participants received same advice regarding obesity, health, nutrition and weight reduction, told successful weight loss depended on reducing energy intake and/or increasing physical activity. Twelve × 90 min sessions held weekly for first 16 weeks with dietitian and clinical psychologist plus four brief weigh in sessions; first 15–20 min of each group session participants given same diet advice as other group; participants discussed application of behavioural strategies based on learning principles following each of 12 didactic sessions including self-monitoring, stimulus control, slowing rate of eating, generating social support, exercise, dietary planning, pre-planning, individual problem-solving, assertiveness and cognitive restructuring. Only average group weight loss reported to group not individual weights.
Control	*All participants received same advice regarding obesity, health, nutrition and weight reduction, told successful weight loss depended on reducing energy intake and/or increasing physical activity.* *Twelve × 1 h group sessions plus four brief 30 min weigh in sessions during initial 16 weeks; diet advice same as Individual group and also fostered high expectation of weight loss based on group support. Only average group weight loss reported to group not individual weights.*
Length of follow-up	*68 weeks*
Results	*At 16 weeks, mean weight change (SD) was –6.90 (7.87) kg in the diet and BT arm compared with –4.60 (7.22) kg in the diet group. Mean weight change in the diet and BT arm compared with the diet group was –2.30 (95% CI –8.92 to 4.32).* At 12 months, mean weight change (SD) was –7.70 (8.09) kg in the diet and BT arm compared with –0.90 (6.17) kg in the diet group. Mean weight change in the diet and BT arm compared with the diet group was –6.80 (95% CI –13.79 to 0.19).
Quality and comments	*Slight difference to HTA due to calculations.* Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. Only used four (in total) of the eight intervention arms. Median weight change assumed to be similar to mean. SDs calculated.

Other outcomes

Wadden 1989 (in HTA) RCT	
Results	*No other outcomes reported.*
Quality and comments	…

Jones 1986 (in HTA) RCT	
Results	*None reported.*
Quality and comments	…

Long 1983 (in HTA) RCT				
Results		**>6.4 kg loss (%)**	**>7.25 kg loss (%)**	**>10.88 kg loss (%)**
	16 weeks diet+BT (*n*=10)	70	50	10
	16 weeks D (n=10)	30	20	10
	68 weeks diet+BT (*n*=9)	55	55	33
	68 weeks diet only (*n*=7)	14	14	14
Quality and comments	…			

Reported harms

Wadden 1989 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Jones 1986 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Long 1983 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Wadden 1989 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	*Included if ≥25 kg above IBW (Metropolitan Life Insurance tables). Excluded if recent MI or evidence of cardiac abnormalities; history of cerebrovascular, kidney or liver disease; cancer, type 1 diabetes, severe psychiatric illness, pregnancy, contraindications to treatment by VLED (assessed at screening), participants agreed not to participate in additional weight loss treatment before follow-up at 1 year post-treatment.*
Recruitment	N/R
Intervention (mode and intensity)	25 weeks, contacted 39 times (90 min each week for 25 weeks then 11 post-treatment visits every other week for first 2 months then once a month for next 4 months then every other month for last 6 months, 3 years and 5 years post-treatment)
Control (mode and intensity)	*16 weeks, contacted 25 times (90minutes each week for 16 weeks then months 1, 2, 3, 6, 9 and 12 post-treatment, 3 years and 5 years post-treatment).*
Delivery of intervention/control (who)	All participants were treated by doctoral level clinical psychologists.
Dropout rates	Unclear, but 68/76 were assessed at 12 months, 50/76 at 36 months and 55/76 at 60 months.

Treatment of dropouts (return to baseline, or last measurement?)	Data for completers only.

Jones 1986 (in HTA) RCT	
Country and setting	UK. NHS outpatient weight reduction clinic (secondary care).
Participants (included/excluded)	*Included if women, aged ≥18 years, judged as suitable by dietitian.* *Excluded if diabetes, pregnancy*
Recruitment	Consecutive referrals to a district dietetic service from medical practitioners.
Intervention (mode and intensity)	17 weeks with follow-up 12 months later (69 weeks in total) contacted 7 times (baseline then week 1 then 4 more sessions at 4 week intervals then 12 months post-treatment)
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Four dietitians, experienced in the dietary treatment of obesity but not behaviour therapy, carried out all the treatments. No additional resources or training were given.
Dropout rates	64% overall at 69 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

Long 1983 (in HTA) RCT	
Country and setting	UK. Outpatient clinic.
Participants (included/excluded)	*Included women, aged 18–60 years, BMI >25 kg/m^2* *Excluded if expectant mothers, diabetes, pre-operative patients, begun weight loss as inpatients, recent dramatic weight reduction.* *Fourteen indicated onset of weight gain in childhood or adolescence, and 15 attributed the weight gain to pregnancy. All had attempted at least one formal weight control method in addition to unsupervised dieting (Weight Watchers mentioned most frequently). Twenty-five reported having at least one overweight parent.*
Recruitment	Consecutive referrals deemed ‘suitable’ by the responsible dietitian.
Intervention (mode and intensity)	16 weeks with follow-up to 1 year post-treatment, contacted 20 times (baseline then weekly for 16 weeks then at 3, 6 and 12 months post-treatment)
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	Four qualified dietitians and one clinical psychologist served as therapists. No therapist had extensive experience of group therapy. Groups were run by a male/female therapist team, whilst individuals were seen by a female dietitian.
Dropout rates	25% in diet and BT, 42% in diet group at 68 weeks
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

1.4.8 Comparison of different behavioural treatments

Weight loss

Perri 2001 RCT	
Aim	To compare extended programmes of relapse prevention or problem-solving with no contact (after completion of a 20 week BT programme).
Participants	Women who were obese (BMI 27–40 kg/m^2).
Intervention	*Initial BT programme: self-monitoring, goal setting, stimulus control* *Initial diet: 1200 kcal/day with low fat (<25% of energy intake)* *Initial activity: home-based walking for 30 min/day 5 days/week.* *Relapse prevention (RP): anticipating, avoiding, coping with lapses (including six sessions on problem-solving techniques)*
Comparison	As above for initial programme Problem-solving: used five-stage problem-solving method in group to solve individuals problems
Length of follow-up	*17 months*
Results	*At 5 months, mean (SD) weight change in kg was –8.41 (4.55) in the BT and RP group, and –9.28 (5.21) in the BT and problem-solving group (PS). Mean weight change in the BT and RP group compared with BT and PS was 0.87 (95% CI –2.05 to 3.79).* *At 11 months, mean (SD) weight change in kg was –9.11 (8.49) in the BT and relapse prevention group, and –11.33 (9.12) in the BT and PS group. Mean weight change in the BT and RP group compared with BT and PS was 2.22 (95% CI –3.05 to 7.49).* *At 17 months, mean (SD) weight change in kg was –5.85 (6.39) in the BT and RP group, and –10.82 (8.65) in the BT and PS group. Mean weight change in the BT and RP group compared with BT and PS was 4.97 (95% CI 0.46 to 9.48).*

Change	***RP*** *(n=22)*	***PS*** *(n=34)*
Lost ≥10%	*21.4%*	***35.3%***
Lost 5–9.9%	*21.4%*	***17.6%***
Lost 0–4.9%	*42.9%*	***38.2%***
Gained weight	***14.3%***	***8.8%***

Quality and comments	Blinded assessment not reported. ITT analysis done but not reported. Random allocation but no description of concealment. *Ten men were recruited, but results for women only – data excluded.* *Also control group (no contact). Results only reported for different extended therapies. Used HTS formula for weight change at 11 months. Results reported as NS between RP and PS but appears to be significant in analysis?*

Other outcomes

Perri 2001 RCT	
Results	*No other outcome reported.*
Quality and comments	RP and PS groups only.

Harms

Perri 2001 RCT	
Harms Quality and comments	None reported.

Generalisability

Perri 2001 RCT	
Country and setting	USA. Not clear.
Participants (included/excluded)	Included if BMI between 27 and 40 kg/m^2, aged 12 to 60 years and had physician approval. No exclusions reported.
Recruitment	Newspaper advertisements.
Randomisation	N/R
Intervention (mode and intensity)	*Initial programme: weekly 2 h sessions for 20 weeks.* *RP: 12 months of biweekly sessions.*
Duration of active intervention	17 months
Comparison (mode and intensity)	*Initial programme: weekly 2 h sessions for 20 weeks.* PS: 12 months of biweekly sessions.
Delivery of intervention/comparison (who)	Clinical psychology graduates for initial BT. Group leaders for RP and PS with experience in conducting BT for obesity.
Dropout rates	*15% for initial programme, then 29% RP and 34% PS at 17 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5 Physical activity interventions (alone or in combination with diet or behaviour therapy)

1.5.1 Physical activity vs control (no treatment)

Weight loss

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Aim	The primary aim of the trial was to compare the isolated and combined effects of the diet and exercise on the variables fibrinogen, fibrinolytic capacity, coagulation factor VII and platelet volume. Secondary aims were the effects on other coagulation and fibrinolytic components and activities; lipids and lipoproteins; fatty acids; glucose and insulin response to a glucose load; clinical, physiological and anthropometric variables; and quality of life
Participants	*Men and women aged 41 to 50 years who were overweight (BMI >24 kg/m^2) and sedentary.* *219 total – 21 F, 198 M. Mean (SD) age 44.9 (2.5) years. Mean (SD) BMI (*kg/m^2*) 29.54 (3.89) diet group (*n=*55), 28.56 (3.22) exercise group (*n=*54), 28.57 (3.47) diet and exercise group (*n=*67), 28.30 (3.15) control group (*n=*43).*
Intervention	For initial 8 weeks the intensity and duration of supervised endurance workouts increased progressively then maintained at three times per week for 1 h each session at 60–80% maximum heart rate as assessed at baseline using treadmill; 60% of each workout was aerobic, 25% circuit training and 15% fast walking/jogging; attendance measured and exercise log book kept. Advised to stop smoking.
Control	*Told not to change lifestyle and that after 12 months would receive dietary advice and supervised physical training. Advised to stop smoking.*
Length of follow-up	12 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –0.9 (4.20) in the activity group, and 1.10 (2.62) in the control group. Mean weight change in the intervention group compared with control was –2.00 (95% CI –3.41 to –0.52).
Quality and comments	TC and LDL levels significantly lower in the exercise and the diet and exercise groups ($p<0.05$). ITT not done. Only blood analyses blinded. Discrepancy between results in published papers. Good concealment of allocation.

Pritchard 1997 (in Shaw CR) RCT	
Aim	To compare the effects of two weight loss interventions, diet or exercise, on changes in bone, fat and lean tissue
Participants	*Healthy men aged 35 to 55 years who were overweight (BMI 26 to 35 kg/m^2). 66 total – all men. Mean age (SD) 44.9 (6.5) years in the activity group (*n=*22), 42.3 (4.5) years in the control group (*n=*20). Mean BMI (SD) (kg/m^2) 29.2 (2.8) in the activity group, 28.6 (2.8) in the control. Data for 12-month completers only (*n=*58 overall).*

Intervention	Participants selected their own unsupervised aerobic exercise regimen of at least three sessions of 30 min each week at 65–75% maximum heart rate; initial heart rate over 33 h normal activity which included the selected exercise used to determine personal heart rate target zone; eleven participants walked, two jogged, two alternated jogging and swimming, three attended the gym and three rode exercise bikes, participants exercised 3–7 sessions per week, advised to avoid change in food intake, completion of daily adherence calendar, at 13 months dietary intervention was added (See Diet review for detail of diet intervention)
Control	*Attended monthly weight monitoring sessions where counselled to follow usual food and exercise habits. Told participants that they would be able to enter the weight loss study at the end of the study. Both diet and physical activity interventions were added at 13 months.*
Length of follow-up	18 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –2.60 (3.00) in the activity group, and 0.30 (2.40) in the control group. Mean weight change in the intervention group compared with control was –2.90 (95% CI –4.68 to –1.12).
Quality and comments	ITT analysis done. Blinded assessment not done. Real possibility of disclosure of allocation, although some attempt made at concealment. Author provided unpublished report. Data up to 12 months only used. Discrepancy in data between reports.

Wood 1988 (in Shaw CR) RCT	
Aim	To determine the influence of two methods for losing fat weight on the levels of plasma lipids and lipoproteins in overweight sedentary men – decreasing energy intake without increasing exercise (diet), and increasing energy expenditure without altering energy intake (exercise, primarily running)
Participants	*Men aged 30 to 59 years, overweight (120 to 160% IBW) and no regular exercise for past 3 months.* *155 M. Mean (SD) age 44.2 (8.2) years diet group (n=51), 44.1 (7.8) years activity group (n=52), 45.2 (7.2) years control (n=52). Mean (SD) weight 93.0 (8.8) kg diet group, 94.1 (8.6) activity group, and 95.4 (10.6) control. (Results for 131 assessed participants).* Noted in HTA as highest mean reported weight (kg)
Intervention	Participants received supervised exercise training session to promote increase in energy expenditure and body fat loss of one-third, consisting of 1 h three times per week including callisthenics, walking, jogging and principally running at 60–80% peak heart rate (according to treadmill test results), advised to increase routine physical activity plus two more sessions per week unsupervised exercise; activity logs kept and advised not to change diet including composition, weight stabilisation last 6 weeks.
Control	*Advised not to make any changes in diet, including composition, exercise or body weight, offered weight loss programme of diet and exercise at end of study.*
Length of follow-up	24 months
Results	*At 7 months, mean (SD) weight change in kg was –3.00 (2.80) in the activity group, and 0.20 (2.50) in the control group. Mean weight change in the intervention group compared with control was –3.00 (95% CI –4.30 to –2.10).* *At 12 months, mean (SD) weight change in kg was –4.00 (3.90) in the activity group, and 0.60 (3.70) in the control group. Mean weight change in the intervention group compared with control was –4.60 (95% CI –6.18 to –3.02).*
Quality and comments	ITT analysis not done. Blinded assessment only in year 2. Random allocation but no description of concealment. Only 12-month outcomes reported in published papers.

Other outcomes

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.20 (0.56) in the activity group, and –0.16 (0.59) in the control group. Mean TC change in the intervention group compared with control was –0.04 (95% CI –0.28 to 0.20). At 12 months, mean (SD) LDL change in mmol/l was –0.13 (0.49) in the activity group, and –0.22 (0.59) in the control group. Mean LDL change in the intervention group compared with control was 0.09 (95% CI –0.13 to 0.31). At 12 months, mean (SD) HDL change in mmol/l was 0.04 (0.14) in the activity group, and 0.02 (0.10) in the control group. Mean HDL change in the intervention group compared with control was 0.02 (95% CI –0.03 to 0.07). At 12 months, mean (SD) TAG change in mmol/l was –0.24 (0.70) in the activity group, and 0.17 (0.92) in the control group. Mean TAG change in the intervention group compared with control was –0.41 (95% CI –0.75 to –0.07). At 12 months, mean (SD) DBP change in mmHg was –2.70 (7.00) in the activity group, and –0.70 (8.52) in the control group. Mean DBP change in the intervention group compared with control was –2.00 (95% CI –5.21 to 1.21). At 12 months, mean (SD) SBP change in mmHg was –2.20 (7.70) in the activity group, and –0.50 (11.15) in the control group. Mean SBP change in the intervention group compared with control was –1.70 (95% CI –5.67 to 2.27). At 12 months, mean (SD) FPG change in mmol/l was –0.09 (0.42) in the activity group, and 0.07 (0.46) in the control group. Mean FPG change in the intervention group compared with control was –0.16 (95% CI –0.34 to 0.02). *The activity group had a significant mean change from baseline in fat intake (as % of energy) of –1.6% ($p<0.05$). No other changes from baseline were significant.* *At 12 months, VO_{2max} had increased by 4.0 ml/kg per min, which was significantly different to the control group ($p<0.05$). No values were reported for the control group.*
Quality and comments	Dietary intake assessed through a validated food-frequency questionnaire. Activity was supervised, and home activity was recorded (no details). Also participants interviewed at 12 months about changes in activity habits.

Pritchard 1997 (in Shaw CR) RCT	
Results	*At 12 months, significant differences from baseline were seen in the activity group compared with control for index of activity (+15.6 vs +6.4%) and energy expenditure (+14.6 vs +6.5%) ($p<0.05$). Also there was a significant increase in dietary calcium in the activity group compared with control (+30.3 vs –0.8%; $p<0.001$).* *No significant differences were seen between activity and control for energy intake, % energy as fat or % energy as protein.* *Also at 12 months, no significant differences were seen from baseline between activity and control in bone mineral density, bone mass, or lean mass. Fat mass decreased in the activity group but increased in the control group (–11.0 vs +0.4%) ($p<0.05$).*
Quality and comments	Dietary intake estimated from participants' 3-day food diaries. Activity from 3-day diaries and 24 h activity logs monthly.

Wood 1988 (in Shaw CR) RCT	
Results	*At 7 months, changes in TAG, HDL and HDL_2 levels were significantly different to controls (–0.25 vs –0.01, $p\leq0.51$, 0.09 vs 0.00 $p\leq0.01$, 0.06 vs 0.00 $p\leq0.01$, respectively). Changes in TC, LDL and HDL_3 levels were not significantly different between groups.* *At 12 months, mean (SD) TC change in mmol/l was –0.25 (0.64) in the activity group, and –0.23 (0.65) in the control group. Mean TC change in the*

	intervention group compared with control was –0.02 (95% CI –0.29 to 0.25). *At 12 months, mean (SD) LDL change in mmol/l was –0.25 (0.61) in the activity group, and –0.21 (0.67) in the control group. Mean LDL change in the intervention group compared with control was –0.04 (95% CI –0.31 to 0.23).* *At 12 months, mean (SD) HDL change in mmol/l was 0.11 (0.15) in the activity group, and –0.02 (0.11) in the control group. Mean HDL change in the intervention group compared with control was 0.13 (95% CI 0.08 to 0.18).* *At 12 months, mean (SD) TAG change in mmol/l was –0.16 (0.53) in the activity group, and 0.08 (0.60) in the control group. Mean TAG change in the intervention group compared with control was –0.24 (95% CI –0.48 to 0.00).* *At 12 months, mean (SD) DBP change in mmHg was –4.10 (8.00) in the activity group, and –2.60 (8.10) in the control group. Mean DBP change in the intervention group compared with control was –1.50 (95% CI –5.11 to 2.11).* *At 12 months, mean (SD) SBP change in mmHg was –6.60 (8.40) in the activity group, and –4.10 (8.00) in the control group. Mean SBP change in the intervention group compared with control was –2.50 (95% CI –6.17 to 1.17).* **TC ratio/HDL cholesterol ratios were significantly lower in the activity group compared with control at both 7 and 12 months (p≤0.05).* *At 12 months, the activity group showed significant changes from baseline compared with control for body fat (–3.7% vs –0.9%) (p<0.01), g of fat per day (–2.2 vs 1.4) (p<0.05), and mono-unsaturated fat intake (–1.1 vs 0.5 g/kcal) (p<0.01). No other changes in outcomes were significant (energy per day, saturated fat, polyunsaturated fat, alcohol, calcium, potassium, sodium levels).* *At 12 months,* VO_{2max} *and treadmill test duration increased significantly in the activity group compared with control (p≤0.001) (treadmill test duration [min] 4.1 vs –2.4* VO_{2max}*, and 0.3 vs –1.6).*
Quality and comments	Dietary intake estimated from participants' 7-day food diaries. Supervised exercise. *In the summary statistics, only the 12-month value is significant?

Reported harms

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Harms	*One death and two cancers (allocation not known).*
Quality and comments	…

Pritchard 1997 (in Shaw CR) RCT	
Harms	Two participants withdrew before completion due to ill health unrelated to the study.
Quality and comments	…

Wood 1988 (in Shaw CR) RCT	
Harms	*One diagnosis of cancer reported in year 2.*
Quality and comments	…

Generalisability

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Country and setting	Norway. Community-based?

Participants (included/excluded)	*Included if aged 41 to 50 years, sedentary (exercise no more than once per week), BMI >24 kg/m^2, DBP 86 to 99 mmHg, TC 5.2 to 7.74 mmol/l, HDL <1.2 mmol/l, fasting serum TAG >1.4 mmol/l. Excluded if overt diabetes or CVD, other disease or drugs that could interfere with test results, treatment with antihypertensive drugs, acetylsalicylic acid, lipid-lowering diet, personal traits unsuitable for inclusion.*
Recruitment	Participants recruited from continuous screening programme of 40-year old men and women in Oslo. No further details reported.
Intervention (mode and intensity)	12 months, contacted 158 times (baseline, three times per week and follow-up at 12 months)
Duration of active intervention	*12 months*
Control (mode and intensity)	*12-month control. Contacted at baseline and 12 months.*
Delivery of intervention/control (who)	N/R other than 'under the guidance of highly qualified instructors'.
Dropout rates	9% in activity group and 0% in control at 12 months (includes five excluded).
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pritchard 1997 (in Shaw CR) RCT	
Country and setting	Australia. Work-based.
Participants (included/excluded)	*Included men aged 35 to 55 years of age, satisfactory cardiovascular fitness test, BMI 26 to 35 kg/m^2, 110 to 130% of IBW, otherwise healthy.* *No details of exclusion criteria given.*
Recruitment	Volunteers recruited from a national business corporation, previously screened as being overweight in a corporate health programme.
Intervention (mode and intensity)	18 months of intervention. Contacted 19 times (baseline then monthly. Also encouraged to attend bimonthly motivational group breakfasts or lunch meetings with guest speakers or videos relevant to diet, exercise and health issues).
Duration of active intervention	*12 months*
Control (mode and intensity)	12 months of control. 6 months of diet and exercise. Contacted at baseline and weight monitored monthly
Delivery of intervention/control (who)	N/R
Dropout rates	*5% in the activity group and 5% in the control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Wood 1988 (in Shaw CR) RCT	
Country and setting	USA. University clinic.
Participants (included/excluded)	*Included men aged 30 to 59 years, 120 to 160% IBW, no regular exercise for past 3 months, non-smokers, clinically healthy, resting clinic BP <160/100mmHg, plasma cholesterol<8.28mmol/l, plasma TAG<5.65mmol/l, average<4 alcoholic drinks per day, expected to reside in Stanford area for at least 12 months, normal ECG during grade treadmill test.* *Excluded if orthopaedic limitations, medications known to effect BP or plasma lipids.*

Recruitment	Potential participants invited to be screened via mass media. Interviewed by telephone, and scheduled for orientation session if criteria met and still interested.
Intervention (mode and intensity)	First 12 months, no details of frequency of contact. In year 2, monthly mailings, telephone contact of 5 to 10mins each during months 13, 14, 15, 18, 21, 24 (for contact groups). In year 2, contacted twice at 18 and 24 months (no contact groups).
Duration of active intervention	*12 months*
Control (mode and intensity)	Contacted three times in year 1 – baseline and 7, 12 months.
Delivery of intervention/control (who)	Exercise supervised by ‘training staff’. No details given.
Dropout rates	2% activity, 6% control in first 12 months. 13% activity 2 (contact) group, 32% in activity 3 (no contact) group at 24 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.2 Physical activity vs information

Weight loss

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis
Participants	People with osteoarthritis, aged 60 years and older who were overweight (BMI ≥28 kg/m^2) Total 316 – 227 F, 89 M. Mean (SD) age years 69 (7.16) years activity (*n*=80), 68 (6.34) years BT (*n*=82). Mean (SD) BMI (kg/m^2) 34.2 (5.37) activity, 34.5 (5.43) BT.
Intervention	Three days/week exercise programme consisted of an aerobic phase (15 min), a resistance-training phase (15 min), a second aerobic phase (15 min), and a cool-down phase (15 min). The first 4 months of the 18-month intervention was facility-based. At any time after the first 4 months, participants who wished to exercise at home underwent a 2-month transition phase during which he or she alternated attendance between the facility and the home. Hence, some participants remained in a facility-based programme, others opted for a home-based programme, and some participants chose a combined facility–home-based programme. Provided with an aerobic exercise prescription that included walking within a heart rate range of 50–75% of heart rate reserve. The resistance-training portion of the programme consisted of two sets of 12 repetitions of the following exercises: leg extension, leg curl, heel raise, and step-up. Cuff weights and weighted vests were used to provide resistance. A 1.0–1.5-min rest interval separated each exercise. Following two orientation sessions, participants began the exercise programme using the lowest possible resistance. Resistance was increased after the participant performed two sets of 12 repetitions for two consecutive days. *For participants in the home-based programme, weights were exchanged at the participant's request or after a determination was made during face-to-face or telephone contact to increase the weights. Telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Exercise and attendance logs were used to gather data and monitor progress.*
Control	The group met monthly for 1 h for the first 3 months. A health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity, and exercise, organised the healthy lifestyle programme. Patients were advised to follow the American College of Rheumatology and European League Against Rheumatism recommendations for weight loss and exercise as treatments for OA. Question-and-answer sessions followed each presentation. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18. During phone contact, information on pain, medication use, illnesses and hospitalisation was obtained.
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –3.46 (6.89) in the activity group, and 1.10 (6.22) in the information group. Mean weight change in the intervention group compared with BT was –4.56 (95% CI –6.61 to –2.51).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated*

Other outcomes

Messier 2004 RCT	
Results	*No significant differences were seen for self-reported physical function, motility, or pain (although pain did improve in all groups over time) in the activity group compared with BT only.*
Quality and comments	…

Reported harms

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant tripped and sustained a laceration to his head. No details of allocation.
Quality and comments	…

Generalisability

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	Included if aged ≥60 years, calculated BMI ≥28 kg/m^2, knee pain on most days of the month, sedentary activity pattern with <20 min of formal exercise once weekly for the past 6 months, self-reported difficulty in at least one of the following activities ascribed to knee pain: walking one-quarter of a mile (three to four city blocks), climbing stairs, bending, stooping, kneeling (e.g., to pick up clothes), shopping, house cleaning or other self-care activities, getting in and out of bed, standing up from a chair, lifting and carrying groceries, or getting in and out of the bath, radiographic evidence of grade I–III tibiofemoral or patellofemoral OA based on weight-bearing anteroposterior and sunrise view radiographs, and willingness to undergo testing and intervention procedures. Excluded if serious medical condition that prevented safe participation in an exercise programme, including symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, chronic obstructive pulmonary disease, severe insulin-dependent diabetes mellitus, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, anaemia, a Mini-Mental State Examination score of <24, inability to finish the 18-month study or unlikely to be compliant, inability to walk without a cane or other assistive device, participation in another research study, reported alcohol consumption of >14 drinks per week, ST segment depression of at least 2 mm at an exercise level of 4 METS or less, hypotension, or complex arrhythmias during a graded exercise test, inability to complete the protocol, in the opinion of the clinical staff, because of frailty, illness, or other reasons.

Recruitment	Mass mailings to age-eligible persons within the target area, targeted mailings to employees of the university and medical centre, presentations to various groups of older adults, mass media advertisement, and placement of posters (with pull-off reply cards attached) in strategic locations. Also, strategies were developed to enhance recruitment among racial minorities, including ads and interviews on minority-run radio stations, newspaper ads in predominantly African American publications, letters to churches attended mainly by minorities, and inserts in these church bulletins. Initial screening for major eligibility criteria was via telephone.
Intervention (mode and intensity)	*Three days/week exercise for 4 months (facility-based), then either home- or facility-based. For participants in the home-based programme, telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Assessment at baseline, 6, 18 months.*
Duration of active intervention	18 months
Control (mode and intensity)	One introductory individual session was followed by 16 weekly sessions (three group sessions and one individual session each month). The transition phase included sessions every other week for 8 weeks (three group sessions and one individual session). The maintenance phase included monthly meetings and phone contacts, alternated every 2 weeks.
Delivery of intervention/control (who)	Exercise: not reported BT: not reported.
Dropout rates	*20% activity, 23% information at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.3 Physical activity vs diet

Weight loss

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Aim	The primary aim of the trial was to compare the isolated and combined effects of the diet and exercise on the variables fibrinogen, fibrinolytic capacity, coagulation factor VII and platelet volume. Secondary aims were the effects on other coagulation and fibrinolytic components and activities; lipids and lipoproteins; fatty acids; glucose and insulin response to a glucose load; clinical, physiological and anthropometric variables; and quality of life
Participants	*Men and women aged 41 to 50 years who were overweight (BMI >24 kg/m^2) and sedentary.* *219 total – 21 F, 198 M. Mean (SD) age 44.9 (2.5) years. Mean (SD) BMI (kg/m^2) 29.54 (3.89) diet group (*n*=55), 28.56 (3.22) exercise group (*n*=54), 28.57 (3.47) diet and exercise group (*n*=67), 28.30 (3.15) control group (*n*=43).*
Intervention	For initial 8 weeks the intensity and duration of supervised endurance workouts increased progressively then maintained at three times per week for 1 h each session at 60–80% maximum heart rate as assessed at baseline using treadmill; 60% of each workout was aerobic, 25% circuit training and 15% fast walking/jogging, attendance measured and exercise log book kept. Advised to stop smoking.

Control	*Dietary counselling with spouse at baseline then individually at 3- and 9-month follow-up sessions. Diet adapted to individual's risk profile with main focus on energy restriction in those overweight, increase in fish and vegetables, decrease in saturated fat, cholesterol, sugar, and salt restriction for those with elevated BP. Weight targets agreed and set. 180 food-frequency questionnaire at baseline and 12 months. Advised to stop smoking.*
Length of follow-up	12 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –0.09 (4.20) in the activity group, and –4.00 (5.05) in the diet group. Mean weight change in the intervention group compared with control was 3.10 (95% CI 1.29 to 4.91).
Quality and comments	TC and LDL levels significantly lower in the exercise and the diet and exercise groups (*p*<0.05). ITT not done. Only blood analyses blinded. Discrepancy between results in published papers. Good concealment of allocation.

Pritchard 1997 (in Shaw CR) RCT	
Aim	To compare the effects of two weight loss interventions, diet or exercise, on changes in bone, fat and lean tissue
Participants	*Healthy men aged 35 to 55 years who were overweight (BMI 26 to 35 kg/m^2). 66 total – all men. Mean age (SD) 44.9 (6.5) years in the activity group (n=22), 43.6 (6.0) years in the diet group (n=20). Mean BMI (SD) (kg/m^2) 29.2 (2.8) in the activity group, 29.0 (2.8) in the diet. Data for 12 month completers only (n=58 overall).*
Intervention	Participants selected their own unsupervised aerobic exercise regimen of at least 3 sessions of 30 min each week at 65–75% maximum heart rate; initial heart rate over 33 h normal activity which included the selected exercise used to determine personal heart rate target zone; eleven participants walked, two jogged, two alternated jogging and swimming, three attended the gym and three rode exercise bikes, participants exercised 3–7 sessions per week, advised to avoid change in food intake, completion of daily adherence calendar, at 13 months dietary intervention was added. (See Diet review for detail of diet intervention.)
Control	*Advised to follow low-fat intake of 20 to 22% energy per day, to avoid foods rich in fat, discouraged from eating more than one sweet per day and more than two alcoholic drinks/day. Personalised diet plan to meet RDI for use in Australia, given* The Weight Loss Guide *by the Australian Heart Foundation. Exercise restricted to pre-study level. Completion of daily adherence calendar. At 13 months, exercise intervention was added.*
Length of follow-up	18 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –2.60 (3.00) in the activity group, and –6.40 (3.30) in the diet group. Mean weight change in the intervention group compared with control was 3.80 (95% CI 1.72 to 5.88).
Quality and comments	ITT analysis done. Blinded assessment not done. Real possibility of disclosure of allocation, although some attempt made at concealment. Author provided unpublished report. Data up to 12 months only used. Discrepancy in data between reports.

Wood 1988 (in Shaw CR) RCT	
Aim	To determine the influence of two methods for losing fat weight on the levels of plasma lipids and lipoproteins in overweight sedentary men – decreasing energy intake without increasing exercise (diet), and increasing energy expenditure without altering energy intake (exercise, primarily running)

Participants	*Men aged 30 to 59 years, overweight (120 to 160% IBW) and no regular exercise for past 3 months.* *155 M. Mean (SD) age 44.2 (8.2) years diet group (*n=51*), 44.1 (7.8) years activity group (*n=52*), 45.2 (7.2) years control (*n=52*). Mean (SD) weight 93.0 (8.8) kg diet group, 94.1 (8.6) activity group, and 95.4 (10.6) control. (Results for 131 assessed participants.)* Noted in HTA as highest mean reported weight (kg).
Intervention	Participants received supervised exercise training session to promote increase in energy expenditure and body fat loss of one-third, consisting of 1 h three times per week including callisthenics, walking, jogging and principally running at 60–80% peak heart rate (according to treadmill test results), advised to increase routine physical activity plus two more sessions per week unsupervised exercise; activity logs kept and advised not to change diet including composition, weight stabilisation last 6 weeks.
Control	*Baseline 7 day diet recall and fat body mass used to provide individual counselling including behavioural strategies (no details), to reduce energy intake to produce gradual weight loss and to lose one-third of body fat (assumed a reduction of 7762 kcal for loss of 1 kg adipose tissue). No change in nutrient composition, requested to remain sedentary, included weight stabilisation for last 6 weeks.*
Length of follow-up	24 months
Results	*At 7 months, mean (SD) weight change in kg was –3.00 (2.80) in the activity group, and –7.60 (3.9) in the diet group. Mean weight change in the intervention group compared with control was 4.60 (95% CI 3.17 to 6.03).* *At 12 months, mean (SD) weight change in kg was –4.00 (3.90) in the activity group, and –7.20 (3.70) in the diet group. Mean weight change in the intervention group compared with control was 3.20 (95% CI 1.62 to 4.78).*
Quality and comments	ITT analysis not done. Blinded assessment only in year 2. Random allocation but no description of concealment. Only 12 month outcomes reported in published papers.

Other outcomes

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.20 (0.56) in the activity group, and –0.23 (0.65) in the diet group. Mean TC change in the intervention group compared with control was 0.03 (95% CI –0.21 to 0.27). At 12 months, mean (SD) LDL change in mmol/l was –0.13 (0.49) in the activity group, and –0.18 (0.72) in the diet group. Mean LDL change in the intervention group compared with control was 0.05 (95% CI –0.19 to 0.29). At 12 months, mean (SD) HDL change in mmol/l was 0.04 (0.14) in the activity group, and 0.05 (0.12) in the diet group. Mean HDL change in the intervention group compared with control was –0.01 (95% CI –0.06 to 0.04). At 12 months, mean (SD) TAG change in mmol/l was –0.24 (0.70) in the activity group, and- 0.23 (1.01) in the diet group. Mean TAG change in the intervention group compared with control was –0.01 (95% CI –0.35 to 0.33). At 12 months, mean (SD) DBP change in mmHg was –2.70 (7.00) in the activity group, and –3.40 (7.21) in the diet group. Mean DBP change in the intervention group compared with control was 0.70 (95% CI –2.07 to 3.47). At 12 months, mean (SD) SBP change in mmHg was –2.20 (7.70) in the activity group, and –6.40 (10.10) in the diet group. Mean SBP change in the intervention group compared with control was 4.20 (95% CI 0.71 to 7.69). At 12 months, mean (SD) FPG change in mmol/l was –0.09 (0.42) in the activity group, and –0.21 (0.50) in the diet group. Mean FPG change in the intervention group compared with control was 0.12 (95% CI –0.06 to 0.30). *The activity group had a significant mean change from baseline in fat intake*

	(as % of energy) of –1.6% ($p<0.05$). No other changes from baseline were significant. This compared with significant changes from baseline in the diet group for energy intake (–550 kcal), protein (–13.4 g), fat (–32.5 g), %energy as fat (–5.1%), carbohydrate (–42.3 g), sugar (–16.8 g), alcohol (–2.5 g), cholesterol (–121 mg), saturated fatty acids (–13.6 g), monounsaturated fatty acids (–12.3 g) and polyunsaturated fatty acids (–4.9 g). *At 12 months,* VO_{2max} *had significantly increased by 4.0 ml/kg per min compared with the diet group (1.70 ml/kg per min).*
Quality and comments	Dietary intake assessed through a validated food-frequency questionnaire. Activity was supervised, and home activity was recorded (no details). Also participants interviewed at 12 months about changes in activity habits.

Pritchard 1997 (in Shaw CR) RCT	
Results	*At 12 months, significant differences from baseline were seen in the activity group compared with diet for index of activity (+15.6 vs +3.4%) and energy expenditure (+14.6 vs +5.9%) ($p<0.05$).* *At 12 months, the activity group increased energy intake by 3.1% compared with a decrease of 30.4% in the diet group. The activity group decreased fat intake by 1.0% compared with 32.0% in the diet group. Energy from protein decreased in the activity group and increased in the diet group (–2.3 vs +23.3%). Also there was a significant increase in dietary calcium in the activity group compared with diet (+30.3 vs –13.6%).* *Also at 12 months, bone mass and bone mineral density decreased in both groups (–0.8 vs –1.4 and –1.1 vs –1.5%, respectively). Fat mass decreased in both groups (–11.0 vs –19.4%).*
Quality and comments	Dietary intake estimated from participants' 3-day food diaries. Activity from 3-day diaries and 24-h activity logs monthly.

Wood 1988 (in Shaw CR) RCT	
Results	*At 7 months, there was no significant differences between the activity and diet groups for changes in TC, LDL, TAG, HDL levels.* *At 12 months, mean (SD) TC change in mmol/l was –0.25 (0.64) in the activity group, and –0.36 (0.56) in the diet group. Mean TC change in the intervention group compared with control was 0.11 (95% CI –0.14 to 0.36).* *At 12 months, mean (SD) LDL change in mmol/l was –0.25 (0.61) in the activity group, and –0.31 (0.64) in the diet group. Mean LDL change in the intervention group compared with control was 0.06 (95% CI –0.20 to 0.32).* *At 12 months, mean (SD) HDL change in mmol/l was 0.11 (0.15) in the activity group, and 0.12 (0.16) in the diet group. Mean HDL change in the intervention group compared with control was –0.01 (95% CI –0.08 to 0.06).* *At 12 months, mean (SD) TAG change in mmol/l was –0.16 (0.53) in the activity group, and –0.27 (0.72) in the diet group. Mean TAG change in the intervention group compared with control was 0.11 (95% CI –0.16 to 0.38).* *At 12 months, mean (SD) DBP change in mmHg was –4.10 (8.00) in the activity group, and –5.60 (7.30) in the diet group. Mean DBP change in the intervention group compared with control was 1.50 (95% CI –1.85 to 4.85).* *At 12 months, mean (SD) SBP change in mmHg was –6.60 (8.40) in the activity group, and –5.70 (7.90) in the diet group. Mean SBP change in the intervention group compared with control was –0.90 (95% CI –4.47 to 2.67).* *TC:HDL cholesterol ratios were not significantly different between the groups at any time point.* *At 12 months, the activity group showed significant changes from baseline compared with diet for grams of fat per day (–2.2 vs 2.0) ($p<0.05$). No other changes in outcomes were significant (% body fat, energy per day, saturated fat, mono- and poly-unsaturated fat, alcohol, calcium, potassium, sodium levels).* *At 12 months,* VO_{2max} *and treadmill test duration increased significantly in the activity group compared with diet (4.1 vs 0.0* VO_{2max}*, and 0.3 vs –0.8 treadmill test duration in min).*

Quality and comments	Dietary intake estimated from participants' 7-day food diaries. Supervised exercise.

Reported harms

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Harms	*One death and two cancers (allocation not known).*
Quality and comments	…

Pritchard 1997 (in Shaw CR) RCT	
Harms	Two participants withdrew before completion due to ill health unrelated to the study.
Quality and comments	…

Wood 1988 (in Shaw CR) RCT	
Harms	*One diagnosis of cancer reported in year 2.*
Quality and comments	…

Generalisability

ODES 1995 (in Shaw CR Anderssen 1996) RCT	
Country and setting	Norway. Community-based?
Participants (included/excluded)	*Included if aged 41 to 50 years, sedentary (exercise no more than once per week), BMI >24 kg/m^2, DBP 86 to 99 mmHg, TC 5.2 to 7.74 mmol/l, HDL <1.2 mmol/l, fasting serum TAG >1.4 mmol/l. Excluded if overt diabetes or CVD, other disease or drugs that could interfere with test results, treatment with antihypertensive drugs, acetylsalicylic acid, lipid-lowering diet, personal traits unsuitable for inclusion.*
Recruitment	Participants recruited from continuous screening programme of 40-year-old men and women in Oslo. No further details reported.
Intervention (mode and intensity)	12 months, contacted 158 times (baseline, three times per week and follow-up at 12 months)
Duration of active intervention	*12 months*
Control (mode and intensity)	Dietary intervention lasted 12 months. 4 contacts (baseline, 3, 9, 12 months).
Delivery of intervention/control (who)	N/R other than exercise 'under the guidance of highly qualified instructors'.
Dropout rates	9% in activity group and 5% in diet group at 12 months, (includes 5 excluded)
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pritchard 1997 (in Shaw CR) RCT	
Country and setting	Australia. Work-based.
Participants (included/excluded)	*Included men aged 35 to 55 years of age, satisfactory cardiovascular fitness test, BMI 26 to 35 kg/m^2, 110 to 130% of IBW, otherwise healthy.* *No details of exclusion criteria given.*

Recruitment	Volunteers recruited from a national business corporation, previously screened as being overweight in a corporate health programme.
Intervention (mode and intensity)	18 months of intervention. Contacted 19 times (baseline then monthly. Also encouraged to attend bimonthly motivational group breakfasts or lunch meetings with guest speakers or videos relevant to diet, exercise and health issues).
Duration of active intervention	*12 months*
Control (mode and intensity)	12 months of control. 6 months of diet and exercise. Contacted at baseline and weight monitored monthly
Delivery of intervention/control (who)	N/R
Dropout rates	*5% in the activity group and 25% in the diet at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Wood 1988 (in Shaw CR) RCT	
Country and setting	USA. University clinic.
Participants (included/excluded)	*Included men aged 30 to 59 years, 120 to 160% IBW, no regular exercise for past 3 months, non-smokers, clinically healthy, resting clinic BP <160/100 mmHg, plasma cholesterol <8.28 mmol/l, plasma TAG <5.65 mmol/l, average less than four alcoholic drinks per day, expected to reside in Stanford area for at least 12 months, normal ECG during grade treadmill test.* *Excluded if orthopaedic limitations, medications known to effect BP or plasma lipids.*
Recruitment	Potential participants invited to be screened via mass media. Interviewed by telephone, and scheduled for orientation session if criteria met and still interested.
Intervention (mode and intensity)	First 12 months, no details of frequency of contact. In year 2, monthly mailings, telephone contact of 5 to 10 min each during months 13, 14, 15, 18, 21, 24 (for contact groups). In year 2, contacted twice at 18 and 24 months (no contact groups).
Duration of active intervention	*9 months*
Control (mode and intensity)	Contacted three times in year 1 – baseline and 7, 12 months.
Delivery of intervention/control (who)	Registered dietitian provided individual counselling. Exercise supervised by ‘training staff’ No details given.
Dropout rates	2% activity, 4% diet in first 12 months. 13% activity 2 (contact) group, 32% in activity 3 (no contact) group at 24 months. 17% diet 2 (contact) group, 20% in diet 3 (no contact) group at 24 months.
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.4 Physical activity and diet vs behaviour therapy

Weight loss

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis
Participants	People with osteoarthritis, aged ≥60 years who were overweight (BMI ≥28 kg/m^2) Total 316 – 227 F, 89 M. Mean (SD) age years 69 (7.16) years activity (*n*=80), 68 (6.34) years BT (*n*=82). Mean (SD) BMI 34.2 9 (kg/m^2) (5.37) activity, 34.5 (5.43) BT.
Intervention	Three days/week exercise programme consisted of an aerobic phase (15 min), a resistance-training phase (15 min), a second aerobic phase (15 min), and a cool-down phase (15 min). The first 4 months of the 18-month intervention was facility-based. At any time after the first 4 months, participants who wished to exercise at home underwent a 2-month transition phase during which he or she alternated attendance between the facility and the home. Hence, some participants remained in a facility-based programme, others opted for a home-based programme, and some participants chose a combined facility–home-based programme. Provided with an aerobic exercise prescription that included walking within a heart rate range of 50–75% of heart rate reserve. The resistance-training portion of the programme consisted of two sets of 12 repetitions of the following exercises: leg extension, leg curl, heel raise and step-up. Cuff weights and weighted vests were used to provide resistance. A 1.0–1.5-min rest interval separated each exercise. Following two orientation sessions, participants began the exercise programme using the lowest possible resistance. Resistance was increased after the participant performed two sets of 12 repetitions for twp consecutive days. *For participants in the home-based programme, weights were exchanged at the participant's request or after a determination was made during face-to-face or telephone contact to increase the weights. Telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Exercise and attendance logs were used to gather data and monitor progress.* *Diet: to produce and maintain an average weight loss of 5% during the 18-month intervention period. Classified as a 600 kcal/day deficit/LED diet.*

Control	Goal was to produce and maintain an average weight loss of 5% during the 18-month intervention period. Dietary intervention was divided into three phases: intensive (months 1–4), transition (months 5–6) and maintenance (months 7–18). Major emphasis of the intensive phase was to heighten awareness of the importance of and need for changing eating habits in order to lower energy intake. Behaviour change was facilitated using self-regulatory skills. These skills included self-monitoring, goal setting, cognitive restructuring, problem-solving, and environmental management. One introductory individual session was followed by 16 weekly sessions (three group sessions and one individual session each month). Each group session included problem-solving, the review of a specific topic, and tasting of several well-balanced, low-fat, nutritious foods prepared with widely available ingredients. The individual sessions were used to review individual progress, solve problems, answer questions and set goals. The transition phase included sessions every other week for 8 weeks (three group sessions and 1 individual session). The goals for this phase included assisting participants who had not reached their weight loss goals in establishing new goals, and maintaining and preventing relapse in those participants who had reached their weight loss goals. The maintenance phase included monthly meetings and phone contacts, alternated every 2 weeks. Additionally, newsletters that provided pertinent nutritional information and notice of upcoming meetings were mailed at regular intervals. The goals of the maintenance phase included assisting participants who had reached their weight loss goals to maintain this weight loss, and providing counselling for participants who had a difficult time losing weight and adhering to the intervention. Adherence to the intervention was based on attendance at scheduled sessions and completion of the monthly assessment of weight.
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –3.46 (6.89) in the activity group, and –4.61 (7.22) in the BT group. Mean weight change in the intervention group compared with BT was –1.15 (95% CI –1.02 to 3.32).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated*

Other outcomes

Messier 2004 RCT	
Results	*No significant differences were seen for self-reported physical function, motility, or pain (although pain did improve in all groups over time) in the activity group compared with BT only.*
Quality and comments	…

Reported harms

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant tripped and sustained a laceration to his head. No details of allocation.
Quality and comments	…

Generalisability

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	Included if aged 60 years or older, calculated BMI ≥28 kg/m^2, knee pain on most days of the month, sedentary activity pattern with <20 min of formal exercise once weekly for the past 6 months, self-reported difficulty in at least one of the following activities ascribed to knee pain: walking one-quarter of a mile (three to four city blocks), climbing stairs, bending, stooping, kneeling (e.g., to pick up clothes), shopping, house cleaning or other self-care activities, getting in and out of bed, standing up from a chair, lifting and carrying groceries, or getting in and out of the bath, radiographic evidence of grade I–III tibiofemoral or patellofemoral OA based on weight-bearing anteroposterior and sunrise view radiographs, and willingness to undergo testing and intervention procedures. Excluded if serious medical condition that prevented safe participation in an exercise programme, including symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, chronic obstructive pulmonary disease, severe insulin-dependent diabetes mellitus, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, and anaemia, a Mini-Mental State Examination score of <24, inability to finish the 18-month study or unlikely to be compliant, inability to walk without a cane or other assistive device, participation in another research study, reported alcohol consumption of more than 14 drinks per week, ST segment depression of at least 2 mm at an exercise level of 4 METS or less, hypotension, or complex arrhythmias during a graded exercise test, inability to complete the protocol, in the opinion of the clinical staff, because of frailty, illness, or other reasons.
Recruitment	Mass mailings to age-eligible persons within the target area, targeted mailings to employees of the university and medical centre, presentations to various groups of older adults, mass media advertisement, and placement of posters (with pull-off reply cards attached) in strategic locations. Also, strategies were developed to enhance recruitment among racial minorities, including advertisements and interviews on minority-run radio stations, newspaper ads in predominantly African American publications, letters to churches attended mainly by minorities, and inserts in these church bulletins. Initial screening for major eligibility criteria was via telephone.
Intervention (mode and intensity)	*Three days/week exercise for 4 months (facility-based), then either home- or facility-based. For participants in the home-based programme, telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Assessment at baseline, 6, 18 months.*
Duration of active intervention	18 months
Control (mode and intensity)	One introductory individual session was followed by 16 weekly sessions (three group sessions and one individual session each month). The transition phase included sessions every other week for 8 weeks (three group sessions and one individual session). The maintenance phase included monthly meetings and phone contacts, alternated every 2 weeks.
Delivery of intervention/control (who)	Exercise: not reported BT: not reported.

Dropout rates	*20% activity, 23% information at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.5 Physical activity and diet vs control (no treatment)

Weight loss

ODES 1995 (in Shaw CR and HTA) RCT	
Aim	The primary aim of the trial was to compare the isolated and combined effects of the diet and exercise on the variables fibrinogen, fibrinolytic capacity, coagulation factor VII, and platelet volume. Secondary aims were the effects on other coagulation and fibrinolytic components and activities; lipids and lipoproteins; fatty acids; glucose and insulin response to a glucose load; clinical, physiological and anthropometric variables; and quality of life
Participants	*Men and women aged 41 to 50 years who were overweight (BMI >24 kg/m^2) and sedentary.* *219 total – 21 F, 198 M. Mean (SD) age 44.9 (2.5) years. Mean (SD) BMI (kg/m^2) 29.54 (3.89) diet group (n=55), 28.56 (3.22) exercise group (n=54), 28.57 (3.47) diet and exercise group (n=67), 28.30 (3.15) control group (n=43).*
Intervention	For initial 8 weeks the intensity and duration of supervised endurance workouts increased progressively then maintained at three times per week for 1 h each session at 60–80% maximum heart rate as assessed at baseline using treadmill; 60% of each workout was aerobic, 25% circuit training and 15% fast walking/jogging, attendance measured and exercise log book kept. Advised to stop smoking. Dietary counselling with spouse at baseline then individually at 3 and 9 month follow-up sessions. Diet adapted to individual’s risk profile with main focus on energy restriction in those overweight, increase in fish and vegetables, decrease in saturated fat, cholesterol, sugar, and salt restriction for those with elevated BP. Weight targets agreed and set. 180 food-frequency questionnaire at baseline and 12 months.
Control	*Told not to change lifestyle and that after 12 months would receive dietary advice and supervised physical training. Advised to stop smoking.*
Length of follow-up	12 months
Results	*Only 12 month outcomes reported.* At 12 months, mean (SD) weight change in kg was –5.60 (4.84) in the activity and diet group, and 1.10 (2.62) in the control group. Mean weight change in the intervention group compared with control was –6.70 (95% CI –8.11 to –5.29).
Quality and comments	TC and LDL levels significantly lower in the exercise and the diet and exercise groups (*p*<0.05). ITT not done. Only blood analyses blinded. Discrepancy between results in published papers. Good concealment of allocation.

Wood 1991 (in HTA) RCT	
Aim	To test the hypothesis that exercise (walking or jogging) will increase HDL-cholesterol levels in moderately overweight, sedentary people who adopt a hypoenergetic National Cholesterol Education Programme (NCEP) diet
Participants	*Sedentary people (exercise less than twice per week) who were moderately overweight (BMI 28 to 34 kg/m^2 for men, 24 to 20 kg/m^2 for women).* *264 total – 132 F, 132 M. Mean (SD) age 39.1 (6.4) years women, 40.3 (6.3) years men. Mean BMI (kg/m^2) (SD) 27.9 (2.2) women, 30.7 (2.2) men.* (Noted as lowest mean BMI in HTA) *87 allocated to diet, 90 to diet and exercise and 87 to control.*

Intervention (including details of diet)	*NCEP step 1 diet consisting of 55% energy as carbohydrate, 30% as fat (saturated fat ≤10%), dietary cholesterol <300 mg/day, energy reduction. Activity was aerobic exercise (brisk walking or jogging) at 60–80% maximum heart rate initially for 25 min three times per week increasing to 45 min three times per week by month 4, monthly activity logs kept.*
Control	Instructed to maintain usual diet and exercise patterns.
Length of follow-up	*12 months*
Results	*Only 12 months outcomes reported.* Women: At 12 months, mean (SD) weight change in kg was –5.10 (5.30) in the activity and diet group, and 1.30 (5.20) in the control group. Mean weight change in the intervention group compared with control was –6.40 (95% CI –8.69 to –4.11). Men: At 12 months, mean (SD) weight change in kg was –8.70 (5.70) in the activity and diet group, and 1.70 (4.80) in the control group. Mean weight change in the intervention group compared with control was –10.40 (95% CI –12.73 to –8.07).
Quality and comments	Significant differences between men in both intervention groups vs control for DBP ($p<0.001$), TC for women in diet group vs control ($p \le 0.01$), and diet and exercise group vs control ($p \le 0.05$), and LDL levels in women in both intervention groups vs control ($p \le 0.05$). Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment.

Midwest Exercise Trial 2003 RCT	
Aim	To determine the efficacy of a known quantity of exercise to prevent weight gain or to facilitate weight loss in sedentary, overweight and moderately obese adults
Participants	People who were overweight (BMI 25 to 24.9 kg/m^2) Total 131 – 43F, 31M (completers only). Women: Mean (SD) age 24 (5) years activity ($n=25$), 21 (4) years control ($n=18$). Mean (SD) BMI (kg/m^2) 28.7 (3.2) activity, 29.3 (2.3) control. Men: Mean (SD) age 22 (5) years activity ($n=16$), 24 (4) years control ($n=15$). Mean (SD) BMI 9 (kg/m^2) 29.7 (2.9) activity, 29.7 (2.9) control.
Intervention	*Exercise consisted primarily of walking on motor-driven treadmills; however, alternate activities such as stationary biking and walking on stationary elliptical trainers were allowed for 20% of the total exercise sessions (one of 5 days). Each participant's exercise prescription was calculated from a maximal treadmill test conducted at baseline and was updated by the results of maximal treadmill tests conducted at 4-month intervals.* *Duration of exercise progressed from 20 min at baseline to 45 min at 6 months and the intensity of exercise progressed from 60% of heart rate reserve at baseline to 75% at 6 months. This level of exercise corresponded to 55–70% of maximal oxygen consumption and was maintained for the remainder of the study. The targeted, minimum energy equivalent of exercise was about 400 kcal per session (about 2000 kcal/week), and this was gradually achieved during the first 6 months and then maintained for the remainder of the study.* *Participants consumed an ad libitum diet that was 30–35% energy as fat, 45–55% as carbohydrate, 10–25% as protein.*
Control	Identical testing, except for that related to the 16-month exercise programme. Instructed to maintain usual physical activity and dietary intake patterns.
Length of follow-up	*16 months*

Results	*Women (MET 2003a):* *At 4 months, mean (SD) weight change in kg was 0.40 (6.03) in the activity and diet group, and 1.50 (6.34) in the control group. Mean weight change in the intervention group compared with control was –1.10 (95% CI –4.86 to 2.66).* *At 9 months, mean (SD) weight change in kg was 0.10 (5.94) in the activity and diet group, and 1.90 (6.45) in the control group. Mean weight change in the intervention group compared with control was –1.80 (95% CI –5.58 to 1.98).* *At 12 months, mean (SD) weight change in kg was 0.70 (6.11) in the activity and diet group, and 2.40 (6.59) in the control group. Mean weight change in the intervention group compared with control was –1.70 (95% CI –5.57 to 2.17).* *At 16 months, mean (SD) weight change in kg was 0.60 (6.08) in the activity and diet group, and 2.90 (6.74) in the control group. Mean weight change in the intervention group compared with control was –2.30 (95% CI –6.22 to 1.62).* *Men (MET 2003b):* *At 4 months, mean (SD) weight change in kg was –2.90 (6.74) in the activity and diet group, and 0.10 (5.94) in the control group. Mean weight change in the intervention group compared with control was –3.00 (95% CI –7.47 to 1.47).* *At 9 months, mean (SD) weight change in kg was –5.30 (7.41) in the activity and diet group, and –1.20 (6.25) in the control group. Mean weight change in the intervention group compared with control was –4.10 (95% CI –8.92 to 0.72).* *At 12 months, mean (SD) weight change in kg was –4.60 (7.22) in the activity and diet group, and –0.60 (6.08) in the control group. Mean weight change in the intervention group compared with control was –4.00 (95% CI –8.69 to 0.69).* *At 16 months, mean (SD) weight change in kg was –5.20 (7.39) in the activity and diet group, and –0.50 (6.06) in the control group. Mean weight change in the intervention group compared with control was –4.70 (95% CI –9.45 to 0.05).* *Exercise prevented weight gain in women and produced weight loss in men. Men in the exercise group had significant mean ± SD decreases in weight (5.2±4.7 kg), BMI (calculated as weight in kilograms divided by the square of height in meters) (1.6±1.4), and fat mass (4.9±4.4 kg) compared with controls. Women in the exercise group maintained baseline weight, BMI, and fat mass, and controls showed significant mean ± SD increases in BMI (1.1±2.0), weight (2.9±5.5 kg), and fat mass (2.1±4.8 kg) at 16 months.*
Quality and comments	*No baseline differences between intervention and control groups.* *Significance differences between men and women for height, weight, % body fat, fat mass, fat-free mass and* VO_{2max}. *Assessment not blinded. ITT analysis not done. Random allocation but no description of concealment. SDs calculated.*

Other outcomes

ODES 1995 (in Shaw CR and HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.48 (0.89) in the activity and diet group, and –0.16 (0.59) in the control group. Mean TC change in the intervention group compared with control was –0.32 (95% CI –0.60 to –0.04). At 12 months, mean (SD) LDL change in mmol/l was –0.39 (0.81) in the activity and diet group, and –0.22 (0.59) in the control group. Mean LDL change in the intervention group compared with control was –0.17 (95% CI –0.43 to 0.09).

	At 12 months, mean (SD) HDL change in mmol/l was 0.13 (0.15) in the activity and diet group, and 0.02 (0.10) in the control group. Mean HDL change in the intervention group compared with control was 0.11 (95% CI 0.06 to 0.16). At 12 months, mean (SD) TAG change in mmol/l was –0.58 (0.97) in the activity and diet group, and 0.17 (0.92) in the control group. Mean TAG change in the intervention group compared with control was –0.75 (95% CI –1.11 to –0.39). At 12 months, mean (SD) DBP change in mmHg was –5.20 (7.26) in the activity and diet group, and –0.70 (8.52) in the control group. Mean DBP change in the intervention group compared with control was –4.50 (95% CI –7.60 to -1.40). At 12 months, mean (SD) SBP change in mmHg was –5.90 (8.87) in the activity and diet group, and –0.50 (11.15) in the control group. Mean SBP change in the intervention group compared with control was –5.40 (95% CI –9.37 to –1.43). At 12 months, mean (SD) FPG change in mmol/l was –0.26 (0.64) in the activity and diet group, and 0.07 (0.46) in the control group. Mean FPG change in the intervention group compared with control was –0.33 (95% CI –0.54 to –0.12). *At 12 months, significant changes from baseline were seen in the activity and diet group for energy intake (–382 kcal), protein (–7.7 g), fat (–26.5 g), % energy as fat (–5.3%), sugar (–19.6 g), cholesterol (–94 mg), saturated fatty acids (–12.1 g), monounsaturated fatty acids (–10.2 g) and polyunsaturated fatty acids (–2.9 g).* *At 12 months,* VO_{2max} *had increased by 6.7 ml/kg per min, which was significantly different to the control group (*p*<0.05). No figures were reported for the control group.*
Quality and comments	Dietary intake assessed through a validated food-frequency questionnaire. Activity was supervised, and home activity was recorded (no details). Also participants interviewed at 12 months about changes in activity habits.

Wood 1991 (in HTA) RCT	
Results	Women: At 12 months, mean (SD) TC change in mmol/l was –0.28 (0.52) in the activity and diet group, and –0.03 (0.47) in the control group. Mean TC change in the intervention group compared with control was –0.25 (95% CI –0.47 to –0.03). Women: At 12 months, mean (SD) LDL change in mmol/l was –0.29 (0.46) in the activity and diet group, and –0.03 (0.41) in the control group. Mean LDL change in the intervention group compared with control was –0.26 (95% CI –0.45 to –0.07). Women: At 12 months, mean (SD) HDL change in mmol/l was 0.02 (0.18) in the activity and diet group, and –0.05 (0.24) in the control group. Mean HDL change in the intervention group compared with control was 0.07 (95% CI –0.02 to 0.16). Women: At 12 months, mean (SD) TAG change in mmol/l was –0.02 (0.26) in the activity and diet group, and 0.13 (0.37) in the control group. Mean TAG change in the intervention group compared with control was –0.15 (95% CI –0.29 to –0.01). Women: At 12 months, mean (SD) DBP change in mmHg was –2.00 (4.10) in the activity and diet group, and 0.90 (5.30) in the control group. Mean DBP change in the intervention group compared with control was –2.90 (95% CI –4.97 to –0.83). Women: At 12 months, mean (SD) SBP change in mmHg was –3.60 (7.70) in the activity and diet group, and –0.20 (6.60) in the control group. Mean SBP change in the intervention group compared with control was –3.40 (95% CI –6.52 to –0.28). Men: At 12 months, mean (SD) TC change in mmol/l was –0.38 (0.87) in the activity and diet group, and –0.14 (0.64) in the control group. Mean TC change in the intervention group compared with control was –0.24 (95% CI –0.58 to

	0.10). Men: At 12 months, mean (SD) LDL change in mmol/l was –0.27 (0.78) in the activity and diet group, and –0.20 (0.59) in the control group. Mean LDL change in the intervention group compared with control was –0.07 (95% CI –0.38 to 0.24). Men: At 12 months, mean (SD) HDL change in mmol/l was 0.14 (0.18) in the activity and diet group, and –0.05 (0.15) in the control group. Mean HDL change in the intervention group compared with control was 0.19 (95% CI 0.12 to 0.26). Men: At 12 months, mean (SD) TAG change in mmol/l was –0.48 (0.75) in the activity and diet group, and 0.18 (0.67) in the control group. Mean TAG change in the intervention group compared with control was –0.66 (95% CI –0.97 to –0.35). Men: At 12 months, mean (SD) DBP change in mmHg was –4.90 (5.70) in the activity and diet group, and 2.10 (5.00) in the control group. Mean DBP change in the intervention group compared with control was –7.00 (95% CI –9.37 to –4.63). Men: At 12 months, mean (SD) SBP change in mmHg was –5.40 (8.30) in the activity and diet group, and 0.10 (7.70) in the control group. Mean SBP change in the intervention group compared with control was –5.50 (95% CI –9.03 to –1.97). *Women: at 12 months, significant decreases from baseline were seen in the activity and diet group compared with the control groups for total energy intake (–2057 vs 60 kJ/day, p≤0.001), total fat intake (–8.8 vs –0.9%, p≤0.001), saturated fat (–3.9 vs –0.4, p≤0.001) and cholesterol intake (–113 vs –5 mg/day, p≤0.001). A significant increase was seen for aerobic capacity (+6.4 vs 0.0 mg/kg per min, p≤0.001). Also, the estimated 12 year CHD risk decreased by 3.5 events/1000 persons in the activity and diet group compared with an increase of 1.3 in the control group (p≤0.001).* *Men: at 12 months, significant changes in baseline were seen in the* activity and diet *group compared with the control groups for total energy intake (–2368 vs 155 kJ/day, p≤0.001), total fat intake (–9.5 vs 0.8%, p≤0.001), saturated fat (–4.2 vs –0.2, p≤0.001) and cholesterol intake (–185 mg/day vs 7 mg/day, p≤0.001). A significant increase was seen for aerobic capacity (+8.6 mg/kg per min vs –0.2 mg/kg per min, p≤0.001). Also, the estimated 12 year CHD risk decreased by 21.8 events/1000 persons in the activity and diet group compared with an increase of 0.6 in the control group (p≤0.001).*
Quality and comments	*Significant differences between men in both intervention groups vs control for DBP (p<0.001), TC for women in diet group vs control (p≤0.01), and diet and exercise group vs control (p≤0.05), and LDL levels in women in both intervention groups vs control (p≤0.05).* Dietary intake estimated from participants' 7-day food diaries, with further probing for more detail by trained interviewers when collecting the data by telephone. Activity assessed by supervising staff.

Midwest Exercise Trial 2003 RCT	
Results	*For both women and men,* VO_{2max} *increased in both intervention and control groups over the 16 months, but were significantly increased in the activity and diet group.* *No significant differences were seen from baseline for energy intake (kcal), carbohydrate or fat intake in any group.* *A significant increase from baseline in protein intake (g) was seen in the intervention group of men (102 g to 106 g at16 months), but this was not seen in any of the other groups.* *FPG was reported at 9 and 16 months, but SDs for the mean change was not. However, only the intervention group of women showed a significant change from control (5.37 vs 5.66 mmol/l at 9 months, 5.06 vs 5.35 mmol/l at 16 months, no p value given).*
Quality and	Possible difference between baseline energy intake for men (3084 kcal

comments	intervention vs 3524 kcal control). Dietary intake was measured during a 2-week period when all meals were taken in the university cafeteria, and food consumption outside was measured using diet recalls. Activity was supervised and recorded by a study investigator.

Reported harms

ODES 1995 (in Shaw CR and HTA) RCT	
Harms	*One death and two cancers (allocation not known).*
Quality and comments	…

Wood 1991 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Midwest Exercise Trial 2003 RCT	
Harms	No major adverse events occurred during the study.
Quality and comments	…

Generalisability

ODES 1995 (in Shaw CR and HTA) RCT	
Country and setting	Norway. Community-based?
Participants (included/excluded)	*Included if aged 41 to 50 years, sedentary (exercise no more than once per week), BMI >24 kg/m^2, DBP 86 to 99 mmHg, TC 5.2 to 7.74 mmol/l, HD L<1.2 mmol/l, fasting serum TAG >1.4 mmol/l. Excluded if overt diabetes or CVD, other disease or drugs that could interfere with test results, treatment with antihypertensive drugs, acetylsalicylic acid, lipid-lowering diet, personal traits unsuitable for inclusion.*
Recruitment	Participants recruited from continuous screening programme of 40-year old men and women in Oslo. No further details reported.
Intervention (mode and intensity)	12 months, contacted 158 times (baseline, three times per week and follow-up at 12 months)
Duration of active intervention	*12 months*
Control (mode and intensity)	*12-month control. Contacted at baseline and 12 months.*
Delivery of intervention/control (who)	N/R other than exercise ‘under the guidance of highly qualified instructors’.
Dropout rates	3% in activity and diet group and 0% in control at 12 months, (includes 5 excluded)
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Wood 1991 (in HTA) RCT	
Country and setting	USA. University clinic?

Participants (included/excluded)	*Included if aged between 25 and 49 years, 120 to 150% IBW, BMI (kg/m^2) 28 to 34 for men, BMI 24 to 30 for women, non-smokers, sedentary (exercise less than twice per week, <30 min per time), resting BP <160/95 mmHg, plasma cholesterol <6.72 mmol/l, plasma TAG <5.65 mmol/l, average less than four alcoholic drinks per day, generally good health.* *Excluded if medication known to affect BP or lipid metabolism, pregnancy, lactating or taking oral contraception in past 6 months or planning pregnancy in subsequent 2 years.*
Recruitment	Potential participants were invited to be screened via mass media, followed with telephone interviews.
Intervention (mode and intensity)	12-month intervention. Contacted 25 times (baseline then weekly for first 3 months, then every other week for 3 months, then monthly)
Duration of active intervention	*12 months for diet. Less clear for activity. Activity was increased unto the maximum at 4 months, and monthly logs were then maintained – so assume 4 months for activity?*
Control (mode and intensity)	*Contacted twice (baseline and 12 months)*
Delivery of intervention/control (who)	Dietary recommendations were presented by a registered dietitian. Group sessions assumed to be dietitian? No details of who supervised activity.
Dropout rates	*18% in diet and activity group and 10% in control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Analyses restricted to individuals with complete data only.

Midwest Exercise Trial 2003 RCT	
Country and setting	USA. University clinics – no further details.
Participants (included/excluded)	Included if aged 17–35 years old and had BMI between 25.0 and 34.9 kg/m^2, met or exceeded the 85th percentile for triceps skinfold thickness of the second National Health and Nutrition Examination Survey population. Participants were sedentary at the time of intake and did not exceed 500 kcal/week of physical activity as measured by a physical activity recall questionnaire. Excluded if had a history of chronic disease (i.e., diabetes, heart disease, etc), elevated BP (>140/90 mmHg), elevated lipid concentrations (cholesterol >6.72 mmol/l; TAG >5.65 mmol/l), or elevated fasting glucose concentrations (>7.8 mmol/l) were excluded. Additionally, participants were excluded if they were smokers, if they took medications that would affect physical performance (i.e., ß-blockers) or metabolism (i.e., thyroid medications or steroids), or if they lacked the ability to perform laboratory tests or participate in exercise of moderate intensity.
Recruitment	Participants were recruited from the University of Nebraska-Kearney, The University of Kansas, and their respective surrounding communities. Participants were ‘compensated’ for participation – no details.
Intervention (mode and intensity)	*Exercise sessions (25 min at baseline to 45 min at 6 months) on 5 days per week for 16 months.* *Assessments at baseline, 4, 9, 12, 16 months. Also additional exercise assessment (about every 2 months and 4 months). Diet assessments at baseline, 9, and 16 months. Also multiple diet recall assessments.*
Duration of active intervention	16 months
Control (mode and intensity)	Assessments at baseline, 4, 9, 12, 16 months. Diet assessments at baseline, 9, and 16 months. Also multiple diet recall assessments.

Delivery of intervention/control (who)	Research assistant supervised exercise sessions.
Dropout rates	*44% dropout overall at 16 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.6 Physical activity and diet vs information

Weight loss

FDPS 2001 (in HTA – diet and physical activity vs control) RCT	
Aim	To determine the feasibility and effects of a programme of changes in lifestyle designed to prevent or delay the onset of type 1 diabetes in participants with IGT.
Participants	People who were overweight (BMI >25 kg/m^2), aged between 40 and 66 years old, and with IGT (plasma glucose 7.8 to 11.0 mmol/l). *522 total – 350 F, 172 M. Mean (SD) age 55 (7) years overall. Mean (SD) BMI 31.3 (4.6), treatment (n=265) , 31.0 (4.5) control (n=257)*
Intervention	Participants informed at start of risk factors for diabetes, 3-day food diary at baseline provided basis for dietary advice in second session, advised to reduce weight to goal of BMI less than 25 kg/m^2 but in practice weight targets were 5–10 kg weight loss; advised to consume >50% energy as carbohydrate, <10% as saturated fat, 20% as mono- and polyunsaturated fat or up to 25% if surplus is from monounsaturated fat; <300 mg/day cholesterol and 1 g protein/kg IBW per day, encouraged to increase fibre intake to 15 g/1000 kcal, encouraged to use low-fat milk products, low-fat meat products, soft margarine and vegetable oil rich in monounsaturated fatty acids (primarily rapeseed oil); energy content re-evaluated if no weight loss at visits, if no weight loss in first 6–12 months and BMI >30 kg/m^2 a VLED is considered (6–12 week duration with group meetings every 1–2 weeks); dietary advice individually tailored and person responsible for preparing meals in family invited to attend sessions (if not the participant), advice tailored to participants educational level. Participants individually guided to increase endurance exercise (programme differed between study centres) also when possible there was a supervised progressive individually tailored circuit type resistance training twice weekly, encouraged to perform 30 min daily moderate exercise, 3-day food diary kept every 3 months, 24-h exercise diary kept every 3 months and 12-month physical activity history completed on annual visit along with 2 km walking test.
Control	*At baseline participants advised to adjust total energy intake to reduce BMI to below 25 kg/m^2, also less than 30% of energy intake from fat, reduce alcohol intake and stop smoking, verbal and written dietary advice, verbal general information regarding health benefits of recreational exercise, additional routine advice at yearly follow-up where 3 day food record assessed and 2 km walking test performed.*
Length of follow-up	*2 to 6 years (mean 3.2 years)*
Results	*Used figures from Lindstrom 2003 as latest publication, so results are different from the HTA figures.* At 12 months, mean (SD) weight change in kg was –4.50 (5.00) in the activity and diet group, and –1.00 (3.70) in the diet group. Mean weight change in the intervention group compared with control was –3.50 (95% CI –4.27 to –2.73) At 24 months, mean (SD) weight change in kg was –3.50 (5.50) in the activity and diet group, and –0.80 (4.40) in the diet group. Mean weight change in the intervention group compared with control was –2.70 (95% CI –3.60 to –1.80). At 36 months, mean (SD) weight change in kg was –3.50 (5.10) in the activity and diet group, and –0.90 (5.40) in the diet group. Mean weight change in the intervention group compared with control was –2.60 (95% CI –3.59 to –1.61).

Quality and comments	Blinded assessment stated as done. ITT analysis not done. Random allocation but no description of concealment. Significant difference between groups regarding SBP (mmHg, SD): 136 (17) control group vs 140 (18) intervention group (*p*=0.03). Twenty-two participants had VLED in year 1 and 25 in year 2 of 3–8 weeks duration and 500–800 kcal/day; before final inclusion criteria decided 4% participants included with one abnormal OGTT only, 6% included based on high plasma glucose (not less than 6.4 mmol/l fasting or random sample after a fast of at least 4 h) together with one high 2 h plasma glucose concentration. Authors contacted, reply received regarding numbers of participants assessed, changes in BP and lipids, energy content of VLED, causes of death and serious adverse events including group allocation.

Other outcomes

FDPS 2001 (in HTA) RCT	
Results	*Used values from Lindstrom 2003 as latest publication, so results are different from the HTA values.* *At 12 months, mean (SD) TC change in mmol/l was –0.10 (0.70) in the activity and diet group, and –0.10 (0.70) in the information group. Mean TC change in the intervention group compared with control was 0.00 (95% CI –0.12 to 0.12).* *At 36 months, mean (SD) TC change in mmol/l was –0.10 (0.90) in the activity and diet group, and 0.10 (0.80) in the information group. Mean TC change in the intervention group compared with control was –0.20 (95% CI –0.36 to –0.04).* *At 12 months, mean (SD) HDL change in mmol/l was 0.05 (0.19) in the activity and diet group, and 0.02 (0.17) in the information group. Mean HDL change in the intervention group compared with control was 0.03 (95% CI 0.00 to 0.06).* *At 36 months, mean (SD) HDL change in mmol/l was 0.14 (0.20) in the activity and diet group, and 0.11 (0.19) in the information group. Mean HDL change in the intervention group compared with control was 0.03 (95% CI –0.01 to 0.07).* *At 12 months, mean (SD) TAG change in mmol/l was –0.02 (0.60) in the activity and diet group, and 0.00 (0.70) in the information group. Mean TAG change in the intervention group compared with control was –0.20 (95% CI –0.31 to –0.09).* *At 36 months, mean (SD) TAG change in mmol/l was –0.10 (0.60) in the activity and diet group, and 0.00 (0.80) in the information group. Mean TAG change in the intervention group compared with control was –0.10 (95% CI –0.23 to 0.03).* *At 12 months, mean (SD) FPG change in mmol/l was –0.20 (0.70) in the activity and diet group, and 0.00 (0.70) in the information group. Mean FPG change in the intervention group compared with control was –0.20 (95% CI –0.32 to –0.08).* *At 36 months, mean (SD) FPG change in mmol/l was0.00 (0.70) in the activity and diet group, and 0.10 (0.70) in the information group. Mean FPG change in the intervention group compared with control was –0.10 (95% CI –0.23 to 0.03). TC:HDL-cholesterol ratios were significantly lower in the activity and diet group compared with information at both 12 and 36 months (*p*<0.005).* *The proportion of sedentary individuals was 14% and 30% at year 1 (*p*<0.0001 for difference between groups) and 17 and 29% at year 3 (*p*=0.0028) in the intervention and control groups, respectively. However, the total amount of reported time spent physically active did not change, but moderate-to-vigorous Leisure Time Physical Activity (LTPA) increased in the intervention group compared with the control group at years 1 and 3.* *The % energy as carbohydrate increased; the % energy of fat, saturated fat, and also monounsaturated fat decreased; the fibre density increased; and cholesterol intake decreased more in the intervention group than the control*

	group during the first year. The absolute amounts of fat decreased, and energy intake decreased in the intervention group more than in the control group. At 3 years the reductions in energy, fat (% energy and g), saturated fat (% energy), and monounsaturated fat (% energy), and the increase in carbohydrates (% energy) and fibre density were still statistically significantly greater in the intervention group.
Quality and comments	Dietary intake was assessed using a 3-day food record at baseline (before the randomisation visit) and before every annual visit. Activity was assessed using the validated Kuopio Ischaemic Heart Disease Risk Factor Study 12-month LTPA questionnaire at baseline and at every annual visit.

Reported harms

FDPS 2001 (in HTA) RCT	
Harms	One death and two cases of breast cancer were reported in the intervention group, and one participant developed cancer of the large intestine in the diet only group. During the first 3 years of the study, 22 people (9%) in the intervention group and 51 (20%) of the diet only group developed diabetes (*p*=0.0001). The use of VLED preparations did not affect diabetes risk; 8% of the users developed diabetes in 3 years.
Quality and comments	…

Generalisability

FDPS 2001 (in HTA) RCT	
Country and setting	Finland. Five participating centres – no further details.
Participants (included/excluded)	*Included if aged 40–65 years, BMI >25 kg/m^2, IGT (2 h plasma glucose 7.8–11.0 mmol/l), OGTT 75 g with a non-diabetic fasting glucose concentration (plasma glucose <7.8 mmol/l), mean value of two OGTTs (less strict criteria used in ≤1% of total number of participants).* *Excluded if previous diagnosis of diabetes mellitus (other than gestational diabetes mellitus), persons involved regularly in vigorous exercise programme, participants receiving treatment to lower plasma glucose (other than routine dietary and health advice), chronic disease making 6-year survival improbable, other medical characteristics likely to interfere with study participation, unbalanced clinical conditions such as thyroid and liver disease.*
Recruitment	From epidemiological surveys, opportunistic population screening with special emphasis on people in high-risk groups (obese, first degree relatives of people with type 2 diabetes). Also through advertisements in local newspapers.
Intervention (mode and intensity)	2–6 years, contacted at baseline, at 1–2 weeks, at 5–6 weeks then at 3, 4 and 6 months and every 3 months thereafter
Duration of active intervention	Diet: 36 months. Physical activity: not clear
Control (mode and intensity)	*2–6 years, contacted at baseline then at annual intervals*
Delivery of intervention/control (who)	A nutritionist gave individualised and group information. The study physician and the nutritionist informed participants of general risk factors for diabetes. Physical activity was delivered either by an exercise instructor or physiotherapist if part of the study team, or if not, by commercial services.

Dropout rates	*13% in the physical activity and diet group and 21% in the diet group at 36 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Data for completers only.

1.5.7 Physical activity and diet vs diet alone

Weight loss

ODES 1995 (in Shaw CR and HTA) RCT	
Aim	The primary aim of the trial was to compare the isolated and combined effects of the diet and exercise on the variables fibrinogen, fibrinolytic capacity, coagulation factor VII and platelet volume. Secondary aims were the effects on other coagulation and fibrinolytic components and activities; lipids and lipoproteins; fatty acids; glucose and insulin response to a glucose load; clinical, physiological and anthropometric variables; and quality of life
Participants	*Men and women aged 41 to 50 years who were overweight (BMI >24 kg/m^2) and sedentary.* *219 total – 21 F, 198 M. Mean (SD) age 44.9 (2.5) years. Mean (SD) BMI (kg/m^2) 29.54 (3.89) diet group (*n*=55), 28.56 (3.22) exercise group (*n*=54), 28.57 (3.47) diet and exercise group (*n*=67), 28.30 (3.15) control group (*n*=43).*
Intervention	For initial 8 weeks the intensity and duration of supervised endurance workouts increased progressively then maintained at three times per week for 1 h each session at 60–80% maximum heart rate as assessed at baseline using treadmill; 60% of each workout was aerobic, 25% circuit training and 15% fast walking/jogging, attendance measured and exercise log book kept. Advised to stop smoking. Dietary counselling with spouse at baseline then individually at 3- and 9-month follow-up sessions. Diet adapted to individual's risk profile with main focus on energy restriction in those overweight, increase in fish and vegetables, decrease in saturated fat, cholesterol, sugar, and salt restriction for those with elevated BP. Weight targets agreed and set. 180 food-frequency questionnaire at baseline and 12 months.
Control	*Dietary counselling with spouse at baseline then individually at 3- and 9-month follow-up sessions. Diet adapted to individual's risk profile with main focus on energy restriction in those overweight, increase in fish and vegetables, decrease in saturated fat, cholesterol, sugar, and salt restriction for those with elevated BP. Weight targets agreed and set. 180 food-frequency questionnaire at baseline and 12 months. Advised to stop smoking.*
Length of follow-up	12 months
Results	*Only 12-month outcomes reported.* At 12 months, mean (SD) weight change in kg was –5.60 (4.84) in the activity and diet group, and –4.00 (5.05) in the diet group. Mean weight change in the intervention group compared with control was –1.60 (95% CI –3.41 to 0.21).
Quality and comments	TC and LDL levels significantly lower in the exercise and the diet and exercise groups ($p<0.05$). ITT not done. Only blood analyses blinded. Discrepancy between results in published papers. Good concealment of allocation.

Pavlou 1989 1 (in HTA) RCT	
Aim	To determine the role of exercise in relation to the type of diet, rate of weight loss and defined exercise experience on long-term maintenance

Participants	Healthy men. *160 total (for complete study) – all men. Mean (SD) age 41.5 (7.59) years activity and LED, 42.9 (6.63) years LED (Pavlou 1ab). Mean (SD) age 45.1 (10.0) years activity and food based PSMF, 49.6 (8.4) years food-based PSMF (Pavlou 1cd). Mean (SD) age 41.8 (10.44) years activity and liquid PSMF, 41.8 (7.57) years liquid PSMF (Pavlou 1ef). Mean (SD) age 46.1 (9.33) years activity and VLED, 44.5 (9.6) years VLED (Pavlou 1gh). Mean BMI 32.54 kg/m^2 activity and LED, 32.4 LED (Pavlou 1ab). Mean BMI 32.07 kg/m^2 activity and food based PSMF, 31.5 food-based PSMF (Pavlou 1cd). Mean BMI 30.13 kg/m^2 activity and liquid PSMF, 34.82 liquid PSMF (Pavlou 1ef). Mean BMI 31.89 kg/m^2 activity and VLED, 33.78 VLED (Pavlou 1gh). Data for completers only. No details of allocation to each group.*
Intervention (including details of diet)	All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts. LED (group a): BEDD where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements PSMF (group c): ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat, fish and fowl; 2.8 g potassium chloride daily PSMF (group e): DPC-70; assumed PSMF 420 kcal/day diet of powdered protein-carbohydrate mix derived from calcium caseinate, egg albumin and fructose dissolved in water or other non-energy liquid, fat content zero, fortified with vitamins and minerals to meet US Recommended Daily Allowance, mix five packets per day in 30oz (85 g) of non-energy liquid and consume no other nutrients; 2.8 g potassium chloride daily VLED (group g): DPC 800; assumed VLED 800 kcal/day diet provided in powdered form to be consumed similarly to DPC-70, provided a complete mixture of nutrients and similar nutritionally to BEDD except for less energy; Activity: exercise 90 min supervised exercise programme three times/week from baseline to week 8 which consisted of 35–60 min of aerobic activity e.g. walk-jog-run (70–85% maximum heart rate), callisthenics and relaxation techniques
Control	*All participants attended weekly educational sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 8, non-energy liquids including coffee were allowed in unrestricted amounts.* *LED (group b): BEDD where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements* *PSMF (group d): ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat, fish and fowl; 2.8 g potassium chloride daily* *PSMF (group f): DPC-70; assumed PSMF 420 kcal/day diet of powdered protein-carbohydrate mix derived from calcium caseinate, egg albumin and fructose dissolved in water or other non-energy liquid, fat content zero, fortified with vitamins and minerals to meet US Recommended Daily Allowance, mix five packets per day in 30oz (85 g) of non-energy liquid and consume no other nutrients; 2.8 g potassium chloride daily* *VLED (group h): DPC 800; assumed VLED 800 kcal/day diet provided in powdered form to be consumed similarly to DPC-70, provided a complete mixture of nutrients and similar nutritionally to BEDD except for less energy;* *Participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks*

Length of follow-up	*86 weeks.*
Results	Only 18-month outcomes reported. Published figures showed results over the initial 12 weeks, but difficult to determine the numbers exactly. At 18 months, mean (SD) weight change in kg was –9.19 (8.52) in the activity and LED group, and –3.57 (6.93) in the LED group. Mean weight change in the intervention group compared with control was –5.62 (95% CI –12.30 to 1.06). At 18 months, mean (SD) weight change in kg was –8.64 (8.36) in the activity and food PSMF group, and –1.13 (6.23) in the food PSMF group. Mean weight change in the intervention group compared with control was –7.51 (95% CI –12.62 to –2.40). At 18 months, mean (SD) weight change in kg was –9.68 (8.65) in the activity and liquid PSMF group, and –0.93 (6.18) in the liquid PSMF group. Mean weight change in the intervention group compared with control was –8.75 (95% CI –15.08 to –2.42). At 18 months, mean (SD) weight change in kg was –12.40 (9.42) in the activity and VLED group, and –3.45 (6.89) in the VLED group. Mean weight change in the intervention group compared with control was –8.95 (95% CI –14.46 to –3.44).
Quality and comments	Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Weight data derived from graph and SDs calculated.

Pavlou 1989 2 (in HTA) RCT	
Aim	To determine the role of exercise in relation to the type of diet, rate of weight loss and defined exercise experience on long-term maintenance.
Participants	Healthy men (no weight inclusion criteria). *24 total – all men. Mean (SD) age 49.2 (6.48) years activity and LED, 44.8 (7.84) years LED (Pavlou 2ab) Mean (SD) age 46.1 (5.14) years activity and food based PSMF, 48.1 (4.65) years food based PSMF (Pavlou 2cd). Mean BMI 31.75 (kg/m^2) activity and LED, 31.92 LED (Pavlou 2ab). Mean BMI 31.11 (kg/m^2) activity and food based PSMF, 30.4 food-based PSMF (Pavlou 2cd). Data for completers only. No details of numbers allocated.*
Intervention (including details of diet)	All participants attended weekly educational sessions up to week 12 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 12, non-energy liquids including coffee were allowed in unrestricted amounts. LED (group a): BEDD where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements PSMF (group c): PSMF, ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat fish and fowl; 2.8 g potassium chloride daily Exercise: 90 min supervised exercise programme three times/week from baseline to week 12 which consisted of 35–60 min of aerobic activity e.g. walk–jog–run (70–85% maximum heart rate), callisthenics and relaxation techniques

Control	*All participants attended weekly educational sessions up to week 12 that included behaviour modification, diet and general nutrition and exercise education; all participants given multivitamins, daily food and activity record to week 12, non-energy liquids including coffee were allowed in unrestricted amounts.* *LED (group b): BEDD where 1000 kcal/day selected from usual four food groups in quantities thought to meet basic requirements.* *PSMF (group d): PSMF, ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of IBW or 1000 kcal/day, no carbohydrate and all fat ingested came from meat fish and fowl; 2.8 g potassium chloride daily* *No exercise: participants to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during initial 8 weeks*
Length of follow-up	168 weeks
Results	*Only 18- and 36-month outcomes reported. Published figures showed results over the initial 12 weeks, but difficult to determine exact numbers from graphs.* At 18 months, mean (SD) weight change in kg was –11.83 (9.26) in the activity and LED group, and –5.75 (7.54) in the LED group. Mean weight change in the intervention group compared with control was –6.08 (95% CI –16.19 to 4.03). At 18 months, mean (SD) weight change in kg was –14.04 (9.89) in the activity and food PSMF group, and –7.29 (7.98) in the food PSMF group. Mean weight change in the intervention group compared with control was –6.75 (95% CI –17.89 to 4.39). At 36 months, mean (SD) weight change in kg was –10.67 (8.93) in the activity and LED group, and –3.25 (6.83) in the LED group. Mean weight change in the intervention group compared with control was –7.42 (95% CI –16.97 to 2.13). At 36 months, mean (SD) weight change in kg was –13.00 (9.59) in the activity and food PSMF group, and –3.83 (7.10) in the food PSMF group. Mean weight change in the intervention group compared with control was –9.17 (95% CI –19.63 to 1.29).
Quality and comments	Blinded assessment not done. Possible ITT analysis. Random allocation but no description of concealment. Weight data derived from graph and SDs calculated.

Wood 1991 (in HTA) RCT	
Aim	To test the hypothesis that exercise (walking or jogging) will increase HDL-cholesterol levels in moderately overweight, sedentary people who adopt a hypoenergetic National Cholesterol Education Programme (NCEP) diet
Participants	*Sedentary people (exercise less than twice per week) who were moderately overweight (BMI 28 to 34 kg/m^2 for men, 24 to 20 kg/m^2 for women).* *264 total – 132 F, 132 M. Mean (SD) age 39.1 (6.4) years women, 40.3 (6.3) years men. Mean BMI (SD)(kg/m^2) 27.9 (2.2) women, 30.7 (2.2) men.* (Noted as lowest mean BMI in HTA.) *Eighty-seven allocated to diet, 90 to diet and exercise, and 87 to control.*
Intervention (including details of diet)	NCEP step 1 diet consisting of 55% energy as carbohydrate, 30% as fat (saturated fat ≤10%), dietary cholesterol <300 mg/day, energy reduction. Activity was aerobic exercise (brisk walking or jogging) at 60–80% maximum heart rate initially for 25 min three times per week increasing to 45 min three times per week by month 4, monthly activity logs kept
Control	*NCEP step 1 diet consisting of 55% energy as carbohydrate, 30% as fat (saturated fat ≤10%), dietary cholesterol <300 mg/day, energy reduction.* *Assumed to have been instructed to maintain usual diet and exercise patterns.*

Length of follow-up	*12 months*
Results	*Only 12 months outcomes reported.* Women: At 12 months, mean (SD) weight change in kg was –5.10 (5.30) in the activity and diet group, and 1.30 (5.20) in the diet group. Mean weight change in the intervention group compared with control was –1.00 (95% CI –3.51 to 1.51). Men: At 12 months, mean (SD) weight change in kg was –8.70 (5.70) in the activity and diet group, and –5.10 (5.80) in the diet group. Mean weight change in the intervention group compared with control was –3.60 (95% CI –6.14 to –1.06).
Quality and comments	Significant differences between men in both intervention groups vs control for DBP ($p<0.001$), TC for women in diet group vs control ($p\le0.01$), and diet and exercise group vs control ($p\le0.05$), and LDL levels in women in both intervention groups vs control ($p\le0.05$). Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment.

Other outcomes

ODES 1995 (in Shaw CR and HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.48 (0.89) in the activity and diet group, and –0.23 (0.65) in the diet group. Mean TC change in the intervention group compared with control was –0.25 (95% CI –0.53 to 0.03). At 12 months, mean (SD) LDL change in mmol/l was –0.39 (0.81) in the activity and diet group, and –0.18 (0.72) in the diet group. Mean LDL change in the intervention group compared with control was –0.21 (95% CI –0.49 to 0.07). At 12 months, mean (SD) HDL change in mmol/l was 0.13 (0.15) in the activity and diet group, and 0.05 (0.12) in the diet group. Mean HDL change in the intervention group compared with control was 0.08 (95% CI 0.03 to 0.13). At 12 months, mean (SD) TAG change in mmol/l was –0.58 (0.97) in the activity and diet group, and –0.23 (1.01) in the diet group. Mean TAG change in the intervention group compared with control was –0.35 (95% CI –0.71 to 0.01). At 12 months, mean (SD) DBP change in mmHg was –5.20 (7.26) in the activity and diet group, and –3.40 (7.21) in the diet group. Mean DBP change in the intervention group compared with control was –1.80 (95% CI –4.44 to 0.84). At 12 months, mean (SD) SBP change in mmHg was –5.90 (8.87) in the activity and diet group, and –6.40 (10.10) in the diet group. Mean SBP change in the intervention group compared with control was 0.50 (95% CI –2.99 to 3.99). At 12 months, mean (SD) FPG change in mmol/l was –0.26 (0.64) in the activity and diet group, and –0.21 (0.50) in the diet group. Mean FPG change in the intervention group compared with control was –0.05 (95% CI –0.26 to –0.16). *At 12 months, significant changes from baseline were seen in the activity and diet group for energy intake (–382 kcal), protein (–7.7 g), fat (–26.5 g), % energy as fat (–5.3%), sugar (–19.6 g), cholesterol (–94 mg), saturated fatty acids (–12.1 g), monounsaturated fatty acids (–10.2 g), and polyunsaturated fatty acids (–2.9 g).* *At 12 months, significant changes from baseline were seen in the diet group for energy intake (–550 kcal), protein (–13.4 g), fat (–32.5 g), % energy as fat (–5.1%), carbohydrate (–42.3 g), sugar (–16.8 g), alcohol (–2.5 g), cholesterol (–121 mg), saturated fatty acids (–13.6 g), monounsaturated fatty acids (–12.3 g) and polyunsaturated fatty acids (–4.9 g).* *At 12 months,* VO$_{2max}$ *had increased by 6.7 ml/kg per min in the activity and*

	diet group, which was significantly different to the diet group (+1.7 ml/kg per min, $p<0.05$*).*
Quality and comments	Dietary intake assessed through a validated food-frequency questionnaire. Activity was supervised, and home activity was recorded (no details). Also participants interviewed at 12 months about changes in activity habits.

Pavlou 1989 1 (in HTA) RCT	
Results	*No other outcomes by different diet groups were reported. BP reported by exercise and diet vs diet only. Added to summary statistics.* *At 6 months, mean (SD) DBP change in mmHg was –11.50 in the activity and diet group, and –2.70 in the diet group (to calculate SDs).* *At 6 months, mean (SD) SBP change in mmHg was –6.30 in the activity and diet group, and –3.90 in the diet group (to calculate SDs).* At 18 months, mean (SD) DBP change in mmHg was –10.40 (8.30) in the activity and diet group, and 1.70 (8.30) in the diet group. Mean DBP change in the intervention group compared with control was –12.10 (95% CI –15.20 to –9.00). At 18 months, mean (SD) SBP change in mmHg was –7.70 (12.70) in the activity and diet group, and 1.20 (12.70) in the diet group. Mean SBP change in the intervention group compared with control was –8.90 (95% CI –13.65 to –4.15).
Quality and comments	…

Pavlou 1989 2 (in HTA) RCT	
Results	*Only* VO_{2max} *at 8 weeks reported by different diet groups.*
Quality and comments	…

Wood 1991 (in HTA) RCT	
Results	Women: At 12 months, mean (SD) TC change in mmol/l was –0.28 (0.52) in the activity and diet group, and –0.39 (0.61) in the diet group. Mean TC change in the intervention group compared with control was 0.11 (95% CI –0.16 to 0.38). Women: At 12 months, mean (SD) LDL change in mmol/l was –0.29 (0.46) in the activity and diet group, and –0.28 (0.63) in the diet group. Mean LDL change in the intervention group compared with control was –0.01 (95% CI –0.27 to 0.25). Women: At 12 months, mean (SD) HDL change in mmol/l was 0.02 (0.18) in the activity and diet group, and –0.15 (0.26) in the diet group. Mean HDL change in the intervention group compared with control was 0.17 (95% CI 0.06 to 0.28). Women: At 12 months, mean (SD) TAG change in mmol/l was –0.02 (0.26) in the activity and diet group, and 0.09 (0.36) in the diet group. Mean TAG change in the intervention group compared with control was –0.11 (95% CI –0.26 to 0.04). Women: At 12 months, mean (SD) DBP change in mmHg was –2.00 (4.10) in the activity and diet group, and –2.20 (5.10) in the diet group. Mean DBP change in the intervention group compared with control was 0.20 (95% CI –1.98 to 2.38). Women: At 12 months, mean (SD) SBP change in mmHg was –3.60 (7.70) in the activity and diet group, and –4.10 (6.00) in the diet group. Mean SBP change in the intervention group compared with control was 0.50 (95% CI –2.64 to 3.64). Men: At 12 months, mean (SD) TC change in mmol/l was –0.38 (0.87) in the activity and diet group, and –0.42 (0.51) in the diet group. Mean TC change in the intervention group compared with control was 0.04 (95% CI –0.28 to 0.36).

	Men: At 12 months, mean (SD) LDL change in mmol/l was –0.27 (0.78) in the activity and diet group, and –0.39 (0.48) in the diet group. Mean LDL change in the intervention group compared with control was 0.12 (95% CI –0.17 to 0.41). Men: At 12 months, mean (SD) HDL change in mmol/l was 0.14 (0.18) in the activity and diet group, and 0.02 (0.17) in the diet group. Mean HDL change in the intervention group compared with control was 0.12 (95% CI 0.04 to 0.20). Men: At 12 months, mean (SD) TAG change in mmol/l was –0.48 (0.75) in the activity and diet group, and –0.12 (0.59) in the diet group. Mean TAG change in the intervention group compared with control was –0.36 (95% CI –0.66to –0.06). Men: At 12 months, mean (SD) DBP change in mmHg was –4.90 (5.70) in the activity and diet group, and –2.40 (6.60) in the diet group. Mean DBP change in the intervention group compared with control was –2.50 (95% CI –5.22 to 0.22). Men: At 12 months, mean (SD) SBP change in mmHg was –5.40 (8.30) in the activity and diet group, and –4.10 (8.10) in the diet group. Mean SBP change in the intervention group compared with control was –1.30 (95% CI –4.92 to 2.32). *Women: at 12 months, a significant increase was seen for aerobic capacity in the activity and diet group compared with diet alone (+6.4 mg/kg/min vs 1.4 mg/kg/min, p≤0.001). Also, the estimated 12yr CHD risk decreased by 3.5 events/1000 persons in the activity and diet group compared with an decrease of 1.0 in the diet group (p≤0.05).* *Men: at 12 months, significant changes in baseline were seen in the activity and diet group compared with the diet groups for total fat intake (–9.5 vs –6.0%, p≤0.05). A significant increase was seen for aerobic capacity (+8.6 mg/kg/min vs +1.6 mg/kg/min, p≤0.001). Also, the estimated 12 year CHD risk decreased by 21.8 events/1000 persons in the activity and diet group compared with an decrease of 12.9 in the diet group (p≤0.05).*
Quality and comments	*Significant differences between men in both intervention groups vs control for DBP (p<0.001), TC for women in diet group vs control (p≤0.01), and diet and exercise group vs control (p≤0.05), and LDL levels in women in both intervention groups vs control (p≤0.05).* Dietary intake estimated from participants' 7-day food diaries, with further probing for more detail by trained interviewers when collecting the data by telephone. Activity assessed by supervising staff.

Reported harms

ODES 1995 (in Shaw CR and HTA) RCT	
Harms	*One death and two cancers (allocation not known).*
Quality and comments	…

Pavlou 1989 1 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Pavlou 1989 2 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wood 1991 (in HTA) RCT	
Harms	None reported.

Quality and comments	…

Generalisability

ODES 1995 (in Shaw CR and HTA) RCT	
Country and setting	Norway. Community-based?
Participants (included/excluded)	*Included if aged 41 to 50 years, sedentary (exercise no more than once per week), BMI >24 kg/m^2, DBP 86 to 9 9mmHg, TC 5.2 to 7.74 mmol/l, HDL <1.2 mmol/l, fasting serum TAG >1.4 mmol/l. Excluded if overt diabetes or CVD, other disease or drugs that could interfere with test results, treatment with antihypertensive drugs, acetylsalicylic acid, lipid-lowering diet, personal traits unsuitable for inclusion.*
Recruitment	Participants recruited from continuous screening programme of 40-year old men and women in Oslo. No further details reported.
Intervention (mode and intensity)	12 months, contacted 158 times (baseline, three times per week and follow-up at 12 months)
Duration of active intervention	*12 months*
Control (mode and intensity)	Dietary intervention lasted 12 months. 4 contacts (baseline, 3, 9, 12 months).
Delivery of intervention/control (who)	N/R other than exercise 'under the guidance of highly qualified instructors'.
Dropout rates	3% in activity and diet group and 5% in diet group at 12 months, (includes five excluded)
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pavlou 1989 1 (in HTA) RCT	
Country and setting	USA. Workplace.
Participants (included/excluded)	*Included men, aged 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment.* *Exclusion criteria not stated.*
Recruitment	Men were recruited from the Boston Police Department and the Metropolitan District Commission. No further details reported.
Intervention (mode and intensity)	8 weeks plus 18 months post-treatment follow-up (weekly from baseline to week 8 then at 8 months and 18 months post-treatment)
Duration of active intervention	8 weeks for diet and activity
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.
Dropout rates	31% overall at 18 months post-treatment.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Pavlou 1989 2 (in HTA) RCT	
Country and setting	USA. Workplace
Participants (included/excluded)	*Included men aged 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment.* *No details of exclusion.*

Recruitment	Men were recruited from the Boston Police Department and the Metropolitan District Commission. No further details reported.
Intervention (mode and intensity)	12 weeks plus 36 months post-treatment follow-up, contacted 16 times (weekly from baseline to week 12 then at 6, 8 and 18 months post-treatment)
Duration of active intervention	8 weeks for diet and activity
Control (mode and intensity)	As above
Delivery of intervention/control (who)	No details.
Dropout rates	13% overall at 36 months post-treatment
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Wood 1991 (in HTA) RCT	
Country and setting	USA. University clinic?
Participants (included/excluded)	*Included if aged between 25 and 49 years, 120 to 150% IBW, BMI 28 to 34 kg/m^2 for men, BMI 24 to 30 kg/m^2 for women, non-smokers, sedentary (exercise less than twice per week, <30 min per time), resting BP <160/9 5mmHg, plasma cholesterol <6.72 mmol/l, plasma TAG <5.65 mmol/l, average less than four alcoholic drinks per day, generally good health.* *Excluded if medication known to affect BP or lipid metabolism, pregnancy, lactating or taking oral contraception in past 6 months or planning pregnancy in subsequent 2 years.*
Recruitment	Potential participants were invited to be screened via mass media, followed with telephone interviews.
Intervention (mode and intensity)	12-month intervention. Contacted 25 times (baseline then weekly for first 3 months, then every other week for 3 months, then monthly)
Duration of active intervention	*12 months for diet. Less clear for activity. Activity was increased unto the maximum at 4 months, and monthly logs were then maintained – so assume 4 months for activity?*
Control (mode and intensity)	12-month intervention. Contacted 25 times (baseline then weekly for first 3 months, then every other week for 3 months, then monthly)
Delivery of intervention/control (who)	Dietary recommendations were presented by a registered dietitian. Group sessions assumed to be dietitian? No details of who supervised activity.
Dropout rates	*18% in diet and activity group and 10% in diet at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Analyses restricted to individuals with complete data only.

1.5.8 Physical activity and behaviour therapy vs information

Weight loss

Wing 1998 (in HTA) RCT	
Aim	To assess the effect of lifestyle intervention over 2 years on changes in weight, CHD risk factors, and incidence of diabetes in overweight adults with a parental history of diabetes
Participants	Adults aged 40 to 55 years who did not have diabetes, and were overweight (30 to 100% of IBW). *154 total – 122 F, 32 M. Mean (SD) age 46.4 (4.5) years exercise (*n*=37), 45.3 (4.9) control (*n*=40). Mean (SD) BMI (kg/m^2) 36.0 (3.7) exercise, 36.0 (5.4) control.*
Intervention	Exercise behaviour topic each week, 50–60 min walk with therapist at each weekly meeting (second supervised walk available each week for weeks 1–10), gradually increased exercise to estimated energy expenditure of 1500 kcal per week (e.g. 3 miles brisk walking 5 days per week), other activities periodically introduced to the participants such as aerobics and line dancing. Each meeting included a lecture on a topic related to changing exercise behaviour (stimulus control, problem-solving, reducing barriers, exercising in different weather conditions, stretching).
Control	*Participants received LEARN behavioural manual with information on healthy eating, exercise and behavioural strategies; participants encouraged to lose weight and exercise on their own, only participated in the assessments*
Length of follow-up	24 months
Results	*At 6 months, mean weight change (SD) was –2.10 (4.20) kg in the activity and BT group compared with –1.50 (2.70) kg in the information group. Mean weight change in the intervention group compared with information was –0.60 (95% CI –2.31 to 1.11).* *At 12 months, mean weight change (SD) was –0.40 (4.80) kg in the activity and BT group compared with –0.30 (4.50) kg in the information group. Mean weight change in the intervention group compared with information was –0.10 (95% CI –2.52 to 2.32).* *At 24 months, mean weight change (SD) was 1.00 (4.70) kg in the activity and BT group compared with –0.30 (4.50) kg in the information group. Mean weight change in the intervention group compared with information was 1.30 (95% CI –0.99 to 3.59)*
Quality and comments	Author confirmed main study and sub-study results. Blinded assessment done. ITT analysis done. Random allocation but no description of concealment.

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis
Participants	People with osteoarthritis, aged 60 years and older who were overweight (BMI ≥28 kg/m^2). Total 316 – 227 F, 89 M. Mean (SD) age years 69 (6.97) years activity and BT (*n*=76), 69 (0.88) years information (*n*=78). Mean (SD) BMI (kg/m^2) 34.0 (6.10) activity and BT, 34.2 (5.30) information.

Intervention	Exercise programme 3 days/week consisted of an aerobic phase (15 min), a resistance-training phase (15 min), a second aerobic phase (15 min), and a cool-down phase (15 min). The first 4 months of the 18-month intervention was facility-based. At any time after the first 4 months, participants who wished to exercise at home underwent a 2-month transition phase during which he or she alternated attendance between the facility and the home. Hence, some participants remained in a facility-based programme, others opted for a home-based programme, and some participants chose a combined facility-home-based programme. Provided with an aerobic exercise prescription that included walking within a heart rate range of 50–75% of heart rate reserve. The resistance-training portion of the programme consisted of two sets of 12 repetitions of the following exercises: leg extension, leg curl, heel raise, and step-up. Cuff weights and weighted vests were used to provide resistance. A 1.0–1.5-min rest interval separated each exercise. Following two orientation sessions, participants began the exercise programme using the lowest possible resistance. Resistance was increased after the participant performed two sets of 12 repetitions for two consecutive days. For participants in the home-based programme, weights were exchanged at the participant's request or after a determination was made during face-to-face or telephone contact to increase the weights. Telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Exercise and attendance logs were used to gather data and monitor progress. Goal was to produce and maintain an average weight loss of 5% during the 18-month intervention period. Dietary intervention was divided into three phases: intensive (months 1–4), transition (months 5–6), and maintenance (months 7–18). Major emphasis of the intensive phase was to heighten awareness of the importance of and need for changing eating habits in order to lower energy intake. Behaviour change was facilitated using self-regulatory skills. These skills included self-monitoring, goal setting, cognitive restructuring, problem-solving, and environmental management. One introductory individual session was followed by 16 weekly sessions (three group sessions and one individual session each month). Each group session included problem-solving, the review of a specific topic, and tasting of several well-balanced, low-fat, nutritious foods prepared with widely available ingredients. The individual sessions were used to review individual progress, solve problems, answer questions and set goals. *The transition phase included sessions every other week for 8 weeks (three group sessions and one individual session). The goals for this phase included assisting participants who had not reached their weight loss goals in establishing new goals, and maintaining and preventing relapse in those participants who had reached their weight loss goals.* *The maintenance phase included monthly meetings and phone contacts, alternated every 2 weeks. Additionally, newsletters that provided pertinent nutritional information and notice of upcoming meetings were mailed at regular intervals. The goals of the maintenance phase included assisting participants who had reached their weight loss goals to maintain this weight loss, and providing counselling for participants who had a difficult time losing weight and adhering to the intervention. Adherence to the intervention was based on attendance at scheduled sessions and completion of the monthly assessment of weight.*

Control	The group met monthly for 1 h for the first 3 months. A health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity and exercise, organised the healthy lifestyle programme. Patients were advised to follow the American College of Rheumatology and European League Against Rheumatism recommendations for weight loss and exercise as treatments for OA. Question-and-answer sessions followed each presentation. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18. During phone contact, information on pain, medication use, illnesses and hospitalisation was obtained.
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –5.20 (7.37) in the activity and BT group, and –1.10 (6.23) in the information group. Mean weight change in the intervention group compared with information was –4.10 (95% CI –6.26 to –1.94).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated*

Other outcomes

Wing 1998 (in HTA) RCT	
Results	*At 6 months, mean (SD) TC change in mmol/l was 0.12 (0.72) in the activity and BT group, and 0.12 (0.50) in the information group. Mean TC change in the activity and BT group compared with information was 0.00 (95% CI –0.30 to 0.30).* *At 6 months, mean (SD) LDL change in mmol/l was 0.03 (0.52) in the activity and BT group, and 0.08 (0.46) in the information group. Mean LDL change in the activity and BT group compared with information was –0.05 (95% CI –0.29 to 0.19).* *At 6 months, mean (SD) HDL change in mmol/l was 0.02 (0.16) in the activity and BT group, and –0.02 (0.11) in the information group. Mean HDL change in the activity and BT group compared with information was 0.04 (95% CI –0.03 to 0.11).* *At 6 months, mean (SD) TAG change in mmol/l was 0.12 (1.64) in the activity and BT group, and 0.29 (0.32) in the information group. Mean TAG change in the activity and BT group compared with information was –0.17 (95% CI –0.74 to 0.40).* *At 6 months, mean (SD) DBP change in mmHg was –1.70 (12.20) in the activity and BT group, and –2.20 (8.00) in the information group. Mean DBP change in the activity and BT group compared with information was 0.50 (95% CI –4.50 to 5.50).* *At 6 months, mean (SD) SBP change in mmHg was –2.40 (18.90) in the activity and BT group, and –2.00 (10.50) in the information group. Mean SBP change in the activity and BT group compared with information was –0.40 (95% CI –7.80 to 7.00).* *At 6 months, mean (SD) FPG change in mmol/l was 0.00 (0.70) in the activity and BT group, and 0.10 (0.50) in the information group. Mean FPG change in the activity and BT group compared with information was –0.10 (95% CI –0.40 to 0.20).* *At 6 months, mean (SD) change in %HbA$_{1c}$ was 0.10 (0.30) in the activity and BT group, and 0.20 (0.40) in the information group. Mean %HbA$_{1c}$ change in the activity and BT group compared with information was –0.10 (95% CI –0.27 to 0.07).* *At 12 months, mean (SD) TC change in mmol/l was 0.36 (0.82) in the activity and BT group, and 0.39 (0.70) in the information group. Mean TC change in the activity and BT group compared with information was –0.03 (95% CI –0.43*

to 0.37).

At 12 months, mean (SD) LDL change in mmol/l was 0.15 (0.54) in the activity and BT group, and 0.24 (0.66) in the information group. Mean LDL change in the activity and BT group compared with information was –0.09 (95% CI –0.40 to 0.22).

At 12 months, mean (SD) HDL change in mmol/l was 0.16 (0.18) in the activity and BT group, and 0.08 (0.16) in the information group. Mean HDL change in the activity and BT group compared with information was 0.08 (95% CI –0.01 to 0.17).

At 12 months, mean (SD) TAG change in mmol/l was 0.26 (2.19) in the activity and BT group, and 0.40 (1.25) in the information group. Mean TAG change in the activity and BT group compared with information was –0.14 (95% CI –1.07 to 0.79).

At 12 months, mean (SD) DBP change in mmHg was 0.90 (9.70) in the activity and BT group, and 4.90 (8.20) in the information group. Mean DBP change in the activity and BT group compared with information was –4.00 (95% CI –8.67 to 0.67).

At 12 months, mean (SD) SBP change in mmHg was 1.10 (15.80) in the activity and BT group, and 1.10 (9.60) in the information group. Mean SBP change in the activity and BT group compared with information was 0.00 (95% CI –6.82 to 6.82).

At 12 months, mean (SD) FPG change in mmol/l was 0.10 (0.70) in the activity and BT group, and 0.00 (0.60) in the information group. Mean FPG change in the activity and BT group compared with information was 0.10 (95% CI –0.24 to 0.44).

At 24 months, mean (SD) TC change in mmol/l was 0.33 (0.64) in the activity and BT group, and 0.18 (0.53) in the information group. Mean TC change in the activity and BT group compared with information was 0.15 (95% CI –0.14 to 0.44).

At 24 months, mean (SD) LDL change in mmol/l was 0.22 (0.61) in the activity and BT group, and 0.03 (0.46) in the information group. Mean LDL change in the activity and BT group compared with information was 0.19 (95% CI –0.08 to 0.46).

At 24 months, mean (SD) HDL change in mmol/l was 0.05 (0.17) in the activity and BT group, and 0.04 (0.24) in the information group. Mean HDL change in the activity and BT group compared with information was 0.01 (95% CI –0.09 to 0.11).

At 24 months, mean (SD) TAG change in mmol/l was 0.33 (1.46) in the activity and BT group, and 0.52 (1.14) in the information group. Mean TAG change in the activity and BT group compared with information was –0.19 (95% CI –0.84 to 0.46).

At 24 months, mean (SD) DBP change in mmHg was 2.00 (8.00) in the activity and BT group, and 2.00 (8.00) in the information group. Mean DBP change in the activity and BT group compared with information was 0.00 (95% CI –3.98 to 3.98).

At 24 months, mean (SD) SBP change in mmHg was 0.90 (13.90) in the activity and BT group, and –1.50 (12.00) in the information group. Mean SBP change in the activity and BT group compared with information was 2.40 (95% CI –4.06 to 8.86).

At 24 months, mean (SD) FPG change in mmol/l was 0.40 (0.90) in the activity and BT group, and 0.20 (0.40) in the information group. Mean FPG change in the activity and BT group compared with information was 0.20 (95% CI –0.15 to 0.55).

At 24 months, mean (SD) change in %HbA$_{1c}$ *was –0.10 (0.50) in the activity and BT group, and –0.10 (0.30) in the information group. Mean %HbA*$_{1c}$ *change in the activity and BT group compared with information was 0.00 (95% CI –0.21 to 0.21).*

At 6, 12, and 24 months, the activity and BT group reported non-significant decreases from baseline in energy intake and percentage of energy from fat (only Block Food-frequency of %fat was significant at 24 months). However,

	greater, often non significant decreases were seen in the information group. VO_{2max} *increased in the activity and BT group significantly at 6 months, but decreased at 24 months (not significant). The information group showed no significant changes from baseline.* *At 24 months, the relative risk (if weight loss of 4.5 kg compared with no weight loss) of developing diabetes in the activity and BT group was about 0.88 and about 0.88 in the information group. For people with IGT, the relative risks were about 0.91 and 0.88 respectively.*
Quality and comments	Dietary intake assessed using self-completed questionnaires and 3-day food diaries. Activity assessed using self-completed questionnaire (administered as an interview).

Messier 2004 RCT	
Results	*At 18 months, significant improvements were seen for self-reported physical function, stair climb time, and pain in the activity and BT group compared with information (p<0.05).*
Quality and comments	…

Reported harms

Wing 1998 (in HTA) RCT	
Harms	7% in the information group and 14% of the activity and BT group developed diabetes during the 24-month study. The development of diabetes was associated with increased initial IGT.
Quality and comments	…

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant tripped and sustained a laceration to his head. No details of allocation.
Quality and comments	…

Generalisability

Wing 1998 (in HTA) RCT	
Country and setting	USA. No further details – university hospital?
Participants (included/excluded)	Included if aged 40–55 years, non-diabetic (confirmed by OGTT), one or two biological parents with type 2 diabetes, 30–100% above IBW. Excluded if diagnosis of diabetes.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*Two years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then two × 6 week course during second year)*
Control (mode and intensity)	Contacted at baseline, 6 months, 1 year and at 2 years.
Duration of active intervention	24 months

Delivery of intervention/control (who)	Group meetings were led by a multidisciplinary team, with primary therapists being a behaviour therapist and an exercise physiologist
Dropout rates	*16% activity and BT and 23% information at 24 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	Included if aged 60 years or older, calculated BMI 28 kg/m^2 or more, knee pain on most days of the month, sedentary activity pattern with <20 min of formal exercise once weekly for the past 6 months, self-reported difficulty in at least one of the following activities ascribed to knee pain: walking one-quarter of a mile (three to four city blocks), climbing stairs, bending, stooping, kneeling (e.g., to pick up clothes), shopping, house cleaning or other self-care activities, getting in and out of bed, standing up from a chair, lifting and carrying groceries, or getting in and out of the bath, radiographic evidence of grade I–III tibiofemoral or patellofemoral OA based on weight-bearing anteroposterior and sunrise view radiographs, and willingness to undergo testing and intervention procedures. Excluded if serious medical condition that prevented safe participation in an exercise programme, including symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, chronic obstructive pulmonary disease, severe insulin-dependent diabetes mellitus, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, and anaemia, a Mini-Mental State Examination score of <24, inability to finish the 18-month study or unlikely to be compliant, inability to walk without a cane or other assistive device, participation in another research study, reported alcohol consumption of more than 14 drinks per week, ST segment depression of at least 2 mm at an exercise level of 4 METS or less, hypotension, or complex arrhythmias during a graded exercise test, inability to complete the protocol, in the opinion of the clinical staff, because of frailty, illness, or other reasons.
Recruitment	Mass mailings to age-eligible persons within the target area, targeted mailings to employees of the university and medical centre, presentations to various groups of older adults, mass media advertisement, and placement of posters (with pull-off reply cards attached) in strategic locations. Also, strategies were developed to enhance recruitment among racial minorities, including ads and interviews on minority-run radio stations, newspaper ads in predominantly African American publications, letters to churches attended mainly by minorities, and inserts in these church bulletins. Initial screening for major eligibility criteria was via telephone.

Intervention (mode and intensity)	*Exercise 3 days/week for 4 months (facility-based), then either home or facility-based. For participants in the home-based programme, telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Assessment at baseline, 6, 18 months. Also introductory individual session was followed by 16 weekly sessions (three group sessions and one individual session each month).* *The transition phase included sessions every other week for 8 weeks (three group sessions and one individual session).* *The maintenance phase included monthly meetings and phone contacts, alternated every 2 weeks. Contacts for the two interventions were done consecutively on the same day and at the same location.*
Duration of active intervention	18 months
Control (mode and intensity)	Group met monthly for 1 h for the first 3 months. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18.
Delivery of intervention/control (who)	Exercise and BT: not reported Information: health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity, and exercise, organised the healthy lifestyle programme.
Dropout rates	*24% activity and BT, 14% information at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.9 Physical activity, diet and behaviour therapy vs control (no treatment)

Weight loss

Jalkanen 1991 (in HTA) RCT	
Aim	To test the effect of a non-pharmacological weight-reduction programme in primary care on cardiovascular risk factors among people who were overweight and had hypertension.
Participants	People who were aged between 35 and 39 years, who were overweight (BMI 27 to 34 kg/m^2) and who also had hypertension (DBP ≥95mmHg). Total 50 – 25 F?, 25 M? *Mean age not stated. Mean (SD) weight 86 (14) kg intervention (*n*=25), 80 (11) kg control.*
Intervention	1000–1500 kcal/day diet, education on behaviour modification and exercise, choice of food, medical aspects of overweight and CVD risk factors, leaflets on reduction of salt and fat consumption and increase in exercise, three exercise sessions with physiotherapist, bicycle trips organised and free tickets for local swimming pool
Control	*Usual visit with nurse every 3 months, offered active treatment at end of the study period, received no personal counselling or advice*
Length of follow-up	12 months
Results	At 12 months, mean (SD) weight change in kg was –4.00 (7.05) in the combined group, and 0.00 (5.92) in the control group. Mean weight change in the intervention group compared with control was –4.00 (95% CI –7.65 to –0.35)
Quality and comments	Weight appears different between groups at baseline. ITT possibly done. Blinded assessment not done. Random allocation but no description of concealment. Mean change in weight and risk factors at 12 months calculated from actual values, SDs also calculated, data show no change in weight, HDL-cholesterol and TAG at 12 months in control group.

Jeffery 1993 (in HTA) RCT	
Aim	To determine the effect of food provision and financial incentives in comparison with standard behaviour therapy
Participants	People who were overweight (14 to 32 kg overweight), aged 25 to 45 years. *Total 202 – 101 F, 101 M. Mean age 37.5 years standard intervention (*n*=40), 38.5 years standard plus food provision (*n*=40), 38.1 years standard plus financial incentives (*n*=41), 37.6 standard plus food provision plus financial incentives (*n*=41), 35.7 years control (*n*=40). Mean BMI (kg/m^2) 30.9 standard, 30.8 standard plus food, 31.1 standard plus cash, 31.1 standard plus food and cash, 31.1 control.*

Intervention	Group behavioural counselling including weigh-in, presentations of information by interventionist, group discussion and a review of progress; participants assigned to an individualised energy goal of 1000 or 1500 kcal/day on basis of baseline body weight to produce estimated weight loss of 1kg per week; participants selected a weight loss goal of 14, 18 or 23 kg, if goal reached participants had energy goals adjusted upwards to a level estimated to maintain this body weight; primary dietary instruction emphasised importance of remaining below energy goals, restriction of fat and increased consumption of complex carbohydrate also stressed; participants initially instructed to walk or bike amount equivalent to 50 kcal per day for 5 days per week, gradually increased to final goal of 1000 kcal per week; daily food records kept for first 20 weeks and for 1 week each month thereafter which included exercise taken; behavioural techniques included stimulus control, problem-solving strategies, social assertion, short-term goal setting and reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking with more positive statements and constructive self-statements, relapse prevention and social support.
Control	Received no intervention. Individuals could do whatever they wished to lose weight on their own, and were asked to return for evaluations at 6, 12 and 18 months.
Length of follow-up	*30 months*
Results	*Six-month results were shown in graphically only (see Comments), details not reported in the text.* At 12 months, mean (SD) weight change in kg was –5.87 (7.58) in the combined group, and –1.51 (6.34) in the control group. Mean weight change in the intervention group compared with control was –4.36 (95% CI –8.22 to –0.50) At 18 months, mean (SD) weight change in kg was –5.55 (7.49) in the combined group, and –0.62 (6.09) in the control group. Mean weight change in the intervention group compared with control was –4.93 (95% CI –8.71 to –1.15) At 30 months, mean (SD) weight change in kg was –3.05 (6.78) in the combined group, and 0.25 (5.99) in the control group. Mean weight change in the intervention group compared with control was –3.30 (95% CI –6.83 to 0.23)
Quality and comments	*Only standard intervention vs control used in analysis.* Mean weight change at 12, 18 and 30 months derived from graph, SDs calculated. ITT done? Blinded assessment not done. Random allocation but no description of concealment.

Ost 1976 (in HTA) RCT	
Aim	To compare the effectiveness of behaviour therapy in the treatment of obesity with fenfluramine and a waiting list control group.
Participants	People who were overweight (15% or moreover IBW) Total 45 – 38 F, 7 M. Mean age 40.9 years overall. Mean *(SD) weight 87.0 kg combined (*n*=15), 81.5 kg control (*n*=15).*
Intervention	All participants received 45 min baseline lecture on food and nutrition. Focus of first four sessions was behaviour therapy consisting of situational control of over eating such as cue avoidance. Focus of sessions 5–7 was 500 kcal/day deficit diet with recommended food plan (based on food exchanges) nearest to this value chosen (1000, 1200, 1500 and 1800 kcal food plans), energy count diary completed. Focus of session 8 was to increase energy expenditure and introduction of regular physical exercise and a daily exercise record, diet and exercise designed to produce 0.7 kg of weight loss per week.

Control	*All participants received 45 min baseline lecture on food and nutrition. Waiting list control condition, participants told could not receive treatment at moment due to large number of applicants and would receive treatment at a later date.*
Length of follow-up	68 weeks
Results	At 16 weeks, mean (SD) weight change in kg was –9.35 (4.47) in the combined group, and –3.51 (4.04) in the control group. Mean weight change in the intervention group compared with control was –5.84 (95% CI –9.40 to –2.28). At 12 months, mean (SD) weight change in kg was –4.60 (6.20) in the combined group, and –2.40 (5.30) in the control group. Mean weight change in the intervention group compared with control was –2.20 (95% CI –7.02 to 2.62).
Quality and comments	*Only combined and control groups used for comparisons.* *Significant difference at baseline in weight between combined and control groups.* ITT done? Blinded assessment not done. Random allocation but no description of concealment.

TOHP Phase I 1993 (in HTA) RCT	
Aim	To determine the feasibility and efficacy of selected non-pharmacological interventions in reducing or preventing an increase in DBP
Participants	People aged between 30 and 54 years who were overweight (between 115% and 165% of IBW) and who had a high-normal DBP (80 to 89 mmHg). *Total 564 – 179 F, 385 M. Mean (SD) age 43.1 (6.0) years combined (n=308), 42.4 (6.2) years control (n=256). Mean (SD) weight 90.2 (13.3) kg combined, 89.3 (13.0) kg control.*
Intervention	Weight reduction intervention focused on reducing energy intake, reducing fat, sugar and alcohol intake; shopping, cooking and food selection behaviours; moderate increase in energy expenditure through walking briskly four to five times per week for 45 min each session at 40–55% heart rate reserve; behavioural self-management through goals, reinforcement, social support, graphing weight, problem-solving, relapse prevention, and coping strategies; food and exercise diaries
Control	*No treatment received.*
Length of follow-up	18 months
Results	At 18 months, mean (SD) weight change in kg was –3.83 (6.12) in the combined group, and 0.07 (4.01) in the control group. Mean weight change in the intervention group compared with control was –3.90 (95% CI –4.77 to –3.03) *At 6 months in the combined group, weight change in men was –6.5 kg compared with –3.7 kg in women.* *At 12 months in the combined group, weight change in men was –5.6 kg compared with –2.7 kg in women.* *At 18 months in the combined group, weight change in men was –4.7 kg compared with –1.6 kg in women.* *Although details of the control group were only reported graphically, the text reports that 'the mean weight of the control men did not change and the mean weight of the control women increased 0.2 kg at 18 months'.* *The difference between men and women was statistically significant for all time points for percentage change from baseline ($p<0.05$). However, the treatment effect was modified more strongly by baseline weight than by sex.*
Quality and comments	Sodium reduction and stress management treatment groups excluded from analyses. Higher proportion of men in combined group than in control ($p=0.016$). ITT possibly done. Blinded assessment not done. Good concealment of allocation.

TOHP Phase II 2001 (in HTA) RCT	
Aim	To determine the feasibility and efficacy of selected non-pharmacological interventions in preventing hypertension
Participants	People aged between 30 and 54 years who were overweight (between about 110 and 165% of IBW) and who had a high-normal DBP (83 to 89 mmHg). *Total 1191 – 409 F, 782 M. Mean (SD) age 43.4 (6.1) years combined (*n*=595), 43.2 (6.1) years control (*n*=596). Mean (SD) weight 93.4 (14.1) kg combined, 93.6 (13.5) kg control.*
Intervention	Four phases of programme including pre-intensive phase of 1–4 months wait before start of treatment when participants advised to prevent weight gain and contacted monthly; intensive phase during initial 14 weeks with mean weight loss goal of at least 4.5 kg or to achieve IBW during first 6 months then to maintain weight, reduced energy intake, count fat intake, increase physical activity four to five times per week at 30–45 min per session at 40–55% heart rate reserve, supervised exercise in four of 14 initial weekly sessions; transitional phase during weeks 15–26 of treatment with behavioural skills such as individual problem-solving, relapse prevention, cognitive reframing and coping imagery; extended phase from week 27 onwards consisted of mini modules including topics such as 'supermarket savvy', 'stress and time management', 'walking across America'.
Control	*No treatment received.*
Length of follow-up	36 to 48 months
Results	*At 6 months, mean (SD) weight change in kg was –4.40 (7.16) in the combined group, and 0.10 (5.94) in the control group. Mean weight change in the intervention group compared with control was –4.50 (95% CI –5.28 to –3.72).* At 12 months, mean (SD) weight change in kg was –3.33 (6.86) in the combined group, and 0.53 (6.06) in the control group. Mean weight change in the intervention group compared with control was –3.86 (95% CI –4.63 to –3.09). At 18 months, mean (SD) weight change in kg was –2.00 (5.80) in the combined group, and 0.07 (4.20) in the control group. Mean weight change in the intervention group compared with control was –2.70 (95% CI –3.30 to –2.10) At 24 months, mean (SD) weight change in kg was –1.22 (6.26) in the combined group, and 1.17 (6.25) in the control group. Mean weight change in the intervention group compared with control was –2.39 (95% CI –3.13 to –1.65) At 36 months, mean (SD) weight change in kg was –0.20 (5.90) in the combined group, and 1.80 (5.30) in the control group. Mean weight change in the intervention group compared with control was –2.00 (95% CI –2.66 to –1.34) *Although baseline weight was a significant predictor of weight loss at 6 months, and reduced the significance of the greater weight loss in men compared with women, greater weight loss in men persisted consistently thereafter, independent of baseline weight.*
Quality and comments	Numbers in each group assumed for 12- and 24-month data derived from graph, SDs calculated. ITT possibly done. Blinded assessment done. Good concealment of allocation.

TONE 1998 (in HTA) RCT	
Aim	To determine whether weight loss or reduced sodium intake is effective in the treatment of older people with hypertension.

Participants	Older people aged 60 to 80 years with hypertension (treated SBP <145 mmHg and DBP <85 mmHg) and who were overweight (BMI ≥27.8 kg/m^2 for men and ≥27.3 kg/m^2 for women). *Total 294 – 162 F, 132 M. Mean (SD) age 66 (5) years combined (*n*=147), 66 (4) years control (*n*=147). Mean (SD) BMI (kg/m*^{2}*) 31.0 (2.3) combined, 31.3 (2.3) control.*
Intervention	*Anti-hypertensive medications withdrawn 90 days after first group intervention sessions, drug specific tapering regimens where participants seen weekly and 3 additional biweekly visits to confirm SBP <150 mmHg and DBP < 90 mmHg.* The group goal was ≥4.5 kg weight loss in 6 months then weight maintenance; individual goals were 5–10% weight loss (depending on baseline BMI) by energy deficit and increase in physical activity; behaviour therapy based on social action theory for lifestyle change, self-monitoring of energy intake, eating behaviours and pulse rate; management of eating behaviours, relapse prevention, participants received individual feedback from food intake records and physical activity records, 'calorie counting' of foods, practical advice on purchase and preparation of inexpensive foods available in supermarkets, group practice of safe, low-level exercise.
Control	Anti-hypertensive medications withdrawn 90 days after first group intervention sessions, drug specific tapering regimens where participants seen weekly and 3 additional biweekly visits to confirm SBP <150 mmHg and DBP < 90 mmHg. *Advised to maintain usual diet and physical activity, speakers who lead discussion on topics unrelated to BP, CVD or diet.*
Length of follow-up	*29 months (median)*
Results	At 12 months, mean (SD) weight change in kg was –5.36 (4.56) in the combined group, and –0.48 (3.24) in the control group. Mean weight change in the intervention group compared with control was –4.88 (95% CI –5.84 to –3.92). At 18 months, mean (SD) weight change in kg was –4.77 (4.52) in the combined group, and –0.21 (3.44) in the control group. Mean weight change in the intervention group compared with control was –4.56 (95% CI –5.55 to –3.57). At 24 months, mean (SD) weight change in kg was –4.58 (4.55) in the combined group, and –0.09 (3.53) in the control group. Mean weight change in the intervention group compared with control was –4.49 (95% CI –5.62 to –3.36) At 30 months, mean (SD) weight change in kg was –4.99 (4.11) in the combined group, and –0.05 (4.17) in the control group. Mean weight change in the intervention group compared with control was –4.94 (95% CI –6.47 to –3.41).
Quality and comments	*Report of two arms of a four-arm study; author provided mean and standard deviation change in weight at 12, 18, 24 and 30 months post randomisation.* ITT not done. Blinded assessment done. Random allocation but no description of concealment.

Other outcomes

Jalkanen 1991 (in HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.20 (1.08) in the combined group, and 0.20 (1.08) in the diet group. Mean TC change in the intervention group compared with control was –0.40 (95% CI –1.04 to 0.24). At 12 months, mean (SD) HDL change in mmol/l was 0.10 (0.29) in the combined group, and 0.00 (0.29) in the control group. Mean HDL change in the intervention group compared with control was 0.10 (95% CI –0.07 to

	0.27). At 12 months, mean (SD) TAG change in mmol/l was –0.50 (0.96) in the combined group, and 0.00 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.50 (95% CI –1.07 to 0.07). At 12 months, mean (SD) DBP change in mmHg was –11.00 (8.30) in the combined group, and –11.00 (8.30) in the control group. Mean DBP change in the intervention group compared with control was 0.00 (95% CI –4.65 to 4.65). At 12 months, mean (SD) SBP change in mmHg was –8.00 (12.70) in the combined group, and –15.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was 7.00 (95% CI –0.11 to 14.11). *Significant increases from baseline in excretion of sodium were seen in both groups (+35 mmol/day combined and +29 mmol/day control,* p*<0.05). The combined group showed a significant increase from baseline in excretion of potassium (+16 mmol/day,* p*<0.01).* *No significant changes were seen from baseline in either group for intake of carbohydrates, or total energy. The combined group decreased fat intake (–14 g/day) compared with the control group that increased fat intake (+9 g/day). Similarly for protein intake (–6 vs +7 g/day, respectively).*
Quality and comments	*Data show no change in weight, HDL-cholesterol and TAG at 12 months in control group.* *Food records kept for 2–3 days three times in the study period.*

Jeffery 1993 (in HTA) RCT	
Results	*Other outcomes were not reported by group.*
Quality and comments	7-day food diary required to be completed for each group session.

Ost 1976 (in HTA) RCT	
Results	*No other outcomes were reported.* *Seven of the control group had tried to reduce weight during the study period. Four stated that the baseline recording of food intake and exercise had influenced their eating habits. Also three reported that the initial lecture had influenced them in a positive way.*
Quality and comments	…

TOHP Phase I 1993 (in HTA) RCT	
Results	*At 6 months, mean (SD) DBP change in mmHg was –6.30 (6.92) in the combined group, and –3.70 (6.18) in the control group. Mean DBP change in the intervention group compared with control was –2.60 (95% CI –3.71 to –1.49).* At 12 months, mean (SD) DBP change in mmHg was –5.40 (8.47) in the combined group, and –3.10 (7.70) in the control group. Mean DBP change in the intervention group compared with control was –2.30 (95% CI –3.69 to –0.91). At 18 months, mean (SD) DBP change in mmHg was –6.16 (5.88) in the combined group, and –3.91 (6.12) in the control group. Mean DBP change in the intervention group compared with control was –2.25 (95% CI –3.25 to –1.25). *At 6 months, mean (SD) SBP change in mmHg was –6.50 (8.65) in the combined group, and –2.70 (7.73) in the control group. Mean SBP change in the intervention group compared with control was –3.80 (95% CI –5.19 to –2.41).* At 12 months, mean (SD) SBP change in mmHg was –5.80 (6.78) in the combined group, and –3.80 (6.16) in the control group. Mean SBP change in the intervention group compared with control was –2.00 (95% CI –3.11 to –

	0.89). At 18 months, mean (SD) SBP change in mmHg was –5.35 (7.19) in the combined group, and –2.45 (7.37) in the control group. Mean SBP change in the intervention group compared with control was –2.90 (95% CI –4.11 to –1.69). *Although there were sex differences in the results for BP, these were largely (but not exclusively) due to the differential weight loss for men and women.* The relative risk of developing hypertension in the intervention group was 0.66 (95% CI 0.46 to 0.94%).
Quality and comments	…

TOHP Phase II 2001 (in HTA) RCT	
Results	*At 6 months, mean DBP change in the intervention group compared with control was –2.70 (95% CI –3.50 to –2.00).* At 18 months, mean (SD) DBP change in mmHg was –4.50 (6.10) in the combined group, and –3.20 (5.80) in the control group. Mean DBP change in the intervention group compared with control was –1.30 (95% CI –2.02 to –0.58). At 36 months, mean (SD) DBP change in mmHg was –3.20 (6.50) in the combined group, and –2.40 (7.00) in the control group. Mean DBP change in the intervention group compared with control was –0.80 (95% CI –1.62 to 0.02). *At 6 months, mean SBP change in the intervention group compared with control was –3.70 (95% CI –4.70 to –2.80).* At 18 months, mean (SD) SBP change in mmHg was –3.60 (7.90) in the combined group, and –1.80 (7.00) in the control group. Mean SBP change in the intervention group compared with control was –1.80 (95% CI –2.70 to –0.90). At 36 months, mean (SD) SBP change in mmHg was –0.80 (8.70) in the combined group, and 0.60 (8.50) in the control group. Mean SBP change in the intervention group compared with control was –1.40 (95% CI –2.44 to –0.36). *At 36 months, women had a smaller reduction in DBP per kg lost than men (0.26 vs 0.41 mmHg,* p=*0.047), but the change in SBP did not differ between men and women.* The relative risk of developing hypertension in the intervention group was 0.58 (95% CI 0.36 to 0.94) at 6 months, 0.78 (95% CI 0.62 to 1.00) at 18 months and 0.81 (95% CI 0.70 to 0.95) at 36 months.
Quality and comments	…

TONE 1998 (in HTA) RCT	
Results	*Other results not reported for overweight participants alone.* The hazard ratio for the primary end point (recurrence of hypertension or cardiovascular events) was 0.65 (95% CI 0.50 to 0.85) for those randomised to weight loss alone compared with controls.
Quality and comments	…

Reported harms

Jalkanen 1991 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Jeffery 1993 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Ost 1976 (in HTA) RCT	
Harms	In the combined group, nine people experienced at least one of the following once or twice during the treatment period: hunger (seven instances), nervousness (three instances), irritation (three instances), tiredness (two instances) and feebleness (two instances). Two reported no side effects at all.
Quality and comments	…

TOHP Phase I 1993 (in HTA) RCT	
Harms	*One death was reported in the intervention group compared with none in the control group.*
Quality and comments	…

TOHP Phase II 2001 (in HTA) RCT	
Harms	*Five people randomised to weight loss died (three CVD) and two in the usual care group died.*
Quality and comments	…

TONE 1998 (in HTA) RCT	
Harms	Two participants with MI were reported in the intervention group. Four people with MI, and two people with cerebrovascular accidents were reported in the control group (which included non-overweight participants). One case of breast cancer and one of pancreatic cancer were reported – no details of group allocation.
Quality and comments	…

Generalisability

Jalkanen 1991 (in HTA) RCT	
Country and setting	*Finland. Primary care hypertension clinics.*
Participants (included/excluded)	*Included if aged 35–59 years, DBP 95 mmHg or more, BMI 27–34 kg/m^2, attending hypertension clinic.* *No exclusion criteria stated.*
Recruitment	Nurses at the clinics selected suitable participants from records.
Intervention (mode and intensity)	12 months, contacted 35 times (baseline then 1.5 h session weekly for first 6 months, then every 3 weeks for next 6 months)
Duration of active intervention	*12 months*
Control (mode and intensity)	*Contacted five times (at baseline then every 3 months for measurements only)*
Delivery of intervention/control (who)	Initial interview with a nutritionist. Doctor delivered lectures on cardiovascular risk factors, medical aspects of being overweight etc. Nutritionist delivered lectures on food selection, low fat cooking etc. Physiotherapist delivered lectures on physical activity. Psychologist delivered lectures on behaviour modification.
Dropout rates	*4% in the combined group and 0% in the control group at 12 months.*

Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

Jeffery 1993 (in HTA) RCT	
Country and setting	USA. Urban communities. Universities? No further details.
Participants (included/excluded)	Included if aged 25–45 years, 14–32 kg overweight, non-smokers, less than three alcoholic drinks per day. Excluded if on special diets, food allergies, not able to exercise, current serious diseases, prescription medications including oral contraceptives
Recruitment	Newspaper advertisements. Radio announcements. Mailed invitations.
Intervention (mode and intensity)	*18 months with follow-up at 30 months, contacted 79 times (baseline then weekly group sessions to week 20 then monthly with weekly weigh-ins)*
Duration of active intervention	18 months
Control (mode and intensity)	Contacted five times; baseline, 6 months, 12 months, 18 months and 30 months
Delivery of intervention/control (who)	Group sessions led by a trained interventionists with advanced degrees in nutrition or behavioural sciences.
Dropout rates	*Overall 13% at 12 months, 15% at 18 months, 24% at 20 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for complete cases only.

Ost 1976 (in HTA) RCT	
Country and setting	Sweden. No further details.
Participants (included/excluded)	*Included if 15% or more overweight.* *No exclusion criteria reported.*
Recruitment	Local newspaper advertisements.
Intervention (mode and intensity)	16 weeks with follow-up at 68 weeks, contacted two times (baseline then 30 min twice per week for 4 weeks then weekly for 12 weeks then at 68 weeks)
Duration of active intervention	16 weeks
Control (mode and intensity)	*Assessed at baseline, 16 weeks and 68 weeks*
Delivery of intervention/control (who)	Three undergraduates with a thorough knowledge of the behavioural method to be used were therapists for the combined group.
Dropout rates	*27% combined and 27% control at 68 weeks.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

TOHP Phase I 1993 (in HTA) RCT	
Country and setting	USA. Multicentre – no further details.

Participants (included/excluded)	*Included if aged 30–54 years, high-normal DBP and not taking antihypertensive drugs for last 2 months, BP based on three visits between 10–30 days apart with cumulative averages of 75–97, 77–94, 80–89 mmHg; BMI 26.1–36.1 kg/m^2 for men and 24.3–36.1 kg/m^2 for women.* *Excluded if clinical or laboratory evidence of cardiovascular or other life-threatening or disabling diseases, diabetes mellitus, chronic renal failure, cancer, pregnancy or wishing to become pregnant, psychiatric disorders, unwillingness or inability to comply with intervention or data collection; cholesterol ≥6.7 mmol/l.*
Recruitment	N/R
Intervention (mode and intensity)	18 months, contacted at baseline then 90 min sessions weekly for first 14 weeks, then every 2 weeks then every month to 18 months
Duration of active intervention	18 months
Control (mode and intensity)	*Assessed five times (baseline, 3, 6, 12 and 18 months)*
Delivery of intervention/control (who)	Group meetings were lead by a registered dietitian and a psychologist or exercise physiologist.
Dropout rates	5% in the combined group and 8% in the control group at 18 months.
Treatment of dropouts (return to baseline, or last measurement?)	If missed an appointment for reasons unrelated to BP, BP treated as missing at random and excluded from the analysis. If the final termination appointment was missed for reasons unrelated to BP, the last valid measure of BP was used.

TOHP Phase II 2001 (in HTA) RCT	
Country and setting	USA. Multicentre – no further details.
Participants (included/excluded)	*Included if 110–165% IBW or BMI 26.1–37.4 kg/m^2 (men), 24.4–37.4 kg/m^2 (women); DBP 83–89 (average of all nine measurements), SBP <140 mmHg, aged 30–54 years, completion and return of 24 h and separate 8 h urine collection and 3-day food record.* *Excluded if medically diagnosed hypertension, history of CVD, diabetes mellitus, malignancy in last 5 years (other than non-melanoma skin cancer), other serious life-threatening illness requiring medical treatment, current use, current use of prescription medication that affects BP and non prescription diuretics, serum creatinine ≥1.7 mg/dl in men and ≥1.5 mg/dl in women or casual serum glucose ≥200 mg/dl; more than 21 alcoholic drinks per week, current pregnancy or intention of pregnancy*
Recruitment	Mass mailings, community screening, media advertising, other referral strategies. Centres were able to tailor the recruitment strategies used as required.
Intervention (mode and intensity)	Minimum of 36 months, contacted three times at baseline plus one individual visit then weekly for 14 weeks, every 2 weeks for the next 6 weeks, three to six mini modules each year supplemented by participant initiated contact every 2 weeks
Duration of active intervention	36 months
Control (mode and intensity)	*Assessed seven times (baseline then every 6 months for a minimum of 36 months)*
Delivery of intervention/control (who)	Group meetings were lead by a dietitian or a health educator.
Dropout rates	8% in the combined group and 7% in the control group at 36 months.

Treatment of dropouts (return to baseline, or last measurement?)	N/R. If participants were prescribed antihypertensive medication, the last value was used. If participants received other medication that affected BP or became pregnant, the value at that visit was treated as missing.

TONE 1998 (in HTA) RCT	
Country and setting	USA. Academic health centres.
Participants (included/excluded)	Included if stable health, aged 60–80 years, mean SBP <145 mmHg, mean DBP <85 mmHg, taking one anti-hypertensive medication, taking two anti-hypertensive medications if successfully stepped down prior to randomisation; obese strata involved people with BMI 27.8 kg/m^2 for men and 27.3kg/m^2 for women; independent in their daily living activities, permission of personal physician, ability to alter diet and increase physical activity. Excluded if cancer in the past 5 years, IDDM, severe hypertension, CVD, peripheral vascular disease, psychiatric illness, current or recent (in last 6 months) drug therapy for asthma or chronic obstructive lung disease, corticosteroid therapy for longer than 1 month, 4.5 kg or more involuntary and unexplained weight loss in the last year, serum creatinine >2 mg/dl, serum potassium >5.5 mEq/l, haemoglobin <11 g/dl, plasma glucose >260 mg/dl, volume of baseline 24 h urine specimen <500 ml, less than 14 alcoholic drinks per week, current or planned participation in another intervention study, another member of household member of TONE.
Recruitment	Mass mailings, BP screening, media advertising, enrolment from participants in previous trials. Centres were able to tailor the recruitment strategies used as required.
Intervention (mode and intensity)	*Median 29 months contacted approximately 45 times (baseline then weekly for first 4 months then fortnightly for the next 3 months then monthly)*
Duration of active intervention	29 months (median)
Control (mode and intensity)	Median 29 months contacted approximately ten times (baseline then quarterly)
Delivery of intervention/control (who)	Groups lead by trained interventionists (often dietitians or exercise counsellors).
Dropout rates	*7% intervention and unclear for the control group at 29 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.5.10 Physical activity, diet and behaviour therapy vs information

Weight loss

Lindahl 1999 (in HTA) RCT	
Aim	To assess the effects of lifestyle intervention on cardiovascular risk factors in general, and specifically on fibrinolysis
Participants	People who were overweight (BMI >27 kg/m^2) and had IGT (abnormal OGTT). *Total 186 – 117 F, 69 M. Mean (SE) age 54.8 (0.94) years combined (*n*=93 completed), 56.2 (0.85) years information (*n*=93 completed). Mean (SD) BMI 31.0 (0.33) kg/m^2 combined, 30.2 (0.33) kg/m^2 information.*
Intervention	Full board for initial month which included 140 h of scheduled activities including aerobic exercise of low to moderate intensity for 2.5 h daily; diet of 1800 kcal/day for men and 1500 kcal/day for women consisting of 20% intake from fat and high in fibre to produce a slow but persistent weight decline; behavioural modification strategies included stress management and relapse prevention; no alcohol was permitted and participants were strongly encouraged not to smoke; additional learning session for 4 days at 12 months
Control	*Health survey and 30–60 min counselling session which included oral and written advice on lifestyle changes regarding IGT and obesity, repeated at 12 months*
Length of follow-up	*12 months*
Results	At 12 months, mean (SD) weight change in kg was –5.40 (4.44) in the combined group, and –0.50 (2.75) in the information group. Mean weight change in the intervention group compared with control was –4.90 (95% CI –5.96 to –3.84).
Quality and comments	Fasting glucose and TAG significantly lower in intervention group a (*p*=0.0001, *p*=0.04 respectively) and intervention group b had a higher BMI (*p*=0.06). ITT not done. Blinded assessment not reported. Random allocation but no description of concealment.

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis
Participants	People with osteoarthritis, aged ≥60 years who were overweight (BMI ≥28 kg/m^2) Total 316 – 227 F, 89 M. Mean (SD) age years 69 (7.16) years activity (*n*=80), 69 (0.88) years information (*n*=78). Mean (SD) BMI (kg/m^2*)* 34.2 (5.37) activity, 34.2 (5.30) information.

Intervention	Exercise programme 3 days/week consisted of an aerobic phase (15 min), a resistance-training phase (15 min), a second aerobic phase (15 min), and a cool-down phase (15 min). The first 4 months of the 18-month intervention was facility-based. At any time after the first 4 months, participants who wished to exercise at home underwent a 2-month transition phase during which he or she alternated attendance between the facility and the home. Hence, some participants remained in a facility-based programme, others opted for a home-based programme, and some participants chose a combined facility–home-based programme. Provided with an aerobic exercise prescription that included walking within a heart rate range of 50–75% of heart rate reserve. The resistance-training portion of the programme consisted of two sets of 12 repetitions of the following exercises: leg extension, leg curl, heel raise and step-up. Cuff weights and weighted vests were used to provide resistance. A 1.0–1.5-min rest interval separated each exercise. Following two orientation sessions, participants began the exercise programme using the lowest possible resistance. Resistance was increased after the participant performed two sets of 12 repetitions for two consecutive days. *For participants in the home-based programme, weights were exchanged at the participant's request or after a determination was made during face-to-face or telephone contact to increase the weights. Telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Exercise and attendance logs were used to gather data and monitor progress.* *Diet: to produce and maintain an average weight loss of 5% during the 18-month intervention period. Classified as a 600 kcal/day deficit/LED diet.* *BT: self-monitoring, goal setting, cognitive restructuring, problem-solving, and environmental management*
Control	The group met monthly for 1 h for the first 3 months. A health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity, and exercise, organised the healthy lifestyle programme. Patients were advised to follow the American College of Rheumatologyand European League Against Rheumatism recommendations for weight loss and exercise as treatments for OA. Question-and-answer sessions followed each presentation. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18. During phone contact, information on pain, medication use, illnesses and hospitalisation was obtained.
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –3.46 (6.89) in the activity group, and –1.10 (6.23) in the information group. Mean weight change in the intervention group compared with information was –2.36 (95% CI –4.41 to –0.31).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated*

Narayan 1998 (in HTA) RCT	
Aim	To test adherence to specific lifestyle interventions among Pima Indians of Arizona, and to compare changes in risk factors for diabetes.
Participants	Pima Indians who were obese (BMI ≥27 kg/m^2 men, ≥25 kg/m^2 women) and were normoglycaemic (2 h plasma glucose <7.8 mmol/l). *Total 95 – 72 F, 23 M. Median age 34 combined (n=48), 33 information (n=47). Median BMI (kg/m^2) 36.5 combined, 33.2 information.*

Intervention	Structured activity and nutritional intervention programme by an American Diabetes Association recommended dietitian, decrease fat intake and alcohol intake and increase fibre. Increase energy expenditure by 700–1000 kcal/week by e.g. walking 10–12 h per month and keeping activity log. Behavioural techniques included role-playing, modelling and problem-solving, food tasting and grocery store tours.
Control	*Self-directed learning with Pima culture appreciation group meetings to discuss current/historical lifestyles, local speakers, participants contributed to newsletters carrying Pima poetry, stories and folklore; basic printed material regarding healthy eating and exercise information, detailed interview of 40–120 min on health and lifestyle.*
Length of follow-up	*52 weeks*
Results	*At 6 months, mean (SD) weight change in kg was 1.00 (6.20) in the combined group, and 0.50 (6.70) in the information group. Mean weight change in the intervention group compared with control was 0.50 (95% CI –2.17 to 3.17).* At 12 months, mean (SD) weight change in kg was 2.50 (6.62) in the combined group, and 0.80 (6.14) in the information group. Mean weight change in the intervention group compared with control was 1.70 (95% CI –0.94 to 4.34).
Quality and comments	Author confirmed numbers assessed in each group at 12 months, medians assumed similar to means and SDs calculated. ITT not done. Blinded assessment not done. Random allocation but no description of concealment. FPG significantly higher in combined group (p=0.03).

Wing 1998 (in HTA) RCT	
Aim	To assess the effect of lifestyle intervention over 2 years on changes in weight, CHD risk factors, and incidence of diabetes in overweight adults with a parental history of diabetes.
Participants	Adults aged 40 to 55 years who did not have diabetes, and were overweight (30 to 100% of IBW). *154 total – 122 F, 32 M. Mean (SD) age 46.3 (3.8) years combined (n=40), 45.3 (4.9) control (n=40). Mean (SD) BMI* (kg/m^2) *35.7 (4.1) combined, 36.0 (5.4) control.*
Intervention	Diet: 800–1000 kcal/day weeks 1–8 then adjusted to 1200–1500 kcal/day by week 16, food diaries reviewed and feedback given, meal plans and shopping lists, behavioural or nutritional topic given at each session (relapse prevention, stimulus control, dealing with eating out, assertion, behaviour chain analysis, problem-solving) Exercise: 50–60 min walk with therapist at each meeting (second supervised walk available each week for weeks 1–10), gradually increased exercise to estimated energy expenditure of 1500 kcal per week (e.g. 3 miles brisk walking 5 days per week), other activities periodically introduced to the participants such as aerobics and line dancing. Also lectures on a topic related to changing exercise behaviour (stimulus control, problem-solving, reducing barriers, exercising in different weather conditions, stretching). (Same number of meetings as diet and exercise alone, so half time spent on diet and half on exercise.)
Control	*Participants received LEARN behavioural manual with information on healthy eating, exercise and behavioural strategies; participants encouraged to lose weight and exercise on their own, only participated in the assessments*
Length of follow-up	24 months

Results	*At 6 months, mean weight change (SD) was –10.30 (7.70) kg in the combined group compared with –1.50 (2.70) kg in the information group.* *Mean weight change in the intervention group compared with information was –8.80 (95% CI –11.67 to –5.93).* *At 12 months, mean weight change (SD) was –7.40 (9.70) kg in the combined group compared with –0.30 (4.50) kg in the information group.* *Mean weight change in the intervention group compared with information was –7.10 (95% CI –10.94 to –3.26).* *At 24 months, mean weight change (SD) was –2.50 (8.40) kg in the combined group compared with –0.30 (4.50) kg in the information group.* *Mean weight change in the intervention group compared with information was –2.20 (95% CI –5.51 to 1.11)*
Quality and comments	Author confirmed main study and sub-study results. Blinded assessment done. ITT analysis done. Random allocation but no description of concealment.

Djuric 2002 RCT	
Aim	To develop effective weight loss methods for women who have had breast cancer.
Participants	Women who had survived breast cancer and who were obese (BMI between 30 and 45 kg/m^2). Total 48 – all female. Age range 36 to 70 years. Mean (SD) BMI (kg/m^2) 35.5 (3.9) overall. No details by group. Allocated: 13 information (control), 10 Weight Watchers, 13 individualised counselling, 11 comprehensive (Weight Watchers plus counselling).
Intervention	*Individual (Djuric 2002a): Goal of weight loss was initial decrease of 10% of baseline weight at 6 months (adjusted if required – IBW vs reasonable body weight).* *Diet: ADA Exchange list diet plan – energy intake decreased by 500–1000 kcal/day. Target fat intake 20–25% of energy, fruits and vegetables five servings per day, protein up to 20% of energy. Increased fibre.* *Activity: 30 to 45 min of moderate activity most days of the week. Pedometers for self-monitoring and goal setting.* *BT: Written information on environmental control, serving size control, exercise, motivation, goal setting, holiday eating, seasonal foods). Behaviour change goals and problem-solving. Taught goal setting, menu planning, self-efficacy, consideration of body image, social support, social eating, removing road blocks, positive thinking, dealing with high risk situations and slips, cue elimination.*
Control	Given NCI ‘Action Guide to Healthy Eating’ and ‘Food Guide Pyramid’ pamphlets. Received no other dietary or exercise instructions or help. Allowed to follow a weight-reduction diet on their own if desired.
Length of follow-up	*12 months*
Results	*Only results at 12 months reported for the information group.* *Individual: At 12 months, mean weight change (SD) was –8.00 (5.50) kg in the combined group compared with 0.85 (6.00) kg in the information group.* *Mean weight change in the intervention group compared with information was –8.85 (95% CI –14.85 to –2.85).* *At 6 months, 33% of the individual group, and 8% of the information group had achieved a 10% weight loss. At 12 months, 22% of the individual group, and 0% of the information group had achieved a 10% weight loss.*
Quality and comments	*No baseline comparison. Only used information and counselling results in this review.* *Blinded assessment not reported. ITT analysis not done. Random allocation but no description of concealment.*

Mayer-Davis 2004RCT	
Aim	To evaluate lifestyle interventions for people with diabetes who live in rural communities.
Participants	People who were overweight (BMI ≥25 kg/m^2) with diabetes, and aged ≥45 years Total 187 – 122 F, 30 M (completers only). Mean (SD) age 59.7 (8.6) years combined intensive (*n*=49), 58.9 (7.8) combined pragmatic (*n*=47), 62.4 (9.5) years information (*n*=56). Mean (SD) BMI (kg/m^2) 37.6 (6.5) combined intensive, 37.5 (6.7) combined pragmatic, 35.2 (7.5) information. Results for completers only.
Intervention	*Combined intensive: given a study goal of 10% weight loss over 12 months. 25% energy from fat, minimum of 150 min of physical activity per week (similar in intensity to brisk walking). BT included self-monitoring, and additional strategies (DPP included problem-solving, managing cues, stimulus control, positive assertion, positive thinking, holiday eating, social support, goal-setting, motivation). Intervention was modified version of the Diabetes Prevention Programme 2002, with focus on diet and activity.* *Combined pragmatic: as above, but condensed to number of hours reimbursed by Medicare for diabetes education for an individual with diabetes.*
Control	Individual session at baseline where given information on diet and physical activity (American Diabetes Association and American Dietetic Association).
Length of follow-up	*12 months*
Results	*At 12 months, mean weight change (SD) was –2.20 (6.54) kg in the combined group compared with –0.30 (6.00) kg in the information group. Mean weight change in the combined group compared with information was –1.90 (95% CI –4.31 to 0.51).* *Results for 3, 6 months and for the combined pragmatic group were presented graphically only. But only significant difference was between the combined intensive and other groups at 6 months (about –2.7 kg, vs –1.0 kg and –0.4 kg,* p*<0.001).* *At 12 months, 49% combined intensive lost 2kg or more compared with about 36% in the combined pragmatic group and 25% information group.*
Quality and comments	*Blinded assessment not reported. ITT analysis not done. Random allocation but no description of concealment. SDs calculated.*

Wolf 2004 RCT	
Aim	To compare the efficacy of lifestyle case management to usual care given in the primary care setting, as measured by clinical, health-related quality of life (HRQOL), and economic outcomes
Participants	People who were overweight (BMI ≥27 kg/m^2) with type 2 diabetes, and aged ≥20 years Total 144 – 87 F, 57 M. Mean (SD) age 53.3 (8.6) years combined (*n*=73), 53.4 (8.0) information (*n*=71). Mean (SD) BMI (kg/m^2) 37.6 (7.7) combined, 37.3 (6.4) information.
Intervention	*Combined: case manager met with participants individually, in groups, and by phone for assessment, goal setting, education, and support.* *Goals were tailored but based on national dietary recommendations for people with type 2 diabetes and obesity. Individual sessions occurred six times throughout the year, totalling 4 h. Participants attended six 1-h small-group sessions. Brief monthly phone contacts provided support. Goals of the intervention were modest weight loss (5% of initial weight) and dietary intake as well as physical activity reflecting national recommendations.*
Control	Usual care participants received educational material and were free to join other weight management or diabetes care programs
Length of follow-up	*12 months*

Results	*At 12 months, mean weight change (SD) was –2.40 (6.59) kg in the combined group compared with 0.60 (6.08) kg in the information group. Mean weight change in the combined group compared with information was –3.00 (95% CI –5.07 to -0.93).* *More participants in the combined group than the information group lost up to 5% (53 vs. 32%) and 5% (20 vs. 14%) of initial weight (p=0.03).*
Quality and comments	*Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment. SDs calculated.*

Other outcomes

Lindahl 1999 (in HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.21 (0.70) in the combined group, and –0.06 (0.49) in the information group. Mean TC change in the intervention group compared with information was –0.15 (95% CI –0.32 to 0.02). At 12 months, mean (SD) FPG change in mmol/l was –0.50 (0.68) in the combined group, and –0.31 (1.14) in the information group. Mean TAG change in the intervention group compared with information was –0.19 (95% CI –0.46 to 0.08). At 12 months, mean (SD) TAG change in mmol/l was –0.16 (0.59) in the combined group, and –0.09 (0.59) in the information group. Mean TAG change in the intervention group compared with information was –0.07 (95% CI –0.24 to 0.10). At 12 months, mean (SD) DBP change in mmHg was –3.20 (7.41) in the combined group, and –0.80 (7.41) in the information group. Mean DBP change in the intervention group compared with information was –2.40 (95% CI –4.53 to –0.27). At 12 months, mean (SD) SBP change in mmHg was –4.90 (14.81) in the combined group, and 1.30 (10.79) in the information group. Mean SBP change in the intervention group compared with information was –6.20 (95% CI –9.92 to –2.48). *Physical fitness improved in the intervention group, compared with a decrease in the information group (+4.15 vs –1.12 ml/kg per min,* p=*0.0088).*
Quality and comments	…

Messier 2004 RCT	
Results	*At 18 months, significant improvements were seen in the 6 min walk distance compared with the information only group (*p*<0.05). No significant differences were seen for self-reported physical function, stair-climb time or pain (although pain did improve in all groups over time).*
Quality and comments	…

Narayan 1998 (in HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was 0.20 (1.08) in the combined group, and 0.10 (1.08) in the information group. Mean TC change in the intervention group compared with information was 0.10 (95% CI –0.35 to 0.55). At 12 months, mean (SD) FPG change in mmol/l was 0.10 (1.35) in the combined group, and 0.10 (1.35) in the information group. Mean TAG change in the intervention group compared with information was 0.00 (95% CI –0.56 to 0.06). At 12 months, mean (SD) DBP change in mmHg was 1.10 (8.30) in the combined group, and –1.00 (8.30) in the information group. Mean DBP

	change in the intervention group compared with information was 2.10 (95% CI –1.33 to 5.53). At 12 months, mean (SD) SBP change in mmHg was 6.00 (12.70) in the combined group, and 4.10 (12.70) in the information group. Mean SBP change in the intervention group compared with information was 1.90 (95% CI –3.35 to 7.15). *Levels of activity (MET – h per month) increased in both groups, but the difference was not significant between groups.* *No significant differences between groups were seen for nutrient intake.*
Quality and comments	Activity and dietary information was collected using Pima-modified instruments.

Wing 1998 (in HTA) RCT	
Results	*At 6 months, mean (SD) TC change in mmol/l was –0.33 (0.61) in the combined group, and 0.12 (0.50) in the information group. Mean TC change in the combined group compared with information was –0.45 (95% CI –0.73 to –0.17).* *At 6 months, mean (SD) LDL change in mmol/l was –0.13 (0.58) in the combined group, and 0.08 (0.46) in the information group. Mean LDL change in the combined group compared with information was –0.21 (95% CI –0.47 to 0.05).* *At 6 months, mean (SD) HDL change in mmol/l was –0.06 (0.16) in the combined group, and –0.02 (0.11) in the information group. Mean HDL change in the combined group compared with information was –0.04 (95% CI –0.11 to 0.03).* *At 6 months, mean (SD) TAG change in mmol/l was –0.69 (1.45) in the combined group, and 0.29 (0.32) in the information group. Mean TAG change in the combined group compared with information was –0.98 (95% CI –1.50 to–0.46).* *At 6 months, mean (SD) DBP change in mmHg was –6.90 (10.40) in the combined group, and –2.20 (8.00) in the information group. Mean DBP change in the combined group compared with information was –4.70 (95% CI –9.29 to –0.11).* *At 6 months, mean (SD) SBP change in mmHg was –12.30 (9.50) in the combined group, and –2.00 (10.50) in the information group. Mean SBP change in the combined group compared with information was –10.30 (95% CI –15.24 to –5.36).* *At 6 months, mean (SD) FPG change in mmol/l was –0.20 (0.40) in the combined group, and 0.10 (0.50) in the information group. Mean FPG change in the combined group compared with information was –0.30(95% CI –0.52 to –0.08).* *At 6 months, mean (SD) change in %HbA$_{1c}$ was 0.03 (0.20) in the combined group, and 0.20 (0.40) in the information group. Mean %HbA$_{1c}$ change in the combined group compared with information was –0.17 (95% CI –0.33 to –0.01).* *At 12 months, mean (SD) TC change in mmol/l was 0.32 (0.64) in the combined group, and 0.39 (0.70) in the information group. Mean TC change in the combined group compared with information was –0.07 (95% CI –0.41 to 0.27).* *At 12 months, mean (SD) LDL change in mmol/l was 0.14 (0.54) in the combined group, and 0.24 (0.66) in the information group. Mean LDL change in the combined group compared with information was –0.10 (95% CI –0.41to 0.21).* *At 12 months, mean (SD) HDL change in mmol/l was 0.12 (0.20) in the combined group, and 0.08 (0.16) in the information group. Mean HDL change in the combined group compared with information was 0.04 (95% CI –0.05 to 0.13).* *At 12 months, mean (SD) TAG change in mmol/l was 0.33 (1.65) in the combined group, and 0.40 (1.25) in the information group. Mean TAG change*

	in the combined group compared with information was –0.07 (95% CI –0.82 to 0.68). *At 12 months, mean (SD) DBP change in mmHg was –1.00 (10.20) in the combined group, and 4.90 (8.20) in the information group. Mean DBP change in the combined group compared with information was –5.90 (95% CI –10.71 to –1.09).* *At 12 months, mean (SD) SBP change in mmHg was –2.90 (14.20) in the combined group, and 1.10 (9.60) in the information group. Mean SBP change in the combined group compared with information was –4.00 (95% CI –10.17 to 2.17).* *At 12 months, mean (SD) FPG change in mmol/l was 0.00 (0.50) in the combined group, and 0.00 (0.60) in the information group. Mean FPG change in the combined group compared with information was 0.00 (95% CI –0.28 to 0.28).* *At 24 months, mean (SD) TC change in mmol/l was 0.09 (0.67) in the combined group, and 0.18 (0.53) in the information group. Mean TC change in the combined group compared with information was –0.09 (95% CI –0.39 to 0.21).* *At 24 months, mean (SD) LDL change in mmol/l was 0.12 (0.52) in the combined group, and 0.03 (0.46) in the information group. Mean LDL change in the combined group compared with information was 0.09 (95% CI –0.15 to 0.33).* *At 24 months, mean (SD) HDL change in mmol/l was 0.02 (0.21) in the combined group, and 0.04 (0.24) in the information group. Mean HDL change in the combined group compared with information was –0.02 (95% CI –0.13 to 0.09).* *At 24 months, mean (SD) TAG change in mmol/l was –0.28 (1.33) in the combined group, and 0.52 (1.14) in the information group. Mean TAG change in the combined group compared with information was –0.80 (95% CI –1.41 to –0.19).* *At 24 months, mean (SD) DBP change in mmHg was –0.20 (10.50) in the combined group, and 2.00 (8.00) in the information group. Mean DBP change in the combined group compared with information was –2.20 (95% CI –6.80 to 2.40).* *At 24 months, mean (SD) SBP change in mmHg was –4.80 (15.00) in the combined group, and –1.50 (12.00) in the information group. Mean SBP change in the combined group compared with information was –3.30 (95% CI –10.00 to 3.40).* *At 24 months, mean (SD) FPG change in mmol/l was 0.50 (1.30) in the combined group, and 0.20 (0.40) in the information group. Mean FPG change in the combined group compared with information was 0.30(95% CI –0.17 to 0.77).* *At 24 months, mean (SD) change in* $\%HbA_{1c}$ *was 0.04 (1.08) in the combined group, and –0.10 (0.30) in the information group. Mean* $\%HbA_{1c}$ *change in the combined group compared with information was 0.14 (95% CI –0.25 to 0.53).* *At 6, 12 and 24 months, the combined group reported significant decreases from baseline in energy intake and percentage of energy from fat (block food-frequency of % energy from fat was significant at 24 months). Smaller, often non-significant decreases were seen in the information group.* VO_{2max} *increased in the combined group significantly at 6 months, and was also increased at 24 months (not significant from baseline). The information group showed no significant changes from baseline.* *At 24 months, the relative risk (if weight loss of 4.5 kg compared with no weight loss) of developing diabetes in the combined group was about 0.88 and about 0.88 in the information group. For people with IGT, the relative risks were about 0.92 and 0.88 respectively.*
Quality and comments	Dietary intake assessed using self-completed questionnaires and 3-day food diaries. Activity assessed using self-completed questionnaire (administered as an interview).

Djuric 2002 RCT	
Results	*At 12 months, the combined group had a reported daily energy intake of 1386 compared with 2120 in the information group (–447 vs –126, respectively, from baseline). Also, fat intake was 24% in the combined group compared with 40% in the information group (–11 vs +7%, respectively, from baseline).*
Quality and comments	Dietary intake from self-reported 3-day food records (after initial training from the dietitian)

Mayer-Davis 2004 RCT	
Results	*(No SDs were reported so not able to add to meta-analysis.)* *At 6 months, no secondary metabolic outcomes (lipids, BP, HbA_{1c}) were significantly different between the combined intensive and information, or between the combined pragmatic and information. However, HbA_{1c} did improve in all groups, but there was no difference between the groups.*
Quality and comments	…

Wolf 2004 RCT	
Results	*(No SDs were reported so not able to add to meta-analysis.)* *HbA1c differed between groups over the intervention period (p=0.02), but was not significantly different at 12 months. Change in weight did not predict change in HbA1c level.* *The 12-month between-group differences in lipid levels were not statistically significant.* *By 12 months, participants in the combined group were taking 0.8 (0.05–1.1) fewer total medications per day than those in the information group (p= 0.03)* *More individuals in the combined group decreased total medications compared with those in the information group (45 vs. 28%, respectively), and fewer individuals in the combined group increased medications compared with those in the usual care group (19 vs. 35%) (p=0.03) at 6 months. Although the magnitude of the differences remained similar (decrease: 57 vs. 39%; increase: 17 vs. 32%), these differences were no longer significant by 12 months (P = 0.13).* *There was a decrease in unique medications primarily due to a decrease in diabetes medications (p=0.003). By 12 months, the combined group reduced diabetes medications 0.46 medications per day more than those in the usual care group (p=0.001). Insulin and sulfonylurea decreased most among participants in the combined group, whereas thiazolidinedione increased slightly among the information group.* *Baseline SF-36 scores were lower than national norms but consistent with scores reported among obese individuals. Change in SF-36 scores in the combined group was significantly different from the information group in seven of nine domains. The domains with greatest improvement in the case management group were emotional role (15.1, 3.4–26.8) and physical role (10, 1.2–24.7).*
Quality and comments	…

Reported harms

Lindahl 1999 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant tripped and sustained a laceration to his head. No details of allocation.
Quality and comments	…

Narayan 1998 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wing 1998 (in HTA) RCT	
Harms	7% in the information group and 15.6% of the combined group developed diabetes during the 24-month study. The development of diabetes was associated with increased initial IGT.
Quality and comments	…

Djuric 2002 RCT	
Harms	One woman withdrew for medical problems, but no details were reported.
Quality and comments	…

Mayer-Davis 2004 RCT	
Harms	None reported.
Quality and comments	…

Wolf 2004 RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Lindahl 1999 (in HTA) RCT	
Country and setting	Sweden. Wellness centres.
Participants (included/excluded)	*Included if BMI >27 kg/m^2, abnormal oral glucose tolerance test.* *Excluded if already taken part in lifestyle modification programme, too physically ill to participate.*
Recruitment	From community intervention programme, potential participants were invited to take part in a health survey.
Intervention (mode and intensity)	1 month with 4-day follow-up stay at 12 months (full board at a wellness centre for initial month)
Duration of active intervention	1 month plus 4 days
Control (mode and intensity)	*At baseline and at 12 months*
Delivery of intervention/control (who)	N/R
Dropout rates	4% combined, 0% information at 12 months
Treatment of dropouts (return to baseline, or last measurement?)	Completers only.

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	Included if aged ≥60 years, calculated BMI ≥28 kg/m^2, knee pain on most days of the month, sedentary activity pattern with <20 min of formal exercise once weekly for the past 6 months, self-reported difficulty in at least one of the following activities ascribed to knee pain: walking one-quarter of a mile (three to four city blocks), climbing stairs, bending, stooping, kneeling (e.g., to pick up clothes), shopping, house cleaning or other self-care activities, getting in and out of bed, standing up from a chair, lifting and carrying groceries, or getting in and out of the bath, radiographic evidence of grade I–III tibiofemoral or patellofemoral OA based on weight-bearing anteroposterior and sunrise view radiographs, and willingness to undergo testing and intervention procedures. Excluded if serious medical condition that prevented safe participation in an exercise programme, including symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, chronic obstructive pulmonary disease, severe insulin-dependent diabetes mellitus, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, and anaemia, a Mini-Mental State Examination score of <24, inability to finish the 18-month study or unlikely to be compliant, inability to walk without a cane or other assistive device, participation in another research study, reported alcohol consumption of more than 14 drinks per week, ST segment depression of at least 2 mm at an exercise level of 4 METS or less, hypotension, or complex arrhythmias during a graded exercise test, inability to complete the protocol, in the opinion of the clinical staff, because of frailty, illness or other reasons.
Recruitment	Mass mailings to age-eligible persons within the target area, targeted mailings to employees of the university and medical centre, presentations to various groups of older adults, mass media advertisement, and placement of posters (with pull-off reply cards attached) in strategic locations. Also, strategies were developed to enhance recruitment among racial minorities, including advertisements and interviews on minority-run radio stations, newspaper ads in predominantly African American publications, letters to churches attended mainly by minorities, and inserts in these church bulletins. Initial screening for major eligibility criteria was via telephone.
Intervention (mode and intensity)	*Exercise 3 days/week for 4 months (facility-based), then either home- or facility-based. For participants in the home-based programme, telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Assessment at baseline, 6, 18 months.*
Duration of active intervention	18 months
Control (mode and intensity)	Group met monthly for 1 h for the first 3 months. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18.
Delivery of intervention/control (who)	Exercise: N/R Information: health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity and exercise, organised the healthy lifestyle programme.
Dropout rates	*20% activity, 14% information at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Narayan 1998 (in HTA) RCT	
Country and setting	USA. No details.
Participants (included/excluded)	*Included if BMI ≥ 27 kg/m^2 (men) and ≥ 25 kg/m^2 (women); normoglycaemia (2 h plasma glucose <7.8 mmol/l), aged 25–54 years.* *Excluded if pregnancy or intention to become pregnant, previous diagnosis of diabetes, current self-reported physical activity ≥20 h per week, prescribed low-fat diet, another household member already randomised to the study, evidence of ischaemic heart disease, chronic illness; current steroid, thiazide or beta-blocker treatment; condition is likely to interfere with informed consent.*
Recruitment	Identified as residents of a specific Indian community (part of an epidemiological study) – then invited for screening.
Intervention (mode and intensity)	52 weeks, contacted minimum 53 times (baseline then weekly group meetings and home visits to week 52)
Duration of active intervention	12 months
Control (mode and intensity)	*52 weeks, contacted 13 times (baseline then monthly to week 52)*
Delivery of intervention/control (who)	Pima Pride (information) group was led by a discussion leader, who was a member of the community. No further details.
Dropout rates	*4% combined, 6% information at 52 weeks*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only

Wing 1998 (in HTA) RCT	
Country and setting	USA. No further details – university hospital?
Participants (included/excluded)	Included if aged 40–55 years, non-diabetic (confirmed by OGTT), one or two biological parents with type 2 diabetes, 30–100% above IBW. Excluded if diagnosis of diabetes.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*Two years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then two × 6-week course during second year)*
Control (mode and intensity)	Contacted at baseline, 6 months, 1 year and at 2 years.
Duration of active intervention	24 months
Delivery of intervention/control (who)	Group meetings were led by a multidisciplinary team, with primary therapists for activity being a behaviour therapist and an exercise physiologist, and for diet a behaviour therapist and a registered dietitian
Dropout rates	*20% combined and 23% information at 24 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Djuric 2002 RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included if aged 18 to 70 years, women who had stage I or II breast cancer diagnosed in past 4 years and were free of any recurrence as confirmed by a physician, BMI between 30 and 45 kg/m^2. Chemotherapy/radiation therapy to have been completed at least 3 months previously (except tamoxifen).

Recruitment	Direct mail to 'Race for Cure' participants, press releases, and brochures at breast clinics.
Intervention (mode and intensity)	*Weekly for 3 months, biweekly for months 3 to 6, monthly thereafter (altered as needed for the individual). Also free to call dietitian at any time. Apart from quarterly assessments, all contact done by telephone. Monthly group meeting held, but no requirement to attend.*
Duration of active intervention	12 months
Control (mode and intensity)	Met with dietitian at quarterly intervals for assessment.
Delivery of intervention/control (who)	Contact and counselling by a registered dietitian (experienced in weight loss counselling in clinical settings).
Dropout rates	*31% combined and 15% information at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Mayer-Davis 2004 RCT	
Country and setting	USA. Primary healthcare centres in rural counties.
Participants (included/excluded)	Included if aged 45 years or older, clinical diagnosis of diabetes, BMI ≥25 kg/m^2. Excluded if limitation that prevented full participation (e.g., recent or multiple MI/stroke, metastatic cancer, inability to walk, severe psychiatric disease, dialysis for end stage renal disease).
Recruitment	Medical record review from diabetes registers at the heathcare centres. Local publication strategies (such as posters).
Intervention (mode and intensity)	*Intensive: met weekly for first 4 months, every other week for next 2 months, once a month for last 6 months (1 h sessions). Pattern was three group sessions, followed by an individual session. Assessments at 3, 6, 12 months.* *Pragmatic: four × 1-h sessions over 12 months (three group, one individual). Assessments at 3, 6, 12 months.*
Duration of active intervention	12 months
Control (mode and intensity)	Individual session at baseline, and assessments.
Delivery of intervention/control (who)	Two nutritionists delivered all sessions, after training. Weekly conference calls were held between the study nutritionists and the research nutritionist to ensure continual high quality delivery, with emphasis on appropriate responses to group or individual needs.
Dropout rates	*19% overall at 12 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers at 12 months only (random subject effects allowed for missing values from follow-up visits)

Wolf 2004 RCT	
Country and setting	USA. Unclear.
Participants (included/excluded)	Included if diagnosed with type 2 diabetes (International Classification of Diseases, 9th Revision [ICD-9] codes 250.XX, 357.2, 362.0, 362.02, or 366.41 and confirmed by physician), use of diabetes medications, BMI>=27 kg/m2, age 20 years or older, ability to comprehend English, and membership in the Southern Health Services (SHS) health plan. Excluded if limitation that prevented full participation (e.g., recent or multiple MI/stroke, metastatic cancer, inability to walk, severe psychiatric disease, dialysis for end stage renal disease).
Recruitment	Identification of eligible participants from SHS data

Intervention (mode and intensity)	*Individual sessions occurred six times throughout the year, totalling 4 h. Participants attended six 1-h small-group sessions. Brief monthly phone contacts provided support.*
Duration of active intervention	12 months
Control (mode and intensity)	Not clear – assumed as for assessment
Delivery of intervention/control (who)	Delivered by a modestly priced, registered dietitian.
Dropout rates	*26% combined; 14% information at 12 months*
Treatment of dropouts (return to baseline, or last measurement?)	Used all available data…but no further details

1.5.11 Physical activity, diet and behaviour therapy vs diet

Weight loss

Blonk 1994 (in HTA) RCT	
Aim	To assess the long-term efficacy of a comprehensive weight reduction programme compared with that of a conventional programme
Participants	People who were overweight (BMI >27 kg/m^2) and who had type 2 diabetes. Total 60 – 40 F, 20 M. Median (range) age 59 (42–69) years combined (*n*=27 out of 30 allocated), 58.5 (29–70) diet (*n*=26 out of 30 allocated). Median (range) BMI (kg/m^2) 31.3 (27.2–44.3) combined (*n*=27 out of 30 allocated), BMI 32.8 (27.9–45.8) diet (*n*=26 out of 30 allocated).
Intervention	All participants underwent 3-month run-in prior to randomisation, seen three times for measurements and twice by dietitian who assessed 3 day food records, all participants instructed not to change their dietary habits; Post randomisation all participants received dietary education counselling programme involving visits to the dietitian every 2 months, 500 kcal/day deficit (minimum 1000 kcal/day) 50–55% energy as carbohydrate, 15% as protein, 30% as fat (emphasising unsaturated fat), 25 g fibre and <300 mg cholesterol per day; adherence assessed at each visit by dietary record. Participants additionally received behavioural modification strategies including self-monitoring, stimulus control, self-reinforcement, cognitive restructuring and relapse prevention training; Participants also received exercise training of 30 min bicycle ergometer at 60–80% maximum heart rate and then 30 min of various sports activities
Control	*All participants underwent 3 month run-in prior to randomisation, seen three times for measurements and twice by dietitian who assessed 3-day food records, all participants instructed not to change their dietary habits;* *Post randomisation all participants received dietary education counselling programme involving visits to the dietitian every 2 months, 500 kcal/day deficit (minimum 1000 kcal/day) 50–55% energy as carbohydrate, 15% as protein, 30% as fat (emphasising unsaturated fat), 25 g fibre and <300 mg cholesterol per day; adherence assessed at each visit by dietary record.*
Length of follow-up	*24 months*
Results	*At 6 months, mean (SD) weight change in kg was –2.90 (6.74) in the combined group, and –1.20 (6.25) in the diet group. Mean weight change in the intervention group compared with control was –1.70 (95% CI –5.20 to 1.80).* At 12 months, mean (SD) weight change in kg was –2.74 (6.69) in the combined group, and –2.07 (6.50) in the diet group. Mean weight change in the intervention group compared with control was –0.67 (95% CI –4.22 to 2.88). At 18 months, mean (SD) weight change in kg was –3.14 (6.80) in the combined group, and –1.08 (6.22) in the diet group. Mean weight change in the intervention group compared with control was –2.06 (95% CI –5.57 to 1.45). At 24 months, mean (SD) weight change in kg was –3.50 (6.91) in the combined group, and –2.10 (3.36) in the diet group. Mean weight change in the intervention group compared with control was –1.40 (95% CI –5.01 to 2.21).
Quality and comments	ITT done. Blinded assessment not done. Random allocation but no description of concealment. Author confirmed study participants were randomly allocated to treatment groups; median change in weight at 12, 18 and 24 months derived from graphs assumed similar to mean, SDs calculated.

Other outcomes

Blonk 1994 (in HTA) RCT	
Results	*At 12 months, mean (SD) TC change in mmol/l was –0.20 (5.97) in the combined group, and 0.10 (5.94) in the diet group. Mean TC change in the combined group compared with diet was –0.30 (95% CI –3.51 to 2.91).* *At 12 months, mean (SD) change in %HbA$_{1c}$ was –0.39 (2.58) in the combined group, and –0.01 (2.58) in the diet group. Mean %HbA$_{1c}$ change in the combined group compared with diet was –0.38 (95% CI –1.77 to 1.01).* *At 18 months, mean (SD) change in %HbA$_{1c}$ was –0.30 (2.58) in the combined group, and –0.10 (2.58) in the diet group. Mean %HbA$_{1c}$ change in the combined group compared with diet was –0.20 (95% CI –1.59 to 1.19).* *At 24 months, mean (SD) change in %HbA$_{1c}$ was –0.01 (2.58) in the combined group, and 0.40 (2.58) in the diet group. Mean %HbA$_{1c}$ change in the combined group compared with diet was –0.41 (95% CI –1.80 to 0.98).* *At 24 months, the change in energy intake did not appear to differ between the groups (+7 combined vs –75 kcal/day diet, no statistics reported).* *Carbohydrate and fat intake altered in proportion to the total energy intake.*
Quality and comments	Dietary intake from 3-day food records.

Reported harms

Blonk 1994 (in HTA) RCT	
Harms	One participant from the combined group dropped out due to mesothelioma.
Quality and comments	…

Generalisability

Blonk 1994 (in HTA) RCT	
Country and setting	Netherlands. No further details.
Participants (included/excluded)	*Included if type 2 diabetes (WHO), normal haematological, liver, kidney, thyroid function, BMI >27 kg/m^2.* *Excluded if history of angina, heart failure, intermittent claudication, proliferative retinopathy, subcutaneous insulin injections, diuretics, beta-blocking agents, drugs for hyperlipidaemia and any other drugs which may influence carbohydrate metabolism, regular physical exercise training.*
Recruitment	N/R
Intervention (mode and intensity)	*24 months, contacted 56 times (baseline then 2 monthly dietitian visit, behaviour therapy sessions once a week for first 2 months then at 4, 8, 12, 16 and 20 weeks, exercise sessions twice a month during months 3–6 and once a week during months 9–12 and 15–18).*
Duration of active intervention	24 months
Control (mode and intensity)	24 months, contacted 13 times (baseline then every 2 months).
Delivery of intervention/control (who)	Dietitian provided dietary education. Group sessions on BT led by a psychologist experienced in eating disorders. Group exercise training led by two physiotherapists.
Dropout rates	*10% combined, 13% diet at 24 months.*

Treatment of dropouts (return to baseline, or last measurement?)	N/R – results for completers only?

1.5.12 Physical activity, diet and behaviour therapy vs behaviour therapy

Weight loss

Bacon 2002 RCT	
Aim	To evaluate the effects of a 'health-centred' non-diet wellness programme, and to compare this to a traditional 'weight loss-centred' diet programme
Participants	78 total – all women. Mean (SD) BMI 35.7 (3.6) kg/m^2 overall. Mean (SD) age 39.9 (4.5) years overall. Thirty-nine assigned to each arm.
Intervention	*Participants were taught to moderately restrict their fat and energy intake and were encouraged to monitor their diet by maintaining a food diary and to monitor their weight weekly.* *Walking at an intensity suggested by training heart rate range was encouraged.* *Information presented was similar to most behavioural weight loss programmes: focus included eating behaviours and attitudes, nutrition, social support, exercise. Methods used were self-monitoring, stimulus control, reinforcement and cognitive change.*
Control	Programme consisted of five aspects: body acceptance, eating behaviour, activity, nutrition, social support. Initial treatment focussed on enhancing body- and self-acceptance, leading as full a life as possible, regardless of weight or success at weight control. Also disentangling feelings of self-worth from weight. Secondary phase focussed on eating behaviour: standard nutritional advice was given, with emphasis on regulating quality and quantity of food according to internal cues of hunger, appetite, and satiety. Activity component helped participants to identify and transform barriers to becoming active and to find activities that were fun and appealing. Support group was used to help women see the common experiences, and gain support and to learn strategies for asserting themselves and effecting change.
Length of follow-up	*12 months*
Results	*At 12 weeks, mean (SD) weight change in kg was –3.70 (4.70) in the combined group, and 0.70 (2.30) in the BT group. Mean weight change in the intervention group compared with BT was –4.04 (95% CI –6.50 to –2.30).* *At 24 weeks, mean (SD) weight change in kg was –4.60 (6.50) in the combined group, and 0.50 (3.40) in the BT group. Mean weight change in the intervention group compared with BT was –5.10 (95% CI –8.03 to –2.17).* *At 52 weeks, mean (SD) weight change in kg was –5.90 (6.30) in the combined group, and –0.10 (4.80) in the BT group. Mean weight change in the intervention group compared with BT was –5.80 (95% CI –8.91 to –2.69).*
Quality and comments	*Classified the weight loss-centred programme as D, BT and physical activity, and the health-centred (non-diet) programme as BT.* *No difference between groups for any outcome variables at baseline. ITT not done. Blinded assessment not reported. Random allocation but no description of concealment.*

Other outcomes

Bacon 2002 RCT	
Results	*Both groups showed a significant decrease from baseline at 12 months (5.19 to 4.34 vs 5.19 to 4.37 mmol/l), but there was not a significant difference between the groups. Similarly for LDL and TAG levels, and SBP.* *HDL levels decreased significantly in both groups at 12 months (1.23 to 1.12 vs 1.19 to 1.05 mmol/l), and the difference between groups was significant (*p*=0.03).* *DBP did not change significantly in either group over time.* *No measure of sleep or activity levels were significantly changed in either group. However, daily energy expenditure decreased significantly in both groups, and was significantly decreased in the combined group compared with BT alone at 12 months (*p*=0.000).* *Significant improvements were seen in both groups for measures of eating behaviour (including disordered eating). However, cognitive restraint increased in the diet group and decreased in the non-diet group (*p*=0.000).*
Quality and comments	Activity from a 7-day activity recall questionnaire. Eating Inventory and Eating Disorder Inventory measured eating behaviour.

Reported harms

Bacon 2002 RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Bacon 2002 RCT	
Country and setting	USA. University clinics?
Participants (included/excluded)	Included if white, female, aged 30 to 45 years, BMI ≥30 kg/m^2, non-smoker, not pregnant, not intending to get pregnant, not lactating, practising birth control if heterosexually active, premenopausal. Also restraint score >15 (indicating a history of chronic dieting), no recent MI, no active neoplasms, no diagnosis of type 1 diabetes or insulin dependent type 2 diabetes, no history of cerebrovascular or renal disease. Excluded if taking medications known to affect weight or energy expenditure (except anti-depressants or SSRIs).
Recruitment	Recruited using print, electronic, and televised media.
Intervention (mode and intensity)	*Attended 24 weekly sessions, each 90 min long. A 6-month aftercare programme was offered, no new material was included. Four testing sessions took place at baseline, 12, 24, 52 weeks.*
Duration of active intervention	6 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Diet programme was taught by an experienced registered dietitian. Non-diet programme was facilitated by a counsellor who has conducted educational and psychotherapeutic workshops and groups using this approach previously.

Dropout rates	*41% diet group, 26% non-diet group at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.13 Physical activity, diet and behaviour therapy vs physical activity

Weight loss

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis
Participants	People with osteoarthritis, aged 60 years and older who were overweight (BMI ≥28 kg/m^2) Total 316 – 227 F, 89 M. Mean (SD) age years 69 (6.97) years activity and BT (*n*=76), 69 (7.16) years activity (*n*=80). Mean (SD) BMI (kg/m^2) 34.0 (6.10) activity and BT, 34.2 (5.37) activity.
Intervention	*See details previously*
Control	See details previously
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –5.20 (7.37) in the activity and BT group, and –3.46 (6.89) in the activity group. Mean weight change in the intervention group compared with activity was –1.74 (95% CI –3.98 to –0.50).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated*

Other outcomes

Messier 2004 RCT	
Results	*At 18 months, no significant improvements were seen for self-reported physical function, motility, or pain between groups.*
Quality and comments	…

Reported harms

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant tripped and sustained a laceration to his head. No details of allocation.
Quality and comments	…

Generalisability

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	See details previously
Recruitment	See details previously
Intervention (mode and intensity)	See details previously
Duration of active intervention	18 months
Control (mode and intensity)	See details previously
Delivery of intervention/control (who)	Exercise and BT: not reported Exercise: not reported
Dropout rates	*24% activity and BT, 20% activity at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.14 Physical activity, diet and behaviour therapy vs diet and behaviour therapy

Weight loss

Wing 1998 (in HTA) RCT	
Aim	To assess the effect of lifestyle intervention over 2 years on changes in weight, CHD risk factors, and incidence of diabetes in overweight adults with a parental history of diabetes
Participants	Adults aged 40 to 55 years who did not have diabetes, and were overweight (30 to 100% of IBW). *154 total – 122 F, 32 M. Mean (SD) age 46.3 (3.8) years combined (*n*=40), 45.0 (4.7) diet and BT (*n*=37). Mean (SD) BMI (kg/m^2) 35.7 (4.1) combined, 36.1 (4.1) diet and BT.*
Intervention	Diet: 800–1000 kcal/day weeks 1–8 then adjusted to 1200–1500 kcal/day by week 16, food diaries reviewed and feedback given, meal plans and shopping lists, behavioural or nutritional topic given at each session (relapse prevention, stimulus control, dealing with eating out, assertion, behaviour chain analysis, problem-solving) Exercise: 50–60 min walk with therapist at each meeting (second supervised walk available each week for weeks 1–10), gradually increased exercise to estimated energy expenditure of 1500 kcal per week (e.g. 3 miles brisk walking 5 days per week), other activities periodically introduced to the participants such as aerobics and line dancing. Also lectures on a topic related to changing exercise behaviour (stimulus control, problem-solving, reducing barriers, exercising in different weather conditions, stretching). (Same number of meetings as diet and exercise alone, so half time spent on diet and half on exercise.)
Control	Diet: 800–1000 kcal/day weeks 1–8 then adjusted to 1200–1500 kcal/day by week 16, food diaries reviewed and feedback given, meal plans and shopping lists, behavioural or nutritional topic given at each session (relapse prevention, stimulus control, dealing with eating out, assertion, behaviour chain analysis, problem-solving)
Length of follow-up	24 months

Results	*At 6 months, mean weight change (SD) was –10.30 (7.70) kg in the combined group compared with –9.10 (6.40) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –1.20 (95% CI –4.64 to 2.24).* *At 12 months, mean weight change (SD) was –7.40 (9.70) kg in the combined group compared with –5.50 (6.90) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –1.90 (95% CI –6.09 to 2.29).* *At 24 months, mean weight change (SD) was –2.50 (8.40) kg in the combined group compared with –2.10 (7.60) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –0.40 (95% CI –4.25 to 3.45).*
Quality and comments	Author confirmed main study and sub-study results. Blinded assessment done. ITT analysis done. Random allocation but no description of concealment.

Foreyt 1993 (in HTA) RCT	
Aim	To compare diet, exercise, and exercise plus diet behavioural treatments in free-living, mildly to moderately obese adults
Participants	People who were aged between 25 and 45 years, and who were overweight (at least 14 kg overweight Metropolitan Life Insurance). Total 80 F, 85 M. Mean age not stated. Mean (SD) weight 97.6 (25.5) kg combined (*n*=42), 93.9 (20.8) kg diet and BT (*n*=42).
Intervention	Help Your Heart Eating Plan consisting of 30% energy as fat, 50% as carbohydrate, 20% as protein; energy intake adjusted so weight loss <1 kg per week, food diaries kept, Contracts to reward behaviour change, stress management, stimulus control and goal setting based on Learn behavioural eating programme. Lectures focused on physical and psychological benefits of exercise, taught a walking programme at an indoor track, graduated exercise with self-monitoring based on heart rate, breathing and effort to 'vigorous' but not 'strenuous' level; exercise increased to goal of three to five sessions of 45 min per week
Control	*Help Your Heart Eating Plan consisting of 30% energy as fat, 50% as carbohydrate, 20% as protein; energy intake adjusted so weight loss was <1 kg per week, food diaries kept,* *Contracts to reward behaviour change, stress management, stimulus control and goal setting based on Learn behavioural eating programme.* *Advised to maintain sedentary lifestyle*
Length of follow-up	2 years
Results	At 12 months, mean weight change (SD) was –8.13 (8.24) kg in the combined group compared with –6.32 (7.70) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –1.81 (95% CI –5.99 to 2.37). At 24 months, mean weight change (SD) was –2.20 (6.70) kg in the combined group compared with 0.90 (7.70) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –3.10 (95% CI –7.94 to 1.74).
Quality and comments	Mean change in weight at 1 year calculated from actual values, SDs also calculated at 1 year. No details of baseline comparability. Blinded assessment not done. ITT analysis not done. Random allocation with attempt at concealment, but some chance of disclosure.

Sikand 1988 (in HTA) RCT	
Aim	To examine the effect of exercise in a VLED programme, in combination with behavioural techniques, nutrition education and group therapy.

Participants	Women who were obese (no definition given). *Total 30 – all women. Mean (SD) age 39.8 (9.1) years combined (*n*=15), 37.8 (8.4) diet and BT (*n*=15). Mean (SD) weight 105.6 (23.6) kg combined, 106.6 (15.2) kg diet and BT.*
Intervention	All participants placed on a VLED (energy content not given) consisting solely of milk-based protein powder for initial 4 months, Received nutritional counselling, group support and discussion of behaviour modification strategies; all participants invited to an ongoing pay-for-service programme offered at clinic sponsoring the study after active treatment period. Received structured aerobic exercise programme twice weekly for first 4 months with additional exercise encouraged on other days
Control	*All participants placed on a VLED (energy content not given) consisting solely of milk based protein powder for initial 4 months.* *Received nutritional counselling, group support and discussion of behaviour modification strategies; all participants invited to an ongoing pay-for-service programme offered at clinic sponsoring the study after active treatment period.* *Participants neither encourage nor discouraged from exercising.*
Length of follow-up	*2 years*
Results	*At 4 months, mean weight change (SD) was –21.80 (12.08) kg in the combined group compared with –17.50 (10.87) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –4.30 (95% CI –14.12 to 5.52).* At 24 months, mean weight change (SD) was –9.10 (9.20) kg in the combined group compared with –0.80 (7.40) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –8.30 (95% CI –16.83 to 0.23).
Quality and comments	Blinded assessment not done. ITT analysis done. Random allocation but no description of concealment.

Wadden 1998 (in HTA) RCT	
Aim	To determine whether exercise improved the maintenance of weight loss 1 year later.
Participants	Women who were overweight (more than 20 kg above IBW Metropolitan Life tables). *Total 128 – all women. Mean (SD) age 40.9 (8.6) overall (*n*=118 of 128 assigned). Mean (SD) BMI (kg/m^2) 36.3 (5.3) overall (*n*=118 of 128 assigned).*
Intervention	925 kcal/day/diet (liquid MR) for weeks 0–16 then 1200–1500 kcal/day to week 48. 90 min group cognitive BT weekly for 28 weeks then biweekly for following 20 weeks. Three × 1 h supervised exercise training per week for first 28 weeks (non-consecutive days) then two sessions per week during weeks 29–48 and one home exercise session per week. Aerobic (HTA group a): step aerobics estimated to expend 300–400 kcal/session. Strength (HTA group b): strength exercise using universal gym of Cybex equipment to expend 150–175 kcal per session, consisted of bench press, latissimus pulldown, chest fly, leg press, leg and arm curls and extensions, sit-ups and back extensions. Mixed (HTA group c): 40% aerobic exercise same as group b and 60% strength exercise same as group c, estimated to expend 225–275 kcal/session.

Control	*925 kcal/day/diet for weeks 0–16 then 1200–1500 kcal/day to week 48.* *90 min group cognitive behaviour therapy weekly for 28 weeks then biweekly for following 20 weeks.* *Advised to continue same lifestyle activities and not to increase exercise from baseline.*
Length of follow-up	*100 weeks*
Results	*Aerobic: At 2 months, mean weight change (SD) was –10.10 (3.70) kg in the combined group compared with –11.40 (3.50) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was 1.30 (95% CI –1.74 to 4.34).* *Strength: At 2 months, mean weight change (SD) was –10.00 (3.90) kg in the combined group compared with –11.40 (3.50) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was 1.40 (95% CI –1.76 to 4.56).* *Mixed: At 2 months, mean weight change (SD) was –10.90 (3.40) kg in the combined group compared with –11.40 (3.50) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was 0.50 (95% CI –2.56 to 3.56).* *Aerobic: At 6 months, mean weight change (SD) was –15.80 (6.80) kg in the combined group compared with –17.70 (5.70) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was 1.90 (95% CI –3.23 to 7.03).* *Strength: At 6 months, mean weight change (SD) was –17.80 (8.80) kg in the combined group compared with –17.70 (5.70) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –0.10 (95% CI –5.96 to 5.76).* *Mixed: At 6 months, mean weight change (SD) was –18.60 (7.30) kg in the combined group compared with –17.70 (5.70) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –0.90 (95% CI –6.37 to 4.57).* *Aerobic: At 12 months, mean weight change (SD) was –13.50 (9.10) kg in the combined group compared with –15.30 (5.30) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was 1.80 (95% CI –3.73 to 7.33).* *Strength: At 12 months, mean weight change (SD) was –17.30 (10.30) kg in the combined group compared with –15.30 (5.30) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –2.00 (95% CI –8.17 to 4.17).* *Mixed: At 12 months, mean weight change (SD) was –16.60 (9.80) kg in the combined group compared with –15.30 (5.30) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –1.30 (95% CI –7.39 to 4.79).* Aerobic: At 24 months, mean weight change (SD) was –8.50 (8.20) kg in the combined group compared with –6.90 (6.30) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –1.60 (95% CI –7.44 to 4.24). Strength: At 24 months, mean weight change (SD) was –10.10 (10.00) kg in the combined group compared with –6.90 (6.30) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –3.20 (95% CI –9.77 to 3.37). Mixed: At 24 months, mean weight change (SD) was –8.60 (10.70) kg in the combined group compared with –6.90 (6.30) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –1.70 (95% CI –8.60 to 5.20).
Quality and comments	Blinded assessment not done. ITT analysis not done. Random allocation but no description of concealment. *Different values to HTA as split control group by three.*

Wing 1988 (in HTA) RCT	
Aim	To determine whether adding exercise to a diet programme promotes weight loss or glycaemic control in people with type 2 diabetes
Participants	People aged 30 to 65 years with type 2 diabetes and who were overweight (more than 20% above IBW) *Total 30 – 21 F, 9 M. Mean (SD) age 56.1 (6.4) years combined (*n=15*), 55.1 (7.2) diet and BT (*n=15*). Mean (SD) BMI (kg/m^2) 38.2 (6.6) combined, 37.9 (6.5) diet and BT.*
Intervention	All participants received behavioural weight control programme including weigh-in, glucose measurement and behavioural modification lecture (slowing down rate of eating, reducing eating signals in the home, social pressures, pre-planning and relapse prevention techniques). 1600 kcal/day diet with daily energy goal to produce 1 kg/week weight loss, reduced fat intake and increase complex carbohydrate intake, food diaries; exercise twice per week as a group and once a week on own, 1 h per session. Walked 3 mile route with therapist three times per week and instructed to exercise additionally once per week on their own
Control	*All participants received behavioural weight control programme including weigh-in, glucose measurement and behavioural modification lecture (slowing down rate of eating, reducing eating signals in the home, social pressures, pre-planning and relapse prevention techniques).* *1600 kcal/day diet with daily energy goal to produce 1 kg per week weight loss, reduced fat intake and increase complex carbohydrate intake, food diaries; exercise twice per week as a group and once a week on own, 1 h per session.* *Instructed not to change baseline level of activity, three meetings per week were used to provide demonstrations and films of new low-energy cooking techniques, portion size estimation and role-ply; numerous social group activities to control for social aspect of exercise condition received by combined group*
Length of follow-up	*62 weeks?*
Results	*Outcomes at 10 weeks were reported but no SDs* *At 10 weeks, mean weight change (SD) was –9.30 (8.55) kg in the combined group compared with –5.60 (7.50) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –3.70 (95% CI –9.70 to 2.30).* At 12 months, mean weight change (SD) was –7.90 (8.15) kg in the combined group compared with –3.80 (6.99) kg in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –4.10 (95% CI –9.77 to 1.57). *Note: 12 months is 62 weeks – 10 weeks intensive intervention and 12 month follow-up*
Quality and comments	*Note: Wing 1988b in HTA analysis.* Blinded assessment done. ITT analysis not done. Random allocation but no description of concealment.

Messier 2004 RCT	
Aim	To determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, mobility in older overweight/obese adults with osteoarthritis
Participants	People with osteoarthritis, aged 60 years and older who were overweight (BMI ≥28 kg/m^2) Total 316 – 227 F, 89 M. Mean (SD) age years 69 (6.97) years activity and BT (*n*=76), 69 (7.16) years activity (*n*=80). Mean (SD) BMI (kg/m^2) 34.0 (6.10) activity and BT, 34.2 (5.37) activity.
Intervention	*See details previously*

Control	See details previously
Length of follow-up	*18 months*
Results	*At 18 months, mean (SD) weight change in kg was –5.20 (7.37) in the combined group, and –4.61 (7.22) in the diet and BT group. Mean weight change in the intervention group compared with diet and BT was –0.59 (95% CI –2.87 to 1.69).*
Quality and comments	*ITT analysis done. Blinded assessment done. Good concealment of allocation. SDs calculated*

Other outcomes

Wing 1998 (in HTA) RCT	
Results	*At 6 months, mean (SD) TC change in mmol/l was –0.33 (0.61) in the combined group, and –0.49 (0.71) in the diet and BT group. Mean TC change in the combined group compared with diet and BT was 0.16 (95% CI –0.16 to 0.48).* *At 6 months, mean (SD) LDL change in mmol/l was –0.13 (0.58) in the combined group, and –0.32 (0.60) in the diet and BT group. Mean LDL change in the combined group compared with diet and BT was 0.19 (95% CI –0.09 to 0.47).* *At 6 months, mean (SD) HDL change in mmol/l was –0.06 (0.16) in the combined group, and –0.10 (0.17) in the diet and BT group. Mean HDL change in the combined group compared with diet and BT was 0.04 (95% CI –0.04 to 0.12).* *At 6 months, mean (SD) TAG change in mmol/l was –0.69 (1.45) in the combined group, and –0.30 (1.45) in the diet and BT group. Mean TAG change in the combined group compared with diet and BT was –0.39 (95% CI –1.09 to 0.31).* *At 6 months, mean (SD) DBP change in mmHg was –6.90 (10.40) in the combined group, and –6.20 (6.90) in the diet and BT group. Mean DBP change in the combined group compared with diet and BT was –0.70 (95% CI –5.02 to 3.62).* *At 6 months, mean (SD) SBP change in mmHg was –12.30 (9.50) in the combined group, and –10.20 (9.20) in the diet and BT group. Mean SBP change in the combined group compared with diet and BT was –2.10 (95% CI –6.62 to 2.42).* *At 6 months, mean (SD) FPG change in mmol/l was –0.20 (0.40) in the combined group, and –0.20 (0.40) in the diet and BT group. Mean FPG change in the combined group compared with diet and BT was 0.00(95% CI –0.19 to 0.19).* *At 6 months, mean (SD) change in %HbA$_{1c}$ was 0.03 (0.20) in the combined group, and 0.10 (0.50) in the diet and BT group. Mean %HbA$_{1c}$ change in the combined group compared with diet and BT was –0.07 (95% CI –0.25 to 0.11).* *At 12 months, mean (SD) TC change in mmol/l was 0.32 (0.64) in the combined group, and 0.26 (0.76) in the diet and BT group. Mean TC change in the combined group compared with diet and BT was 0.06 (95% CI –0.29 to 0.41).* *At 12 months, mean (SD) LDL change in mmol/l was 0.14 (0.54) in the combined group, and 0.12 (0.73) in the diet and BT group. Mean LDL change in the combined group compared with diet and BT was 0.02 (95% CI –0.30 to 0.34).* *At 12 months, mean (SD) HDL change in mmol/l was 0.12 (0.20) in the combined group, and 0.10 (0.16) in the diet and BT group. Mean HDL change in the combined group compared with diet and BT was 0.02 (95% CI –0.07 to 0.11).* *At 12 months, mean (SD) TAG change in mmol/l was 0.33 (1.65) in the*

	combined group, and 0.55 (3.77) in the diet and BT group. Mean TAG change in the combined group compared with diet and BT was –0.22 (95% CI –1.64 to 1.20). *At 12 months, mean (SD) DBP change in mmHg was –1.00 (10.20) in the combined group, and 3.40 (8.10) in the diet and BT group. Mean DBP change in the combined group compared with diet and BT was –4.40 (95% CI –9.08 to 0.28).* *At 12 months, mean (SD) SBP change in mmHg was –2.90 (14.20) in the combined group, and 1.30 (8.30) in the diet and BT group. Mean SBP change in the combined group compared with diet and BT was –4.20 (95% CI –10.02 to 1.62).* *At 12 months, mean (SD) FPG change in mmol/l was 0.00 (0.50) in the combined group, and 0.20 (0.80) in the diet and BT group. Mean FPG change in the combined group compared with diet and BT was –0.20 (95% CI –0.53 to 0.13).* *At 24 months, mean (SD) TC change in mmol/l was 0.09 (0.67) in the combined group, and –0.12 (0.61) in the diet and BT group. Mean TC change in the combined group compared with diet and BT was 0.21 (95% CI –0.10 to 0.52).* *At 24 months, mean (SD) LDL change in mmol/l was 0.12 (0.52) in the combined group, and –0.16 (0.63) in the diet and BT group. Mean LDL change in the combined group compared with diet and BT was 0.28 (95% CI 0.00 to 0.56).* *At 24 months, mean (SD) HDL change in mmol/l was 0.02 (0.21) in the combined group, and 0.02 (0.20) in the diet and BT group. Mean HDL change in the combined group compared with diet and BT was 0.00 (95% CI –0.10 to 0.10).* *At 24 months, mean (SD) TAG change in mmol/l was –0.28 (1.33) in the combined group, and 0.19 (2.42) in the diet and BT group. Mean TAG change in the combined group compared with diet and BT was –0.47 (95% CI –1.39 to 0.45).* *At 24 months, mean (SD) DBP change in mmHg was –0.20 (10.50) in the combined group, and 3.00 (7.80) in the diet and BT group. Mean DBP change in the combined group compared with diet and BT was –3.20 (95% CI –7.66 to 1.26).* *At 24 months, mean (SD) SBP change in mmHg was –4.80 (15.00) in the combined group, and –0.80 (9.40) in the diet and BT group. Mean SBP change in the combined group compared with diet and BT was –4.00 (95% CI -10.06 to 2.06).* *At 24 months, mean (SD) FPG change in mmol/l was 0.50 (1.30) in the combined group, and 0.30 (1.00) in the diet and BT group. Mean FPG change in the combined group compared with diet and BT was 0.20 (95% CI –0.36 to 0.76).* *At 24 months, mean (SD) change in %HbA_{1c} was 0.04 (1.08) in the combined group, and –0.10 (0.50) in the diet and BT group. Mean %HbA_{1c} change in the combined group compared with diet and BT was 0.14 (95% CI –0.27 to 0.55).* *At 6, 12, and 24 months, the combined group reported significant decreases from baseline in energy intake and percentage of energy from fat (block food-frequency of % energy as fat was significant at 24 months). At 6, 12 and 24 months, the diet group reported significant decreases from baseline in energy intake and percentage of energy from fat.* VO_{2max} *increased in the combined group significantly at 6 months, and was also increased at 24 months (not significant from baseline). The diet and BT group increased significantly at 6 months (+2.35 vs +3.06 ml/kg per min in the combined group), but not at 24 months from baseline.* *At 24 months, the relative risk (if weight loss of 4.5 kg compared with no weight loss) of developing diabetes in the combined group was about 0.88 and about 0.89 in the diet and BT group. For people with IGT, the relative risks were about 0.92 and 0.96 respectively.*
Quality and	Dietary intake assessed using self-completed questionnaires and 3-day food

comments	diaries. Activity assessed using self-completed questionnaire (administered as an interview).

Foreyt 1993 (in HTA) RCT	
Results	*No group differences were found in cardiovascular fitness (VO_{2max}) at 12 months.*
Quality and comments	…

Sikand 1988 (in HTA) RCT	
Results	*No other outcomes reported.*
Quality and comments	…

Wadden 1998 (in HTA) RCT	
Results	*No other outcomes reported.*
Quality and comments	…

Wing 1988 (in HTA) RCT	
Results	*TC at 12 months – not added, as HTA figures cannot be replicated* *At 12 months, mean (SD) HDL change in mmol/l was 0.06 (0.29) in the combined group, and 0.10 (0.29) in the diet and BT group. Mean HDL change in the combined group compared with diet and BT was –0.04 (95% CI –0.26 to 0.18).* *At 12 months, mean (SD) TAG change in mmol/l was –0.64 (0.96) in the combined group, and 0.03 (0.96) in the diet and BT group. Mean TAG change in the combined group compared with diet and BT was –0.67 (95% CI –1.38 to 0.04).* *At 12 months, mean (SD) %HbA_{1c} change was 0.04 (1.08) in the combined group, and –0.10 (0.50) in the diet and BT group. Mean %HbA_{1c} change in the combined group compared with diet and BT was 0.14 (95% CI –0.27 to 0.55).* *At 12 months, there was a significant reduction in medication in the combined group compared with the diet and BT group (83% had reduced medication compared with 38% respectively,* $p<0.05$*). There was also a significant reduction in the dosage (50% compared with 0% respectively,* $p<0.01$*).* *Increased energy expenditure was seen in the combined group compared with the diet and BT group. Energy intake did not differ between the groups, although both groups did decrease intake from baseline.*
Quality and comments	Dietary intake from 3-day food records. Activity from self-reported questionnaires.

Messier 2004 RCT	
Results	*At 18 months, no significant improvements were seen for self-reported physical function, motility, or pain between groups.*
Quality and comments	…

Reported harms

Wing 1998 (in HTA) RCT	
Harms	15.6% in the combined group and 30.3% of the diet and BT group developed diabetes during the 24-month study. The development of diabetes was associated with increased initial IGT.
Quality and	…

comments	

Foreyt 1993 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Sikand 1988 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wadden 1998 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Wing 1988 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Messier 2004 RCT	
Harms	Two deaths occurred, but were unrelated to the interventions. One participant tripped and sustained a laceration to his head. No details of allocation.
Quality and comments	…

Generalisability

Wing 1998 (in HTA) RCT	
Country and setting	USA. No further details – university hospital?
Participants (included/excluded)	Included if aged 40–55 years, non-diabetic (confirmed by OGTT), one or two biological parents with type 2 diabetes, 30–100% above IBW. Excluded if diagnosis of diabetes.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*Two years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then two × 6-week course during second year)*
Duration of active intervention	24 months
Control (mode and intensity)	2 years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then two × 6-week course during second year).
Delivery of intervention/control (who)	Group meetings were led by a multidisciplinary team, with primary therapists for activity being a behaviour therapist and an exercise physiologist, and for diet a behaviour therapist and a registered dietitian.
Dropout rates	*20% combined and 5% diet and BT at 24 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Foreyt 1993 (in HTA) RCT	
Country and setting	USA. No further details.

Participants (included/excluded)	*Included if aged between 25–45 years, ≥14 kg overweight (Metropolitan Life Insurance tables), not taking regular exercise, $100 deposit (refunded in increments according to number of sessions attended).* *No exclusion criteria stated.*
Recruitment	Media announcements
Intervention (mode and intensity)	12 months plus follow-up visit at 2 years, contacted 24 times (baseline, 12 weekly then 3 biweekly then 8 monthly then at 2 years).
Duration of active intervention	*12 months*
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	1-h long group sessions led by registered dietitians with training and experience in behaviour modification.
Dropout rates	50% combined and 64% diet and BT at 24 months (only invited completers back at 2 years)
Treatment of dropouts (return to baseline, or last measurement?)	*Completers only*

Sikand 1988 (in HTA) RCT	
Country and setting	USA. No details.
Participants (included/excluded)	Included women, aged 21–60 years, obese (no definition). No exclusion criteria reported.
Recruitment	N/R
Intervention (mode and intensity)	*Four months, with telephone follow-up at 2 years, contacted 34 times (baseline, twice weekly for initial 4 months then at 2 years).*
Duration of active intervention	4 months
Control (mode and intensity)	Four months, with telephone follow-up at 2 years, contacted 18 times (baseline, weekly for initial 4 months then at 2 years).
Delivery of intervention/control (who)	Each visit involved a medical consultation and nutritional counselling but no details of who did these was reported.
Dropout rates	*53% combined, 47% diet and BT at 2 years*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only

Wadden 1998 (in HTA) RCT	
Country and setting	USA. University clinics.
Participants (included/excluded)	Included women, >20 kg above IBW (Metropolitan Life Insurance tables). Excluded if medical contraindications, bulimia nervosa, other major psychiatric disturbance, and medication known to affect weight.
Recruitment	N/R
Intervention (mode and intensity)	*Forty-eight weeks with follow-up at 1-year post-treatment (100 weeks), contacted 40 times (baseline then weekly for initial 28 weeks then biweekly for next 20 weeks then at 100 weeks).*
Duration of active intervention	48 weeks
Control (mode and intensity)	As above

Delivery of intervention/control (who)	Group sessions and refeeding protocol supervised by a registered dietitian. Also clinical psychologists involved in group sessions. Exercise sessions were led by graduate students in exercise physiology.
Dropout rates	*40% overall at 100 weeks.*
Treatment of dropouts (return to baseline, or last measurement?)	Dropouts were retained until time of attrition.

Wing 1988 (in HTA) RCT	
Country and setting	USA. No further details.
Participants (included/excluded)	Included if had type 2 diabetes (as defined by National Diabetes Data Group), >20% above IBW, 30–65 years. Excluded if known CHD, on medication that would affect weight loss and or measurement of heart rate, orthopaedic problems which would limit walking.
Recruitment	N/R
Intervention (mode and intensity)	*62? weeks, contacted 53 times (baseline then three times per week for first 10 weeks then weekly for weeks 11–20 then monthly to 72 weeks)*
Duration of active intervention	62 weeks?
Control (mode and intensity)	As above
Delivery of intervention/control (who)	N/R
Dropout rates	*13% combined, 0% diet and BT at 62 weeks?*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only

Messier 2004 RCT	
Country and setting	USA. Older Americans Independence Centre.
Participants (included/excluded)	See details previously
Recruitment	See details previously
Intervention (mode and intensity)	See details previously
Duration of active intervention	18 months
Control (mode and intensity)	See details previously
Delivery of intervention/control (who)	Exercise and BT: not reported Exercise: not reported
Dropout rates	*24% activity and BT, 20% activity at 24 months*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.5.15 Physical activity, diet and behaviour therapy vs physical activity and behaviour therapy

Weight loss

Wing 1998 (in HTA) RCT	
Aim	To assess the effect of lifestyle intervention over 2 years on changes in weight, CHD risk factors, and incidence of diabetes in overweight adults with a parental history of diabetes

Participants	Adults aged 40 to 55 years who did not have diabetes, and were overweight (30 to 100% of IBW). *154 total – 122 F, 32 M. Mean (SD) age 46.3 (3.8) years combined (n=40), 46.4 (4.5) activity and BT (n=37). Mean (SD) BMI (kg/m^2) 35.7 (4.1) combined, 36.0 (3.7) activity and BT.*
Intervention	Diet: 800–1000 kcal/day weeks 1–8 then adjusted to 1200–1500 kcal/day by week 16, food diaries reviewed and feedback given, meal plans and shopping lists, behavioural or nutritional topic given at each session (relapse prevention, stimulus control, dealing with eating out, assertion, behaviour chain analysis, problem-solving) Exercise: 50–60 min walk with therapist at each meeting (second supervised walk available each week for weeks 1–10), gradually increased exercise to estimated energy expenditure of 1500 kcal per week (e.g. 3 miles brisk walking 5 days per week), other activities periodically introduced to the participants such as aerobics and line dancing. Also lectures on a topic related to changing exercise behaviour (stimulus control, problem-solving, reducing barriers, exercising in different weather conditions, stretching). (Same number of meetings as diet and exercise alone, so half time spent on diet and half on exercise.)
Control	Exercise behaviour topic each week, 50–60 min walk with therapist at each weekly meeting (second supervised walk available each week for weeks 1–10), gradually increased exercise to estimated energy expenditure of 1500 kcal/week (e.g. 3 miles brisk walking 5 days per week), other activities periodically introduced to the participants such as aerobics and line dancing. Each meeting included a lecture on a topic related to changing exercise behaviour (stimulus control, problem-solving, reducing barriers, exercising in different weather conditions, stretching).
Length of follow-up	24 months
Results	*At 6 months, mean weight change (SD) was –10.30 (7.70) kg in the combined group compared with –2.10 (4.20) kg in the activity and BT group. Mean weight change in the intervention group compared with activity and BT was –8.20 (95% CI –11.27 to –5.13).* *At 12 months, mean weight change (SD) was –7.40 (9.70) kg in the combined group compared with –0.40 (4.80) kg in the activity and BT group. Mean weight change in the intervention group compared with activity and BT was –7.00 (95% CI –10.90 to –3.10).* *At 24 months, mean weight change (SD) was –2.50 (8.40) kg in the combined group compared with 1.00 (4.70) kg in the activity and BT group. Mean weight change in the intervention group compared with activity and BT was –3.50 (95% CI –6.85 to –0.15).*
Quality and comments	Author confirmed main study and sub-study results. Blinded assessment done. ITT analysis done. Random allocation but no description of concealment.

Other outcomes

Wing 1998 (in HTA) RCT	
Results	*At 6 months, mean (SD) TC change in mmol/l was –0.33 (0.61) in the combined group, and 0.12 (0.72) in the activity and BT group. Mean TC change in the combined group compared with activity and BT was –0.45 (95% CI –0.78 to –0.12).* *At 6 months, mean (SD) LDL change in mmol/l was –0.13 (0.58) in the combined group, and 0.03 (0.52) in the activity and BT group. Mean LDL change in the combined group compared with activity and BT was –0.16 (95% CI –0.43 to 0.11).*

At 6 months, mean (SD) HDL change in mmol/l was –0.06 (0.16) in the combined group, and 0.02 (0.16) in the activity and BT group. Mean HDL change in the combined group compared with activity and BT was –0.08 (95% CI –0.16 to 0.00).
At 6 months, mean (SD) TAG change in mmol/l was –0.69 (1.45) in the combined group, and 0.12 (1.64) in the activity and BT group. Mean TAG change in the combined group compared with activity and BT was –0.81 (95% CI –1.57 to–0.05).
At 6 months, mean (SD) DBP change in mmHg was –6.90 (10.40) in the combined group, and –1.70 (12.20) in the activity and BT group. Mean DBP change in the combined group compared with activity and BT was –5.20 (95% CI –10.74 to 0.34).
At 6 months, mean (SD) SBP change in mmHg was –12.30 (9.50) in the combined group, and –2.40 (18.90) in the activity and BT group. Mean SBP change in the combined group compared with activity and BT was –9.90 (95% CI –17.16 to –2.64).
At 6 months, mean (SD) FPG change in mmol/l was –0.20 (0.40) in the combined group, and 0.00 (0.70) in the activity and BT group. Mean FPG change in the combined group compared with activity and BT was –0.20 (95% CI –0.48 to 0.08).
At 6 months, mean (SD) change in %HbA$_{1c}$ was 0.03 (0.20) in the combined group, and 0.10 (0.30) in the activity and BT group. Mean %HbA$_{1c}$ change in the combined group compared with activity and BT was –0.07 (95% CI –0.19 to 0.05).
At 12 months, mean (SD) TC change in mmol/l was 0.32 (0.64) in the combined group, and 0.36 (0.82) in the activity and BT group. Mean TC change in the combined group compared with activity and BT was –0.04 (95% CI –0.42 to 0.34).
At 12 months, mean (SD) LDL change in mmol/l was 0.14 (0.54) in the combined group, and 0.15 (0.54) in the activity and BT group. Mean LDL change in the combined group compared with activity and BT was –0.01 (95% CI –0.29 to 0.27).
At 12 months, mean (SD) HDL change in mmol/l was 0.12 (0.20) in the combined group, and 0.16 (0.18) in the activity and BT group. Mean HDL change in the combined group compared with activity and BT was –0.04 (95% CI –0.14 to 0.06).
At 12 months, mean (SD) TAG change in mmol/l was 0.33 (1.65) in the combined group, and 0.26 (2.19) in the activity and BT group. Mean TAG change in the combined group compared with activity and BT was 0.07 (95% CI –0.93 to 1.07).
At 12 months, mean (SD) DBP change in mmHg was –1.00 (10.20) in the combined group, and 0.90 (9.70) in the activity and BT group. Mean DBP change in the combined group compared with activity and BT was –1.90 (95% CI –7.11 to 3.31).
At 12 months, mean (SD) SBP change in mmHg was –2.90 (14.20) in the combined group, and 1.10 (15.80) in the activity and BT group. Mean SBP change in the combined group compared with activity and BT was –4.00 (95% CI –11.75 to 3.75).
At 12 months, mean (SD) FPG change in mmol/l was 0.00 (0.50) in the combined group, and 0.10 (0.70) in the activity and BT group. Mean FPG change in the combined group compared with activity and BT was –0.10 (95% CI –0.42 to 0.22).
At 24 months, mean (SD) TC change in mmol/l was 0.09 (0.67) in the combined group, and 0.33 (0.64) in the activity and BT group. Mean TC change in the combined group compared with activity and BT was –0.24 (95% CI –0.56 to 0.08).
At 24 months, mean (SD) LDL change in mmol/l was 0.12 (0.52) in the combined group, and 0.22 (0.61) in the activity and BT group. Mean LDL change in the combined group compared with activity and BT was –0.10 (95% CI –0.38 to 0.18).

	At 24 months, mean (SD) HDL change in mmol/l was 0.02 (0.21) in the combined group, and 0.05 (0.17) in the activity and BT group. Mean HDL change in the combined group compared with activity and BT was –0.03 (95% CI –0.12to 0.06). *At 24 months, mean (SD) TAG change in mmol/l was –0.28 (1.33) in the combined group, and 0.33 (1.46) in the activity and BT group. Mean TAG change in the combined group compared with activity and BT was –0.61 (95% CI –1.30 to 0.08).* *At 24 months, mean (SD) DBP change in mmHg was –0.20 (10.50) in the combined group, and 2.00 (8.00) in the activity and BT group. Mean DBP change in the combined group compared with activity and BT was –2.20 (95% CI –6.80 to 2.40).* *At 24 months, mean (SD) SBP change in mmHg was –4.80 (15.00) in the combined group, and 0.90 (13.90) in the activity and BT group. Mean SBP change in the combined group compared with activity and BT was –5.70 (95% CI –12.84 to 1.44).* *At 24 months, mean (SD) FPG change in mmol/l was 0.50 (1.30) in the combined group, and 0.40 (0.90) in the activity and BT group. Mean FPG change in the combined group compared with activity and BT was 0.10 (95% CI –0.45 to 0.65).* *At 24 months, mean (SD) change in %HbA_{1c} was 0.04 (1.08) in the combined group, and –0.10 (0.50) in the activity and BT group. Mean %HbA_{1c} change in the combined group compared with activity and BT was 0.14 (95% CI –0.27 to 0.55).* *At 6, 12, and 24 months, the combined group reported significant decreases from baseline in energy intake and percentage of energy from fat (block food-frequency of % energy as fat was significant at 24 months). At 6, 12, and 24 months, the activity and BT group reported non-significant decreases from baseline in energy intake and percentage of energy from fat (only block food-frequency of % energy as fat was significant at 24 months).* VO_{2max} *increased in the combined group significantly at 6 months, and was also increased at 24 months (not significant from baseline).* VO_{2max} *increased in the activity and BT group significantly at 6 months, but decreased at 24 months (not significant).* *At 24 months, the relative risk (if weight loss of 4.5 kg compared with no weight loss) of developing diabetes in the combined group was about 0.88 and about 0.88 in the activity and BT group. For people with IGT, the relative risks were about 0.92 and 0.91, respectively.*
Quality and comments	Dietary intake assessed using self-completed questionnaires and 3-day food diaries. Activity assessed using self-completed questionnaire (administered as an interview).

Reported harms

Wing 1998 (in HTA) RCT	
Harms	15.6% in the combined group and 14% of the activity and BT group developed diabetes during the 24-month study. The development of diabetes was associated with increased initial IGT.
Quality and comments	…

Generalisability

Wing 1998 (in HTA) RCT	
Country and setting	USA. No further details – university hospital?
Participants (included/excluded)	Included if aged 40–55 years, non-diabetic (confirmed by OGTT), one or two biological parents with type 2 diabetes, 30–100% above IBW. Excluded if diagnosis of diabetes.
Recruitment	Newspaper advertisements.
Intervention (mode and intensity)	*2 years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then two × 6-week course during second year)*
Duration of active intervention	24 months
Control (mode and intensity)	Two years, contacted approximately 52 times (baseline, weekly for first 6 months then every 2 weeks for next 6 months then two × 6-week course during second year).
Delivery of intervention/control (who)	Group meetings were led by a multidisciplinary team, with primary therapists for activity being a behaviour therapist and an exercise physiologist, and for diet a behaviour therapist and a registered dietitian.
Dropout rates	*20% combined and 16% activity and BT at 24 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.5.16 Intensity of physical activity

Weight loss

Anderson 1999 RCT	
Aim	To examine short- and long-term changes in weight, body composition, and cardiovascular risk profiles produced by diet combined with either programmed aerobic exercise or lifestyle activity in obese women.
Participants	Forty women with a mean (SD) age of 42.9 (8.3) years, weight of 89.2 (11.6) kg, height of 165.0 (7.1) cm and BMI of 32.9 (4.3) kg/m^2. All women reported not participating in a structured exercise programme for the 6 months prior to the start of the intervention.
Intervention	All participants asked to consume a self-selected, low-fat, LED of approximately 1200 kcal/day as per American Heart Association. All participants received a similar cognitive behavioural weight loss programme, a modified version of the LEARN Programme for Weight Control. The participants in the diet plus structured aerobic exercise attended three step aerobic classes. The length and intensity of classes was gradually increased. It was estimated that participants expended approximately 450 to 500 kcal per step aerobic workout. From weeks 14–16 participants were assisted in developing a long-term individualised programme of structured aerobic exercise.
Comparison	Participants in the lifestyle group were advised to increase their levels of moderately intense physical activity by 30 min/day on most days of the week. They discussed strategies for accumulating activity and expending energy throughout the day. They were taught to incorporate short bouts of activity into their daily schedules. Participants were given three-dimensional accelerometers to wear each week to provide ongoing feedback about their levels of physical activity. Units of physical activity were converted to energy expenditure. Participants were provided a graph of daily activity each week at the end of their group meeting.
Length of follow-up	16 week RCT with 1-year follow-up
Results	Thirty-eight (98%) of 40 women completed the 16-week study. Thirty-three (82.5%) of 40 women completed the entire 68-week study – 16 in the lifestyle group and 17 in the aerobic group. Weight losses of the two groups did not differ significantly at any time. Using an LOCF analysis, researchers found that participants across conditions lost a mean (SD) weight of 2.2 (1.2) kg by week 4, 4.6 (1.8) kg by week 8, and 6.5 (3.0) kg at week 12. At week 16, weight loss in the lifestyle group was 7.9 (4.2) kg and in the aerobic group was 8.3 (3.8) kg (within groups, *p*<0.001; between groups, *p*=0.08). Participants in the lifestyle group who were assessed at the 1-year follow-up (week 68) had regained a mean (SD) weight of 0.08 (4.6) kg from the end of treatment while the aerobic group had regained weight of 1.6 (5.5) kg (*p*=0.06). At week 68 participants were asked to report the percentage of weeks that they accumulated ≥30 min of moderate intensity exercise (e.g. brisk walking) on at least 5 days of the week for the 12 months after the intervention. There were no differences between groups in adherence to physical activity. No differences were found between the most active third, the middle third and the least active third in weight regain at the 3 and 6 month follow-up but at the 9 month visit, the least active group had regained significantly (*p*<0.02) more weight (3.76 [2.4] kg) than the most active group which, by contrast, had lost weight (–3.14 [4.6] kg). At the 12 month follow-up the least active group had regained significantly more of their lost weight than the middle (0.21[5.5] kg), *p*=0.021, or the most (–1.98 [4.3] kg) active groups (*p*=0.001). No differences were found between the most active and the middle group at any time during the follow-up period.
Quality and comments	ITT analysis not described. No blinding possible. There was random allocation, but no description of concealment.

Sponsor details	NIH grant, NRS and RSD Awards

Jacobsen 2003 RCT	
Aim	To compare the effects of long-term (72 weeks) continuous (CON) and intermittent (INT) exercise on attrition and adherence without a behavioural weight loss programme.
Participants	Fifty-two moderately obese (mean BMI >32 kg/m^2), previously sedentary women with oxygen consumption at or below the 'Fair Category' according to the American Heart Associations Fitness Classifications
Intervention	Participants were randomised to one of two levels of exercise. The CON group walked for 30 min at 60–75% of heart rate reserve, three times per week within the Human Performance Laboratory at the University of Nebraska
Comparison	INT group walked briskly at 50–65% of heart rate reserve two times per day, 15 min per session, 5 days/week at their home or work site. A minimum of 2 h was recommended to elapse between exercise sessions.
Length of follow-up	72 weeks
Results	For participants who completed the study, body weight did not change for CON from 80.17±5.75 kg at baseline to 79.70±5.40 at 16 months. For INT body weight did not change form baseline 85.85±13.13 kg to 16 months 85.05±12.90 kg.
Quality and comments	An RCT in which blinding was not possible and allocation concealment was not described. High attrition rate (58%).
Sponsor details	American Heart Association

Jakicic 1999 RCT	
Aim	To investigate whether exercise adherence in obese females, participating in a behavioural weight loss programme, is improved by prescribing daily exercise in multiple short bouts compared with continuous exercise and to determine whether multiple short bouts of daily exercise can produce significant improvements in cardiorespiratory fitness.
Participants	48 sedentary, overweight (mean [SD] BMI 32.8 [4.0] kg/m^2) women between the ages of 25–45 years. Sedentary was defined as <20 min/day of exercise on <3 days per week for 6 months.
Intervention	All participants participated in an 18-month behavioural weight loss programme with weekly meetings during months 1–6, biweekly meetings during months 7–12 and monthly meetings during months 13–18. All participants were also instructed to reduce both daily energy and fat intake. Home-based exercise similar to brisk walking prescribed as follows: 49 women instructed to exercise 5 days/week 20 min/day during weeks 1–4, 30 min/day weeks 5–8 and 40 min/day for the duration of the study. Exercise was performed in one long bout (LB).
Comparison	51 women instructed to exercise 5 days/week with duration progressing from 20 min/day to 40 min/day by the ninth week. The exercise was divided into multiple 10 min bouts that were performed at convenient times throughout the day, progressing from 2–4 short exercise bouts (SB) per day by week 9. 48 women whose exercise prescription was identical to the short bout group except that they were also provided with home treadmills (SBEQ).
Length of follow-up	18 months

Results	115 women of 148 randomised participants completed the study. Using an ITT analysis, there was NS difference weight loss at 6 or 18 months between the LB and either the SB group or the SBEQ group. At 18 months mean (SD) weight loss was significantly greater in the SBEQ group compared with the SB group (–7.4 kg [7.8 kg] vs –3.7 [6.6] kg; *p*<0.05). Weight loss was significantly at 18 months among those who reported exercising for ≥200 min/week compared with those exercising <150 min/week or ≥150 min/week (*p*<0.05). There were no significant differences between LB and SB/SBEQ groups for measures of body composition. However, changes in percentage of body fat and fat mass were significantly greater over time in the SBEQ group compared with the SB group (*p*<0.01 and *p*<0.01).
Quality and comments	Participants were randomly assigned to treatment groups. Allocation concealment not described. Blinding of participants not possible. Blinding of evaluators not described. ITT analysis done.
Sponsor details	NIH

Jakicic 2003 RCT	
Aim	To compare the effects of different durations and intensities of exercise on 12 month weight loss and cardiorespiratory fitness.
Participants	201 women with BMI 27–40 (mean BMI in each treatment group 32.2–32.8); age 21–45; sedentary, exercising less than 3 days/week for less than 20 min/day.
Intervention	All participants participated in an 18-month behavioural weight loss programme with weekly meetings during initial 24 weeks of treatment and biweekly meetings for the remainder of the study period. All participants were also instructed to reduce both daily energy (1200–1500 kcal) and fat intake (20–30%) Participants were randomised to one of four exercise groups of varying intensity and duration. vigorous intensity/high duration moderate intensity/high duration moderate intensity/moderate duration vigorous intensity/moderate duration. Walking was the primary form of exercise and treadmills were provided.
Comparison	See above
Length of follow-up	12 months
Results	Weight loss was significant in all groups but there was no significant difference of either exercise duration or intensity on changes in body weight between groups. A similar pattern of change in BMI was observed. In ITT, mean (SD) weight loss following 12 months of treatment was statistically significant (*p*<0.001) in all exercise groups (vigorous intensity/high duration=8.9 [7.3] kg; moderate intensity/high duration=8.2 [7.6] kg; moderate intensity/moderate duration=6.3 [5.6] kg; vigorous intensity/moderate duration=7.0 [6.4] kg), with no significant difference between groups. Mean (SD) cardiorespiratory fitness levels also increased significantly (*p*=0.04) in all groups (vigorous intensity/high duration=22.0 [19.9]%; moderate intensity/high duration=14.9 [18.6]%; moderate intensity/moderate duration=13.5 [16.9]%; vigorous intensity/moderate duration=18.9 [16.9]%), with no difference between groups. Post hoc analysis revealed that percentage weight loss at 12 months was associated with the level of physical activity performed at 6 and 12 months.
Quality and comments	Participants were randomly assigned to treatment groups. Allocation concealment not described. Blinding of participants not possible. Blinding of evaluators not described. ITT analysis done. A control group that did not perform exercise would also have been a valuable comparator. Participants were women only.
Sponsor details	NIH and NHLBI

Jeffery 1998 RCT	
Aim	To examine two strategies for enhancing exercise adherence in obese individuals in a weight loss programme.
Participants	29 men and 167 women
Intervention	Four intervention groups: all received the same behaviour therapy as control. Supervised exercise group had a goal of 1000 kcal/week and had supervised walking sessions three times per week. The trainer group had all of the above but also had a personal trainer who walked with participants and made reminder phone calls before each walking session and scheduled make up sessions as necessary. The incentive group received a financial incentive for walking rather than a trainer: $1 per walk for first 25 walks, $1.50 per walk for the next 50 walks, $2 per walk for next 50 walks and $3 per walk for any remaining walks. The fourth group had both personal trainers and financial rewards for walking.
Comparison	SBT group received a behavioural counselling and diets of 100 kcal/day if weight was <91 kg and 1500 kcal if weight was ≥91 kg. Participants were asked to walk or bike the equivalent of 250 kcal/week and to gradually increase to 1000 kcal/week. Behavioural techniques included stimulus control, problem-solving, social assertion, short term goal-setting and enhancing motivation, relapse prevention, and social support.
Length of follow-up	18 months
Results	Analysis of weight loss controlled for gender and baseline weight and centre. The SBT group had significantly greater weight loss from baseline to 18 months than the four intervention groups (*p*<0.03).

	Mean weight change in kg		
	Baseline to 6 months	**6 to 18 months**	**Baseline to 18 months**
SBT	–8.3	0.9	–7.6
Supervised	–6.0	2.9	–3.8
Trainer	–5.6	3.4	–2.9
Incentive	–6.7	2.1	–4.5
Trainer plus incentive	–7.9	2.2	–5.1

Quality and comments	RCT in which blinding was not possible. Allocation concealment not discussed.
Sponsor details	NHLBI

Jeffery 2003 RCT	
Aim	To evaluate whether prescribing higher exercise levels in behavioural weight loss programs would enhance short and long term weight loss outcomes.
Participants	Obese men and women, age 25–50 years, free from serious concurrent medical or psychological problems thought to interfere with treatment. An effort was made to recruit equal numbers of male and female participants. 58% of the sample was female. *n*=202
Intervention	Participants were randomly assigned to one of two study groups. All participants received identical training in diet and behaviour control skills (stimulus control, problem-solving, goal setting, social support, motivation, relapse prevention). They were given different EE goals. The high physical activity group was prescribed an EE of 2500 kcal/week.
Comparison	The comparison group, or SBT group was prescribed an EE of 1000 kcal/week.
Length of follow-up	18 months
Results	Mean weight loss at 6, 12, and 18 months were 8.1±7.4, 6.1±8.8, 4.1±8.3 kg in the SBT group and 9.0±7.1, 8.5±7.9, 6.7±8.1 kg in the HPA group. Differences in weight loss between treatments were not significant at 6 months (*p*=0.45) or 12 months (*p*=0.07). At 18 months results were significant (*p*=0.04).

Quality and comments	Participants were randomised by unknown method. Allocation concealment was not described. It was not possible to blind participants or researchers to treatment. Loss to follow-up was considered in the analysis
Sponsor details	NHLBI

Other outcomes

Anderson 1999 RCT	
Results	Changes in body fat and fat-free mass (FFM) At the end of 16 weeks, the lifestyle group reduced mean (SD) body fat by 6.2 (4.1) kg while the aerobic group lost 7.4 (3.7) kg (*p*<0.001). The percentage of body fat was reduced to 45.5 (6.2)% in the lifestyle group and to 41.9 (4.3)% in the aerobic group after 16 weeks of treatment (*p*<0.001). Mean reductions in FFM were greater than 1.4 (1.3) kg for the lifestyle group compared with 0.5 (1.3) for the aerobic group (*p*=0.03). Cardiovascular risk factors: Significant reductions in TC, TAG, LDL and HDL were observed in both groups after 16 weeks of treatment (tables illegible). TC remained unchanged at week 16 but was significantly reduced in the lifestyle group at week 68. No differences were found between treatment groups in the change in serum lipid or lipoprotein levels (*p* range 0.62–0.93). BP: Resting systolic BP decreased significantly (*p*<0.001) during the 16 weeks of treatment and remained lower than baseline values in the lifestyle group at week 68, but there were no significant differences. Oxygen uptake: There were significant improvements over time in maximum oxygen uptake (*p*<0.001) with no significant differences between groups. Mood: There were no significant differences between conditions in baseline or week 16 scores on the Beck Depression Inventory.
Quality and comments	This study also reported changes in body fat, FFM, aerobic fitness, BP, lipids and lipoproteins and mood. The results of this study indicated that an active lifestyle may help to maintain weight loss.

Jacobsen 2003 RCT	
Results	Aerobic capacity significantly improved 8% for CON and 6% for INT. Twenty-four hour energy and macronutrient intake did not change for CON or INT across the duration of this study. Attrition was higher for the continuous group than the intermittent group in the first 24 weeks of the programme (*p*<0.05). By week 32 of the study, the continuous group had 58% attrition. The attrition rate in the INT group steadily increased in the time period from 24 to 60 weeks.
Quality and comments	….

Jakicic 1999 RCT	
Results	All groups showed an increase in cardiorespiratory fitness from baseline to 18 months with no significant differences between groups.
Quality and comments	Length of exercise times were self-reported and therefore potentially subject to recall bias.

Jakicic 2003 RCT	
Results	All groups showed significant within group increased in oxygen consumption following 12 months of treatment but there were no significant effects of either exercise intensity or duration on changes in cardiorespiratory fitness between

	groups across 12 months of treatment. Changes in body weight and BMI were significantly greater at 12 months in participants who reported ≥200 min/week of exercise compared with those who exercised >150 min or were inconsistent (*p*<0.001). Weight loss in the group with 150 min/week or more of exercise did not differ from other groups.
Quality and comments	…

Jeffery 1998 RCT	
Results	Used singly, the trainer and incentive interventions each approximately doubled the number of walks attended over 18 months and used together, the number of walks attended was increased threefold. Total attendance at supervised walking sessions over 18 months across treatment groups was correlated with overall weight change (*p*<0.0001). A dose response relationship was also observed. Little long-term benefit was associated with 1000 kcal/week whereas 2.5 times this amount was associated with near perfect weight maintenance.
Quality and comments	…

Jeffery 2003 RCT	
Results	Across all participants significant associations observed. In the SBT group the total change in exercise energy expended was significantly associated with weight change (*p*<0.05) and the change in energy expended by walking was marginally associated with weight change (*p*<0.07). In the High Physical Activity group both the total change in exercise energy expended and the change in heavy intensity exercise energy expended were significantly associated with weight change (*p*<0.01 for both). Both groups reported significant (*p*<0.001) declines in energy intake and in the percentage of energy from fat between baseline and at each assessment. The treatment groups did not differ from each other. Also small subset of participants (Raynor 2004) showed increased variety (*p*<0.001) in low fat breads and vegetables and decreased variety (*p*<0.001) in high-fat foods and fats, oils and sweets over the 18-month study. This was associated with reduced percentage dietary fat and weight loss.
Quality and comments	…

Harms

Anderson 1999 RCT	
Harms	None reported. However, there is a question about the reported lowering of HDL in participants.
Quality and comments	…

Jacobsen 2003 RCT	
Harms	None reported.
Quality and comments	…

Jakicic 1999 RCT	
Harms	None reported.
Quality and comments	…

Jakicic 2003 RCT	
Harms	None reported.
Quality and comments	…

Jeffery 1998 RCT	
Harms	None reported.
Quality and comments	…

Jeffery 2003 RCT	
Harms	The HPA consistently reported more exercise related injuries or illnesses than did the SBT group and the average difference between the two groups at 18 months was significant (*p* value not provided).
Quality and comments	…

Generalisability

Anderson 1999 RCT	
Country and setting	USA; home setting possible for all exercise interventions
Participants (included/excluded)	Twenty-eight women were white; ten were African American and two were Mexican American. All women were obese but otherwise healthy. Women were included if no structured exercise for 6 months. Excluded if they had a diagnosis of bulimia nervosa, binge eating disorder, significant depression or other psychiatric disturbances.
Recruitment	Not described
Randomisation	N/R
Intervention (mode and intensity)	LEARN: 16 weekly 60-min sessions in groups of ten. Activity: three weekly aerobics classes in a dance studio
Duration of active intervention	Sixteen-week programme followed by four quarterly follow-up meetings and a week 68 report.
Comparison (mode and intensity)	LEARN: as above Activity: self-directed, 30 min/day on most days of the week. Kept daily records.
Delivery of intervention/comparison (who)	LEARN: Group session lead by masters- or doctoral-level psychologists. Activity: lead by a certified aerobics instructor
Dropout rates	2% dropout for 16-week study and 17.5% dropout for 68-week study.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Jacobsen 2003 RCT	
Country and setting	USA; the CON group exercised in the context of laboratory environment – this may have influenced attrition rates
Participants (included/excluded)	Overweight sedentary females only
Recruitment	N/R
Randomisation	N/R
Intervention (mode and intensity)	See above
Duration of active intervention	72 weeks

Comparison (mode and intensity)	See above
Delivery of intervention/comparison (who)	University of Nebraska researchers
Dropout rates	58% attrition rate, which varied as noted above.
Treatment of dropouts (return to baseline, or last measurement?)	ITT not done but an analysis of baseline physical characteristics for participants who finished the study vs those who withdrew showed that those who withdrew were heavier and younger than those who finished the study.

Jakicic 1999 RCT	
Country and setting	USA; home-based exercise
Participants (included/excluded)	Obese, sedentary women ages 25–45; excluded if taking medication that would limit participation or affect body weight or if unable to participate fully or were pregnant.
Recruitment	Newspaper advertisement
Randomisation	N/R
Intervention (mode and intensity)	Behaviour: 18-month behavioural weight loss programme with weekly meetings during months 1–6, biweekly meetings during months 7–12 and monthly meetings during months 13–18. Activity: Instructed to exercise 5 days/week 20 min/day during weeks 1–4, 30 min/day weeks 5–8 and 40 min/day for the duration of the study.
Duration of active intervention	18 months
Comparison (mode and intensity)	Behaviour: as above Activity: instructed to exercise 5 d/week with duration progressing from 20 min/day to 40 min/day by the ninth week (SB). Identical to the short bout group except that they were also provided with home treadmills (SBEQ).
Delivery of intervention/comparison (who)	No details reported
Dropout rates	23%
Treatment of dropouts (return to baseline, or last measurement?)	Dropouts included in analysis – return to baseline and no exercise assumed.

Jakicic 2003 RCT	
Country and setting	USA; home-based exercise
Participants (included/excluded)	Obese, sedentary women aged 25–45 years; excluded if history of MI; taking medication that would affect heart rate response during exercise or affect metabolism or weight loss; being treated for psychological conditions or pregnant.
Recruitment	N/R
Randomisation	N/R
Intervention (mode and intensity)	Behaviour: weekly meetings during initial 24 weeks of treatment and biweekly meetings for the remainder of the study period. Also contacted in months 7 to 12 biweekly by telephone for about 10 min by a member of the research team. Activity: see above for details
Duration of active intervention	12 months
Comparison (mode and intensity)	As above
Delivery of intervention/comparison (who)	N/R

Dropout rates	*6%*
Treatment of dropouts (return to baseline, or last measurement?)	Baseline values carried forward.

Jeffery 1998 RCT	
Country and setting	Two US urban communities- Pittsburgh, Pennsylvania and Minneapolis-St Paul, Minnesota.
Participants (included/excluded)	Primarily female but this factor was controlled for in the analysis
Recruitment	Media advertisement from two urban communities
Randomisation	N/R
Intervention (mode and intensity)	Behaviour: groups of about 20 people met weekly for 24 weeks, then monthly. Activity: supervised walking sessions three times per week. The trainer group had all of the above but also had a personal trainer who walked with participants and made reminder phone calls before each walking session and scheduled make up sessions as necessary. The incentive group received a financial incentive for walking rather than a trainer: $1 per walk for first 25 walks, $1.50 per walk for the next 50 walks, $2 per walk for next 50 walks and $3 per walk for any remaining walks. The fourth group had both personal trainers and financial rewards for walking.
Duration of active intervention	18 months
Comparison (mode and intensity)	As above for behaviour
Delivery of intervention/comparison (who)	Groups led by trained interventionists with advanced degrees in nutrition or behavioural sciences. Also trainer was student or staff assistant.
Dropout rates	87% of those enrolling completed the 6 month evaluations and 78% completed the 18 month evaluations
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Jeffery 2003 RCT	
Country and setting	USA; home-based exercise for SBT group but HPA group had exercise coaches and a small monetary incentive for achieving or exceeding the EE goal of 2500 kcal/week.
Participants (included/excluded)	Obese middle-aged men and women
Recruitment	Public advertisement
Randomisation	N/R
Intervention (mode and intensity)	SBT: weekly meetings for first 6 months, biweekly 6 to 12 months, monthly from 12 to 18 months. Groups of less than 20 people.
Duration of active intervention	18 months
Comparison (mode and intensity)	As above
Delivery of intervention/comparison (who)	Led by trained interventionists (experience in content and behaviour). Exercise coaches met with small groups before/after each exercise session. Also reviewed progress and provided extra support as needed.

Dropout rates	Retention rates at 6, 12 and 18 months were 90%, 82% and 87% in the SBT group and 94%, 79% and 80% in the HPA group. Examination of the baseline characteristics of study completers and dropouts at 18 months indicated no significant differences in body weight, sex, exercise level, energy intake or percentage of energy from fat.
Treatment of dropouts (return to baseline, or last measurement?)	N/R

1.6 Pharmacological interventions

1.6.1 Orlistat

Included in HTA (O'Meara or Avenell)

Weight loss

Broom 2002 (in Avenell HTA Broom 2001a) RCT	
Aim	To assess the efficacy of orlistat therapy for weight loss and cardiovascular risk factor reduction in obese individuals with one or more defined cardiovascular risk factor (IGT, dyslipidaemia, hypertension).
Participants	People who were obese (BMI ≥28 kg/m^2) with one or more defined cardiovascular risk factor (IGT, dyslipidaemia, hypertension). *Total 522 – 409 F, 113 M. Mean (SD) age 46.7 (11.4) years orlistat (*n=259*), 45.3 (11.5) years control (*n=263*). Mean (SD) BMI (kg/m^2) 37.1 (6.4) orlistat, 37.0 (6.2) control.*
Intervention	Two weeks pre-treatment phase consisting of single-blind placebo and 600 kcal/day deficit (minimum 1200 kcal/day), 30% energy intake from fats, food and beverage intake diary. Diet: deficit diet continued post randomisation to month 6 then reduced a further 300 kcal/day to week 52. Drug: 120 mg orlistat three times daily with main meals.
Control	*As above except* *Drug: placebo three times daily with main meals.*
Length of follow-up	12 months
Results	*Weight loss during the run-in period was not reported.* At 12 months, mean weight change (SD) was –5.80 (8.50) kg in the orlistat group compared with –2.30 (6.40) kg in the control group. Mean weight change in the intervention group compared with control was –3.50 (95% CI –4.79 to –2.21). *At 12 months, more participants in the orlistat group achieved a 5% or more weight loss than in the control group (55.6 vs 24.3%,* p*<0.0001).*
Quality and comments	Blinded assessment not reported. *ITT analysis done?* Random allocation but no description of concealment. SDs for change in risk factor outcomes at 12 months calculated. SDs for change in HbA$_{1c}$ and mean and SD change in fasting plasma glucose at 12 months obtained from Roche report. *Weight loss reported does not take into account the weight loss over the 2-week dietary lead in period.*
Sponsor details	*Roche Pharmaceuticals*

Broom 2002 (in Avenell HTA Broom 2001b) RCT	
Aim	To investigate the effect of orlistat on body weight and plasma lipid parameters in people who were obese and had hypercholesterolaemia.
Participants	People who were obese (BMI ≥30 kg/m^2) and had hypercholesterolaemia. *Total 137 – 83 F, 54 M. Mean (SD) age 52.1 (9.2) years orlistat (*n=66*), 51.0 (10.5) years control (*n=71*).*
Intervention	Diet: 600 kcal/day deficit diet from each of five major food groups with 30% energy intake from fat, maximum 300 mg/day cholesterol. Activity: advice on physical activity. Drug: orlistat 120 mg three times daily with main meals for 52 weeks (double-blind to week 24 then open label design weeks 25–52).

Control	As above except: *Drug: placebo three times daily with main meals for first 24 weeks then orlistat 120 mg three times daily in open label design for weeks 25–52*
Length of follow-up	52 weeks
Results	*No run-in period was included in the trial design.* *At 6 months, mean weight change (SD) was –4.40 (7.16) kg in the orlistat group compared with –2.60 (6.65) kg in the control group. Mean weight change in the intervention group compared with control was –1.80 (95% CI –4.12 to 0.52).* *At 12 months, mean weight change (SD) was –4.97 (5.40) kg in the orlistat group compared with –4.28 (5.82) kg in the control group. Mean weight change in the intervention group compared with control was –0.69 (95% CI –2.57 to 1.19).* *At the end of 24 weeks, 44% of the orlistat group compared with 18% of the placebo group has lost at least 5% of initial body weight (p<0.001) and 7.6% compared with 4.2% had lost at least 10% (not significant).*
Quality and comments	Blinded assessment not reported. *ITT analysis done?* Random allocation but no description of concealment. SDs calculated and denominators assumed correct. *SDs calculated for 6-month weight loss using HTA formula. Also, different values to HTA for 12 months as used values from Broom (2002b).*
Sponsor details	Roche Products Limited

Davidson 1999 (in Avenell and O'Meara HTA) RCT	
Aim	To test the hypothesis that orlistat combined with dietary intervention is more effective than placebo plus diet for weight loss and maintenance over 2 years.
Participants	People who were obese (BMI between 30 and 43 kg/m^2). *Total 880 – 741 F, 139 M. Mean (SEM) 43.3 (0.6) years orlistat (n=657), 44.0 (0.7) years control (n=223). Mean (SEM) BMI (kg/m^2) 36.5 (0.9) orlistat, 36.2 (0.1) control.*
Intervention	500–800 kcal/day deficit with 30% energy intake from fat in 4 weeks single-blind placebo pre-treatment phase. Diet: 500–800 kcal/day deficit with 30% energy intake from fats continued for 2 years, if participant still losing weight in last 3 months of year 1 then energy intake increased 200–300 kcal/day; food diaries kept by participant and used periodically for counselling with dietitian; once daily multivitamin containing all fat-soluble vitamins (CENTRUM) given in year 1 only if serum vitamin values decreased to below reference range on two consecutive visits Activity: participant encouraged to increase activity by walking briskly 20–30 min per week throughout 2 years. BT: four behaviour modification sessions on weight loss in year 1 then four weight-maintenance seminars in year 2. Drug: 120 mg orlistat three times daily for year 1. Re-randomised at week 52 to placebo three times daily orlistat 120 mg three times daily orlistat 60 mg three times daily.
Control	As above except *Drug: placebo three times daily for year 1 and year 2.*
Length of follow-up	2 years

Results	*Both treatment arms lost about 2.3 kg during the run-in period.* At 12 months, mean weight change (SD) was –8.76 (9.48) kg in the orlistat group compared with –5.81 (10.01) kg in the control group. Mean weight change in the intervention group compared with control was –2.95 (95% CI –4.45 to –1.45). *At 12 months, 65.7% of the orlistat group compared with 43.6% of the placebo group lost more than 5% of initial body weight (p<0.01). 38.9% of the orlistat group compared with 24.8% of the placebo group lost 10% or more of initial body weight (p=0.004).* *At 24 months, mean weight change (SD) was –5.56 (7.49) kg in the orlistat group compared with –0.18 (6.38) kg in the control group. Mean weight change in the intervention group compared with control was –5.38 (95% CI –6.97 to –3.79).* At 24 months compared with 12 months, mean weight change (SD) was 3.20 (5.57) kg in the orlistat group compared with 5.63 (4.93) kg in the control group. Mean weight change in the intervention group compared with control was –2.43 (95% CI –3.64 to –1.22). *At 24 months, 34.1% of the orlistat group compared with 17.5% of the placebo group lost more than 10% of initial body weight (p=0.02).* *Of those treated with orlistat for 24 months, weight gain was significantly less (mean 3.2kg) compared with those who received placebo (mean 5.63 kg) (p<0.001).*
Quality and comments	Blinded assessment not reported. *ITT analysis done?* Random allocation but no description of concealment. 2-year results only stated for participants receiving placebo/placebo and orlistat. *Used HTA weight maintenance figures and denominators to calculate loss at 24 months with HTA formula SDs.*
Sponsor details	Hoffman-La Roche Inc

NB: have included the 5% and 10% weight loss, but this is >5%, 10% NOT ≥5%, 10% as in other studies.

Finer 2000 (in Avenell and O'Meara HTA) RCT	
Aim	To assess the efficacy and tolerability of orlistat, in combination with dietary advice, in producing and maintaining weight loss over a 12-month period.
Participants	People who were obese (BMI between 30 and 43 kg/m^2). *Total 218 – 193 F, 25 M. Mean (SD) age 41.5 (10.5) years orlistat (n=110), 41.4 (10.0) years control (n=108). Mean (SD) BMI (kg/m^2) 36.8 (3.6) orlistat, 36.8 (3.7) control.*
Intervention	Pre-treatment phase of 4-week single blind run-in, then: Diet: 600 kcal/day deficit diet (minimum 1200 kcal/day) 30% fat, alcohol 150 g/week, aimed to produce initial weight loss 0.25–0.5 kg/week, reduced further 300 kcal/day at week 24 until week 52 (or reduced to 1000 kcal/day if already at 1200 kcal/day). Drug: 120 mg orlistat three times daily.
Control	As above except *Drug: placebo three times daily.*
Length of follow-up	12 months
Results	*Weight loss during the run-in period was about 3 kg.* At 12 months, mean weight change (SD) was –3.29 (6.85) kg in the orlistat group compared with –1.31 (6.29) kg in the control group. Mean weight change in the intervention group compared with control was –1.98 (95% CI –3.73 to –0.23). *At 12 months, 35% of the orlistat group compared with 21% of the placebo group lost more than 5% of initial body weight (p=0.02). 16% of the orlistat group compared with 6% of the placebo group lost more than 10% of initial body weight (p=0.02).*
Quality and comments	Blinded assessment done. *ITT analysis done?* Good concealment of allocation. SDs for change in weight calculated.

Sponsor details	Hoffman-La Roche
NB: have included the 5% and 10% weight loss, but this is >5%, 10% NOT ≥5%, 10% as in other studies.	

Hauptman 2000 (in Avenell and O'Meara HTA) RCT	
Aim	To evaluate the efficacy of orlistat in producing and maintaining long-term weight loss, and in improving obesity-related risk factors in individuals who are obese and who received limited dietary and behavioural counselling.
Participants	People who were obese (BMI of 30 to 44 kg/m^2). *Total 635 – 497 F, 138 M. Mean (SD) age 42.6 (11.68) years orlistat 60 mg (n=213), 43.2 (10.14) years orlistat 120 mg (n=210), 41.6 (10.19) years control (n=212). Mean (SD) BMI 35.8 (4.38) orlistat 60 mg, 36.0 (2.90) orlistat 120 mg, 36.1 (4.37) control at 4 weeks prior to randomisation.*
Intervention	Four weeks single blind placebo pre-treatment phase of 1200 kcal/day diet for participants who weighed <90 kg initially or 1500 kcal/day for participants who weighed ≥90 initially; 30% energy as fat, 50% as carbohydrate, 20% as protein, maximum 300 mg/day cholesterol, maximum ten alcoholic drinks per week; dietary guidance on intake from study physician at start of pre-treatment only. Diet: diet continued for first 52 weeks then increased by 300 kcal/day for participants still losing weight at end week 52 or no dietary adjustment for those weight stable until week 104. BT: participants viewed videos on behaviour modification techniques for weight control 4 times in first 52 weeks, weight management and diet pamphlets for weight maintenance given 4 times during weeks 53–104 based on 'Live for Life' programme. Activity: all participants encouraged to increase physical activity by brisk walking 20–30 min three to five times per week; dietary records kept ten times during study. Drug – orlistat 60 mg: 60 mg orlistat three times daily with main meals. Drug – orlistat 120 mg: 120 mg orlistat three times daily with main meals.
Control	*As above except* *Drug: placebo three times daily with main meals.*
Length of follow-up	24 months
Results	*Mean change in body weight during the run-in period was –2.73 kg for placebo, –2.49 kg orlistat 60 mg, and –2.54 kg orlistat 120 mg.* *Orlistat 60 mg: at 6 months, mean weight change (SD) was –4.43 (7.17) kg in the orlistat group compared with –1.97 (6.47) kg in the control group. Mean weight change in the intervention group compared with control was –2.46 (95% CI –3.76 to –1.16).* *Orlistat 60 mg: At 12 months, mean weight change (SD) was –4.59 (7.21) kg in the orlistat group compared with –1.41 (6.31) kg in the control group. Mean weight change in the intervention group compared with control was –3.18 (95% CI –4.47 to –1.89).* *Orlistat 60 mg: At 18 months, mean weight change (SD) was –3.29 (6.85) kg in the orlistat group compared with –0.20 (5.97) kg in the control group. Mean weight change in the intervention group compared with control was –3.56 (95% CI –4.79 to –2.33).* *Orlistat 60 mg: At 24 months, mean weight change (SD) was –2.48 (6.62) kg in the orlistat group compared with 1.08 (6.22) kg in the control group. Mean weight change in the intervention group compared with control was –3.05 (95% CI –4.26 to –1.84).* *Orlistat 60 mg: At 18 months compared with 12 months, mean weight change (SD) was 1.30 (6.28) kg in the orlistat group compared with 1.21 (6.26) kg in the control group. Mean weight change in the intervention group compared with control was 0.09 (95% CI –1.10 to 1.28).* *Orlistat 60 mg: At 24 months compared with 12 months, mean weight change (SD) was 2.62 (6.66) kg in the orlistat group compared with 2.49 (6.62) kg in the*

	control group. Mean weight change in the intervention group compared with control was 0.13 (95% CI –1.13 to 1.39). Orlistat 120 mg: At 6 months, mean weight change (SD) was –5.46 (7.46) kg in the orlistat group compared with –1.97 (6.47) kg in the control group. Mean weight change in the intervention group compared with control was –3.49 (95% CI –4.82 to –2.16). Orlistat 120 mg: At 12 months, mean weight change (SD) was –5.40 (7.44) kg in the orlistat group compared with –1.41 (6.31) kg in the control group. Mean weight change in the intervention group compared with control was –3.99 (95% CI –5.31 to –2.67). Orlistat 120 mg: At 18 months, mean weight change (SD) was –3.68 (6.96) kg in the orlistat group compared with –0.20 (5.97) kg in the control group. Mean weight change in the intervention group compared with control was –3.66 (95% CI –4.90 to –2.42). Orlistat 120 mg: At 24 months, mean weight change (SD) was –2.48 (6.62) kg in the orlistat group compared with 1.08 (6.22) kg in the control group. Mean weight change in the intervention group compared with control was –3.56 (95% CI –4.79 to –2.33). Orlistat 120 mg: At 18 months compared with 12 months, mean weight change (SD) was 1.72 (6.40) kg in the orlistat group compared with 1.21 (6.26) kg in the control group. Mean weight change in the intervention group compared with control was 0.51 (95% CI –0.70 to 1.72). Orlistat 120 mg: At 24 months compared with 12 months, mean weight change (SD) was 2.92 (6.74) kg in the orlistat group compared with 2.49 (6.62) kg in the control group. Mean weight change in the intervention group compared with control was 0.43 (95% CI –0.84 to 1.70). *At 12 months, 50.5% of the orlistat 120 mg group compared with 30.7% of the placebo group lost 5% or more of initial body weight (p<0.01).* *At 12 months, 48.8% of the orlistat 60 mg group compared with 30.7% of the placebo group lost 5% or more of initial body weight (p<0.01).* *At 12 months, 28.6% of the orlistat 120 mg group compared with 11.3% of the placebo group lost 10% or more of initial body weight (p<0.01).* *At 12 months, 24.4% of the orlistat 60 mg group compared with 11.3% of the placebo group lost 10% or more of initial body weight (p<0.01).* *At 24 months, 34.3% of the orlistat 120 mg group compared with 24.1% of the placebo group lost 5% or more of initial body weight (p=0.02).* *At 24 months, 33.8% of the orlistat 60 mg group compared with 24.1% of the placebo group lost 5% or more of initial body weight (p=0.03).* *At 24 months, 18.6% of the orlistat 120 mg group compared with 6.6% of the placebo group lost 10% or more of initial body weight (p=0.001).* *At 24 months, 14.6% of the orlistat 60 mg group compared with 6.6% of the placebo group lost 10% or more of initial body weight (p=0.08).* *Participants in all groups regained some weight during the 24 months, weight regain in year 2 was greater in the placebo group. Weight regain (as a percentage of weight lost in year 1) was 60% in the placebo group compared with 37% and 38% in the orlistat 60 mg and 120 mg groups, respectively.*
Quality and comments	Blinded assessment not reported. *ITT analysis done?* Good concealment of allocation. Change in weight including SDs calculated (change from –4 weeks to week 52 minus change from –4 weeks to week 0), change in risk factors calculated from actual values, SDs also calculated.
Sponsor details	None mentioned, first author at Hoffman-La Roche Inc.

Hill 1999 (in Avenell and O'Meara HTA) RCT	
Aim	To test the hypothesis that orlistat, combined with appropriate dietary and behavioural counselling, effectively diminishes the weight regain that generally occurs after a period of conventional hypo-energetic dieting. Also to evaluate the long-term effects of orlistat on obesity-related CVD risk factors.

Participants	People who were overweight or obese (BMI between 28 and 43 kg/m^2). *Total 720 – 605 F, 115 M. Mean (SEM) age 46.8 (0.8) years orlistat 30 mg (*n*=186), 46.1 (0.7) years orlistat 60 mg (*n*=171), 45.9 (0.7) years orlistat 120 mg (*n*=179), 46.4 (0.7) control (*n*=184). Mean (SEM) BMI (kg/m^2) 32.6 (0.2) orlistat 30 mg, 32.9 (0.2) orlistat 60 mg, 32.8 (0.2) orlistat 120 mg, 32.8 (0.2) control.*
Intervention	Six-month pre-treatment phase consisting of 1000 kcal/day deficit, 30% energy as fat, 50% as carbohydrate, 20% as protein, to produce weight loss 0.5–1 kg/week; dietary counselling, four sessions of behavioural modification programme (University of Minnesota's Wise Weighs) and encouraged to increase activity to brisk walking 20–30 min five times per week, standard multivitamin–multimineral tablets once daily (CENTRUM) from start of pre-treatment to end of study. Diet: from randomisation, participants prescribed maintenance diet where individual energy requirements reassessed according to body weight at week 22 of pre-treatment phase; increase in energy intake prescribed to match anticipated metabolic requirements over 1 year, if participants gained weight they were encouraged to maintain this higher weight. BT: dietary and behavioural counselling given to all, dietary records Drug – orlistat 30 mg: 30 mg orlistat three times daily Drug – orlistat 60 mg: 60 mg orlistat three times daily Drug – orlistat 120 mg: 120 mg orlistat three times daily
Control	As above except: *Drug: placebo three times daily.*
Length of follow-up	12 months
Results	*Mean weight loss over the run-in period (6 months) was –10.33 kg for placebo, –10.06 kg orlistat 30 mg, –10.00 kg orlistat 60 mg and –9.86 kg orlistat 120 mg.* Orlistat 30 mg: At 12 months, mean weight change (SD) was 4.91 (7.30) kg in the orlistat group compared with 4.40 (7.16) kg in the control group. Mean weight change in the intervention group compared with control was 0.51 (95% CI –1.32 to 2.34). Orlistat 60 mg: At 12 months, mean weight change (SD) was 3.84 (7.00) kg in the orlistat group compared with 4.40 (7.16) kg in the control group. Mean weight change in the intervention group compared with control was –0.56 (95% CI –2.36 to 1.24). Orlistat 120 mg: At 12 months, mean weight change (SD) was 2.62 (6.66) kg in the orlistat group compared with 4.40 (7.16) kg in the control group. Mean weight change in the intervention group compared with control was –1.78 (95% CI –3.55 to 0.01). *Treatment with orlistat 120 mg three times per day resulted in significantly less weight regain than placebo. People treated with orlistat 120 mg regained about half as much weight as those in the placebo group.*

	Weight regain at 12 months (as % of weight loss in 6-month lead in)			
Group	*≤25%*	*25 to 50%*	*50 to 75%*	*>75%*
Placebo	*29.9*	*22.8*	*15.2*	*32.1*
Orlistat 30 mg	*32.3*	*20.4*	*18.3*	*29.0*
Orlistat 60 mg	*30.4*	*25.7*	*25.1*	*18.7**
Orlistat 120 mg	*47.5***	*22.9*	*17.3*	*12.3**

**Significantly different from placebo and orlistat 30 mg,* p*<0.05*
***Significantly different from all other groups,* p*<0.05*

Quality and comments	Blinded assessment not reported. *ITT analysis done?* Random allocation but no description of concealment. All outcomes calculated from initial values to week 52 minus initial values to end of 6 month lead-in (denominators differ), SDs for weight change calculated. Body weight significantly different in orlistat 60 mg three times daily from all other groups (*p*<0.05) accounted for by higher proportion of men to women in the orlistat 60 mg group.
Sponsor details	Hoffman-La Roche

NB: have included the 5% weight loss, but this is >5%, NOT ≥5%, as in other studies.

Hollander 1998 (in Avenell and O'Meara HTA) RCT	
Aim	To investigate the long-term weight loss efficacy of orlistat in obese people with type 2 diabetes, maintained on oral sulfonylureas, and to determine whether this treatment improves glycaemic control and lipid status more than dietary treatment alone.
Participants	People who were obese (BMI 28 to 40 kg/m^2) and who had type 2 diabetes maintained on oral sulfonylureas. Total 321 – 157 F, 164 M. Mean (SD) age 55.4 (8.8) years orlistat (*n*=162), 54.7 (9.7) year control (*n*=159). Mean (SD) BMI 34.5 (3.2) kg/m^2 orlistat, 34.0 (3.4) kg/m^2 control.
Intervention	Five weeks pre-treatment phase single blind with mildly hypoenergetic diet. Diet: then 500 kcal/day deficit from baseline to week 52, additional diet counselling and a standardised commercially available vitamin supplement given if two consecutive vitamin measures fell below reference range. Drug: 120 mg orlistat three times daily taken with meals.
Control	As above except: *Drug: placebo three times daily taken with meals.*
Length of follow-up	12 months
Results	*Weight loss during the run-in period was –2.24kg in the placebo group, and –2.07kg in the orlistat group.* At 12 months, mean weight change (SD) was –3.84 (5.00) kg in the orlistat group compared with –1.43 (5.10) kg in the control group. Mean weight change in the intervention group compared with control was –2.41 (95% CI –3.54 to –1.28). *At 12 months, 48.8% of the orlistat group compared with 22.6% of the placebo group lost 5% or more of initial body weight (*p*<0.001).* *At 12 months, 17.9% of the orlistat group compared with 8.8% of the placebo group lost 10% or more of initial body weight (*p*=0.017).*
Quality and comments	Blinded assessment done. Possible ITT analysis. Good concealment of allocation. All mean and standard deviation change in weight and risk factor outcomes obtained from Roche report.
Sponsor details	Hoffman-La Roche

Lindgarde 2000 (in Avenell HTA) RCT	
Aim	To assess the effect of orlistat on body weight and cardiovascular risk profile in people who are obese.
Participants	People who were obese (BMI 28 to 38 kg/m^2) with at least one obesity associated cardiovascular risk factor. *Total 376 – 239 F, 137 M. Mean (SD) age 53.7 (9.4) years orlistat (*n*=190), 53.2 (9.9) years control (*n*=186). Mean (SD) BMI 33.2 (3.0) kg/m^2 orlistat, 33.2 (3.1) kg/m^2 control. Results from 2 weeks prior to randomisation.*
Intervention	Two weeks single blind placebo plus mildly hypoenergetic diet consisting of 600 kcal/day deficit (minimum 1200 kcal/day) 30% energy from fat. Diet: diet continued up to month 6 when energy content reduced additional 300 kcal/day; participants also received dietary counselling as part of self-help weight control educational package including leaflets and videotape given at start of run-in phase. Activity: participants encouraged to increase physical activity by taking 30 min walk each day. Drug: 120 mg orlistat three times daily.
Control	*As above except:* *Drug: placebo three times daily.*
Length of follow-up	12 months

Results	*During the 2-week run-in period, people lost about 1.4 kg.* At 12 months, mean weight change (SD) was –4.20 (7.03) kg in the orlistat group compared with –2.90 (6.74) kg in the control group. Mean weight change in the intervention group compared with control was –1.30 (95% CI –2.69 to 0.09). *At 12 months, 54.2% of the orlistat group compared with 40.9% of the placebo group lost 5% or more of initial body weight (p<0.001).* *At 12 months, 19.2% of the orlistat group compared with 14.6% of the placebo group lost 10% or more of initial body weight (not significant).*
Quality and comments	Blinded assessment not reported. Random allocation but no description of concealment. Possibly ITT, all randomised participants included in ITT analysis, but participants withdrawn by investigators if compliance <60%. Change including SDs, in weight and risk factor outcomes at 12 months calculated (change from –2 weeks to week 52 minus change from –2 weeks to week 0). SDs for change in weight also calculated.
Sponsor details	Roche AB

Rossner 2000 (in Avenell and O'Meara HTA) RCT	
Aim	To determine the effect of orlistat on long-term weight loss, to determine the extent to which orlistat minimises weight regain in the second year of treatment, and to assess the effects of orlistat on obesity-related risk factors
Participants	People who were overweight or obese (BMI 28 to 43 kg/m^2). *Total 718 – 591 F, 127 M. Mean (SD) age 44.7 (10.7) years orlistat 60 mg (n=242), 43.6 (11.4) years orlistat 120 mg (n=244), 44.3 (10.8) years control (n=243). Mean (SD) BMI 35.2 (3.9) kg/m^2 orlistat 60 mg, 34.7 (3.7) kg/m^2 orlistat 120 mg, 35.5 (4.1) kg/m^2 control.*
Intervention	Four weeks pre-treatment phase consisting of single blind placebo and 600 kcal/day deficit, 30% energy intake from fat, Other: all participants ceased taking vitamin supplements prior to study and if vitamin or beta-carotene levels fell below clinical reference range on two consecutive measurements then participants were given supplements; Diet: at randomisation deficit diet continued and during second year diet was adjusted as follows; for participants who had lost ≥3 kg between weeks 40 and 52, daily energy intake was prescribed at a level equivalent to estimated energy intake minus 10% kcal/day; those participants who lost <3 kg no dietary adjustment made Drug – orlistat 60 mg: 60 mg orlistat three times daily with breakfast lunch and dinner Drug – orlistat 120 mg: 120 mg orlistat three times daily with breakfast, lunch and dinner
Control	*As above except:* *Drug: placebo three times daily with breakfast lunch and dinner.*
Length of follow-up	24 months

Results	*Weight loss during the run-in period was not reported, but assumed mean to be about 2 kg.* *Orlistat 60 mg: At 12 months, mean weight change (SD) was –6.50 (7.75) kg in the orlistat group compared with –4.40 (7.16) kg in the control group. Mean weight change in the intervention group compared with control was –2.10 (95% CI –3.43 to –0.77).* *Orlistat 60 mg: At 24 months, mean weight change (SD) was –4.60 (7.22) kg in the orlistat group compared with –2.30 (6.57) kg in the control group. Mean weight change in the intervention group compared with control was –2.30 (95% CI –3.53 to –1.07).* *Orlistat 60 mg: At 24 months compared with 12 months, mean weight change (SD) was 1.90 (6.45) kg in the orlistat group compared with 2.10 (6.51) kg in the control group. Mean weight change in the intervention group compared with control was –0.20 (95% CI –1.35 to 0.95).* Orlistat 120 mg: At 12 months, mean weight change (SD) was –8.13 (8.22) kg in the orlistat group compared with –5.23 (7.40) kg in the control group. Mean weight change in the intervention group compared with control was –2.90 (95% CI –4.30 to –1.50). Orlistat 120 mg: At 24 months, mean weight change (SD) was –5.98 (7.61) kg in the orlistat group compared with –3.06 (6.78) kg in the control group. Mean weight change in the intervention group compared with control was –2.92 (95% CI –4.21 to –1.63). Orlistat 120 mg: At 24 months compared with 12 months, mean weight change (SD) was 2.15 (6.52) kg in the orlistat group compared with 2.17 (6.53) kg in the control group. Mean weight change in the intervention group compared with control was –0.02 (95% CI –1.19 to 1.15). *Significantly more people treated with orlistat 120 mg lost more than 5% of initial body weight after 1 and 2 years of treatment than placebo (*p*<0.001). 31.2% (*p*=0.002) and 38.3% (*p*<0.001) of those in the orlistat 60 mg and 120 mg groups lost more than 10% of their initial body weight after 1 year compared with 18.8% of placebo-treated participants. A weight loss of more than 10% was maintained in the second year by 18.6%, 29.0% (*p*<0.05), and 28.2% (*p*<0.05) of people receiving placebo, orlistat 60 mg, and orlistat 120 mg, respectively.*
Quality and comments	Blinded assessment not reported. Random allocation but no description of concealment. *ITT done?* Roche provided denominators, change in risk factors calculated, SDs calculated, weight change from randomisation to 12 months and 24 months derived from graph. Baseline data for safety population only. *Used HTA formula for SDs. Values for 5/10% read off Figure 3.*
Sponsor details	Hoffman-La Roche

Sjöström 1998 (in Avenell and O'Meara HTA) RCT	
Aim	To assess the efficacy and tolerability of orlistat in promoting weight loss and preventing weight regain in people who are obese over a 2-year period.
Participants	People who were overweight or obese (BMI 28 to 47 kg/m^2) *Total 683 – 567 F, 116 M. Mean (range) age 45.2 (20 to 76) years orlistat (*n*=343), 44.3 (18 to 77) control (*n*=340). Mean BMI 36.1 kg/m^2 orlistat, 36.2 kg/m^2 control.*

Intervention	Four weeks pre-treatment consisting of single blind placebo three times daily with meals and 600 kcal/day deficit with 30% energy intake from fat. Diet: first 24 weeks all participants continued 600 kcal/day deficit (minimum 1200 kcal/day) then until week 52 reduced additional 300 kcal/day (minimum 1000 kcal/day); diet designed to cause weight loss of 0.25–0.5 kg/week and consisted of 30% energy intake as fat, 50% as carbohydrate, 20% as protein, 300 mg/day cholesterol, three main meals and optional snack daily, 150 mg/week alcohol; year 2 all participants advised on weight maintenance diet and not to return to hypoenergetic diet; additional dietary counselling or vitamin supplements given when necessary if two consecutive measures were below normal range. Drug: orlistat 120 mg three times daily baseline to week 104
Control	*As above except:* *Drug: placebo three times daily baseline to week 104*
Length of follow-up	*24 months*
Results	Assumed mean weight loss in 4 week run-in was 2.2 kg. At 12 months, mean weight change (SD) was –8.10 (8.21) kg in the orlistat group compared with –3.90 (7.02) kg in the control group. Mean weight change in the intervention group compared with control was –4.20 (95% CI –5.35 to –3.05). *At the end of year 1, 9.3% of the orlistat group vs 2.1% of the placebo group had lost >20% of initial body weight; 29.5 vs 15.6% had lost 10.1–20.0% of bodyweight; 29.7 vs 31.5% had lost 5.1–10.0% of bodyweight; and 23.6 vs 32.7% had lost 0.1–5.0% of bodyweight. 7.9 vs 18.2% had unchanged or increased bodyweight.* *In former placebo-group participants, orlistat reduced bodyweight (LSM difference in weight loss orlistat–placebo 3.6 kg [SE=0.6];* p*=0.001). In former orlistat-group participants, the weight regain was smaller with orlistat than with placebo (LSM difference in weight loss orlistat–placebo 2.4 kg;* p*<0.001). After 2 years of continuous orlistat treatment, 57.1% of the patients maintained a weight loss greater than 5%; the corresponding percentage for 2 years' placebo treatment was 37.4%.*
Quality and comments	Blinded assessment not reported. Good concealment of allocation. *ITT done?* Mean change in weight and risk factor data calculated from actual values. SDs calculated, assumed mean weight loss in 4 week run-in=2.2 kg. Actual weight loss not reported at 24 months for placebo-placebo group, orlistat-orlistat group. No SDs for other outcomes.
Sponsor details	Hoffman-La Roche

NB: have included the 5% and 10% weight loss, but this is >5%, 10% NOT ≥5%, 10% as in other studies.

Other outcomes

Broom 2002 (in Avenell HTA Broom 2001a) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.12 (1.08) in the orlistat group, and 0.16 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.28 (95% CI –0.47 to –0.09). At 12 months, mean (SD) LDL change in mmol/l was –0.30 (0.74) in the orlistat group, and –0.02 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.28 (95% CI –0.41 to –0.15). At 12 months, mean (SD) TAG change in mmol/l was 0.44 (0.96) in the orlistat group, and 0.17 (0.96) in the control group. Mean TAG change in the intervention group compared with control was 0.27 (95% CI 0.75 to 0.43). At 12 months, mean (SD) %HbA$_{1c}$ change was 0.08 (0.43) in the orlistat group, and 0.19 (0.58) in the control group. Mean TAG change in the intervention group compared with control was –0.11 (95% CI –0.20 to –0.02). At 12 months, mean (SD) DBP change in mmHg was –5.50 (8.30) in the orlistat

	group, and –3.10 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –2.40 (95% CI –3.82 to –0.98). At 12 months, mean (SD) SBP change in mmHg was –6.00 (12.70) in the orlistat group, and –2.30 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –3.70 (95% CI –5.88 to –1.52). At 12 months, mean (SD) FPG change in mmol/l was –0.19 (1.26) in the orlistat group, and 0.06 (1.02) in the control group. Mean FPG change in the intervention group compared with control was –0.25 (95% CI –0.45 to –0.05). *No analysis of outcomes independent of weight loss was reported.*
Quality and comments	…

Broom 2002 (in Avenell HTA Broom 2001b) RCT	
Results	*At 6 months, mean (SD) TC change in mmol/l was –0.83 (0.12) in the orlistat group, and –0.27 (0.10) in the control group. Mean TC change in the intervention group compared with control was –0.56 (95% CI –0.60 to –0.52).* *At 6 months, mean (SD) LDL change in mmol/l was –0.71 (0.12) in the orlistat group, and –0.31 (0.12) in the control group. Mean LDL change in the intervention group compared with control was –0.40 (95% CI –0.44 to –0.36).* *At 6 months, mean (SD) HDL change in mmol/l was –0.19 (0.10) in the orlistat group, and –0.11 (0.03) in the control group. Mean LDL change in the intervention group compared with control was –0.08 (95% CI –0.11 to –0.05).* *At 6 months, mean (SD) TAG change in mmol/l was –0.15 (0.25) in the orlistat group, and –0.42 (0.26) in the control group. Mean FPG change in the intervention group compared with control was 0.27 (95% CI 0.18 to 0.36).* *At 12 months, mean (SD) TC change in mmol/l was –0.96 (1.04) in the orlistat group, and –0.67 (1.04) in the control group. Mean TC change in the intervention group compared with control was –0.29 (95% CI –0.64 to 0.06).* *At 12 months, mean (SD) LDL change in mmol/l was –0.91 (1.00) in the orlistat group, and –0.40 (1.05) in the control group. Mean LDL change in the intervention group compared with control was –0.51 (95% CI –0.85 to –0.17).* *At 12 months, mean (SD) HDL change in mmol/l was –0.29 (0.45) in the orlistat group, and –0.23 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.06 (95% CI –0.19 to 0.07).* *At 12 months, mean (SD) FPG change in mmol/l was –0.40 (1.35) in the orlistat group, and –0.10 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.30 (95% CI –0.75 to 0.15).* *At 12 months, although the weight loss in both groups was similar, people who had been taking orlistat throughout had significantly improved TC and LDL levels. This was interpreted by the authors as suggesting that orlistat had a lipid-lowering effect independent of weight loss.*
Quality and comments	Not able to calculate FPG at 6 months as no SDs?

Davidson 1999 (in Avenell and O'Meara HTA) RCT	
Results	At 12 months, mean (SD) DBP change in mmHg was –1.00 (8.30) in the orlistat group, and 1.30 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –2.30 (95% CI –3.56 to –1.04). At 12 months, mean (SD) SBP change in mmHg was –0.80 (12.70) in the orlistat group, and 1.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –1.80 (95% CI –3.73 to 0.13). At 24 months, mean (SD) TC change in mmol/l was 0.11 (1.08) in the orlistat group, and 0.21 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.10 (95% CI –0.40 to 0.20). At 24 months, mean (SD) LDL change in mmol/l was 0.05 (0.74) in the orlistat group, and 0.04 (0.74) in the control group. Mean LDL change in the intervention group compared with control was 0.01 (95% CI –0.20 to 0.22). At 24 months, mean (SD) HDL change in mmol/l was 0.11 (0.29) in the orlistat group, and 0.15 (0.29) in the control group. Mean HDL change in the intervention

	group compared with control was –0.04 (95% CI –0.12 to 0.04). At 24 months, mean (SD) TAG change in mmol/l was –0.07 (0.96) in the orlistat group, and 0.15 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.22 (95% CI –0.49 to 0.05). At 24 months, mean (SD) FPG change in mmol/l was 0.06 (0.31) in the orlistat group, and 0.26 (0.38) in the control group. Mean FPG change in the intervention group compared with control was –0.20 (95% CI –0.30 to –0.10). *Improvements in TC and LDL levels were independent of the greater weight loss achieved in the orlistat group. Whereas, improvements in insulin levels were associated with weight loss.* *Levels of fat-soluble vitamins and beta-carotene generally remained within the reference range in all treatment groups throughout the study. Vitamins D (*p*=0.001) and E (*p*=0.003) levels decreased significantly in the orlistat-treated group vs placebo at the end of year 1, but mean serum levels remained within the reference range. When corrected for LDL-cholesterol, vitamin E levels were unchanged in the orlistat-treated participants. Supplementation was required in 14.1% of participants treated with orlistat 120 mg for 2 years vs with 6.5% of placebo recipients. All participants receiving supplementation attained normal serum vitamin levels by the end of the study and no participants were withdrawn due to low values.*
Quality and comments	…

Finer 2000 (in Avenell and O'Meara HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.05 (0.76) in the orlistat group, and 0.30 (0.68) in the control group. Mean TC change in the intervention group compared with control was –0.35 (95% CI –0.54 to –0.16). At 12 months, mean (SD) LDL change in mmol/l was –0.11 (0.63) in the orlistat group, and 0.21 (0.53) in the control group. Mean LDL change in the intervention group compared with control was –0.32 (95% CI –0.47 to –0.17). At 12 months, mean (SD) HDL change in mmol/l was 0.15 (0.23) in the orlistat group, and 0.16 (0.21) in the control group. Mean HDL change in the intervention group compared with control was –0.01 (95% CI –0.07 to 0.05). *More people treated with orlistat were given vitamin supplementation (1.8% vitamin A, 8.0% vitamin D, 3.6% vitamin E compared with 0.9% for each vitamin in the control group). Beta-carotene supplements were given to 0.9% of people in the orlistat group.* *Significant differences were seen in the changes of levels of vitamin E and beta-carotene between the orlistat and placebo groups (–2.08 µmol/l,* p*<0.001, and –0.11 µmol/l,* p*<0.001), but not for vitamins A or D. No significant change occurred in the mean vitamin E:cholesterol ratio at 12 months.* *No analysis of outcomes independent of weight loss was reported.*
Quality and comments	…

Hauptman 2000 (in Avenell and O'Meara HTA) RCT	
Results	*Orlistat 60 mg: At 12 months, significant changes (*p*<0.05) from baseline compared with placebo were seen at 12 months in TC (–0.06 vs 0.30), LDL-cholesterol (–0.07 vs 0.25) and HDL-cholesterol (0.05 vs 0.11).* *Orlistat 60 mg: At 24 months, significant changes (*p*<0.05) from baseline compared with placebo were seen at 12 months in TC (0.05 vs 0.44), and LDL cholesterol (–0.01 vs 0.36).* Orlistat 120 mg: At 12 months, mean (SD) TC change in mmol/l was –0.04 (1.08) in the orlistat group, and 0.30 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.34 (95% CI –0.55 to –0.13). Orlistat 120 mg: At 12 months, mean (SD) LDL change in mmol/l was –0.12 (0.74) in the orlistat group, and 0.25 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.37 (95% CI –0.51 to –0.23). Orlistat 120 mg: At 12 months, mean (SD) HDL change in mmol/l was 0.06 (0.29)

in the orlistat group, and 0.11 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.05 (95% CI –0.11 to 0.01).
Orlistat 120 mg: At 12 months, mean (SD) TAG change in mmol/l was 0.06 (0.96) in the orlistat group, and –0.10 (0.96) in the control group. Mean TAG change in the intervention group compared with control was 0.16 (95% CI –0.02 to 0.34).
Orlistat 120 mg: At 12 months, mean (SD) FPG change in mmol/l was 0.03 (1.35) in the orlistat group, and 0.11 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.08 (95% CI –0.34 to 0.18).
Orlistat 120 mg: At 12 months, mean (SD) DBP change in mmHg was –1.00 (8.30) in the orlistat group, and 2.00 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –3.00 (95% CI –4.58 to –1.42).
Orlistat 120 mg: At 12 months, mean (SD) SBP change in mmHg was 2.00 (12.70) in the orlistat group, and 3.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –1.00 (95% CI –3.42 to 1.42).
Orlistat 120 mg: At 24 months, mean (SD) TC change in mmol/l was 0.25 (1.08) in the orlistat group, and 0.44 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.19 (95% CI –0.40 to 0.02).
Orlistat 120 mg: At 24 months, mean (SD) LDL change in mmol/l was 0.06 (0.74) in the orlistat group, and 0.36 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.30 (95% CI –0.44 to –0.16).
Orlistat 120 mg: At 24 months, mean (SD) HDL change in mmol/l was 0.07 (0.29) in the orlistat group, and 0.09 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.02 (95% CI –0.08 to 0.04).
Orlistat 120 mg: At 24 months, mean (SD) TAG change in mmol/l was 0.21 (0.96) in the orlistat group, and –0.05 (0.96) in the control group. Mean TAG change in the intervention group compared with control was 0.26 (95% CI 0.08 to 0.44).
Orlistat 120 mg: At 24 months, mean (SD) FPG change in mmol/l was 0.16 (1.35) in the orlistat group, and 0.24 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.08 (95% CI –0.34 to 0.18).
Orlistat 120 mg: At 24 months, mean (SD) DBP change in mmHg was 1.00 (8.30) in the orlistat group, and 4.00 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –3.00 (95% CI –4.58 to –1.42).
Orlistat 120 mg: At 24 months, mean (SD) SBP change in mmHg was 4.00 (12.70) in the orlistat group, and 5.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –1.00 (95% CI –3.42 to 1.42).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) TC change in mmol/l was 0.29 (1.08) in the orlistat group, and 0.14 (1.08) in the control group. Mean TC change in the intervention group compared with control was 0.15 (95% CI –0.06 to 0.36).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) LDL change in mmol/l was 0.18 (0.74) in the orlistat group, and 0.11 (0.74) in the control group. Mean LDL change in the intervention group compared with control was 0.07 (95% CI –0.07 to 0.21).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) HDL change in mmol/l was 0.01 (0.29) in the orlistat group, and –0.02 (0.29) in the control group. Mean HDL change in the intervention group compared with control was 0.03 (95% CI –0.03 to 0.09).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) TAG change in mmol/l was 0.15 (0.96) in the orlistat group, and 0.05 (0.96) in the control group. Mean TAG change in the intervention group compared with control was 0.10 (95% CI –0.08 to 0.28).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) FPG change in mmol/l was 0.13 (1.35) in the orlistat group, and 0.13 (1.35) in the control group. Mean FPG change in the intervention group compared with control was 0.00 (95% CI –0.26 to 0.26).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) DBP change in mmHg was 2.00 (8.30) in the orlistat group, and 2.00 (8.30) in the control group. Mean DBP change in the intervention group compared with control was 0.00 (95% CI –1.58 to 1.58).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) SBP change

	in mmHg was 2.00 (12.70) in the orlistat group, and 2.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was 0.00 (95% CI –2.42 to 2.42). *Mean plasma levels of vitamins A, D and E, and beta-carotene remained within the reference range in all treatment groups throughout the 2-year study. Vitamin A and vitamin E levels increased during the study in all treatment groups, while vitamin D and beta-carotene levels decreased in all treatment groups. Two consecutive low vitamin E and beta-carotene values occurred more frequently in people treated with orlistat compared with those given placebo, while the frequency of two consecutive low vitamin A and D values was not significantly different among treatment groups. Supplementation with beta-carotene was required and received by 2.4, 4.3 and 6.3% of those in the placebo, 60 mg orlistat, and 120 mg orlistat groups, respectively. Overall, <1.9% of all the participants required and received vitamin A or E supplementation. Almost all those who needed vitamin supplementation achieved normal levels by the end of the study.* *No analysis of outcomes independent of weight loss were reported.*
Quality and comments	…

Hill 1999 (in Avenell and O'Meara HTA) RCT	
Results	Orlistat 120 mg: At 12 months, mean (SD) TC change in mmol/l was 0.08 (1.08) in the orlistat group, and 0.17 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.09 (95% CI –0.40 to 0.22). Orlistat 120 mg: At 12 months, mean (SD) LDL change in mmol/l was –0.05 (0.74) in the orlistat group, and 0.12 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.17 (95% CI –0.38 to 0.04). Orlistat 120 mg: At 12 months, mean (SD) HDL change in mmol/l was –0.04 (0.29) in the orlistat group, and 0.00 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.04 (95% CI –0.12 to 0.04). Orlistat 120 mg: At 12 months, mean (SD) TAG change in mmol/l was 0.02 (0.96) in the orlistat group, and 0.14 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.12 (95% CI –0.39 to 0.15). *Orlistat 30 mg: at 12 months, compared with placebo, significant differences were seen for levels of TC (LSM% change –3.75,* p*=0.007), and LDL-cholesterol (LSM% change –6.54,* p*=0.001). (Changes from pre-6 month lead in period).* *Orlistat 60 mg: at 12 months, compared with placebo, significant differences were seen for levels of TC (LSM% change –3.37,* p*=0.001), LDL-cholesterol (LSM% change –5.74,* p*=0.006), and HDL cholesterol (LSM% change –5.34,* p*=0.006). (Changes from pre-6 month lead in period).* *The significant changes in TC and LDL levels in the orlistat 120 mg group persisted even after adjustment for the greater weight loss.* *People received standard vitamin supplements throughout the 1-y treatment phase of the trial; accordingly, mean concentrations of vitamins A, D and E and of beta-carotene remained within the reference ranges, although vitamin E and ß-carotene were significantly lower in the orlistat treatment groups than in the placebo group at the end of the study (*p*<0.001). Few participants (<4%) met the criteria for additional vitamin supplementation during the study and those who did receive supplementation had normal values at the end of the study.*
Quality and comments	…

Hollander 1998 (in Avenell and O'Meara HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.05 (0.60) in the orlistat group, and 0.41 (0.70) in the control group. Mean TC change in the intervention group compared with control was –0.46 (95% CI –0.61 to –0.31). At 12 months, mean (SD) LDL change in mmol/l was –0.12 (0.74) in the orlistat group, and 0.22 (0.70) in the control group. Mean LDL change in the intervention group compared with control was –0.34 (95% CI –0.48 to –0.20). At 12 months, mean (SD) HDL change in mmol/l was 0.06 (0.20) in the orlistat

	group, and 0.06 (0.20) in the control group. Mean HDL change in the intervention group compared with control was 0.00 (95% CI –0.04 to 0.04). At 12 months, mean (SD) TAG change in mmol/l was 0.02 (0.80) in the orlistat group, and 0.28 (1.00) in the control group. Mean TAG change in the intervention group compared with control was –0.26 (95% CI –0.46 to –0.06). At 12 months, mean (SD) HbA1c% change was –0.15 (1.00) in the orlistat group, and 0.32 (1.10) in the control group. Mean TAG change in the intervention group compared with control was –0.47 (95% CI –0.71 to –0.23). At 12 months, mean (SD) DBP change in mmHg was –1.01 (8.00) in the orlistat group, and 0.23 (8.90) in the control group. Mean DBP change in the intervention group compared with control was –1.24 (95% CI –3.14 to 0.66). At 12 months, mean (SD) SBP change in mmHg was 0.21 (12.80) in the orlistat group, and 4.15 (14.20) in the control group. Mean SBP change in the intervention group compared with control was –3.94 (95% CI –6.97 to –0.91). At 12 months, mean (SD) FPG change in mmol/l was 0.04 (1.60) in the orlistat group, and 0.70 (1.80) in the control group. Mean FPG change in the intervention group compared with control was –0.66 (95% CI –1.04 to –0.28). *TC and LDL levels were independent of weight loss. Improvements in %*HbA_{1c}*, however, were related closely to degree of weight loss.* *Non-clinically relevant changes in a number of laboratory parameters occurred at a similar incidence in both treatment groups. There was no evidence for the development of gallstones or renal stones after orlistat treatment. Mean plasma levels of vitamins A, D and E, and beta-carotene remained within the reference range throughout the study. After 52 weeks of treatment, mean vitamin E and beta-carotene levels were significantly lower in the orlistat group compared with the placebo group (*p*<0.001). However, there was no significant change in the vitamin E:LDL ratio in either group. As a consequence of having two or more consecutive low vitamin levels, vitamin D supplementation was instituted in 7% of placebo-treated participants and 17% of orlistat-treated participants; vitamin E supplementation was given to 1% of both treatment groups; and 9% of the orlistat group received beta-carotene supplementation. All people receiving supplementation attained normal levels with treatment, and none were withdrawn because of low vitamin values. In addition, mean PT values, used as a surrogate marker of vitamin K, were not different between the orlistat and placebo groups and did not fall below the reference range.*
Quality and comments	Values in published paper different to HTA values – used HTA values.

Lindgarde 2000 (in Avenell HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was 0.03 (1.08) in the orlistat group, and 0.26 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.23 (95% CI –0.45 to –0.01). At 12 months, mean (SD) LDL change in mmol/l was –0.22 (0.74) in the orlistat group, and 0.07 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.29 (95% CI –0.44 to –0.14). At 12 months, mean (SD) HDL change in mmol/l was 0.03 (0.29) in the orlistat group, and 0.08 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.05 (95% CI –0.11 to 0.01). At 12 months, mean (SD) TAG change in mmol/l was 0.18 (0.96) in the orlistat group, and 0.04 (0.96) in the control group. Mean TAG change in the intervention group compared with control was 0.14 (95% CI –0.05 to 0.33). At 12 months, mean (SD) %HbA_{1c}change was –0.25 (0.78) in the orlistat group, and –0.05 (0.51) in the control group. Mean TAG change in the intervention group compared with control was –0.20 (95% CI –0.33 to –0.07). At 12 months, mean (SD) DBP change in mmHg was –0.90 (8.30) in the orlistat group, and -1.30 (8.30) in the control group. Mean DBP change in the intervention group compared with control was 0.40 (95% CI –1.28 to 2.08). At 12 months, mean (SD) SBP change in mmHg was –0.50 (12.70) in the orlistat group, and –0.90 (12.70) in the control group. Mean SBP change in the

	intervention group compared with control was 0.40 (95% CI –2.17 to 2.97). At 12 months, mean (SD) FPG change in mmol/l was –0.46 (1.35) in the orlistat group, and 0.08 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.54 (95% CI –0.81 to –0.27). *Treatment with orlistat was associated with significantly greater improvements in TC, LDL, FPG and* HbA_{1c} *levels, and these were generally greater for people who had achieved ≥5% or ≥10% weight loss.* *Similar improvements in CHD risk factors were also seen with orlistat in the subgroup of patients with type 2 diabetes. After 54 weeks, mean fasting glucose was reduced by 1.63 mmol/l (13.6%) in the orlistat group, compared with a reduction of 0.28 mmol/l (1.1%) with placebo (*p*<0.01). Orlistat was also associated with a significantly greater improvement in* HbA_{1c} *(±0.65 [7.5%] vs ±0.14% [1.4%] with placebo;* p*<0.05). The improvement in glycaemic control achieved by people in the orlistat group resulted in a higher proportion of orlistat-treated patients being able to stop or reduce their dosage of anti-diabetic medication (23.3 vs 18.2% of placebo-treated group). Improvements in TC and LDL-cholesterol were also greater with orlistat compared with placebo in patients with type 2 diabetes, although these did not reach statistical significance (± 4.3 vs ±1.0% and 10.4 vs ±3.9%, respectively).*
Quality and comments	…

Rossner 2000 (in Avenell and O'Meara HTA) RCT	
Results	*Orlistat 60 mg: No significant differences were seen (least squares mean difference) between placebo and orlistat 60 mg at 12 months or at 24 months.* Orlistat 120 mg: At 12 months, mean (SD) TC change in mmol/l was –0.35 (1.08) in the orlistat group, and –0.05 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.30 (95% CI –0.49 to –0.11). Orlistat 120 mg: At 12 months, mean (SD) LDL change in mmol/l was –0.33 (0.74) in the orlistat group, and –0.06 (0.70) in the control group. Mean LDL change in the intervention group compared with control was –0.27 (95% CI –0.40 to –0.14). Orlistat 120 mg: At 12 months, mean (SD) HDL change in mmol/l was 0.08 (0.29) in the orlistat group, and 0.15 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.07 (95% CI –0.12 to –0.02). Orlistat 120 mg: At 12 months, mean (SD) TAG change in mmol/l was –0.09 (0.96) in the orlistat group, and –0.08 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.01 (95% CI –0.18 to 0.16). Orlistat 120 mg: At 12 months, mean (SD) DBP change in mmHg was –0.90 (8.30) in the orlistat group, and –1.30 (8.30) in the control group. Mean DBP change in the intervention group compared with control was 0.40 (95% CI –1.09 to 1.89). Orlistat 120 mg: At 12 months, mean (SD) SBP change in mmHg was –2.70 (12.70) in the orlistat group, and –1.90 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –0.80 (95% CI –3.08 to 1.48). Orlistat 120 mg: At 12 months, mean (SD) FPG change in mmol/l was 0.01 (1.35) in the orlistat group, and 0.10 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.09 (95% CI –0.33 to 0.15). Orlistat 120 mg: At 24 months, mean (SD) TC change in mmol/l was 0.03 (1.08) in the orlistat group, and 0.31 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.28 (95% CI –0.47 to –0.09). Orlistat 120 mg: At 24 months, mean (SD) LDL change in mmol/l was 0.04 (0.74) in the orlistat group, and 0.28 (0.70) in the control group. Mean LDL change in the intervention group compared with control was –0.24 (95% CI –0.37 to –0.11). Orlistat 120 mg: At 24 months, mean (SD) HDL change in mmol/l was 0.12 (0.29) in the orlistat group, and 0.16 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.04 (95% CI –0.09 to 0.01). Orlistat 120 mg: At 24 months, mean (SD) TAG change in mmol/l was –0.10 (0.96) in the orlistat group, and –0.05 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.05 (95% CI –0.22 to 0.12).

Orlistat 120 mg: At 24 months, mean (SD) DBP change in mmHg was –0.40 (8.30) in the orlistat group, and 0.00 (8.30) in the control group. Mean DBP change in the intervention group compared with control was 0.40 (95% CI –1.09 to 1.89).
Orlistat 120 mg: At 24 months, mean (SD) SBP change in mmHg was –0.60 (12.70) in the orlistat group, and 1.20 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –1.80 (95% CI –4.08 to 0.48).
Orlistat 120 mg: At 24 months, mean (SD) FPG change in mmol/l was 0.04 (1.35) in the orlistat group, and –0.02 (1.35) in the control group. Mean FPG change in the intervention group compared with control was 0.06 (95% CI –0.18 to 0.30).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) TC change in mmol/l was 0.38 (1.08) in the orlistat group, and 0.36 (1.08) in the control group. Mean TC change in the intervention group compared with control was 0.02 (95% CI –0.17 to 0.21).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) LDL change in mmol/l was 0.37 (0.74) in the orlistat group, and 0.34 (0.74) in the control group. Mean LDL change in the intervention group compared with control was 0.03 (95% CI –0.10 to 0.16).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) HDL change in mmol/l was 0.04 (0.29) in the orlistat group, and 0.01 (0.29) in the control group. Mean HDL change in the intervention group compared with control was 0.03 (95% CI –0.02 to 0.08).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) TAG change in mmol/l was –0.01 (0.96) in the orlistat group, and 0.03 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.04 (95% CI –0.21 to 0.13).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) DBP change in mmHg was 1.30 (8.30) in the orlistat group, and 1.30 (8.30) in the control group. Mean DBP change in the intervention group compared with control was 0.00 (95% CI –1.49 to 1.49).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) SBP change in mmHg was 2.10 (12.70) in the orlistat group, and 3.10 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –1.00 (95% CI –3.28 to 1.28).
Orlistat 120 mg: At 24 months compared with 12 months, mean (SD) FPG change in mmol/l was 0.03 (1.35) in the orlistat group, and –0.12 (1.35) in the control group. Mean FPG change in the intervention group compared with control was 0.15 (95% CI –0.09 to 0.39).
*Participants treated with orlistat reported significantly greater satisfaction with their weight loss medication than did placebo participants after 1 and 2 years (*p*<0.001 in the orlistat 120 mg group;* p*<0.05 in the orlistat 60 mg group). Participants taking orlistat 120 mg also expressed greater satisfaction both with losing weight and their weight loss programme (*p*=0.011 and* p*=0.002, respectively, after 2 years). Overall satisfaction with treatment, as expressed by the treatment index, was significantly greater among participants taking orlistat than placebo recipients after 2 years (*p*<0.001 and* p*<0.05 in the orlistat 120 mg and 60 mg groups, respectively).*
*Orlistat-treated participants also reported less overweight distress than participants receiving placebo and this became statistically significant in the orlistat 120 mg group after 2 years (*p*<0.05). There were no significant differences between treatment groups in depression scores after either 1 or 2 years.*
No clinically significant changes were observed in any laboratory parameters. The changes that were noted were sporadic, resolved spontaneously, and occurred with similar frequencies in all treatment groups. Mean plasma levels of vitamins A, D (measured as 25-cholecalciferol), E, and K (determined indirectly from prothrombin time) and beta-carotene remained within reference ranges in all three groups over the 2 years of treatment. No participants were withdrawn because of low vitamin values. For most participants dietary advice and/or vitamin supplementation were sufficient to restore vitamin levels to pre-treatment values and during the study. Twenty-seven people required vitamin supplementation

	because of low vitamin values (placebo, n*=1; orlistat 60 mg,* n*=14; orlistat 120 mg,* n*=12). The majority (73%) of these incidences occurred in Year 1. Differences in mean plasma values for vitamins D and E and beta-carotene between orlistat-treated participants and participants taking placebo were, however, statistically significant (*p*<0.001). The vitamin E:LDL-cholesterol ratio increased during the study, indicating that there was no loss of vitamin E protection against LDL-induced atherogenesis during treatment with orlistat.* *No analysis of association with weight loss was reported.*
Quality and comments	…

Sjöström 1998 (in Avenell and O'Meara HTA) RCT	
Results	At 12 months, mean (SD) TC change in mmol/l was –0.08 (1.08) in the orlistat group, and 0.23 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.31 (95% CI –0.47 to –0.15). At 12 months, mean (SD) LDL change in mmol/l was –0.09 (0.74) in the orlistat group, and 0.13 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.22 (95% CI –0.33 to –0.11). At 12 months, mean (SD) HDL change in mmol/l was 0.10 (0.29) in the orlistat group, and 0.10 (0.29) in the control group. Mean HDL change in the intervention group compared with control was 0.00 (95% CI –0.04 to 0.04). At 12 months, mean (SD) TAG change in mmol/l was –0.07 (0.96) in the orlistat group, and 0.06 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.13 (95% CI –0.27 to 0.01). At 12 months, mean (SD) DBP change in mmHg was –2.10 (8.30) in the orlistat group, and 0.20 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –2.30 (95% CI –3.54 to -1.06). At 12 months, mean (SD) SBP change in mmHg was –2.00 (12.70) in the orlistat group, and 1.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –3.00 (95% CI –4.90 to –1.10). At 12 months, mean (SD) FPG change in mmol/l was –0.21 (1.35) in the orlistat group, and –0.06 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.15 (95% CI –0.35 to 0.05). *At 24 months, significant differences were seen between the orlistat-orlistat and the placebo-placebo groups for levels of TC, LDL-cholesterol, TAG and FPG, but not for HDL-cholesterol and SBP or DBP.* *TC and LDL levels fell in the orlistat group further than would have been expected from weight loss alone.* *During months 12 to 24, people who remained on orlistat compared with those randomised to placebo regained, on average, half as much weight (LSM 2.4 kg,* p*<0.001).* *There were no clinically or statistically significant changes in the mean values of any laboratory measurements during the study, and the frequency of laboratory abnormalities was evenly distributed between the treatment groups. After an initial small decrease, mean concentrations of vitamins A, D and E, and beta-carotene stabilised and remained within normal clinical ranges throughout the study in both groups. During year one, 41 participants in the orlistat group and 18 in the placebo group had two or more consecutive low vitamin concentrations recorded, but only 16 and four participants, respectively, received vitamin supplementation. During year two, vitamin supplementation was received by four participants in the orlistat/orlistat group, by one placebo/placebo participant, by three participants in the placebo/orlistat group, and by one participant in the orlistat/placebo group. Pharmacokinetic analysis of blood samples showed measurable, but minute, concentrations (0·208–2·078 µg/l) of unchanged orlistat in the plasma of only a few participants at 24 weeks (13/281 [4.6%] orlistat-treated participants), 52 weeks (17/236 [7.2%]), and 104 weeks (2/75 [2.7%]). These findings indicate low systemic absorption of orlistat after 2 years of treatment, with no evidence of accumulation.*
Quality and	No SDs for other outcomes at 24 months. Only results for placebo–placebo and

comments	orlistat–orlistat group at 24 months.

Reported harms

Broom 2002 (in Avenell HTA Broom 2001a) RCT	
Results	*Overall incidence of adverse events was similar in both groups, with the exception of certain GI events, known to be associated with the drug mechanism. 63% in the orlistat group and 47% in the control group reported GI events. Most of these were of mild to moderate intensity and of short duration, occurring and resolving soon after the initiation of orlistat treatment. Thirteen people in the orlistat group and six people in the control group withdrew because of GI events.* *Thirteen people in the orlistat group and 17 in the control group experienced serious adverse events (no details), none of which were considered by the investigators to have a probable causal relationship with the stud medication.* One death from cancer was reported in the orlistat group (not related to the treatment).
Quality and comments	…

Broom 2002 (in Avenell HTA Broom 2001b) RCT	
Results	*95.5% of people in the orlistat group and 85.9% of the control group reported at least one adverse event However, most were normally mild, self-limiting, and with the exception of certain GI system events were not considered by the investigators to be related to the study medication.* *More people in the orlistat group experienced GI adverse events (86.6 vs 42.3%). The majority of events were transient and mild to moderate in intensity. Seven people withdrew from the orlistat group and three people from the control group because of GI events.* *Four serious events (elective cytoscopy and hydrodistension, stroke, sleep disorder, benign breast cyst) occurred in the orlistat group, compared with ten in the control group (radiculitis, cellulitis, limb pain, hiatus hernia, gastric ulcer, oesophageal reflux, anaemia, pregnancy, cholecystectomy).* *In the open label phase, adverse events were reported in 92.9% of those who remained on orlistat, and 96.3% of those who switched to orlistat. Again, GI events were the most commonly reported (54.8% of those who remained, and 75.9% of those who switched). Ten people withdrew during this phase because of the GI events.* *Six adverse events occurred in those people who remained on orlistat (neuropathic toe ulcer, cellulitis, Bell's palsy, bleeding and injury due to road traffic accident, suicide attempt), and one adverse event in those who switched (abdominal pain).*
Quality and comments	…

Davidson 1999 (in Avenell and O'Meara HTA) RCT	
Results	*Overall incidence of adverse events was similar in placebo and orlistat groups. However, there were more adverse GI events associated with orlistat. At least one GI event was experienced by 79% of people in the orlistat group compared with 59% of participants in the placebo group. The majority of those treated with orlistat experienced one or two of these GI events, which typically occurred early during treatment, were mild to moderate in intensity, and generally resolved spontaneously. Seven types of GI events occurred with at least a 5% incidence rate and in twice as many people in the orlistat group: flatus with discharge (40.1%), oily spotting (32.7%), faecal urgency (29.7%), fatty/oily stool (19.8%), oily evacuation (14.3%), faecal incontinence (11.8%), and increased defecation (11.1%).*

	Seven people in the orlistat group and two in the placebo group withdrew because of GI events. The adverse event rate was lower in year 2 than in year 1 and did not differ between groups. *One (0.51%) of the 197 placebo-treated women and three (0.54%) of the 548 women treated with orlistat 120 mg were diagnosed as having breast cancer during the 2-year period following randomisation. One of the orlistat-treated participants had a 1-cm tumour identified 32 days after randomisation. Two participants, one taking orlistat and one taking placebo, had mammograms prior to starting the study that revealed pre-existing breast malignancies.*
Quality and comments	…

Finer 2000 (in Avenell and O'Meara HTA) RCT	
Results	*Except for GI events, adverse events were similar in both groups, mild to moderate in intensity and mainly temporal. GI events occurred more frequently in the orlistat group (82.1 vs 56.4% had at least one GI event). 59% had a specific GI event compared with 15.4% of the control group. Most occurred early in the study and were generally transient (≤4 days). Most people in both groups had only one or two episodes of GI symptoms, but others did experience more. Nine orlistat- and seven placebo-treated people withdrew because of adverse events.* *Gallstone formation was not increased by weight loss associated with orlistat use. 7% and 11% of orlistat- and placebo-treated people developed gallbladder abnormalities. 3% of orlistat- and 2% of placebo-treated participants developed renal abnormalities.*
Quality and comments	…

Hauptman 2000 (in Avenell and O'Meara HTA) RCT	
Results	*In general, adverse events in all groups were transient, mild, or moderate in intensity and resolved without intervention. With the exception of GI events, the incidence and type of adverse events were similar in all treatment groups. Adverse events accounted for the withdrawal of 7.1% (*n*=15), 6.6% (*n*=14), and 11.0% (*n*=23) of those in the placebo and 60-mg and 120-mg orlistat groups, respectively, over 104 weeks of double-blind treatment; this was not significantly different among groups. As expected from the mechanism, the incidence of GI events was higher in the orlistat groups. Over 2 years, 59%, 72% and 79% of people in the placebo, 60-mg orlistat, and 120-mg orlistat groups, respectively, reported GI events (*p*=0.003 for placebo vs 60 mg of orlistat and *p*=0.001 for placebo vs 120 mg of orlistat). Specific GI events possibly or probably related to orlistat treatment occurred significantly more frequently in both orlistat groups compared with placebo (*p*=0.001). Most GI events were mild to moderate in intensity, were limited to only one or two episodes per person, and occurred early during treatment. Few GI events were reported during the second year of the study. Ten people (4.7%) in the 60-mg orlistat group and 12 (5.7%) in the 120-mg orlistat group withdrew from the study prematurely because of GI events, compared with 3 (1.4%) in the placebo group.*
Quality and comments	…

Hill 1999 (in Avenell and O'Meara HTA) RCT	
Results	*During the 1-year treatment period, the percentage of people who reported at least one adverse event was 7–8% greater in the orlistat-treated groups than in the placebo group. This difference was primarily due to an increased incidence of GI events in the orlistat-treated participants, with similar adverse events for all other body systems across treatment groups. The percentage of participants reporting GI events was 68.1% in the placebo group, 82.3% in the 30-mg orlistat group, 91.8% in the 60-mg orlistat group and 95.0% in the 120-mg orlistat group. In general, adverse events were mild to moderate in intensity and resolved without*

	intervention. *Some GI events occurred in a greater percentage of those in the orlistat-treated groups. However, most people experienced only one or two episodes and most GI events were mild to moderate in intensity, occurred early during treatment, and resolved spontaneously. Withdrawals from the study related to GI events were 0.5% in the placebo group, 5.4% in the 30-mg orlistat group, 7.0% in the 60-mg orlistat group and 11.7% in the 120-mg orlistat group.*
Quality and comments	…

Hollander 1998 (in Avenell and O'Meara HTA) RCT	
Results	*Adverse events occurred at a similar overall incidence in both treatment groups. However, there were more GI events associated with orlistat. There were 79% of people in the orlistat group vs 59% in the placebo group who experienced at least one GI event. The majority of those on orlistat experienced one or two of these events. GI events occurred early during treatment, were mild to moderate in intensity, were generally transient, and resolved spontaneously. The number of people who withdrew because of GI events was seven in the orlistat group vs two in the placebo group.*
Quality and comments	…

Lindgarde 2000 (in Avenell HTA) RCT	
Results	*The overall incidence of adverse events was similar in the placebo and orlistat groups, with the exception of certain GI events known to be associated with the inhibitory effect of orlistat on dietary fat absorption. 80% of people in the orlistat group and 39% in the placebo group reported GI events. Most of these were of mild to moderate intensity and of short duration, and most occurred soon after the initiation of orlistat treatment. Five participants in the orlistat group and one in the placebo group withdrew from the study because of GI events. A total of 19 participants in the orlistat group and five in the placebo group experienced serious adverse events, none of which were considered by the investigators to have a probable causal relationship with the study medication. One death occurred in the orlistat group; the participant had type 2 diabetes and severe arteriosclerosis, and died as a result of a brain stem infarction.*
Quality and comments	…

Rossner 2000 (in Avenell and O'Meara HTA) RCT	
Results	*With the predictable exception of more frequent GI events following orlistat treatment, the adverse event profiles were similar in all three treatment groups throughout the study and were generally mild to moderate and resolved spontaneously. The majority of these events occurred early during treatment, were mild to moderate in intensity, resolved spontaneously, and were limited to only one or two episodes per participant. There were 49 severe GI events reported during the 2 years of the study: placebo, n=8; orlistat 60 mg, n=16; and orlistat 120 mg, n=25. The majority of severe GI events (n=38) occurred during the first year of the study.* *During the 2 years of this study, two serious adverse events were considered to be at least possibly related to orlistat treatment: one a case of cholelithiasis and one a case of diverticulitis. However, neither resulted in discontinuation of study medication. Six (2.5%) participants in the placebo group, 23 (9.6%) in the orlistat 60 mg group and 19 (7.9%) in the orlistat 120 mg group withdrew from the study prematurely due to adverse events. GI events were the most common side effect associated with premature withdrawal in all three groups with 2 (0.8%), 12 (5%) and 9 (3.7%) participants from the placebo, orlistat 60 mg and orlistat120 mg groups, respectively, discontinuing the study in 2 years.* *Five participants were diagnosed with breast cancer during the 2-year study. One*

	participant in the orlistat 60 mg group was diagnosed 36 days after randomised treatment. Four other cases occurred in postmenopausal women (one in the placebo group and three in the orlistat 120 mg group).
Quality and comments	…

Sjöström 1998 (in Avenell and O'Meara HTA) RCT	
Results	The overall frequency of adverse events was slightly higher in the orlistat group than in the placebo group during year 1 (94 vs 82%); and similar in the four treatment groups during year 2. With the exception of some GI events, the adverse events were judged by the investigators to be unrelated or remotely related to treatment. Most of the GI events happened early in orlistat treatment and were of short duration (≤4 days). Participants treated with orlistat experienced far fewer GI events during year 2 than in year 1. *Serious adverse events were reported by 24 participants in the placebo group and 25 in the orlistat group during year 1, with only one adverse event in each group being judged by the investigators to be related to treatment. Similarly, two serious adverse events that were judged possibly related to treatment happened during year 2. One case of GI neoplasm occurred in a participant treated with placebo for 2 years. No other malignant disorders were observed in the course of this study. The total number of premature withdrawals was higher in the placebo group than in the orlistat group during year 1 (83 vs 61) and virtually the same in both groups during year 2 (45 vs 46). Adverse GI events, however, were a more common reason for premature withdrawals in the orlistat group than in the placebo group.*
Quality and comments	…

Generalisability

Broom 2002 (in Avenell HTA Broom 2001a) RCT	
Country and setting	UK. General practices and hospital clinics.
Participants (included/excluded)	*Included men and non-pregnant women, aged 18–80 years, BMI ≥28 kg/m^2, at least one of the following: IGT (serum glucose ≥8.0 mmol/l, 2 h after a standard OGTT); hypercholesterolaemia (total serum cholesterol ≥5.2 mmol/l or LDL-cholesterol ≥4.2 mmol/l at screening); hypertension (sitting DBP 90–105 mmHg); compliance ≥60% throughout the study. Excluded if lactating, women of child bearing potential not using adequate contraception, MI, coronary artery bypass graft, percutaneous coronary angioplasty in prior 3 months; GI surgery for weight reduction, active GI disorders, such as peptic ulcer disease or malabsorption syndromes; pancreatic disease, history of post surgical adhesions, excessive alcohol intake or substance abuse; participants who required any drug which might alter body weight or plasma lipids such as appetite suppressants, lipid-lowering resins, retinoids and fish oil supplements; administration of systemic steroids (other than hormone replacement therapy) not permitted; concomitant pharmacotherapy for type 2 diabetes, hypertension or hypercholesterolaemia not permitted.*
Recruitment	Initial screening visit, but no details of how recruited.
Randomisation	Done using a minimisation algorithm: primary defined cardiovascular risk factor, study centre, BMI, weight loss during run-in.
Intervention (mode and intensity)	12 months, contacted 13 times (baseline then at monthly intervals).
Duration of active intervention	52 weeks
Control (mode and intensity)	As above

Delivery of intervention/control (who)	N/R, but '80% of participants were treated at GP centres where staff would *not* be as experienced at dietary counselling/weight management as staff at specialist obesity centres'.
Dropout rates	30% orlistat, 40% control at 12 months
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Broom 2002 (in Avenell HTA Broom 2001b) RCT	
Country and setting	UK. Outpatient clinics specialising in obesity and/or dyslipidaemia.
Participants (included/excluded)	*Included if aged ≥18 years, women of childbearing potential if using adequate protection, BMI ≥30 kg/m^2, total plasma cholesterol ≥6.5 mmol/l, or plasma LDL-cholesterol ≥4.2 mmol/l.* *Excluded if myocardial infarction or major surgery in last 3 months; GI or pancreatic disease, type 1 diabetes, uncontrolled hypertension, history of carcinoma, GI surgery for weight loss, post-surgical adhesions, bulimia or laxative abuse, drug or alcohol abuse, treatment with drugs altering appetite or lipid concentrations, fish oil supplements, retinoids, systemic steroids (other than sex hormone replacements) or anticoagulants.*
Recruitment	Recruited from specialist outpatient clinics. No further details.
Randomisation	No details other than participants were randomised.
Intervention (mode and intensity)	*52 weeks contacted 11 times (baseline, every 4 weeks up to week 24 then at weeks 30, 36, 44 and 52)*
Duration of active intervention	Twenty-four weeks double-blind, then 28 week open-label trial where people could choose to remain/switch to orlistat as desired.
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Dietary advice was provided initially and reinforced at the open-label stage by a state-registered dietitian.
Dropout rates	*33% orlistat, 15.5% control at 52 weeks (from paper, not HTA report)*
Treatment of dropouts (return to baseline, or last measurement?)	Missing values replaced using the LOCF method.

Davidson 1999 (in Avenell and O'Meara HTA) RCT	
Country and setting	USA. Clinical research centres – no further details.
Participants (included/excluded)	*Included if aged >18 years, BMI 30–43 kg/m^2, adequate contraception in women of childbearing potential, all vitamin and mineral preparations were discontinued 8 weeks prior to start of study, 75% or more treatment compliance by capsule count during 4 week run-in period, 70% or more treatment adherence in year 1 in order to continue to year 2.* *Excluded if weight loss >4 kg in previous 3 months, frequently changed smoking habits or had stopped smoking in last 6 months, history of or presence of substance abuse, excessive alcohol intake, significant cardiac, renal, hepatic, GI, psychiatric or endocrine disorder; drug-treated type 2 diabetes mellitus, concomitant use of medications altering appetite or lipid levels.*
Recruitment	*Recruited through the clinical research centres.*
Randomisation	Weight change in the 4-week lead-in period was used to stratify for randomisation (a measure of weight loss potential).
Intervention (mode and intensity)	24 months, contacted 23 times (baseline, every 2 weeks to week 16 then every 4 weeks to week 52 then every 8 weeks to week 104)
Duration of active intervention	*24 months*
Control (mode and intensity)	*As above*

Delivery of intervention/control (who)	Dietitians provided instruction on dietary intake recording as part of the behaviour modification programme, and then used the diaries for counselling. No further details for BT or activity components.
Dropout rates	31% orlistat, 41% control at 12 months. 31% orlistat120-placebo, 29% orlistat120–orlistat120, 33% orlistat120–orlistat60, 57% placebo–placebo at 24 months.
Treatment of dropouts (return to baseline, or last measurement?)	The last value carried-forward technique was used for years 1 and 2 analyses. The last value carried-forward analysis method uses all follow-up data, including that obtained from participants who withdrew prematurely, with the last recorded data point used in statistical analysis. All reported data are the actual observed values rather than derived data from carrying forward the last recorded values.

Finer 2000 (in Avenell and O'Meara HTA) RCT	
Country and setting	UK. Centres – no further details.
Participants (included/excluded)	*Included if aged ≥18 years, BMI 30–43 kg/m², women of childbearing potential if using adequate contraceptive precautions, >75% compliance (returned tablets) during run-in phase* *Excluded if weight loss >4 kg in 3 months prior to screening, history of severe systemic disease including diabetes, uncontrolled hypertension, previous GI disease, surgery for weight reduction, history of post-surgical adhesions, history of or presence of cancer, psychiatric or neurological disorder requiring chronic medications or liable to prejudice participant compliance, alcohol or substance abuse, bulimia or laxative abuse, pregnancy, lactation, post-menopausal women, amenorrhoeic <1 year, drugs capable of influencing body weight, resins for lipid lowering, anti-coagulants, digoxin or lipid-soluble vitamin supplements within previous month.*
Recruitment	*Recruited at five centres in the UK by local advertisement or by referral from general practitioners.*
Randomisation	Weight change in the 4-week lead-in period was used to stratify for randomisation (a measure of weight loss potential).
Intervention (mode and intensity)	12 months, contacted 17 times (baseline, before and after 4 week run-in, every 2 weeks until week 12 then every month until month 12)
Duration of active intervention	*12 months*
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	No details reported
Dropout rates	36% orlistat, 42% control at 12 months
Treatment of dropouts (return to baseline, or last measurement?)	LOCF.

Hauptman 2000 (in Avenell and O'Meara HTA) RCT	
Country and setting	USA. Primary care centres.

Participants (included/excluded)	*Included if aged >18 years, BMI 30–44 kg/m^2, completed 4-week pre-treatment phase with 75% or more compliance (by capsule count). Excluded if pregnant, lactating, women of childbearing potential not taking adequate contraception; weight loss >4 kg last 3 months, history of significant cardiac, renal, hepatic, GI disorders; uncontrolled hypertension or other clinically significant condition; GI surgery for weight reduction; bulimia or laxative and/or substance abuse, abnormal laboratory measures (values 10% or greater than reference value for the normal range and sufficient to require medical follow-up by study physician); change in smoking habits in previous 6 months, use of any drug which might influence body weight or food intake in 8 weeks prior to screening.*
Recruitment	N/R
Randomisation	No details, but participants had to be compliant during the run-in to be entered into the double-blind phase.
Intervention (mode and intensity)	104 weeks, contacted 21 times (baseline, every 2 weeks for first month then every 4 weeks until week 52 then every 8 weeks until week 104).
Duration of active intervention	24 months
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	Participants received dietary guidance from the study physician only at the start of the placebo lead-in phase. Participating physicians did not receive any specific training in nutrition or weight management techniques beyond the same instructional materials given to the participants. Registered dietitians or behavioural psychologists were *not* involved in nutritional or behavioural counselling at any stage of the study. No group meetings or counselling sessions were held.
Dropout rates	28% orlistat 60 mg, 28% orlistat 120 mg, 42% control at 24 months.
Treatment of dropouts (return to baseline, or last measurement?)	The LOCF technique was employed for 1- and 2-year analyses. However, all reported data are the actual observed values rather than derived data from carrying forward the last recorded values.

Hill 1999 (in Avenell and O'Meara HTA) RCT	
Country and setting	USA. Clinical research centres.
Participants (included/excluded)	*Included if aged ≥18 years, BMI 28–43 kg/m^2, lost ≥8% of initial body weight during 6 month run-in phase* *Excluded if ever had significant medical disorders, uncontrolled hypertension, recurrent nephrolithiasis, symptomatic cholelithiasis, active GI disorders, type 2 diabetes, pancreatic disease, cancer, pregnancy, lactating women, history or presence of substance abuse, eating disorders, excessive alcohol intake, significantly abnormal laboratory test results, previous GI surgery for weight reduction, history of post-surgical adhesions, any medications known to influence body weight, appetite or lipid concentrations taken in 8 weeks prior to screening.*
Recruitment	N/R
Randomisation	Only people who lost ≥8% of initial weight during the 6-month run-in period were randomised. Randomisation was stratified by weight loss (≤10% or not).
Intervention (mode and intensity)	12 months, contacted 11 times (baseline, every 2 weeks during month 1 then every month to month 5 then every 2 months to month 12)
Duration of active intervention	12 months (after 6 months pre-treatment)
Control (mode and intensity)	*As above*

Delivery of intervention/control (who)	N/R
Dropout rates	*25% orlistat 30 mg, 23% orlistat 60 mg, 30% orlistat 120 mg, 27% placebo at 12 months*
Treatment of dropouts (return to baseline, or last measurement?)	Last observation data carried forward. However, all reported data were actual observed rather than derived values, whereas the technique of carrying forward the last observation was applied only for analyses of statistical significance.

Hollander 1998 (in Avenell and O'Meara HTA) RCT	
Country and setting	USA. No details of setting other than 'centres', assumed to be university diabetic clinics?
Participants (included/excluded)	*Included if aged >18 years, BMI 28–40* kg/m^2*, type 2 diabetes, clinically stable on glyburide or glypizide for 6 months or more;* HbA_{1c} *6.5–10% at screening, fasting plasma glucose 5.6–12.2 mmol/l at end of fourth week of pre-treatment, blood levels of fat soluble vitamins above lower limit of normal reference range, completion and compliance by tablet count of 70% or more during pre-treatment* *Excluded if pregnant, lactating, women of child bearing potential not taking adequate contraceptive measures, clinically relevant conditions e.g. psychiatric disorders, substance abuse, cholecystitis, pancreatic disease, uncontrolled hypertension; significant complications associated with diabetes, weight loss of >4 kg during last 3 months, history of recurrent nephrolithiasis or symptomatic cholelithiasis; GI surgery for weight reduction, history of bulimia or laxative abuse or if they had taken any drug that might influence body weight or plasma lipids in 8 weeks prior to start of study.*
Recruitment	No details reported.
Randomisation	Participants from the run-in period were randomised if they were compliant, HbA_{1c} levels were between 6.5 and 10% at screening, FPG of 5.6–12.2 mmol/l at end of lead in period, blood levels of fat soluble vitamins above the lower limit of the normal reference range. Randomisation was stratified by both weight loss and FPG (four groups).
Intervention (mode and intensity)	12 months, contacted 14–27 times (baseline, weeks 1 and 2 then every 2–4 weeks).
Duration of active intervention	*12 months*
Control (mode and intensity)	As above
Delivery of intervention/control (who)	N/R
Dropout rates	*15% orlistat, 28% placebo at 12 months*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Lindgarde 2000 (in Avenell HTA) RCT	
Country and setting	Sweden. Primary care centres.

Participants (included/excluded)	*Included if aged 18–75 years, BMI 28–38 kg/m^2, not pregnant, fasting serum glucose ≥6.7 mmol/l, or confirmed type 2 diabetes treated with sulfonylurea or metformin but not insulin; total serum cholesterol ≥6.5 mmol/l or more and/or LDL-cholesterol ≥4.2 mmol/l on at least two occasions or prescribed lipid lowering medications; DBP ≥90 mmHg on at least two occasions or confirmed hypertensive treated with antihypertensive medication* *Excluded if insulin treated, women of childbearing potential who were lactating or using inadequate contraception; myocardial infarction within 3 months prior to screening, GI surgery for weight reduction, active GI disorders, such as peptic ulcer disease or malabsorption syndromes (with the exception of controlled lactose intolerance), pancreatic disease, history of post-surgical adhesions, excessive alcohol or substance abuse, participants requiring any drug which might alter body weight or plasma lipids, such as appetite suppressants, lipid-lowering resins, retinoids or fish oil supplements; systemic steroids (other than hormone replacement therapy) and insulin)*
Recruitment	N/R
Randomisation	Minimisation method: primary defined cardiovascular risk factor, study centre, and weight loss achieved during run-in period (≤1 kg or >1 kg).
Intervention (mode and intensity)	*12 months, contacted 11 times (baseline, twice in first month then monthly to month 6 then every 2 months to month 12).*
Duration of active intervention	12 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	All dietary advice given by a practice nurse (rather than a dietitian).
Dropout rates	*16% orlistat, 12% control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Rossner 2000 (in Avenell and O'Meara HTA) RCT	
Country and setting	Europe. Centres – no details.
Participants (included/excluded)	*Included if aged ≥18 years, BMI 28–43 kg/m^2, completed 4-week pre-treatment phase and 75% or more compliance (by capsule count).* *Excluded if pregnant, lactating, women of childbearing potential not taking adequate contraception, clinically significant conditions (excluding obesity) that might effect study outcome, >4 kg weight loss in previous 6 months,* stopped smoking in previous 6 months, *GI surgery for weight loss, history of post surgical adhesions or of bulimia or laxative abuse; any drug that might influence body weight or serum lipids taken in 8 weeks prior to screening; uncontrolled hypertension, drug- treated diabetes mellitus, history or presence of symptomatic cholelithiasis.*
Recruitment	N/R
Randomisation	Had to show ≥75% compliance in the run-in period. No other details.
Intervention (mode and intensity)	24 months, contacted 18 times (baseline, every 2 weeks for first 2 months then monthly up to month 6 then every 2 months to month 24).
Duration of active intervention	*24 months*
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	Participants received advice from a dietitian.

Dropout rates	*25% orlistat 60 mg, 26% orlistat 120 mg, 35% control at 12 months.* 42% orlistat 60 mg, 35% orlistat 120 mg, 44% control at 24 months.
Treatment of dropouts (return to baseline, or last measurement?)	Last value carried forward.

Sjöström 1998 (in Avenell and O'Meara HTA) RCT	
Country and setting	Europe. No further details.
Participants (included/excluded)	*Included if aged ≥18 years, BMI 28–47 kg/m^2, women of childbearing potential if using adequate contraception, >75% compliance during pre-treatment phase at end of year 1 in order to continue to year 2.* *Excluded if serious diseases including uncontrolled hypertension (DBP ≥105 mmHg) and pharmacologically treated diabetics, weight loss >4 kg in 3 months prior to screening, surgery for weight reduction, history of post surgical adhesions, bulimia or laxative abuse, use of any drug which might influence body weight or plasma lipids in last month; drug or alcohol abuse*
Recruitment	From hospital waiting lists or by local advertising.
Randomisation	Had to be >75% compliant. Stratified by weight loss during run-in period (≤2 kg or >2 kg
Intervention (mode and intensity)	Four weeks pre-treatment phase, 52 weeks treatment then reassigned for further 52 weeks treatment, contacted 25 times (baseline, every 2 weeks until week 12 then every month until month 12 then 8 visits in year 2).
Duration of active intervention	*24 months*
Control (mode and intensity)	*As above*
Delivery of intervention/control (who)	*N/R*
Dropout rates	18% orlistat, 24% control at 52 weeks, 16% orlistat, 19% control at 104 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	LOCF

Additional studies (not in HTA Avenell or O'Meara)

Weight loss

Bakris 2002 RCT	
Aim	To investigate the hypothesis that weight reduction with orlistat plus mild energy restriction leads to better BP control than diet alone in obese individuals with inadequately controlled hypertension.
Participants	People with inadequately controlled hypertension who were overweight (BMI between 28 and 43 kg/m^2). Total 532 – 325 F, 207 M. Mean (SD) age 53.2 (0.5) years orlistat (*n*=267), 52.5 (0.5) years control (*n*=265). Mean (SD) BMI 35.8 (3.9) kg/m^2 orlistat , 35.4 (4.0) kg/m^2 control.
Intervention	*Diet: nutritionally balanced hypoenergetic diet (estimated energy requirements – 600 kcal/day) with no more than 30% of energy as fat.* Antihypertensive medication was continued as established prior to study entry. If the BP on any two visits and at any time during the study became uncontrolled, i.e. exceeded 179 mmHg systolic and/or 109 mmHg diastolic, modification of the hypertension medication was prescribed by the primary physician. Such modification of medication was also allowed if the BP exceeded 159/95 mmHg after 16 weeks. Uncontrolled hypertension did not necessitate study withdrawal. The primary physician was allowed to modify antihypertensive medications as needed according to his/her own judgment, with the exception of diuretic therapy, which had to remain stable for the duration of the study. *Activity: encouraged to participate in moderate physical activity as deemed appropriate by their physician.* *Lifestyle intervention literature was made available to all participants during the study and all met with a dietitian periodically to review dietary instructions and food records.* *Drug: orlistat 120 mg three times per day with meals.*
Control	*As above except* Drug: placebo three times per day with meals.
Length of follow-up	*12 months*
Results	*The trial design did not include a run-in period.* *At 12 months, mean weight change (SD) was –5.40 (6.40) kg in the orlistat group compared with –2.70 (6.40) kg in the control group. Mean weight change in the intervention group compared with control was –2.70 (95% CI –3.79 to –1.61).* *At 12 months, 45.7% of the orlistat group compared with 22.6% of the placebo group lost more than 5% of initial body weight (*p*<0.001).*
Quality and comments	*Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment.* *More women than men were in both groups, and most participants were white.*
Sponsor details	*None reported. Corresponding author based at Hoffman-La Roche.*

**NB: have included the 5% weight loss, but this is >5% NOT ≥5% as in other studies.

Derosa 2003 RCT	
Aim	To assess obese participants with hypercholesterolaemia who were prescribed a standardised diet, comparing the action of orlistat, fluvastatin, orlistat plus fluvastatin, and placebo on anthropometric measures, BP and lipid profile.
Participants	People who were obese (BMI >30 kg/m^2), aged >40 years of age, with TC of ≥6.15 mmol/l (240 mg/dl). Total 50 – 26 F, 24 M (overall 99). Mean (SD) age 51.6 (8.3) years orlistat (*n*=27), 52.4 (10.2) years control (*n*=23). Mean (SD) BMI 32.0 (1.3) kg/m^2 orlistat, 31.7 (1.0) kg/m^2 control.

Intervention	*Four week, single-blind placebo pre-treatment with a 1500 kcal/day diet (54% energy as carbohydrate, 24% as protein, 22% as lipids (6% saturated fat), 108 mg cholesterol, 35 g fibre). Also, physical aerobics activity (≥30 min, 4 days/week) by bicycle.* *Diet: continued from pre-treatment. Food diaries and discussion used to ensure dietary and exercise compliance.* *Activity: as pre-treatment.* *BT: behaviour modification programme – participant discussion and assessment of diaries (self-monitoring?).* *Drug: orlistat 120 mg three times per day after each meal (two placebo per day).*
Control	*As above except* Drug: placebo five times per day
Length of follow-up	*12 months*
Results	*Weight loss during run-in period not reported.* *At 6 months, mean weight change (SD) was –5.10 (7.36) kg in the orlistat group compared with –4.20 (7.10) kg in the control group. Mean weight change in the intervention group compared with control was –0.90 (95% CI –4.99 to 3.19).* *At 12 months, mean weight change (SD) was –8.60 (8.35) kg in the orlistat group compared with –7.60 (8.07) kg in the control group. Mean weight change in the intervention group compared with control was –1.00 (95% CI –5.65 to 3.65).* *5% and 10% responders not reported.*
Quality and comments	*Only results of orlistat and placebo group reported. Assume baseline to be after 4-week lead in period.* *Blinded assessment not reported. ITT analysis not done. Attempt at concealment, but chance of disclosure. Reported SDs very low so used HTA formula.*
Sponsor details	*None reported.*

Kelley 2002 RCT	
Aim	To assess the effects of orlistat on weight loss, glycaemic control, and cardiovascular risk factors in people who are overweight or obese with insulin-treated type 2 diabetes.
Participants	People who were overweight or obese (BMI 28 to 43 kg/m^2) with insulin-treated type 2 diabetes. Total 535 – 301 F, 234 M. Mean (SD) age 57.8 (8.2) years orlistat (*n*=266), 58.0 (8.2) years control (*n*=269). Mean (SD) BMI 35.8 (3.3) kg/m^2 orlistat, 35.6 (4.9) kg/m^2 control.
Intervention	Diet: nutritionally balanced energy-deficit diet designed to induce a weight loss of 0.25–0.5 kg per week. 30% of energy as fat, 50% as carbohydrate, and 20% as protein, with a maximum of 300 mg/day of cholesterol. Additional dietary instruction was provided at predetermined intervals during the study, and dietary compliance was monitored by the use of dietary intake records. At week 24, the prescribed energy intake was further reduced by 200 kcal/day (with a minimum energy intake of at least 1200 kcal/day) to compensate for reduced energy requirements induced by weight loss. BT: Lifestyle and behavioural modification literature were available throughout the study. Activity: encouraged to participate in moderate physical activity. *Drug: orlistat 120 mg three times per day.* *Investigators were instructed to try to maintain stable doses of insulin and other diabetes medications, but they had the option to adjust doses.*
Control	*As above except:* Drug: placebo three times per day.
Length of follow-up	*12 months*

Results	*A run-in period was not used.* *At 12 months, mean weight change (SD) was –3.89 (4.40) kg in the orlistat group compared with –1.27 (4.59) kg in the control group. Mean weight change in the intervention group compared with control was –2.62 (95% CI –3.38 to –1.86).* *At 12 months, 32.7% of the orlistat group compared with 13.0% of the placebo group lost 5% or more of initial body weight (*p*<0.0001).* *At 12 months, 10.2% of the orlistat group compared with 3.7% of the placebo group lost 10% or more of initial body weight (*p*<0.001).*
Quality and comments	*Calculated SDs from SEMs.* *Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment.*
Sponsor details	*Hoffman-La Roche*

Krempf 2003 RCT	
Aim	To determine the effect of orlistat on weight reduction and the long-term maintenance of this weight loss when associated with a continuous mildly energy-reduced diet.
Participants	People who were overweight (BMI ≥28 kg/m^2). Total 696 – 601 F, 95 M. Mean (SD) age 40 (11.1) years orlistat (*n*=346), 42 (11.2) years control (*n*=350). Mean (SD) BMI 36.0 (5.6) kg/m^2 orlistat, 36.2 (5.6) kg/m^2 control.
Intervention	*15 day placebo run-in period. Diet started at the beginning of the run-in period* *Diet: as per run-in, initial energy intake determined from food diaries and individually tailored diets (restricted energy by 20%, 30% of intake from fat). Intake reduced by 10% (never below 1200 kcal/day) if weight stable or gained.* *Drug: orlistat 120 mg three times per day.*
Control	*As above except:* Drug: placebo three times per day.
Length of follow-up	*18 months*
Results	*During the run-in period, weight loss was about 1.35kg (calculated from graph).* *At 12 months, mean weight change (SD) was –5.95 (8.00) kg in the orlistat group compared with –3.05 (6.78) kg in the control group. Mean weight change in the intervention group compared with control was –2.90 (95% CI –4.00 to –1.80).* *At 18 months, mean weight change (SD) was –5.05 (7.34kg in the orlistat group compared with –1.35 (6.30) kg in the control group. Mean weight change in the intervention group compared with control was –3.70 (95% CI –4.72 to –2.68)* *Mean weight regain between 12 and 18 months was lower in the orlistat group (1.2 vs 1.4 kg) but the difference was not statistically significant.* *At 12 months, 65.9% of the orlistat group compared with 46.4% of the placebo group lost 5% or more of initial body weight (*p*<0.0001).* *At 12 months, 32.9% of the orlistat group compared with 24.5% of the placebo group lost 10% or more of initial body weight (*p*=0.04).* *At 18 months, 58.3% of the orlistat group compared with 37.8% of the placebo group lost 5% or more of initial body weight (*p*<0.0001).* *At 18 months, 33.6% of the orlistat group compared with 16.8% of the placebo group lost 10% or more of initial body weight (*p*<0.0001).* *More people in the orlistat group maintained the ≥10% weight loss compared with placebo (28.1% vs 13.8%,* p*=0.0004).*
Quality and comments	*Calculated SDs from SEMs. People in the control group were significantly older than in the orlistat group (42 vs 40 years,* p*=0.04).* *Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment.* *Calculated from week 0 weight loss – assumed to be 1.35 kg (from graph). HTA formula used for SDs.*
Sponsor details	*Roche*

Miles 2002 RCT	
Aim	To assess the effect of orlistat on body weight, glycaemic control and cardiovascular risk factors in people with metformin-treated type 2 diabetes
Participants	People with metformin-treated type 2 diabetes and who were overweight (BMI of 28 to 43 kg/m^2). Total 504 – 242 F, 262 M. Mean (SD) age 52.4 (6.3) years orlistat (*n*=250), 53.7 (6.4) years control (*n*=254). Mean (SD) BMI 35.6 (4.7) kg/m^2 orlistat, 35.2 (3.2) kg/m^2 control.
Intervention	*Diet: reduced-energy diet (about 600 kcal daily deficit) based on American Diabetes Association recommendations and containing 30% of energy as fat, 50% as carbohydrate, and 20% as protein, with a maximum cholesterol content of 300 mg/day. Energy content calculated from an estimate of initial energy requirements and was designed to promote a weight loss of 0.25–0.5 kg/week. Daily energy intake was reduced by an additional 200 kcal after 6 months to compensate for the reduction in energy requirements caused by weight loss, with a minimum intake of 1200 kcal/day. Participants received dietary counselling at baseline and at regular intervals throughout the study.* *Activity: encouraged to increase their level of physical activity.* *Other: multivitamin supplement prescribed to be taken daily at least 2 h before or after the evening dose of study medication. Diabetes medications were changed when hypoglycaemia occurred or when deterioration in glycaemic control was observed.* *Drug: orlistat 120 mg three times per day with main meals*
Control	As above except Drug: placebo three times per day with main meals
Length of follow-up	*12 months*
Results	*A run-in period was not used.* *At 12 months, mean weight change (SD) was –4.70 (7.25) kg in the orlistat group compared with –1.80 (3.02) kg in the control group. Mean weight change in the intervention group compared with control was –2.90 (95% CI –3.87 to –1.93).* *At 12 months, 39.0% of the orlistat group compared with 15.7% of the placebo group lost 5% or more of initial body weight (*p*=0.008).* *At 12 months, 14.1% of the orlistat group compared with 3.9% of the placebo group lost 10% or more of initial body weight (*p*=0.003).*
Quality and comments	*Calculated SDs from SEMs.* *Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment.*
Sponsor details	*Hoffman-La Roche*

Poston 2003 RCT	
Aim	To evaluate the effectiveness of a culturally appropriate lifestyle intervention combined with orlistat in producing weight loss in Mexican American women who were obese
Participants	Mexican American women who were obese (BMI ≤27 kg/m^2). Total 108 – all women. Mean (SD) age 42.4 (9.2) years orlistat (*n*=56), 43.7 (9.2) years control (*n*=52). Mean (SD) BMI 37.8 (6.2) kg/m^2 orlistat, 36.0 (5.2) kg/m^2 control.

Intervention	*Diet: instructed to lower energy intake by at least 500 energy/day to achieve a weight loss of about 0.45 kg (1 lb) per week. Fat intake limited to 30% of total energy intake. Used nutrition manual with 16 weight-loss lessons and 11 maintenance activities.* *Activity: to increase activity to minimum five times/week for 30 min per session for a total of ≥150 min/week. Primary exercise was walking. Also used exercise contracts and incentives to motivate participants.* *BT: classes which included nutrition component (food demonstrations of modified traditional dishes), problem-solving and role-playing (including identifying problem eating situations and setting exercise objectives), social support strategies, discussions on activity. Programme was culturally adapted with bilingual materials and instructor, modification of native diets, tailored rationales for diet and exercise (e.g. importance of family involvement, improving health rather than just appearance).* *Other: vitamin and mineral supplementation (one per day).* *Drug: orlistat 120 mg three times per day with meals.*
Control	Waiting list control.
Length of follow-up	*12 months*
Results	*A run-in period was not used.* *At 6 months, mean weight change (SD) was –5.20 (7.39) kg in the orlistat group compared with –1.00 (6.20) kg in the control group. Mean weight change in the intervention group compared with control was –4.20 (95% CI –6.77 to –1.63).* *At 12 months, mean weight change (SD) was –5.60 (7.50) kg in the orlistat group compared with –0.30 (6.00) kg in the control group. Mean weight change in the intervention group compared with control was –5.30 (95% CI –7.85 to –2.75).* *Significantly more women in the intervention group achieved 5% or more weight loss (*p*<0.000 for 6 and 12 months) and 10% or more weight loss (*p*=0.008 at 6 and 12 months) compared with waiting list control.*
Quality and comments	*Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment. SDs calculated using HTA formula. Open label study. Read 5/10% values off Figures 2 and 3 for analysis.*
Sponsor details	*Roche*

Swinburn 2005 RCT	
Aim	To compare the effect of orlistat and placebo on the predicted 10-year CVD risk in obese people with one or more cardiovascular risk factors treated for 12 months, in conjunction with a fat-reduced, but otherwise ad libitum, diet.
Participants	People who were overweight (BMI between 30 and 50 kg/m^2) with at least one cardiovascular risk factor Total 339 – 193 F, 146 M. Mean (SD) age 52.0 (7.5) years orlistat (*n*=170), 52.5 (7.4) years control (*n*=169). Mean (SD) BMI 37.6 (5.1) kg/m^{2}orlistat, 38.0 (4.9) kg/m^{2}control.
Intervention	*Pre-treatment 4-week, single-blind, placebo lead-in period with advice on reducing dietary fat and increasing physical activity levels (moderate-intensity physical activity of at least 30 min per day on most days). Received advice from a dietitian about identifying the sources of dietary fat (such as through label reading) and reducing them as much as possible by using a variety of strategies, including fat-reduced cooking methods. Aim to reduce daily dietary fat intake to between 25 and 30% of total daily energy intake or about 40 g/day.* *Diet: given further advice on maintaining a fat-reduced diet.* *Activity: given further advice on maintaining a regular physical activity.* *Other: diaries (self-monitoring) and goal setting.* *Drug: orlistat 120 mg three times per day.*
Control	As above except: Drug: placebo three times per day.
Length of follow-up	*12 months*

Results	*Weight loss during run-in period not reported.* *At 12 months, mean weight change (SD) was –4.70 (7.70) kg in the orlistat group compared with –0.90 (4.20) kg in the control group. Mean weight change in the intervention group compared with control was –3.80 (95% CI –5.12 to –2.48).* *5% and 10% responders not reported.*
Quality and comments	*Blinded assessment not reported. ITT analysis done. Random allocation but no description of concealment.* *Higher proportion of women in the orlistat group compared with control. Two people with left ventricular hypertrophy in the control group.*
Sponsor details	*Hoffman-La Roche*

Toplak 2005 RCT	
Aim	To determine the effect of two different levels of energy deficit on weight loss in obese people treated with orlistat.
Participants	People who were obese (BMI 30 to 43 kg/m^2, with a body weight of ≥90 kg and a WC of ≥88 cm (women) or ≥102 cm (men). Total 356 – 277 F, 79 M. Mean (SD) age 41.1 (12.1) years orlistat+1000 kcal/day deficit (*n*=141), 41.3 (11.0) years orlistat+500 kcal/day deficit (*n*=215). Mean (SD) BMI 37.4 (3.6) kg/m^2 orlistat+1000 kcal/day deficit, 37.3 (3.4) kg/m^2 orlistat+500 kcal/day deficit.
Intervention	*Diet: 1000 kcal/day deficit diet consisted of 30% of energy as fat, 50% as carbohydrate and 20% as protein. Energy intake prescribed for each individual on the basis of estimated daily maintenance energy requirements (1.3 × calculated basal metabolic rate).* *Activity: encouraged to increase physical activity.* *Drug: orlistat 120 mg three times daily.* *Participants who achieved ≥5% reduction in body weight after both 3 and 6 months eligible to continue treatment for the entire study period (12 months) and those who did not excluded from the study. After 6 and 9 months of treatment, energy intake restriction adjusted in order to maintain a 500 or 1000 kcal/day deficit.* *Allowed to continue with any antihypertensive medication during the study. If possible, dose of concomitant medication maintained constant throughout the course of the study. However, if clinically indicated, dose of concomitant medication could be titrated. Additionally, concomitant antihypertensive and lipid-lowering medications could be discontinued during the study if, during clinical assessment, it observed that such medications were no longer required.*
Control	As above except: Diet: 500 kcal/day deficit diet consisted of 30% of energy as fat, 50% as carbohydrate and 20% as protein. Energy intake prescribed for each individual on the basis of estimated daily maintenance energy requirements (1.3 × calculated basal metabolic rate).
Length of follow-up	*12 months*
Results	*No run-in period used.* *At 12 months, mean weight change (SD) was –9.52 (7.52) kg in the orlistat+1000 kcal group compared with –8.62 (6.61) kg in the orlistat+500 kcal group. Mean weight change in the intervention group compared with control was –0.90 (95% CI –2.51 to 0.71).* *(At 3 months, 75% of participants achieved 5% weight loss. Of these, 92% achieved 5% weight loss at month 6. Those who did not achieve a 5% weight loss at both months 3 and 6 were excluded from the study at month 6.)* *After 12 months of treatment with orlistat, 85% and 84% of participants in the 1000 and 500 kcal/day deficit groups, respectively, achieved 5% weight loss, and 53% and 50% respectively, achieved 10% weight loss compared with baseline. In addition, 21% and 23% in the 1000 and 500 kcal/day deficit groups, respectively, achieved 15% weight loss, and 11% and 7% respectively, achieved 20% weight loss compared with baseline.*

Quality and comments	*Blinded assessment not done. ITT analysis done. Good concealment of allocation – central randomisation.*
Sponsor details	*Hoffman-La Roche*

Torgerson 2004 RCT	
Aim	To determine the long-term effect of orlistat, in combination with lifestyle changes in reducing progression to type 2 diabetes and body weight over 4 years in obese, non-diabetic participants who had either normal glucose tolerance (NGT) or IGT. Also to determine the effect of orlistat treatment on weight-related metabolic abnormalities associated with increased risk for CVD and the safety and tolerability of orlistat over 4 years.
Participants	People who had NGT or IGT who were also obese (BMI ≥30 kg/m^2) Total 3277 – 1810 F, 1467 M. Mean (SD) age 43.0 (8.0) years orlistat (*n*=1640), 43.7 (8.0) years control (*n*=1637). Mean (SD) BMI 37.3 (4.2) kg/m^2 orlistat, 37.4 (4.5) kg/m^2 control.
Intervention	*Diet: reduced-energy diet (about 800 kcal/day deficit) containing 30% of energy as fat and not more than 300 mg of cholesterol per day. Prescribed energy intake readjusted every 6 months to account for any weight lost during the preceding months. Received dietary counselling every 2 weeks for the first 6 months and monthly thereafter.* *Activity: encouraged to walk at least 1 extra km per day in addition to their usual physical activity. Kept physical activity diaries.* *Drug: orlistat 120 mg three times per day with meals.*
Control	As above except: Drug: placebo three times per day with meals.
Length of follow-up	*4 years*
Results	*No run-in period used.* *At 12 months, mean weight change (SD) was –10.60 (8.91) kg in the orlistat group compared with –6.20 (7.67) kg in the control group. Mean weight change in the intervention group compared with control was –4.40 (95% CI –5.02 to –3.78).* *At 48 months, mean weight change (SD) was –5.80 (7.56) kg in the orlistat group compared with –3.00 (6.76) kg in the control group. Mean weight change in the intervention group compared with control was –2.80 (95% CI –3.55 to –2.05).* *At 12 months, 72.8% of the orlistat group compared with 45.1% of the placebo group lost 5% or more of initial body weight (*p*<0.001).* *At 12 months, 41.0% of the orlistat group compared with 20.8% of the placebo group lost 10% or more of initial body weight (*p*<0.001).* *At 48 months, 52.8% of the orlistat group compared with 37.3% of the placebo group lost 5% or more of initial body weight (*p*<0.001).* *At 48 months, 26.2% of the orlistat group compared with 15.6% of the placebo group lost 10% or more of initial body weight (*p*<0.001).*
Quality and comments	*Blinded assessment not reported. ITT analysis done for time to diabetes only? Attempt at concealment but possibility of disclosure (sealed envelopes).* *HTA formula used.*
Sponsor details	*Hoffman-La Roche*

Other outcomes

Bakris 2002 RCT	
Results	*At 12 months, mean (SD) TC change in mmol/l was –0.36 (0.94) in the orlistat group, and –0.04 (0.79) in the control group. Mean TC change in the intervention group compared with control was –0.32 (95% CI –0.47 to –0.17).* *At 12 months, mean (SD) LDL change in mmol/l was –0.31 (0.76) in the orlistat group, and –0.11 (0.70) in the control group. Mean LDL change in the intervention*

	group compared with control was –0.20 (95% CI –0.32 to –0.08). *Changes in HDL-cholesterol and TAG were not significant but details were not reported.* *At 12 months, mean (SD) DBP change in mmHg was –11.40 (8.30) in the orlistat group, and –9.20 (8.40) in the control group. Mean DBP change in the intervention group compared with control was –2.20 (95% CI –3.62 to –0.78).* *At 12 months, mean (SD) SBP change in mmHg was –13.30 (15.20) in the orlistat group, and –11.00 (15.00) in the control group. Mean SBP change in the intervention group compared with control was –2.30 (95% CI –4.87 to 0.27).* *Significant reductions in insulin levels were seen in both groups (–41.2 vs –26.7 pmol/l) but these were not significantly different between the groups.* *A 30% reduction in cardiovascular risk score occurred significantly more frequently in the orlistat group than in the placebo group (36.1 vs 24%,* $p<0.05$*).* *The reduction in sitting diastolic BP was significantly greater in people with diabetes randomised to receive orlistat (–15.3±2.1 vs –6.4±1.0 mmHg,* $p=0.028$*).* *Among those with diabetes who completed 52 weeks, a significantly greater percentage of those randomised to orlistat reached goal BP (10/11; 91%) than of those receiving diet only (3/9; 33%;* $p=0.009$*). Weight loss in orlistat-treated vs placebo-treated people with diabetes was not statistically different (–9.1±1.5 vs –4.3±0.8 kg,* $p=0.092$*).* *Overall, BP medication changes occurred in 131 participants during the trial. In 18 orlistat-treated people, medications were reduced at 23 weeks (mean) compared with 11 placebo participants where medication reduction occurred at 22 (mean) weeks. Medication increases occurred in 42 orlistat-treated vs 40 placebo-treated participants. These changes occurred at 22±3 weeks in the orlistat group vs 25±6 weeks in placebo (not significant). Finally, medications were substituted in eight orlistat-treated and four placebo-treated individuals at 25±6 and 33±8 weeks, respectively (not significant).* *Those participants in whom medication could be reduced had significantly greater weight loss (–11±11%) than those in whom an increase in medication was deemed necessary (–5±6%,* $p=0.009$*).* *No analysis of outcomes independent of weight loss was reported.*
Quality and comments	…

Derosa 2003 RCT	
Results	*At 6 months, no significant changes were seen in SBP, DBP, TC, LDL, HDL or TAG levels.* *At 12 months, mean (SD) DBP change in mmHg was –4.00 (8.30) in the orlistat group, and –2.00 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –2.00 (95% CI –6.70 to 2.70).* *At 12 months, mean (SD) SBP change in mmHg was –6.00 (12.70) in the orlistat group, and –4.00 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –2.00 (95% CI –9.19 to 5.19).* *When the 12-month lipid and TAG figures were converted to mmol/l, the values appeared very different (for example –1 mmol/l for TC level) so have not added to analysis. But authors reported significant % changes in TC and LDL levels from baseline for both groups, and for the orlistat group for TAG (*$p<0.05$*). Significant differences were seen between groups for TC and LDL (*$p<0.05$*).* *No analysis of outcomes independent of weight loss was reported.*
Quality and comments	Could not add 6 months results to meta-analysis as no SDs reported. For 12-month results, assumed SDs to be similar to those of other studies. Results for completers only.

Kelley 2002 RCT	
Results	*At 12 months, mean (SD) TC change in mmol/l was –0.30 (0.58) in the orlistat group, and 0.08 (0.59) in the control group. Mean TC change in the intervention group compared with control was –0.38 (95% CI –0.48 to –0.28).* *At 12 months, mean (SD) LDL change in mmol/l was –0.38 (0.42) in the orlistat*

	group, and –0.08 (0.42) in the control group. Mean LDL change in the intervention group compared with control was –0.30 (95% CI –0.37 to –0.23). *At 12 months, mean (SD) HDL change in mmol/l was 0.02 (0.08) in the orlistat group, and 0.05 (0.09) in the control group. Mean HDL change in the intervention group compared with control was –0.03 (95% CI –0.04 to –0.02).* *At 12 months, mean (SD) TAG change in mmol/l was 0.18 (1.33) in the orlistat group, and 0.31 (1.10) in the control group. Mean TAG change in the intervention group compared with control was –0.13 (95% CI –0.34 to 0.08).* *At 12 months, mean (SD)* HbA_{1c} *% change was –0.62 (0.66) in the orlistat group, and –0.27 (0.68) in the control group. Mean TAG change in the intervention group compared with control was –0.35 (95% CI –0.46 to –0.24).* *At 12 months, mean (SD) DBP change in mmHg was –2.30 (5.83) in the orlistat group, and –1.00 (4.24) in the control group. Mean DBP change in the intervention group compared with control was –1.30 (95% CI –2.16 to –0.44).* *At 12 months, mean (SD) SBP change in mmHg was –1.20 (8.32) in the orlistat group, and –0.90 (8.47) in the control group. Mean SBP change in the intervention group compared with control was –0.30 (95% CI –1.71 to 1.11).* *At 12 months, mean (SD) FPG change in mmol/l was –1.63 (2.49) in the orlistat group, and –1.08 (2.54) in the control group. Mean FPG change in the intervention group compared with control was –0.55 (95% CI –0.97 to –0.13).* HbA_{1c} *improvements remained significant after adjustment for weight loss. Similarly for changes in TC and LDL levels.* *A greater reduction in insulin dose was associated with orlistat than with placebo treatment (–8.1 vs –1.6 units/day,* p*=0.007). A greater proportion of people achieved ≥5% reduction of insulin dose in the orlistat treatment group compared with placebo (41 vs 31%,* p*<0.001), whereas fewer of those in the orlistat than in the placebo group increased their insulin dose by ≥5% (12 vs 26%,* p*<0.001). More orlistat- (41.3%) than placebo-treated participants (30.9%) decreased the dose or discontinued at least one oral diabetes medication during the study; conversely, dose increase or the addition of at least one new diabetes medication occurred less frequently in orlistat- (14.7%) than in placebo-treated people (31.7%) (*p*<0.0001). There was a greater reduction in sulfonylurea dose in the orlistat group compared with placebo. Changes in metformin dose were not different between groups.*
Quality and comments	SDs calculated from SEMs, but seem high for TAG and FPG.

Krempf 2003 RCT	
Results	*At 18 months, TC levels were reduced by ≥20% in 10.1% of the orlistat group, compared with 2.6% of those in the placebo group. LDL levels were reduced by ≥20% in 19.9% of the orlistat group, compared with 6.6% of the placebo group (no* p *values reported).* *In those participants classified as at risk (FPG ≥6.05 mmol/l, LDL ≥3.36 mmol/l, HDL <0.90 mmol/l, TAG ≥2.54 mmol/l, SBP ≥140 mmHg, and DBP ≥90 mmHg), significant changes in the orlistat group compared with placebo were seen at 18 months for FPG (–0.86 vs –0.29 mmol/l,* p*<0.05), %LDL-cholesterol (–13.0 vs –7.0%,* p*<0.001). No significant differences were seen for HDL or TAG levels, or for SBP and DBP, but all the changes were in the right direction.* *No analysis of outcomes independent of weight loss was reported, although the authors did note 'beneficial changes in lipid levels that were greater than could be expected by weight loss alone'.* *Food intake reported only overall, not by groups. However, there was no statistical difference for energy and nutrient intakes between the two groups.*
Quality and comments	…

Miles 2002 RCT	
Results	*At 12 months, mean (SD) TC change in mmol/l was –0.27 1.08) in the orlistat group, and 0.06 (1.08) in the control group. Mean TC change in the intervention*

	group compared with control was –0.33 (95% CI –0.52 to –0.14). *At 12 months, mean (SD) LDL change in mmol/l was –0.25 (0.74) in the orlistat group, and 0.05 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.30 (95% CI –0.43 to –0.17).* *At 12 months, mean (SD) HDL change in mmol/l was 0.09 (0.29) in the orlistat group, and 0.10 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.01 (95% CI –0.06 to 0.04).* *At 12 months, mean (SD) TAG change in mmol/l was –0.25 (0.96) in the orlistat group, and 0.03 (0.96) in the control group. Mean TAG change in the intervention group compared with control was –0.28 (95% CI –0.45 to –0.11).* *At 12 months, mean (SD) %*HbA_{1c} *change was –0.75 (0.66) in the orlistat group, and –0.41 (0.65) in the control group. Mean TAG change in the intervention group compared with control was –0.34 (95% CI –0.45 to –0.23).* *At 12 months, mean (SD) SBP change in mmHg was –2.10 (12.70) in the orlistat group, and –0.30 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –1.80 (95% CI –4.02 to 0.42).* *At 12 months, mean (SD) FPG change in mmol/l was –2.00 (1.61) in the orlistat group, and –0.70 (1.63) in the control group. Mean FPG change in the intervention group compared with control was –1.30 (95% CI –1.58 to -1.02).* *Compared with placebo treatment, orlistat therapy was associated with reductions in both daily metformin dose (–16± 24 vs 49±24 mg/day,* p=*0.013) and relative sulfonylurea dose, expressed as percent change, with doses standardised to a percentage of maximum daily dose (–11.5±3.6 vs –0.9±2.6%,* p=*0.027). Twice as many people in the orlistat than in the placebo group either reduced or discontinued one or more diabetes medications (17.1 v. 8.2%). More placebo- than orlistat-treated participants required additional or increased dosages of diabetes medication (21.7 vs 12.2%). These changes in diabetes medication usage were significantly different between treatment groups (*p=*0.0004).*
Quality and comments	Assumed SDs similar to other studies.

Poston 2003 RCT	
Results	*Women in the intervention group had significant improvements in TC (*p=*0.029) and LDL-cholesterol (*p=*0.006) (not sure of the time point). No other (usual) outcomes were significant.* *No analysis of outcomes independent of weight was reported.*
Quality and comments	Did not use SDs from other trials for analysis as this trial was very different and similar effects could not be assumed.

Swinburn 2005 RCT	
Results	*At 12 months, mean (SD) TC change in mmol/l was –0.08 (0.73) in the orlistat group, and 0.16 (0.68) in the control group. Mean TC change in the intervention group compared with control was –0.24 (95% CI –0.39 to –0.09).* *At 12 months, mean (SD) LDL change in mmol/l was –0.12 (0.65) in the orlistat group, and 0.11 (0.62) in the control group. Mean LDL change in the intervention group compared with control was –0.23 (95% CI –0.37 to –0.09).* *At 12 months, mean (SD) HDL change in mmol/l was 0.04 (0.18) in the orlistat group, and 0.08 (0.19) in the control group. Mean HDL change in the intervention group compared with control was –0.04 (95% CI –0.08 to 0.00).* *At 12 months, mean (SD) TAG change in mmol/l was 0.01 (0.73) in the orlistat group, and 0.06 (0.57) in the control group. Mean TAG change in the intervention group compared with control was –0.05 (95% CI –0.19 to 0.09).* *At 12 months, mean (SD) %*HbA_{1c} *change was –0.04 (0.60) in the orlistat group, and 0.15 (0.60) in the control group. Mean TAG change in the intervention group compared with control was –0.19 (95% CI –0.32 to –0.06).* *At 12 months, mean (SD) DBP change in mmHg was –2.96 (8.01) in the orlistat group, and –1.37 (8.59) in the control group. Mean DBP change in the intervention group compared with control was –1.59 (95% CI –3.36 to 0.18).* *At 12 months, mean (SD) SBP change in mmHg was –4.05 (13.00) in the orlistat*

	group, and –0.51 (14.70) in the control group. Mean SBP change in the intervention group compared with control was –3.54 (95% CI –6.49 to –0.59). *At 12 months, mean (SD) FPG change in mmol/l was –0.19 (1.13) in the orlistat group, and 0.29 (1.42) in the control group. Mean FPG change in the intervention group compared with control was –0.48 (95% CI –0.75 to –0.21).* *No analysis of association with weight loss was reported.* *Vitality (SF-36) was the only domain to have a statistically significant ($p=0.006$) difference between the two groups at 52 weeks with the orlistat group having a higher score.* *In people taking medication for diabetes, lipids or hypertension, there were significant changes towards fewer or lower-dose medications for diabetes ($p=0.026$) and hypertension ($p=0.0062$), but not for lipids ($p=0.42$).* *The baseline (week 0) median 10-year risk of a CVD event (Framingham score) was moderately low at about 10%. At week 52 the median 10-year CVD risk was 0.083 (range: 0.008 to 0.304) in the orlistat group and 0.100 (range: 0.013 to 0.386) in the placebo group. This difference in the changes between the two groups was non-significant ($p=0.091$).*
Quality and comments	…

Toplak 2005 RCT	
Results	*At 12 months, mean (SD) DBP change in mmHg was –3.80 (8.50) in the 1000 kcal deficit group, and –2.60 (9.60) in the 500 kcal deficit group. Mean DBP change in the 1000 kcal deficit group compared with 500 kcal deficit was –1.20 (95% CI –3.28 to 0.88).* *At 12 months, mean (SD) SBP change in mmHg was –6.00 (13.90) in the 1000 kcal deficit group, and –6.00 (13.00) in the 500 kcal deficit group. Mean SBP change in the 1000 kcal deficit group compared with 500 kcal deficit was –0.00 (95% CI –3.07 to 3.07).* *At 12 months, mean (SD) FPG change in mmol/l was –0.20 (0.60) in the 1000 kcal deficit group, and 0.00 (1.90) in the 500 kcal deficit group. Mean FPG change in the 1000 kcal deficit group compared with 500 kcal deficit was –0.20 (95% CI –0.53 to 0.13).* *Changes in %TC, %LDL, %HDL, were all significantly different from baseline for both 1000 kcal deficit and the 500 kcal deficit groups, apart from %TAG which were not significantly different from baseline in either group.* *When a subgroup of analysis of people with risk factors at baseline was done, all changes were significant from baseline ($p<0.001$) apart from %HDL-cholesterol (only significant from baseline in the 1000 kcal deficit group +16.9%, $p<0.05$ and NS from baseline for the 500 kcal deficit group, +8.2%) Similarly for %TAG (–37.4%, $p<0.001$ in the 1000 kcal deficit group vs –11.1% in the 500 kcal deficit group, NS).* *No analysis of association with weight loss was reported.* *Reported difference in energy intake, as determined by self-reported participant food diaries, was –111 kcal deficit/day at month 6 (1511 vs 1400 kcal/day; $p=0.0083$) and –95 kcal/day at month 12 (1564 vs 1469 kcal/day; $p=0.0580$).* *Reported difference in fat intake at 12 months was approximately 2 g/day (53 vs 51 g, $p=0.6151$).*
Quality and comments	

Torgerson 2004 RCT	
Results	*At 12 months, mean (SD) TC change in mmol/l was –0.51 (1.08) in the orlistat group, and –0.08 (1.08) in the control group. Mean TC change in the intervention group compared with control was –0.43 (95% CI –0.51 to –0.35).* *At 12 months, mean (SD) LDL change in mmol/l was –0.42 (0.74) in the orlistat group, and –0.06 (0.74) in the control group. Mean LDL change in the intervention group compared with control was –0.36 (95% CI –0.42 to –0.30).* *At 12 months, mean (SD) HDL change in mmol/l was 0.04 (0.29) in the orlistat*

	group, and 0.10 (0.29) in the control group. Mean HDL change in the intervention group compared with control was –0.06 (95% CI –0.08 to –0.04). *At 12 months, mean (SD) TAG change in mmol/l was –0.12 (0.96) in the orlistat group, and –0.12 (0.96) in the control group. Mean TAG change in the intervention group compared with control was 0.00 (95% CI –0.07 to 0.07).* *At 12 months, mean (SD) DBP change in mmHg was –3.60 (8.30) in the orlistat group, and –2.60 (8.30) in the control group. Mean DBP change in the intervention group compared with control was –1.00 (95% CI –1.62 to –0.38).* *At 12 months, mean (SD) SBP change in mmHg was –7.30 (12.70) in the orlistat group, and –5.20 (12.70) in the control group. Mean SBP change in the intervention group compared with control was –2.10 (95% CI –3.05 to –1.15).* *At 12 months, mean (SD) FPG change in mmol/l was 0.10 (1.35) in the orlistat group, and 0.20 (1.35) in the control group. Mean FPG change in the intervention group compared with control was –0.10 (95% CI –0.20 to 0.00).* *At 48 months, all changes were significantly different between groups (p<0.01) except for %TAG.* *No analysis of outcomes independent of weight loss was reported.* *During 4 years of treatment, orlistat plus lifestyle changes significantly decreased the progression to type 2 diabetes compared with placebo plus lifestyle changes (p=0.0032). Cumulative incidence rates after 4 years were 6.2 vs 9.0%. The hazard ratio (0.627, 95% CI 0.455 to 0.863) corresponded to a 37.3% decrease in the risk of developing diabetes with orlistat compared with placebo.* Exploratory analyses: In people with IGT at baseline, orlistat plus lifestyle changes significantly decreased the progression to type 2 diabetes when diagnosed on the basis of a single test (*p*=0.0024). Cumulative incidence rates after 4 years were 18.8 vs 28.8%, corresponding to a 45% risk reduction (hazard ratio 0.551). In addition, orlistat plus lifestyle changes significantly decreased the progression to type 2 diabetes when diagnosed by repeat positive testing in this subgroup with IGT (*p*=0.0171). Cumulative incidence rates after 4 years were 8.3% with orlistat vs 14.2% with placebo, corresponding to a 52% risk reduction (hazard ratio 0.482). *In people with NGT at baseline, the progression rate to type 2 diabetes with placebo was very low (2.7% over 4 years) and insufficient to detect a statistically significant difference compared with orlistat (2.6% over 4 years).* *Independent of orlistat or placebo treatment, the relative risk of developing type 2 diabetes was greater in participants with IGT than in those with NGT, in men than in women, in older than in younger individuals, and in individuals with a higher BMI.* *Weight loss was significantly greater with orlistat than placebo in both participants with IGT at baseline (5.7 kg with orlistat vs 3.0 kg with placebo; p<0.01) and participants with NGT (5.8 vs 3.0 kg, respectively; p<0.001).* *There was no difference in the progression rate from NGT to IGT over 4 years between orlistat- and placebo treated individuals (27.6 vs 30.5%, p=0.1521).* *There were statistically significant decreases in the orlistat group compared with the placebo group after 4 years of treatment for all assessed fat-soluble vitamins (vitamin A –0.22 vs 0.19 µmol/l, p<0.05; 25-hydroxycholecalciferol –17.2 vs –13.0 nmol/ml, p<0.001; vitamin E –2.8 vs 0.4 µmol/l, p<0.001; and vitamin* K_1 *–0.08 vs 0.07 µg/l, p<0.001), with the exception of 1,25-hydroxycholecalciferol (–15.8 vs –14.0 pmol/ml). However, the mean level of each assessed vitamin remained well within its reference range at all times during the 4-year study for both the orlistat and placebo groups. Decreases were seen early and then were maintained over the treatment period. In people with normal baseline vitamin levels, the proportions with two subsequent, consecutive abnormally low values was similar in the orlistat and placebo groups for vitamin A (5.5 vs 4.4%, respectively) and notably different only for vitamin E (3.2 vs 0.5%, respectively). Proportions for all other vitamin levels were <1% and similar between treatment groups*
Quality and comments	Used % change to calculate absolute changes from baseline. Assumed SDs as for other studies. Could not add 48-month data to analysis as no SDs from other studies at that time point.

Reported harms

Bakris 2002 RCT	
Harms	At least one adverse event was reported by more participants in the orlistat-treated group (89%) than in the placebo group (71%). This difference was due primarily to the greater number of adverse events involving the GI system in the orlistat-treated group compared with the placebo-treated group. GI adverse effects were reported by 72.5% in the orlistat-treated group, compared with 43.6% in the placebo-treated group. The adverse GI effects occurred early during therapy, and their frequency tended to decrease with continued treatment. 15 of 200 (7.5%) of those who developed GI symptoms on orlistat stopped the medication for this reason, vs six of 120 (5.0%) in the control group. In the majority, the symptoms resolved without sequelae despite continued therapy. No deaths occurred during the study. Serious adverse events (necessitating or prolonging hospitalization) were reported in 29 people, of whom 14 were in the orlistat-treated group. In these people with insufficiently controlled hypertension, two in the orlistat group suffered a myocardial infarction, two had chest pain and one had an episode of atrial fibrillation. There were no episodes of uncontrolled BP reported in the orlistat-treated group. In the placebo-treated group, one had accelerated hypertension, one suffered a myocardial infarction, one had a worsening of atherosclerotic coronary artery disease and two had an episode of chest pain. A ductal carcinoma in situ was reported in one placebo-treated participant. One participant in the orlistat group and four in the placebo group withdrew from the study because of a serious adverse event. A reduction in study drug dosage occurred after a serious adverse event in eight orlistat-treated people and in nine receiving placebo.
Quality and comments	…

Derosa 2003 RCT	
Harms	*Only 3.0% of all participants experienced side effects (no details by group). Three people withdrew due to adverse events related to orlistat (two in the orlistat group, and one in the orlistat+fluvastatin group).*
Quality and comments	Less detailed reporting than other studies. Also far less GI events experienced/reported.

Kelley 2002 RCT	
Harms	GI events were the most commonly reported adverse event in both groups and were reported more frequently in the orlistat- (80%) than in the placebo-treated group (62%; $p<0.05$). Most people with GI events reported a single episode, and most GI events in both treatment groups were of mild to moderate intensity. Episodes of hypoglycaemia occurred in a greater proportion of orlistat- than placebo-treated participants (16.9 and 9.7%, respectively, $p<0.05$). In the majority of people, hypoglycaemic symptoms were mild to moderate, with blood glucose levels ranging from 2.2 to 6.9 mmol/l. Only four (one in the placebo and three in the orlistat group) required medical intervention due to hypoglycaemia. The incidence of adverse events related to other organ systems was similar in placebo- and orlistat-treated participants. More orlistat- (13%) than placebo-treated participants (8%) discontinued treatment because of an adverse event, whereas a lower percentage of orlistat- than placebo-treated participants (37 vs 46%) withdrew for other reasons.
Quality and comments	…

Krempf 2003 RCT	
Harms	*Overall proportion of people with at least one adverse event was higher in the orlistat group (86.1 vs 72.3%,* $p<0.001$*). The percentage of people experiencing GI events was higher again in the orlistat group (63.3 vs 36.3%). These GI events*

	occurred primarily during the first month of treatment and resolved spontaneously. 6.9% of the orlistat group and 3.4% of the placebo group (23 people overall) withdrew because of adverse events. Five events in the orlistat group and four in the placebo group were serious – seven of which were deemed 'doubtfully related' to the treatment. Non-clinically relevant changes in safety parameters occurred at a similar incidence in both groups.
Quality and comments	…

Miles 2002 RCT	
Harms	More people in the placebo group withdrew prematurely from the study than in the orlistat group (44 vs 35%, *p*<0.05). Of these, more orlistat- than placebo-treated participants (10 vs 5%, *p*<0.05) discontinued treatment because of an adverse event. Adverse event profiles were similar in the two treatment groups, with the exception of a higher incidence of GI events associated with orlistat. A total of 83% of people in the orlistat group experienced at least one GI event compared with 62% in the placebo group. More than 75% of those who had GI events reported only a single episode. The majority of GI events were mild, transient, and occurred during the early phase of treatment. Hypoglycaemic episodes occurred in 10% of orlistat-treated people compared with 4% of placebo-treated participants. None required medical intervention for hypoglycaemia, with symptoms reported as mild to moderate in intensity in both groups.
Quality and comments	…

Poston 2003 RCT	
Harms	Only adverse events for the orlistat group were reported. No adverse events were reported by participants that required trial termination. At 6 months, 37 (expected) GI events were reported, and 32 (expected) GI events at 12 months.
Quality and comments	…

Swinburn 2005 RCT	
Harms	One hundred and thirty-five participants (39.8%) reported adverse events before randomisation. The GI system was most frequently involved with 18.3% of these participants reporting adverse events. After randomization, almost all participants in each treatment group experienced at least one adverse event: 94.7% in the orlistat group and 93.5% in the placebo group. Almost all of these were minor with only 9.4% (orlistat) and 7.1% (placebo) experiencing more serious adverse events. The most frequently affected body system for any adverse event was the GI system with 82.4% in the orlistat group (mainly related to fatty/oily stools), compared with that with 60.4% in the placebo group (*p*=0.0005). In general, adverse events were mild to moderate in intensity. For all other events reported in more than ten participants in either treatment group, there were no statistically significant differences between the two treatment groups. There were five participants (2.9%) in the orlistat group and two participants (1.2%) in the placebo group who withdrew because of adverse GI events.
Quality and comments	…

Toplak 2005 RCT	
Harms	The adverse event profile was similar between the treatment groups. The most frequent adverse events in both the groups were GI in nature and were considered related to the pharmacological action of orlistat. Headache (18%) and nasopharyngitis (19%) were the most common non-GI events in both the groups.

	The majority of adverse events were mild or moderate in intensity. Of 19 people reporting serious adverse events, only four were considered treatment-related. In one participant in the 500 kcal/day deficit group, abdominal pain and cholelithiasis were considered possibly related to treatment; pancreatitis (500 kcal/day group, *n*=1), chest pain (*n*=1) and anal fissure (*n*=1) (1000 kcal/day group) were considered remotely related to treatment. Treatment was discontinued due to adverse events in 20 participants (eight in the 500 kcal/day deficit group and 12 in the 1000 kcal/day deficit group). In ten of these, adverse events, in most cases GI, were considered treatment-related. There were no significant changes in vital signs or laboratory parameters in the safety population, which included all participants who received at least one dose of study medication and had at least one safety evaluation taken before and after the treatment.
Quality and comments	…

Torgerson 2004 RCT	
Harms	Orlistat was well tolerated during the study. The overall incidence of adverse events was similar in the two treatment groups, with the exception of a higher incidence of GI events. Most GI events were mild to moderate in intensity and occurred during the early phase of treatment. During the first year of treatment, the proportion of participants experiencing at least one GI event with orlistat or placebo was 91 vs 65%, respectively. This compares with 36 vs 23% for orlistat or placebo, respectively, during the 4th year. Over the 4-year period, a similar proportion of placebo-treated participants had at least one serious adverse event as compared with orlistat-treated participants (13 vs 15%). Similar proportions of serious GI events occurred in the placebo (*n*=32; 2%) and orlistat (*n*=32; 2%) groups. No deaths were attributed to study medication. Overall, 4% of placebo participants and 8% of orlistat participants withdrew from the study because of adverse events or laboratory abnormalities; the difference was primarily due to GI events.
Quality and comments	…

Generalisability

Bakris 2002 RCT	
Country and setting	USA. Referral centres – assumed to be hypertension clinics?
Participants (included/excluded)	Included if BMI between 28 and 43 kg/m^2, were taking at least one antihypertensive medication and had a sitting DBP between 96 and 109 mmHg on two consecutive visits. Antihypertensive medication dose(s) had to be stable for at least 12 weeks preceding study entry. Individuals with easily controlled and stable diabetes were allowed to participate. Excluded if unstable medical and/or psychiatric illness, recent (within 12 weeks before study entry) initiation or change in diuretic therapy, previous GI surgery for weight reduction, and any active GI disorders such as malabsorption syndrome except more than mild lactose intolerance, diarrhoea or constipation, history of bulimia or laxative abuse, substance abuse, including alcohol, and unwillingness or inability to comply with protocol requirements. Pregnant or lactating women, women of childbearing potential not using acceptable contraceptive methods. The use of nicotine replacement therapy, appetite suppressants, fish-oil supplements, oral retinoids, chronic systemic steroids other than sex hormone replacement and gonadotropin releasing hormone was prohibited during the study, as was acute antidepressant or anxiolytic therapy.
Recruitment	No details other than from referral centres.

Randomisation	No details other than participants were randomised.
Intervention (mode and intensity)	*Baseline visit and 11 follow-up visits spread over the 52-week duration of the study*
Duration of active intervention	12 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Participants met with the study dietitian at each follow-up visit.
Dropout rates	*42% orlistat, 62% placebo at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	In the final analysis of each group, LOCF for endpoint analysis, irrespective of its actual timing during the study.

Derosa 2003 RCT	
Country and setting	Italy. University (lipids?) clinic
Participants (included/excluded)	Included if aged over 40 years, BMI >30 kg/m^2, had TC ≥6.15 mmol/l, SPB <140 mmHg, DBP <90 mmHg, non-smokers, normal thyroid function. No details of exclusions.
Recruitment	Selected from clinic database.
Randomisation	Weight change in the 4-week lead-in period was used to stratify for randomisation (a measure of weight loss potential).
Intervention (mode and intensity)	*12 months – assessed 3 monthly, met with dietitian 3 monthly*
Duration of active intervention	12 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Met with dietitian for counselling and behaviour modification programme (recording food intake) every 3 months.
Dropout rates	*7% orlistat, 0% placebo at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

Kelley 2002 RCT	
Country and setting	USA. (Diabetes care?) centres
Participants (included/excluded)	Included if aged 40–65 years, BMI 28–43 kg/m^2 and a stable weight (<3 kg weight change) for 3 months before study entry, treatment with a stable daily dose (±10%) of insulin for 6 weeks before study entry, and an HbA$_{1c}$ of 7.5–12.0% at screening. Women with childbearing potential were required to have a negative serum pregnancy test at screening and to use an acceptable form of contraception throughout the study. Excluded if diabetes treatment included a thiazolidinedione or if diabetic medications, with the exception of insulin, had changed during the 12 weeks before screening. Other exclusion criteria were medical history or presence of renal, hepatic, or endocrine disorders that could affect the results of the study, previous bariatric surgery, use of approved or experimental weight reduction medications or treatments, presence of malabsorption syndrome, presence of bulimia or laxative abuse, or presence of disorders that could affect compliance with the requirements of the study.
Recruitment	No details reported.
Randomisation	Stratified by %HbA$_{1c}$ levels (≤10%).
Intervention (mode and intensity)	*2 week screening, followed by 52 week intervention – seen at 2–4 weekly intervals*
Duration of active intervention	12 months

Control (mode and intensity)	As above
Delivery of intervention/control (who)	At the baseline visit, participants received diet instructions from a registered dietitian. Also seen at pre-determined (no details) intervals for additional dietary instructions.
Dropout rates	*50% orlistat, 54% control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	All efficacy variables were analysed using the LOCF technique.

Krempf 2003 RCT	
Country and setting	France. Hospital centres.
Participants (included/excluded)	Included if aged 18 to 65 years, BMI ≥28 kg/m^2. Excluded if serious eating disorder, type 1 or type 2 diabetes, pregnant or lactating women, smoking one or more pack of cigarettes per day or intention to stop smoking during the trial, previous surgery for obesity, known or suspected substance abuse, significant thyroid, renal, hepatic, GI or immune disorders, or concomitant use of medication that alter body weight, appetite or the absorption of food.
Recruitment	N/R
Randomisation	N/R
Intervention (mode and intensity)	*18 months – clinic visit every month for assessment.*
Duration of active intervention	18 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	N/R
Dropout rates	*39% orlistat, 43% placebo at 18 months*
Treatment of dropouts (return to baseline, or last measurement?)	Analysis by observed results only, and by LOCF.

Miles 2002 RCT	
Country and setting	US and Canada. (Diabetes) centres – no details.
Participants (included/excluded)	Included if type 2 diabetes, aged 40–65 years, BMI of 28–43 kg/m^2, maintained stable weight for ≥3 months, HbA$_{1c}$ between 7.5 and 12.0%, and had received metformin treatment at 1000–2550 mg/day for at least 6 weeks. Sulfonylurea therapy in combination with metformin was permitted as long as the sulfonylurea dose was stable for 12 weeks before study entry. Excluded if receiving insulin, thiazolidinediones or alpha-glucosidase inhibitors, any clinical condition that might affect study endpoints, including renal, hepatic, or endocrine disorders, poorly controlled hypertension (SBP ≥160 mmHg or DBP ≥100 mmHg), active GI disease, previous bariatric surgery, a history of bulimia, substance abuse, or the use of any weight loss medications. Women who were pregnant, lactating, or of childbearing potential were also excluded.
Recruitment	N/R
Randomisation	No details reported.
Intervention (mode and intensity)	*Initial screening visit – clinic visits at weeks 0, 2, 4, 8, 12, 16, 20, 24, 30, 36, 42, 48, 52.*
Duration of active intervention	12 months
Control (mode and intensity)	As above

Delivery of intervention/control (who)	N/R
Dropout rates	*35% orlistat, 44% placebo at 12 months*
Treatment of dropouts (return to baseline, or last measurement?)	N/R

Poston 2003 RCT	
Country and setting	USA. No details of setting – community based?
Participants (included/excluded)	Included women of Mexican origin, BMI ≥27 kg/m^2. Women with borderline/definite hypertension with physician's consent. Excluded if serious medical conditions that precluded participation, physician unwilling to consent, not going to reside in Houston area for full 12 months of the study.
Recruitment	N/R
Randomisation	No details reported.
Intervention (mode and intensity)	*Twenty-four weekly classes, six bimonthly, and three monthly maintenance classes (each 60 min) .*
Duration of active intervention	12 months
Control (mode and intensity)	Waiting list control
Delivery of intervention/control (who)	Classes led by a bilingual instructor with training in cognitive behavioural modification. Activity encouraged by an 'instructor', assumed to be as for behavioural modification.
Dropout rates	*43% orlistat, 34% control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis used LOCF. All reported data used actual observed values (not those derived using last observed values), unless specifically noted.

Swinburn 2005 RCT	
Country and setting	Australia and New Zealand. Clinical research centres.
Participants (included/excluded)	Included if aged 40 to 70 years, BMI between 30 and 50 kg/m^2 and one or more of the following concomitant conditions: hypercholesterolaemia: serum TC of >5.5mmol/l and/or LDL-cholesterol of >3.5 mmol/l and clinically stable if on treatment; hypertension: SBP >140 mmHg and/or DBP >90 mmHg and clinically stable if on treatment; type-2 diabetes treated with dietary modification or any oral hypoglycaemic agent for at least 6 months and clinically stable (HbA$_{1c}$ 6.5 to 10%). Excluded if history of significant cardiac, renal, hepatic, GI or endocrine disorders, uncontrolled hypertension, previous GI surgery for weight reduction, history of post-surgical adhesions, smoking, history or presence of substance abuse, bulimia, type-1 diabetes, psychiatric disorders or active GI disease.
Recruitment	N/R
Randomisation	Minimisation algorithm used, but no further details.
Intervention (mode and intensity)	*Clinic visits scheduled for initial screening and beginning and end of 4-week lead-in phase. During the 52-week treatment period, participants were examined fortnightly for the first month, then every month.*
Duration of active intervention	12 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Dietitian delivered dietary advice.

Dropout rates	*22% orlistat, 19% control at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Analyses were performed for both the 'observed' data and the data after the LOCF methods.

Toplak 2005 RCT	
Country and setting	Austria, Germany, Belgium, France, Switzerland, Canada, Brazil, Mexico and Australia. Medical departments of university and country hospitals.
Participants (included/excluded)	Included if BMI 30 to 43 kg/m^2, aged 18 to 70 years with a body weight ≥90 kg and WC ≥88 cm (women) or ≥102 cm (men). Excluded if change in body weight 3 kg in the 3 months prior to screening; presence of diabetes mellitus; uncontrolled hypertension; myocardial infarction within 6 months; surgical treatment for obesity; substance abuse; or participation in a weight loss/maintenance programme, diet or weight loss clinical study within the last 6 months. Co-administration of the following medications not allowed during this study: resins for lipid lowering, fish oil supplements, cyclosporin, systemic steroids, appetite suppressants, oral anticoagulants and antiarrhythmics.
Recruitment	N/R
Randomisation	No details.
Intervention (mode and intensity)	*Dietary counselling performed every 2 weeks for the first month, monthly until month 3 and every 3 months thereafter.*
Duration of active intervention	12 months
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Study dietitian evaluated individual’s daily food diary (assumed to give dietary counselling?).
Dropout rates	*35% 1000 kcal/day deficit diet, 42% 500 kcal/day deficit diet at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Participants who subsequently withdrew from the study had their last observation carried forward.

Torgerson 2004 RCT	
Country and setting	Sweden. Medical centres.
Participants (included/excluded)	Included if aged 30–60 years, BMI≥30 kg/m^2, non-diabetic glucose tolerance as assessed by a 75-g OGTT performed at baseline using venous whole blood and the 1994 WHO criteria (2-h whole blood glucose <10.0 mmol/l and fasting whole blood glucose <6.7 mmol/l. People with IGT were also eligible for inclusion, and the criteria for IGT were fasting whole blood glucose <6.7 mmol/l and 2-h whole blood glucose 6.7–10.0 mmol/l. Excluded if a change in body weight >2 kg between the screening and baseline examinations and a BP above 165 mmHg systolic or 105 mmHg diastolic on the same two consecutive visits, diabetes mellitus, myocardial infarction within 6 months, symptomatic cholelithiasis, GI surgery for weight reduction or peptic ulcer, active GI disorder or pancreatic disease, malignancy, significant psychiatric or neurological disorder, abuse or previous participation in any trial of orlistat.
Recruitment	Advertisements in daily newspapers.
Randomisation	No details.
Intervention (mode and intensity)	*Dietary counselling every 2 weeks for the first 6 months and monthly thereafter.*
Duration of active intervention	4 years

Control (mode and intensity)	As above
Delivery of intervention/control (who)	N/R
Dropout rates	*10% orlistat, 21% control at 48 months. 48% orlistat, 66% control at 48 months*
Treatment of dropouts (return to baseline, or last measurement?)	LOCF

1.6.2 Sibutramine

Included in HTA (Avenell)

Weight loss

Apfelbaum 1999 (In Avenell HTA)	
Aim	*To determine the efficacy of long-term treatment with sibutramine in maintaining or improving weight loss in obese patients who had lost weight with a VLED.*
Participants	Included patients were aged 18 to 55 years, with a BMI greater than 30 kg/m^2. 160 patients entered the double-blind period, 82 of whom were randomly assigned to sibutramine and 78 to placebo.
Intervention	*Patients were enrolled in a 4±1 week, site-specific VLED (220–800 kcal daily) to provide substantial weight loss before randomisation. Patients who lost at least 6 kg after the VLED and still fulfilled the entry criteria entered the 12 months double-blind treatment phase of the trial. They were randomly assigned in blocks of four to receive either white capsules containing sibutramine (10 mg) or matching placebo capsules, once daily in the morning. The VLED was stopped at entry to the double-blind period. All patients received dietary counselling according to published French guidelines to decrease their total energy intake by 20% to 30% compared with their pre-VLED intake.*
Control	Placebo white capsules given once daily.
Length of follow-up	*4±1 plus 12 months.*

Results	Weight change in the two groups between screening and baseline (randomisation were as follows: 103.4±17.5 kg to 95.7±16.9 for the sibutramine group, and 105.1±20.3 kg to 97.7±19.7 kg for the placebo group. In an ITT analysis, mean (±SD) absolute weight change at 1 year (or study endpoint) was -5.2 (±7.5) kg in the 81 patients in the sibutramine group and +0.5 (±5.7) kg in the 78 patients in the placebo group (*p*=0.004). Significantly greater weight loss occurred with sibutramine than placebo at each monthly assessment (*p*<0.05). One month after stopping treatment the two treatment groups were comparable for mean weight gain: sibutramine 1.6 (±1.5) kg, compared with placebo, 1.0 (±2.1) kg. Three months after cessation, the mean weight gain was 4.3 (±3.1) kg in the sibutramine group, compared with 2.3 (±2.9) kg in the placebo group. At the end of the study at least 86% of patients in the sibutramine group had lost at least 5% of their screening body weight, compared with 55% of those in the placebo group (*p*<0.001). Similarly, 54% of those in the sibutramine group had lost at least 10% of their body weight compared with 23% in the placebo group (*p*<0.001). 17% of the patients in the sibutramine group had lost 20% or more of their body weight, compared with 3% in the placebo group (*p*<0.01).

Change from baseline	**Endpoint (end of trial or last observation)**		**Month 12**	
	Sibutramine (*n*=81)	**Placebo (*n*=78)**	**Sibutramine (*n*=54)**	**Placebo (*n*=45)**
Weight loss	74%*	38%	74%†	**40%**
No change	0%	3%	0%	**2%**
Weight gain	**26%**	**59%**	**26%**	**58%**

*$p<0.0001$
†$p<0.001$

Quality and comments	*RCT. No details of randomisation or blinding were given. Adequate concealment method.*
Sponsor details	*Study medication provided by Knoll Pharmaceuticals.*

McMahon 2000 (in Avenell HTA)	
Aim	*To investigate the effects of sibutramine 20 mg once daily or placebo on body weight in obese hypertensive patients* (hypertension well controlled)
Participants	224 obese (BMI 27–40 kg/m^2), hypertensive patients. Hypertension was well controlled with a calcium channel blocker, with or without concomitant thiazide diuretic therapy *Mean (SD) age 52.3 (10.0) years sibutramine (*n*=150), 52.9 (8.7) years placebo (*n*=74). Mean (SD) BMI 34.5 (3.4) kg/m^2 sibutramine, 34.0 (4.0) kg/m^2 placebo.*
Intervention	*Initial screening phase, a 2 to 10 week placebo run-in period,* *Patients were randomised to a 2:1 ration to either sibutramine or placebo treatment taken once daily. During the initial 6 weeks, patients given sibutramine had their doses increased from 5 mg to 20 mg per day in 5 mg increments every 2 weeks.* *37% of the patients in the sibutramine group were on concomitant diuretics, compared with 38% in the placebo group.* *Patients received brief general dietary counselling regarding weight reduction at the initial run-in visit only.*
Control	Placebo with dietary counselling as above.
Length of follow-up	*52 weeks continuous treatment.*

Results	For patients receiving sibutramine, weight loss occurred during the first 6 months of treatment and was maintained to the end of the 12-month treatment period. The mean change in body weight among patients receiving sibutramine at week 52 was –4.4 kg, corresponding to a 4.7% decrease. This was significantly different from that of patients receiving placebo (–0.5 kg; $p<0.05$). Patients receiving sibutramine also had significantly greater decreases in BMI, waist and hip circumferences, and waist-hip ratio compared with patients receiving placebo ($p<0.05$). Mean percentage change in body weight among African American patients receiving sibutramine (–4.0%) was comparable with that for white patients (–4.9%). Of those patients receiving sibutramine, 40.1% lost 5% or more of body weight (5% responders) and 13.4% lost 10% or more of body weight (10% responders) vs 8.7% and 4.3%, respectively, of patients receiving placebo ($p<0.05$).
Quality and comments	Randomised, placebo-controlled, parallel-group comparison. No details of randomisation, or concealment method provided. ITT done – LOTF. *SD values used as in HTA.*
Sponsor details	*Knoll pharmaceuticals*

Smith 2001 (In Avenell HTA)	
Aim	*To assess the long-term weight reduction efficacy, tolerability, and safety of sibutramine used once daily in conjunction with behaviour modification to treat mild to moderate obesity.*
Participants	Individuals aged 18 to 65 years old, who were mildly to moderately obese (BMI 27 to 40 kg/m^2).
Intervention	*Participants were given standardised dietary advice and advice sheets to be followed throughout the study. They were advised to include a variety of vegetables and fresh fruit, bread, cereal, potatoes or rice; and they were told to substitute low-energy foods such as fresh fruits and baked potatoes for sugary and fried foods such chocolate and biscuits.* *Eligible patients then entered a 2-week single-blind placebo run-in period. At the ed of this run-in period, those who still met the criteria entered a 12-month double-blind treatment phase. Entry was restricted to those able to follow dietary advice as determined by the investigator. Patients were randomised to once daily treatment with placebo or sibutramine 10 mg or 15 mg dispensed in identical capsules, which were pre-packaged and coded by the sponsor according to a computer-generated randomisation list.*
Control	Placebo once daily and dietary advice for 12 months
Length of follow-up	*12 months*
Results	Of 510 who entered the run-in period, 485 continued for the double-blind period. No weight loss figures were reported after the run-in period. Mean weight change (95% CI) after 12 months of treatment was as follows: –1.6 (–2.3 to–0.9) kg for the placebo group; –4.4 (–5.4 to –3.4) kg for the 10 mg sibutramine group; and –6.41(–7.4 to –5.3) kg for the 15 mg sibutramine group. (Overall level of significance for comparison of treatment groups: 10 mg sibutramine vs placebo, $p=0.04$; 15 mg sibutramine vs placebo $p<0.001$; 10 mg vs 15 mg sibutramine $p>0.05$). The percentage of participants that lost ≥ 5% baseline weight was as follows: 32 (20) for the placebo group; 60 (39) ($p<0.001$) for the 10 mg sibutramine group; and 87 (57) ($p<0.001$) for the 15 mg sibutramine group. The percentage of participants that lost ≥10% baseline weight was as follows: 11 (7) for the placebo group; 30 (19) ($p<0.01$) for the 10 mg sibutramine group; and 52 (34) ($p<0.001$) for the 15 mg sibutramine group.
Quality and comments	*Double-blind randomised trial. No details of blinding. Adequate randomisation and concealment process. High dropout rate.*
Sponsor details	*Knoll Laboratories*

STORM James 2000 (In Avenell HTA as STORM) (also Hansen 2001 and Van Baak 2003)	
Aim	*To determine the effect of sibutramine in weight maintenance after weight loss.*
Participants	Sex: 390 women, 77 men Age: mean (SD) 40.6 (10.1) Mean (SD) weight: 102.6 kg (15.5) BMI (kg/m^2): mean (SD) 36.6 (4.1) Baseline comparability: yes
Intervention	Description of intervention: a + b: 6-month open pre-treatment weight reduction phase consisting of 10 mg sibutramine daily plus 600 kcal/day deficit plus 30 min daily extra walking plus advice on behaviour modification a: 10 mg sibutramine daily b: placebo daily a + b: sibutramine (or placebo) increased to 15 mg if more than 1 kg weight regain occurred after pre-treatment phase or since last dose increase providing dose stable for minimum of 2 months, if further weight increases dose increased to maximum 20 mg daily, dose reduced by 5 mg each time if patient could not tolerate higher dose, activity and behavioural advice, 600 kcal/day deficit (EE=resting metabolic rate × physical activity level) consisting of 45–50% energy as carbohydrate, 30% as fat, 15–20% as protein Provided more than 5% weight loss with less than a 2 kg weight gain form months 4 to 6 was achieved, participants were then randomly assigned at 6 months, on a 3/1 basis to sibutramine or placebo.
Control	Placebo for 18 months. The taste of the capsule was identical provided they were swallowed whole.
Length of follow-up	*Initial 6 months and then for a further 18 months*
Results	Allocated: a: 352 b: 115 Completed: a: 206 b: 57 *At the weight maintenance baseline (after the 6 months of the weight loss period) the sibutramine group had a mean weight (SD) of 102.3 kg (15.0) and the placebo a mean weight of 102.1 (16.1) kg. At 24 months the mean weight change from baseline (SD) was –8.9 (8.1) kg in the sibutramine group and –4.9 (5.9) kg in the placebo group.* *Of those who entered the weight-maintenance phase on sibutramine, 69% maintained at least 5% weight loss 18 months later, 46% maintained at least 10% weight loss and 27% maintained full initial weight loss.*
Quality and comments	Randomisation: 3:1, computer generated list maintained centrally. Allocation concealment: A Assessor blinding: no details given
Sponsor details	*BASF Pharma*

Wadden 2001 (In Avenell HTA)	
Aim	*To assess the benefits of adding lifestyle modification to the pharmacological treatment of obesity.*
Participants	53 women with 47.2±9.8 years; weight 101.3±9.7 kg; height 164.1±6.0 cm; and BMI 37.7±3.6 kg/m^2.

Intervention	*Fifty-five women were assigned to one of three treatment groups:* *(1) (*n*=19) drug-alone: balanced diet of 1200–1500 kcal/day with approximately 15% of the energy as protein, 30% as fat, and 55% as carbohydrate. 10 mg/day of sibutramine was given at week 0, which was increased to 15 mg/day at week 8.* *(2) (*n*=17) drug-plus-lifestyle modification: lifestyle modification session (during the first 20 weeks. 10 mg/day of sibutramine were given at week 0, which was increased to 15mg/day at week 8.* *(3) (*n*=17) drug-plus-lifestyle with a portion-controlled diet: same treatment as those in the drug plus lifestyle and additionally for the first 16 weeks, and they were given a 1000 kcal/day portion-controlled diet. At week 17, participants gradually decreased their consumption of liquid supplement, so that at week 20 they were prescribed a 1200–1500 kcal/day diet of conventional foods.*
Control	Three treatment groups
Length of follow-up	*12 months*
Results	At month 12, patients treated with the drug alone lost (mean±SD) 4.1±6.3% of their initial body weight compared with significantly (p<0.05) larger losses in the drug-plus-lifestyle group of 10.8±10.3% and the combined treatment group of 16.5±8.0%. Women in the two lifestyle groups achieved a significantly (p<0.05) greater percentage of their expected weight loss than those in the drug-alone group.
Quality and comments	*No details on randomisation were given. No concealment or blinding methods applied.* *Values of other outcomes were not given by groups at 52 weeks, as the only one group data was reported.*
Sponsor details	*Novartis Nutrition for OPTIFAST, and Knoll Pharmaceutical CO for providing sibutramine.*

Other outcomes

Apfelbaum 1999 (In Avenell HTA)	
Results	*TAG levels were reduced and HDL-cholesterol levels were increased in the sibutramine group compared with the placebo group at 12 months (*p*<0.05). LDL-cholesterol levels increased in both groups from the levels at baseline.* *There were no statistically significant changes between treatment groups in SBP.*
Quality and comments	…

McMahon 2000 (in Avenell HTA)	
Results	*Treatment with sibutramine was associated with significant improvements in metabolic parameters compared with placebo at week 52, including serum levels of TAG, HDL-cholesterol, glucose and uric acid. Treatment with sibutramine was associated with significant improvement in several scales of the Impact of Weight on Quality of Life questionnaire compared with placebo (results not shown). At week 28 of treatment, all patients receiving sibutramine had significant improvement in mean scores for Mobility and Activities of Daily Living (*p*<0.05 vs all patients receiving placebo), and sibutramine 5% and 10% responders showed improvement in mean scores for Health, Mobility, and Activities of Daily Living (*p*<0.05 vs all patients receiving placebo). At week 52, sibutramine 5% and 10% responders demonstrated significant improvement in mean scores for Health and Activities of Daily Living; sibutramine 5% responders also showed significant improvement in mean score for Mobility (*p*<0.05 vs all patients receiving placebo).* Treatment with sibutramine was associated with a small numerical mean increase in SBP that was not statistically significantly different from that in the placebo group. The mean change in DBP (2.0 mmHg) for patients receiving sibutramine was significantly greater than that for patients receiving placebo (–1.3 mmHg; p<0.05).

	The proportion of patients receiving sibutramine who experienced a potentially clinically significant increase from baseline in SBP or DBP (>10 mmHg at three consecutive visits) was comparable with that among patients receiving placebo The incidence of these changes in SBP or DBP was similar among African Americans and whites. The proportion of patients experiencing an increase from baseline in pulse rate greater than ten per min for three consecutive visits was greater for patients receiving sibutramine than for patients receiving placebo.
Quality and comments	…

Smith 2001 (In Avenell HTA)	
Results	*There were statistically significant changes in triglycerides compared with placebo (+3.2%) at month 6 for the sibutramine 10 and 15 mg treatment groups (–10.8%,* p<*0.05 and –10.0%,* p<*0.01, respectively).* *There were no statistically or clinically significant differences between the treatment groups for change in either the Beck Depression Inventory of the State Anxiety Inventory.* *Differences in mean changes in BP were not statistically significant between the sibutramine and placebo groups, except for a mean increase in DBP in the sibutramine 10 mg treatment group.*
Quality and comments	…

STORM James 2000 (In Avenell HTA) (also Hansen 2001 and Van Baak 2003)	
Results	*There were decreases in levels of serum TAG, VLDL-cholesterol, insulin C-peptide, and uric acid, but not in levels of LDL-cholesterol, which were maintained for up to 2 years and were proportional to weight loss. On the other hand, HDL-cholesterol levels (baseline levels: 1.24±0.38 mmol/l for sibutramine and 1.24±0.35 mmol/l for the placebo group) increased significantly after month 6 (1.41±0.35 in the sibutramine group and 1.35±0.36 for the placebo group) and at month 24 the values were 1.48±0.38 for the sibutramine and 1.35±0.38 for the placebo group (*p<*0.001).*
Quality and comments	…

Wadden 2001 (In Avenell HTA)	
Results	*Women in the two lifestyle groups were significantly more satisfied with the medication and with changes in weight, health, appearance, and self-esteem (*p<*0.05 for all). Women in the two lifestyle groups were significantly (*p<*0.05) more satisfied with sibutramine at months 6 and 12 than were patients treated with sibutramine alone.* *Significant reductions were observed at 12 months in TAG and LDL-cholesterol levels but systolic and DBP both increased significantly (*p<*0.05 for all).* *Increases in BP in the 13 of the 43 patients who had baseline BPs of ≥130 mmHg and/or ≥85 mmHg were of the same magnitude as those in the normotensive patients.*
Quality and comments	…

Reported harms

Apfelbaum 1999 (In Avenell HTA)	
Results	*Adverse events were reported by 96.6% of participants in the sibutramine group and 87.8% in the placebo group. Headache was the most frequent adverse event: 28.1% in the sibutramine group and 23.0% in the placebo group. Also 20.5% of*

	participants in the sibutramine group reported dry mouth, compared with 0% in the placebo group. The majority of the events were mild to moderate severity. 6.2% reported serious adverse events in the sibutramine group (potentially two being caused by treatment) and 6.8% in the placebo group. *Pulse rate increased significantly in the sibutramine group, compared with the placebo group at all time points (*p*<0.05).*
Quality and comments	…

McMahon 2000 (in Avenell HTA)	
Results	*Most adverse events reported for patients receiving sibutramine or placebo were mild to moderate in severity and transient. The most commonly reported adverse events (occurring in 10% of patients in either treatment group) are shown in Table 5. With the exception of dry mouth and constipation, incidence rates of these adverse events were similar in patients receiving sibutramine and placebo. Of patients receiving sibutramine, 20.0% (*n*=30) were discontinued from the study owing to an adverse event compared with 10.8% (*n*=8) receiving placebo (Table 5). The most common adverse event resulting in discontinuation was hypertension, reported for 5.3% (*n*=8) of patients receiving sibutramine and 1.4% (*n*=1) of patients receiving placebo. Four of the patients receiving sibutramine who were discontinued from the study owing to hypertension met the protocol-mandated criteria for discontinuation (mean increase from baseline in DBP >15 mmHg or DBP >100 mmHg at a single visit); the other four patients were discontinued from the study at an investigator's discretion. Only two patients had a DBP >100 mmHg, and none had a DBP >110 mmHg. Overall, discontinuation rates were comparable between sibutramine and placebo (Table 5).*
Quality and comments	…

Smith 2001 (In Avenell HTA)	
Results	Dry mouth occurred significantly more frequently with 10 mg (19 patients) or 15 mg (21 patients) sibutramine than with placebo (two patients; *p*<0.001). Eight serious adverse events led to early withdrawal during the double-blind phase of the study (two in each sibutramine groups and four in the placebo group).
Quality and comments	…

STORM James 2000 (In Avenell HTA) (also Hansen 2001 and Van Baak 2003)	
Results	*Eighteen patients were withdrawn because of increases in BP. The mean BP increase over 2 years was 1.4 (SD 9.3) mmHg; SBP increased by 0.1 (12.9) mmHg; DBP by 2.3 (9.4) mmHg.*
Quality and comments	…

Wadden 2001 (In Avenell HTA)	
Results	*Eight women took reduced doses of sibutramine hydrochloride because of increased BP or pulse rate, and doses were reduced in two other women because of disturbed sleep and in a third women because of reports of severe heartburn.*
Quality and comments	…

Generalisability

Apfelbaum 1999 (In Avenell HTA)	
Country and setting	France. Hospital research centre
Participants (included/excluded)	Included patients were aged 18 to 55 years, with a BMI >30 kg/m^2. Exclusion criteria encompassed the following parameters: obesity of endocrine origin, patients with type 2 diabetes mellitus who were receiving insulin or who were poorly controlled, patients with a supine DBP >100 mmHg. Also patients with medical illness, electrocardiographic or laboratory abnormalities, and patients who had unsuccessfully followed a VLED in the previous 6 months. Patients could not be more than borderline depressed on the clinical global impression scale, and were also not allowed to take any other therapies that might alter body weight or interfere with the study medication.
Recruitment	From 12 medical centres in France that had a special interest in obesity or endocrinology.
Intervention (mode and intensity)	*At baseline and every 3 months for 1 year, each participant met with a dietitian. The patients' subjective assessment of ease in complying with the dietary advice was assessed using a visual analogue scale ('easy to follow diet' to 'unable to follow diet').*
Duration of active intervention	4±1 weeks followed by 12 months double-blind.
Control (mode and intensity)	Patients were enrolled in a 4±1 week, site-specific, VLED (220–800 kcal daily) to provide substantial weight loss before randomisation. Patients who lost at least 6 kg after the VLED and still fulfilled the entry criteria entered the 12 months double-blind treatment phase of the trial. Controls received white capsules (matching sibutramine) placebo capsules, once daily in the morning.
Delivery of intervention/control (who)	Only dietitian is mentioned for the assessment of compliance with the dietary advice.
Dropout rates	32%
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed with the LOCF.

McMahon 2000 (in Avenell HTA)	
Country and setting	USA. Clinical research centre

Participants (included/excluded)	Inclusion criteria consisted of patients ≥18 years of age with a BMI between 27 and 40 kg/m^2, a diagnosis of hypertension for at least 12 months before screening, and adequate medical control of hypertension. Hypertension was to be controlled using a constant dose of a calcium channel blocker (amlodipine besylate, diltiazem hydrochloride, felodipine, etc.) for at least 60 days immediately preceding the screening visit and during the run-in period. Use of a single thiazide diuretic in addition to a calcium channel blocker for hypertension was allowed, provided that the dose of the thiazide diuretic was stable during the same period. Adequate control was defined as having a mean DBP of 95 mmHg or less during the run-in period; variations in mean DBP measured at three consecutive run-in visits and variations in individual measurements during each of these qualifying run-in visits had to be within 10 mmHg. Concomitant therapy with a single antilipidaemic agent, diuretic, or -adrenergic receptor antagonist was allowed, provided that the dose was stable for at least 60 days preceding screening. Female patients who were at least 2 years postmenopausal, had undergone surgical sterilisation, or were using adequate contraceptive measures were enrolled. All patients had to provide written informed consent and had to demonstrate compliance (by pill count) of at least 75% during the placebo run-in period. Patients were excluded if they had an elevated BP secondary to a concurrent medical condition (other than obesity), a pulse rate greater than 95 per min at baseline, or DBP greater than 95 mmHg at any run-in visit. Other exclusion criteria were a history of significant cardiac disease, endocrine abnormalities, impairment of a major organ system, convulsions, severe cerebral trauma or stroke, hypersensitivity to two or more classes of drugs, adverse reactions to central nervous system stimulants, and substance abuse within 2 years before screening. In addition, gastric surgery to reduce weight or participation in a formal weight-loss programme within 3 months before screening, previous administration of sibutramine at any time or use of another investigational drug within 30 days before this study, and concomitant therapy with other weight-loss products were reasons for exclusion. Patients were discontinued from the study if they had an increase from baseline in DBP >15 mmHg, an absolute DBP >100 mmHg, or a pulse rate of ≥105 per min at any visit.
Recruitment	Not stated.
Intervention (mode and intensity)	Clinic visits occurred every 2 weeks during the placebo run-in period and during the first 8 weeks following randomisation and then every 4 weeks during the remainder of the treatment period.
Duration of active intervention	52 weeks
Control (mode and intensity)	As above
Delivery of intervention/control (who)	Not clear
Dropout rates	47% in the sibutramine group and 45% in the placebo group.
Treatment of dropouts (return to baseline, or last measurement?)	LOCF

Smith 2001 (In Avenell HTA)	
Country and setting	UK. Primary care setting.

Participants (included/excluded)	Individuals who had not lost more than 3 kg of weight during the previous 3 months, whose obesity was not of endocrine origin, and who did not have diabetes mellitus. They had to have a seated pulse rate of 100 beats per min or lower and a seated DBP of ≤100 mmHg. Hypertensive patients were included only if the condition had been stabilised with medication for 6 months. Individuals receiving laxatives, anorectic agents, diuretics, bulking agents, antidepressants or any other medication that could alter body weight were excluded.
Recruitment	Patients identified by primary care physicians.
Intervention (mode and intensity)	
Duration of active intervention	12 months
Control (mode and intensity)	Placebo once daily for 12 months.
Delivery of intervention/control (who)	The investigator delivered dietary advice and compliance with the advice, and recorded patients' weight at each visit.
Dropout rates	Placebo (51%), sibutramine 10 mg (49%) and sibutramine 15 mg (42%)
Treatment of dropouts (return to baseline, or last measurement?)	All efficacy analyses used the LOCF.

STORM James 2000 (In Avenell HTA) (also Hansen 2001 and Van Baak 2003)	
Country and setting	Eight European specialist centres.
Participants (included/excluded)	Inclusion criteria: either sex, 17–65 years, BMI 30–45 kg/m^2, lost ≥5% initial weight in 6 month open weight reduction phase with <2 kg weight gain between months 4 and 5 or months 5 and 6; women of childbearing potential if using adequate contraception, hypertensive patients stabilised on therapy. Exclusion criteria: endocrine related obesity, recent weight changes (loss or gain >4 kg in past 3 months, specified disease e.g. myxoedema (hypothyroidism); Cushing's syndrome; diabetes mellitus; significant neurological or psychological illness such as epilepsy, schizophrenia or depression; or eating disorder such as bulimia, severe somatic disease, hepatic or renal dysfunction; a history of heart failure, ischemic heart disease, stroke, transient ischemic attacks or unstable hypertension (persistent DBP >95 mmHg or pulse rate >100 beats per min); those with significant abnormalities on ECG; patients on such drugs as anorectics, oral beta-blockers, agonists such as those used for treating asthma, steroids, thyroid preparations, or diuretics for non-hypertensive purposes
Recruitment	From local health centres and screened medically for their suitability for the trial.
Intervention (mode and intensity)	a + b: 6-month open pre-treatment weight reduction phase consisting of 10 mg sibutramine daily plus 600 kcal/day deficit plus 30 min daily extra walking plus advice on behaviour modification a: 10 mg sibutramine daily b: placebo daily *a + b: sibutramine (or placebo) increased to 15 mg if more than 1 kg weight regain occurred after pre-treatment phase or since last dose increase providing dose stable for minimum of 2 months, if further weight increases dose increased to maximum 20 mg daily, dose reduced by 5 mg each time if patient could not tolerate higher dose, activity and behavioural advice, 600 kcal/day deficit (EE=resting metabolic rate × physical activity level) consisting of 45–50% energy as carbohydrate, 30% as fat, 15–20% as protein.*
Duration of active intervention	6 months plus 18 months

Control (mode and intensity)	As seen above
Delivery of intervention/control (who)	Dietitian and physician
Dropout rates	*Dropouts: a: 59% b: 50%*
Treatment of dropouts (return to baseline, or last measurement?)	*ITT: yes for weight outcome only*

Wadden 2001 (In Avenell HTA)	
Country and setting	USA. University research clinic
Participants (included/excluded)	Women who had a BMI of 30 to 45 kg/m^2 and who were free of physical contraindications including types 1 or 2 diabetes mellitus; uncontrolled hypertension; a history of cerebrovascular, cardiovascular, kidney or liver disease; the use of medications known to affect body weight; pregnancy or lactation; a weight loss of ≥5 kg and/or the use of anorectic agents in the previous 6 months; and the use of selective serotonin reuptake inhibitors, monoamine oxidase inhibitors, or other medications contraindicated with the use of sibutramine. Additionally, contraindications were as follows: current psychotherapy; bulimia nervosa; major depression; as suggested by a score higher than 25 on the Beck Depression inventory; or other psychiatric illness that significantly disrupted daily functioning.
Recruitment	Selected from more than 300 respondents to advertisements in local newspapers.
Intervention (mode and intensity)	*The drug-alone group met with a physician. They were instructed to consume a balanced diet of 1200–1500 kcal/day with approximately 15% of energy from protein, 30% from fat and 55% from carbohydrate. They were also encouraged to gradually increase their exercise to four to five sessions per week for 30 to 40 min per session. 10 mg/day of sibutramine were given at week 0, which was increased to 15 mg/day at week 8.* *The drug-plus-lifestyle group had sibutramine delivered and had physician visits as scheduled with the drug alone group and also a weekly group lifestyle modification session (during the first 20 weeks) conducted by doctoral-level psychologists Traditional behavioural topics including stimulus control, slowing the rate of eating, social support, and cognitive restructuring were delivered.* *The combined treatment group received the same treatment as those in the drug plus lifestyle and additionally for the first 16 weeks, and they were given a 1000 kcal/day portion-controlled diet. At week 17, participants gradually decreased their consumption of liquid supplement, so that at week 20 they were prescribed a 1200–1500 kcal/day diet of conventional foods, similar to the patients in the other two conditions.*
Duration of active intervention	12 months
Control (mode and intensity)	Three treatment groups
Delivery of intervention/control (who)	Physician and doctoral level psychologists.
Dropout rates	31.6% dropped out in the drug alone group, as 23.5% in the drug-plus-lifestyle group
Treatment of dropouts (return to baseline, or last measurement?)	LOCF was used, in which patient’s body weight at the time of attrition was included at the 6- and 12-month assessments. A more conservative ITT analysis was also conducted in which participants who discontinued treatment were assumed to gain 0.3 kg/month after leaving the study.

Additional studies (not in HTA Avenell, or in 'O'Meara as 'company submission')

Weight loss

Hainer 2005	
Aim	*To reveal whether baseline BMI, and psychobehavioural and nutritional markers, were significant predictors of the change in BMI observed after 4 and 12 months in obese women enrolled in a weight reduction programme, including LED, increased physical activity, cognitive behaviour therapy and sibutramine. The impact of changes in psychobehavioural and nutritional markers observed after 4 and 12 months of treatment on BMI changes was also investigated.*
Participants	Eighty eligible participants with a mean age of 43.9±10.6 years and a mean BMI of 36.7±4.8 kg/m^2.
Intervention	*All patients were given a 5–6 MJ/day diet, with approximately 50–60% of energy from carbohydrate, 15–20% from protein and 25–30% from fat. They were advised to distribute their daily intake over four to five meals.* *All patients, regardless of their baseline physical activity level, were instructed to increase their routine daily physical activity. A 30 min walking, 5 days/week, was recommended as a minimum increase in daily physical activity* *Drug: after the double-blind, placebo controlled 4-month phase, participants received either sibutramine (10 mg/day) or placebo. Subsequently, an open phase continued until month 12, in which sibutramine was administered to all participants.*
Control	Placebo
Length of follow-up	*12 months*
Results	n=*38 in sibutramine group and* n=*42 in placebo group.* *Weight loss (SD) in the sibutramine group was significantly higher than in the placebo group: 9.0 (8.4) vs 4.9 (7.3) kg (*p*<0.001). At month 12, a significant (*p*<0.001) body weight loss vs baseline values was shown in both groups. Significant decreases in BMI and WC were also registered, although results not shown.* *No values for 5% and 10% responders were reported.*
Quality and comments	*Randomised, double-blind, placebo controlled trial. No details on randomisation, concealment method or blinding were provided.* *HTA formula used to calculate SD values.* *No values for other outcomes were reported, thus not added in meta-analysis.*
Sponsor details	*Study grants COST and IGA.*

Hauner 2004	
Aim	To evaluate, in a primary care setting, the effect of a standardised non-pharmacological treatment programme and 15 mg sibutramine or placebo on long-term weight reduction in obese participants with a BMI ≥30 and <40 kg/m^2.
Participants	The ITT population consisted of 348 participants. The mean age of the ITT population was 42.7±11.7 years and the mean height 168.3±9.1 cm. The overall mean weight was 100.5±14.8 kg and the mean BMI 35.4±3.4 kg/m^2. Weight, age, height, BMI, WC and WHR at baseline were comparable for each treatment group, and there were less males in the sibutramine than in the placebo group (21.8 vs 29.3%, *p*<0.05).

Intervention	*Educational sessions: standardised information on the treatment programme including food choice, physical activity, motivational issues and behaviour modification.* *Diet: dietary counselling based on WHO formula for energy intake. Recommendations to achieve an energy deficit of at least 500 kcal, although not greater than 1000 kcal/day.* *Physical activity: to excess energy expenditure (exceeding 1000 kcal/week) by additional physical activity, such as low to moderate brisk walking, three to five times per week, for 30 min.* *Drug: 15 mg sibutramine once daily*
Control	*Placebo*
Length of follow-up	*54 weeks continuous therapy*
Results	n=*174 in the sibutramine and* n=*174 in the placebo group.* *Mean weight change (SD) was –8.1 kg (7.74) in participants under sibutramine treatment, and –5.1 (SD 6.73) kg in participants under placebo.* *Statistically significant more participants in the sibutramine group lost more than 5% and more than 10% of their baseline weight. In the active treatment group 62.6% of the participants experienced a 5% weight loss response against 41.4% in the placebo group (*p*<0.001) and 40.8% had a greater than 10% weight loss response compared with 10.0% of the patients receiving placebo (*p*<0.001).*
Quality and comments	*Randomised, double-blind, placebo-controlled trial. Details of randomisation and concealment not given. ITT analysis performed.* *SD values calculated from 95% CI*
Sponsor details	*Knoll Deutschland GmbH*

Kaukua 2004 (In O'Meara as Rissanen 1998)	
Aim	To evaluate the effects of 12-month treatment with sibutramine 15 mg daily compared with placebo on health-related quality of life (HRQL) in obese type II diabetes patients.
Participants	Obese (BMI ≥28 kg/m^2) type 2 diabetes patients (1985) aged 25–70 years
Intervention	The partcipants were enrolled in a 2-week single-blind run-in period with a modestly hypoenergetic diet (700 kcal daily deficit) and then randomised to receive either sibutramine 15 mg (*n*=114, 60% female) or placebo (*n*=122, 58% female) once daily with the hypoenergetic diet for 12 months.
Control	Placebo once daily with a 700 kcal hypoenergetic diet for 12 months.
Length of follow-up	*12 months*
Results	*No results for weight loss in run-in phase were given.* The mean weight change was greater in the sibutramine group (–7.1 kg) than in the placebo group (–2.6 kg, *p*<0.001).
Quality and comments	*No details of randomisation were given. Single-blinded in run-in phase then double blinded for rest of the trial. No details given. No concealment was reported.* *Values for other outcomes such as glycaemic control and haemodynamic variables did not provide SD, SEM or 95% CI, and for this reason were not included in meta-analysis.*
Sponsor details	*Knoll Laboratories*

McMahon 2002	
Aim	*To investigate the effects of sibutramine 20 mg once daily or placebo on body weight in obese hypertensive patients.*
Participants	220 obese (BMI 27–40 kg/m^2), hypertensive patients. Hypertension was well controlled with an ACE inhibitor, with or without concomitant thiazide diuretic therapy

Intervention	*Initial screening phase, a 2–10 week placebo run-in period,* *Patients were randomised to a 2:1 ratio to either sibutramine or placebo treatment taken once daily with 4oz (113 g) of water. During the initial 8 weeks, patients given sibutramine had their doses increased from 5 to 20 mg per day in 5 mg increments every 2 weeks. Treatment of hypertension continued for the 52 weeks of the study.* *48.5% of the patients in the sibutramine group were on concomitant diuretics, compared with 55.4% in the placebo group.* *All participants were given general dietary advice regarding weight reduction* *After week 52, patients attended a follow-up visit within 10–14 days; those who were withdrawn early attended a follow-up visit within 10–14 days after their last study visit.*
Control	Placebo group under general dietary advice regarding weight reduction and 55.4% were under concomitant diuretics.
Length of follow-up	*52 weeks continuous treatment. 10–14 days after treatment follow-up.*
for the un-in phase. *n*=146 to the sibutramine group a d *n*=74 to the placebo group. The silbtramine group had signifi antly ($p \geq 0.05$) greater significantly ($p \geq 0.05$) greater decreases from baseline in weight-related variables at week 52 compared with the placebo group. In the ITT analysis, patients treated with sibutramine lost a mean (SD) of 4.5 (7.19) kg of their body weight, compared with a mean of 0.4 (6.03) kg in patients treated with placebo ($p \leq 0.05$). Patients in the sibutramine group had a significantly larger mean reduction (5.3 cm) in WC, compared with patients treated with placebo (1.3 cm). The treatment differences in weight loss were statistically significant ($p \leq 0.001$) at all visits from week 4 onwards. *When compared with the placebo group, the sibutramine group had significantly higher percentages of 5% responders (42.8 vs 8.3%, respectively, LOCF) and 10% responders (13.1 vs 2.8%, respectively, LOCF) ($p \leq 0.05$).*	
Quality and comments	Randomised, placebo-controlled, parallel-group comparison. Although in study design it is mentioned that study is double-blinded, in the treatment schedule only single-blinded is mentioned. Trial. No details of randomisation, or concealment method provided. *SD values used as in HTA.*
Sponsor details	*Abbott Laboratories*

McNulty 2003 (In O'Meara as Williams)	
Aim	To evaluate the effects of sibutramine (15 and 20 mg/day) on weight, metabolic control, and BP in metformin-treated obese participants with type 2 diabetes.
Participants	Participants comprised 85 men (44%) and 109 women (56%) aged 27–69 years. There were no significant differences between centres in sex distribution, age, diabetes duration, or the dosage (mean 1250 mg/day) or duration of metformin treatment. At entry, 70 participants (36%) were hypertensive according to WHO criteria, and 56 (29%) were taking anti-hypertensive treatment, with 17 (9%) receiving lipid-lowering drugs
Intervention	Patients were given each centre's standard dietary advice by a dietitian and/or specialist nurse and returned within 4 weeks for random allocation to 15 or 20 mg/day sibutramine or placebo. For tolerability reasons, patients in the 20 mg sibutramine group took 15 mg sibutramine daily for the first 2 weeks. Patients were reviewed every 4 weeks, when dietetic advice was reinforced, medication compliance checked by capsule count, and adverse events and medication changes recorded. Glycaemic control was monitored 3-monthly by fasting glucose and HbA_{1c}. Metformin dosage was adjusted if necessary, but other antidiabetic drugs were not used.
Control	Placebo once daily for 12 months
Length of follow-up	*12 months*
Results	Sixty-eight patients were assigned to 15 mg/day sibutramine, 62 to 20 mg/day sibutramine, and 64 to placebo. Placebo-treated patients showed no weight change at any time; 88% of participants (56 of 63) either gained weight or lost <5%, whereas only 12% lost ≥5%, and none lost ≥10%. With 15 mg/day sibutramine, average weight fell over 6 months to 5.3 kg (about 6%) below baseline and was then maintained throughout treatment. The 20 mg dose caused greater weight loss, averaging 8 kg (about 8%) below baseline from 8 months to the end of treatment. Significantly more sibutramine-treated participants lost ≥5% weight (46 and 65% with 15 and 20 mg, respectively), whereas 14% of participants receiving 15 mg/day and 27% of participants taking 20 mg lost ≥10%
Quality and comments	*Double-blind RCT. No details of randomisation, blinding or concealment were given. Authors state that the dropout rate is unlikely to have influenced the outcome.* *SD values calculated with HTA formula (weight).* *SD values used from other HTA studies, except for HDL-cholesterol, as SD values quite different from trial to trial in the HTA report.*
Sponsor details	*Study medication provided by Knoll Pharmaceuticals.*

Porter 2004	
Aim	To evaluate the benefit of sibutramine hydrochloride monohydrate within a weight management programme
Participants	The mean (SD) weight in the drug group was 108.2 (22.7) kg compared with 103.5 (18.5) kg in the non-drug group (p=0.05). The mean (SD) BMI (kg/m^2) in the drug group was 38.6 (7.0) compared with 36.8 (5.6) in the non-drug group (p=0.01)
Intervention	*Participants were randomised to receive sibutramine or no drug treatment, but all participants were enrolled in the Kaiser Permanente Weight Management Program (KPWMP). The KPWMP is a physician-led, multidisciplinary programme.* *Drug: participants randomised to receive sibutramine received a prescription for 10 mg of sibutramine to be taken daily. If 1.8 kg was not lost in the first 4 weeks, the dosage was increased to 15 mg daily. The dosage was not increased in the participant lost more than 4.5 kg by the 4-week visit. The dosage was decreased by 5 mg daily if significant changes in BP or heart rate occurred or if intolerable adverse events were experienced. The dosage of sibutramine could be increased to 15 mg daily at 3 or 6 months, but not after 6 months.*

Control	Group with no drug treatment although enrolled in the KPWMP, as described above.
Length of follow-up	*12 months*
Results	n=*296 in the drug group and* n=*292 in the non-drug group.* *The mean weight change (SD) from baseline to 6 months was significantly greater in the drug group –6.8 (5.7) kg compared with –3.1 (6.15) kg in the non-drug group.* *In regard to BMI category of <35 kg/m*^{2}*, the mean (SD) percentage change in weight for the drug group was –6.7 (6.8)% compared with –1.5 (4.4) % for the non-drug group; and for BMI of ≥40 the percentage change was –5.2 (4.8)% for the drug group compared with –3.1 (7.6)% for the non-drug group.* *From 6 to 12 months the mean weight change (SD) 0.5 (3.9) kg in the drug group compared with 0.6 (4.3) kg in the non-drug group.* *BMI and percentage body fat did not significantly change between 6 and 12 months.* *Significantly more patients in the drug group experienced a 5% or greater weight loss at 12 months (47.3 vs 19.1%,* p*<0.001).*
Quality and comments	*RCT, with adequate concealment method although not blinded. Randomisation was completed using a computer-generated random numbers table. Study assignments were placed in envelopes that were opened at the end of the baseline visit by the study coordinator.* *Authors mention high dropout rate, although the exact value is not mentioned in text.* *ITT analysis was performed, with missing data being replaced by data from the last available recorded visit.* *Patients had financial commitments to participate in the study. Participants paid for the AHA classes ($140) and the KPWMP ($100). Participants who completed 6 months of the study received a $50 gift cheque. Participants who completed 12 months of the study received and additional $100 gift cheque.* *HTA formula used for SD calculations* *BP and blood chemistry values were not reported at 12 months. Therefore they were not included in the meta-analysis.*
Sponsor details	*Funding obtained from Abbott Laboratories*

Redmon 2003 and Redmon 2005	
Aim	*The aim of this study was to evaluate the effects of a combination weight loss programme, using intermittent LEDs, energy-controlled meal replacement products and sibutramine, on weight loss, diabetes control and cardiovascular risk factors in overweight or obese participants with type 2 diabetes. Two-year effects were assessed in Redmon 2005.*
Participants	Sixty-one participants were randomised to treatment groups.

Intervention	*Participants in both groups received individual counselling by a registered dietitian. At baseline, each subject's basal energy requirement was calculated, and resting energy expenditure was measured. Using these data and an estimate of the subject's typical activity level, the dietitian prescribed an individualised diet that would promote a 500–1000 kcal reduction in daily energy.* *Participants in both groups also received an individualised exercise prescription that included, at a minimum, walking for 30 min three times weekly in addition to usual activity. All participants received an educational programme of dietary, exercise, and behavioural strategies to facilitate weight loss using a commercially available dietary and lifestyle modification resource.* *Participants in the combination treatment group also received: (1) 10 mg sibutramine daily with the option to increase to 15 mg daily after 6 months if BMI remained >27 kg/m^2; (2) LEDs providing 900–1300 kcal/day made up exclusively of meal replacement products (meal shakes or meal bars, 220 kcal/serving, four to six servings daily) for seven consecutive days every 2 months; and (3) between LED weeks, use of one meal replacement product and one snack bar daily (120 kcal/snack bar) to replace one usual meal and snack and thereby facilitate achievement of the goal of a 500–1000-kcal/day reduction in energy intake.*
Control	Standard treatment as described above
Length of follow-up	*2 years*
Results	n=29 *in standard therapy group and n=30 in combination therapy group.* *At 12 months, mean weight change (SD) in the standard therapy group was –0.8 (4.8) kg and in the combination group was –7.3 (7.1) kg (p<0.001).* *At 12 months, mean BMI change (SD) in the standard therapy group was –0.3 (1.6) kg/m^2, whilst in the combination therapy group the change was –2.6 (14.2) kg/m^2 (p<0.001). Decreases in fat mass and lean body mass were also significantly greater in the combination therapy group than in the standard therapy group.* *At the end of the 2 years, weight change (SD) was –4.6±5.7 kg for the combination group (p=0.001) and in the standard therapy group weight change at 2 years was –8.1±8 kg (p<0.001).* *Mean weight loss was greatest at 10 months in the combination therapy group. There was then a slow regain over the subsequent 14 months.* *Women had a significantly greater weight loss than men after 12 months of combination therapy (8.6±1.5 vs 4.7±0.9%, p=0.03).* *No analysis was performed for the patients who lost more than 5% or 10% of their weight.*
Quality and comments	*Participants were randomly assigned to either a standard therapy or combination therapy group by a single study coordinator using a random allocation schedule provided by the study statistician. The study coordinator was blinded to the randomisation schedule. Randomisation was stratified by sex.* *Meal replacement products and snack bars were provided by Slim Fast Foods Company* *Redmon 2005 data was not included in meta-analysis, as data was not complete for both combined and standard groups.*
Sponsor details	*Resources and grants from Abbott Laboratories and Slim Fast Nutrition Institute.*

Sanchez-Reyes 2004	
Aim	*To assess the effect on body weight and glycaemic control of sibutramine in combination with glibenclamide in obese Hispanic patients with type 2 diabetes.*
Participants	Obese Hispanic patients who had type 2 diabetes for which they were receiving glibenclamide monotherapy.
Intervention	Drug: 10 mg daily for 12 months Diet: 30 kcal/kg ideal body weight, with 50% of energy from carbohydrate, 30% from lipids and 20% from protein. *Physical activity: patients were advised to walk for 30 min/day.*

Control	Placebo group. Participants of placebo group were given same diet, physical activity advice and glibenclamide.
Length of follow-up	*12 months continuous treatment*
Results	*86 participants;* n*=44 for sibutramine;* n*=42 for placebo.* In the sibutramine group, mean (SD) body weight was reduced from 73.9 (10.3) kg at baseline to 69.8 (10.6) kg at month 12; BMI decreased from 29.9 (2.6) to 28.2 (2.9) kg/m^2; WC was reduced from 94.9 (8.4) to 90.8 (8.4) cm. In the placebo group, the corresponding changes were from 74.5 (10.3) kg at baseline to 73.1 (11.2) kg at 12 months; from 30.1 (2.5) to 29.5 (2.9) kg/m^2; from 94.4 (7.3) to 93.1 (8.3) cm ($p<0.05$). Patients who received sibutramine had a significant loss in mean (SD) fat mass from baseline at 12 months (23.8 [7.2] vs 19.9 [6.8] kg; $p<0.05$,), whereas the change in fat mass was not significant in patients who received placebo (25.1 [8.1] vs 23.0 [6.4] kg). There was no difference in body fat between groups at the end of the study. The proportions of 5% and 10% responders were: 59.1% (26/44) and 25.0% (11/44) in the sibutramine group, compared with 16.7% (7/42) and 4.8% (2/482) in the placebo group (p<0.05), respectively.
Quality and comments	Randomised, double-blind, placebo-controlled Trial. No details of randomisation, or concealment method provided. *Could not calculate SD for meta-analysis.*
Sponsor details	*Abbott Mexico?*

Other outcomes

Hainer 2005	
Results	*Non-significant changes were reported in SBP and DBP and heart rate. Sibutramine induced a significant decline in plasma TAG and atherogenic index. Mean reported daily energy intake decreased by 1729 kJ (23%) (*p*<0.001). Reported fat intake decreased from 62.9 to 47.7 g/d (*p*<0.001) and % energy consumed as fat declined from 32.1 to 28.0 (*p*=0.004).* *Significant changes in all Eating Inventory parameters and in the Beck Depression Inventory score were demonstrated as a result of sibutramine treatment at month 4. Restraint increased whilst disinhibition and hunger decreased. Changes in all three parameters of the Eating Inventory at month 4 were significantly more evident in the sibutramine group than in the placebo group. The change in Beck Depression Inventory score at month 4 was not different between the two groups.*
Quality and comments	…

Hauner 2004	
Results	*Blood lipids: the mean change (SD) in TC was –0.06 (0.92) mmol/l in the participants of the sibutramine group and –0.04 (0.92) mmol/l in the placebo group. For LDL-cholesterol, the change in the participants receiving sibutramine was –0.16 (0.79) mmol/l and in the participants on placebo was –0.22 (1.1) mmol/l. In regard to HDL-cholesterol, participants receiving sibutramine had a significant change by 0.14 (0.26) mmol/l vs a change by 0.1 (0.40) mmol/l in the participants of the placebo group. TAG levels changed by –0.11 (0.79) mmol/l in participants on sibutramine treatment and changed by 0.19 (2.51) mmol/l in the placebo group. Nevertheless, the change was not significant between the two groups* *SBP decreased by (mean [SD]) 2.9 (14.7) mmHg in the sibutramine group and by 1.5 (16.4) mmHg in the placebo treatment group at 54 weeks. In DBP the decrease was 0.3 (10.5) mmHg in the sibutramine group and 1.3 (9.9) mmHg in the placebo group. There was no significant difference in BP decrease between the two treatment groups.*
Quality and	…

comments	

Kaukua 2004 (in O'Meara as Rissanen 1998)	
Results	*The scores on physical functioning and Health Change increased in both groups during the study, although no significant differences were reported between the two groups. The weight loss at 12 months was correlated with the increase in the scores of physical functioning (p=0.005) and health change (p<0.001). None of the other scales on RAND-36 showed statistically significant changes.* *The mean change in SBP was 4.1 mmHg in the sibutramine group and 3.6 mmHg in the placebo group (p=0.81). The mean change in DBP was 1.7 and –0.2 mmHg in the sibutramine and placebo groups, respectively.* *In the sibutramine group the change in DBP was inversely associated with the changes in the scores of physical functioning (p=0.035), vitality (p<0.001), mental health (p<0.026), general health (p=0.048) and health change (p=0.017). On the other hand, in the placebo group, there were no associations between changes in HRQL scores and haemodynamic variables.* *When HRQL changes were examined in categories of weight loss, the scores on physical functioning and health change increased with ≥5% weight loss, but the scores on vitality and general health increased only after ≥15% weight loss.* *There was no significant change in the glycaemic control in either study group during the trial (–0.2% to 0.3%, % for* HbA_{1c}*).* *Decrease in HbA1c was associated with increases in the scores of physical functioning, general health, vitality, mental health, and health change.*
Quality and comments	…

McMahon 2002	
Results	*At week 52 mean supine DBP was 82.8 mmHg with placebo treatment compared with 85.5 mmHg under sibutramine (p=0.004) and mean supine SBP was 130.4 mmHg with placebo compared with 133.1 mmHg with sibutramine (p=0.0497). Sibutramine group had greater decreases (–0.10 mmol/l) compared with (–0.06 mmol/l). Decreases in TAG, increases in HDL-cholesterol and decreases in VLDL-cholesterol were more visible in the sibutramine group than in the placebo group (p≤0.05).* *At week 28 of treatment, all undertaking sibutramine had significant improvement in mean scores for mobility and activities of daily living (p<0.05 vs all patients receiving placebo), and sibutramine 5% and 10% responders showed improvement in mean scores for health, mobility and activities of daily living (p<0.05 vs all patients receiving placebo). At week 52, sibutramine 5% and 10% responders demonstrated significant improvement in mean scores for health and Activities of daily living; sibutramine 5% responders also demonstrated significant improvement in mean score for mobility (p<0.05) vs all patients receiving placebo).*
Quality and comments	…

McNulty 2003 (In O'Meara as Williams)	
Results	HbA_{1c} concentrations did not change significantly among the treatment groups), but it fell significantly (0.7±0.3%, *p*<0.02) in participants who lost 5–10% of weight and significantly further (1.2±0.4%, *p*< 0.0001) in those losing ≥10%. Among the sibutramine-treated patients, percentage weight loss was significantly correlated with the fall in HbA_{1c} (*r*=0.43, *p*<0.001, for the 15 mg group and *r*=0.32, *p*<0.02, for the 20 mg group), but no correlation was seen in the placebo group, where average weight was unchanged (*r*=0.5, *p*=0.73). Fasting plasma glucose similarly showed no overall differences between the three treatment groups but fell significantly by 1.8 mmol/l (*p*<0.001) in patients (sibutramine-treated only) who lost ≥10%. Fasting plasma insulin showed no significant changes with 15 mg sibutramine or placebo, but the final concentration was significantly decreased with 20 mg sibutramine compared with placebo.

	Neither TC nor LDL-cholesterol showed any significant changes in any treatment group, but HDL-cholesterol showed slight but significant rises of 0.1 mmol/l with both 15 and 20 mg sibutramine. The TC:HDL cholesterol ratio showed a slight but statistically significant fall (10%) with 15 mg sibutramine but no significant change with 20 mg sibutramine. In participants who lost ≥5 or ≥10% weight, TC:HDL cholesterol ratio also showed modest but significant falls of 8% (*p*=0.011) and 16% (*p*=0.002), respectively. TAG levels did not alter significantly with placebo or 15 mg sibutramine but fell significantly by 0.2 mmol/l (9%) with 20 mg sibutramine. In participants losing ≥5 and ≥10% weight, TAG fell significantly by 0.3 mmol/l (13%, *p*<0.01) and 0.8 mmol/l (29%, *p*<0.01), respectively.
Quality and comments	…

Porter 2004	
Results	*The mean change in TC was 0.01 (95% CI –0.07 to 0.09) mmol/l in the drug group vs 0.05 (95% CI –0.04 to 0.13) mmol/ in the non-drug group (*p*=0.38). The mean change in TAG was –0.15 mmol/l (95% CI 0.24 to –0.05 mmol/l) in the drug group compared with –0.09 mmol/l (95% CI,–0.18 to 0.008 mmol/l) (*p*=0.35).* *The mean change in HDL-lipoprotein was 0.01 (95% CI –0.01 to 0.03) mmol/l in the drug group compared with 0.01 (95% CI, –0.02 to 0.04) mmol/l in the non-drug group (*p*=0.87). The mean change in LDL-cholesterol was 0.02 (95% CI –0.04 to 0.09) mmol/l in the drug group compared with 0.07 (95% CI –0.005 to 0.14) mmol/l in the non-drug group (p=0.39).* *The mean change in glucose was –0.04 (95% CI –0.21 to 0.12) mmol/l in the drug group compared with –0.1 (95% CI –0.3 to 0.02) mmol/l in the non-drug group (*p*=0.30).* *No significant changes occurred in BP from baseline to 6 months in either group, or at 12 months. Authors did not report values for 12 months, thus we could not include them in the meta-analysis.*
Quality and comments	…

Redmon 2003 and 2005	
Results	*HbA_{1c} decreased (SD) 0.6±1.6% in the combination therapy group, but was unchanged in the standard therapy group (*p*=0.05). Absolute values at 1 year were 8.2±0.2 and 7.5±0.3% in the standard therapy and combination groups, respectively.* *For the observed range of weight change (–10 to +4 kg), there was a significant positive linear association between change in weight at 1 year and change in HbA_{1c} (*p*=0.006).* *Changes in BP, pulse rate, and fasting plasma lipids did not differ between the two groups at 12 months.* *Only changes in systolic BP were significant, and only changes in the combination group were reported at year 2.*
Quality and comments	The authors contended that any effect of weight loss to reduce BP was offset by an effect of sibutramine to increase BP.

Sanchez-Reyes 2004	
Results	The fasting glucose concentration decreased (SD) from 7.8 (29.4) to 6.3 (32.0) mmol/l (all *p*<0.001) in the sibutramine group, and from 7.8 (25.2) to 6.9 (38.3) mmol/l (*p*<0.05) in the placebo group. In the sibutramine group, mean (SD) HbA_{1c} values were 8.9 (1.2)% at baseline, 8.3 (1.1)% at 6 months and 8.3 (1.2) % at 12 months (*p*< 0.01, 6 and 12 months vs baseline). Corresponding HbA_{1c} values in the placebo group (%) were 9.0 (1.2), 9.0 (1.2) and 9.1 (1.3), respectively; there were no significant changes from baseline. At 6 and 12 months, HbA_{1c} values were significantly lower in the sibutramine group compared with the placebo group (*p*<0.05).

	Small but significant decreases in mean BP were observed throughout the trial in both groups (p<0.05). Five patients in the sibutramine group and four in the placebo group had clinically significant increases in BP (>150/110 mmHg), and one patient in the sibutramine group had a clinically significant increase in heart rate to >100 beats per min.
Quality and comments	…

Reported harms

Hainer 2005	
Results	Side effects were rare in both groups, except for dry mouth, which was more frequently reported in the sibutramine group than in the placebo (20.0 vs 5.7%, p=0.027).
Quality and comments	…

Hauner 2004	
Results	*87.8% of participants in the sibutramine treatment group experienced adverse events, and 83.5% in the placebo group. These included: back pain, bronchitis, sinusitis and gastritis. Headache, dry mouth and constipation belong to the more specific adverse event profile of sibutramine and were more frequently reported in the sibutramine group when compared with the placebo group*
Quality and comments	…

Kaukua 2004 (In O'Meara as Rissanen 1998)	
Results	*In the sibutramine group the increase in DBP was associated with negative changes in HRQL.*
Quality and comments	…

McMahon 2002	
Results	*Adverse events were reported by 96.6% of participants in the sibutramine group, and 87.8% in the placebo group. Headache was the most frequent adverse event: 28.1% in the sibutramine group and 23.0% in the placebo group. Also 20.5% of participants in the sibutramine group reported dry mouth, compared with 0% in the placebo group. The majority of the events were mild to moderate severity. 6.2% reported serious adverse events in the sibutramine group (potentially two being caused by treatment) and 6.8% in the placebo group.*
Quality and comments	…

McNulty 2003 (In O'Meara as Williams)	
Results	Individual BP responses varied widely in all three treatment groups. A few sibutramine-treated patients showed marked BP rises, but systolic and DBP also rose in some placebo-treated patients, being higher at completion than at baseline in over 40% of cases. BP changes were influenced by weight change. With 15 mg sibutramine, systolic BP did not change significantly in participants who lost ≥5 or ≥10% weight, whereas the ≥5% responders with 20 mg sibutramine showed a mean placebo-subtracted fall of 4.6±2.0 mmHg (*p* =0.053 vs all placebo participants). Placebo-treated participants who lost ≥5% weight showed a systolic decrease of 3.3±1.4 mmHg. For >5% weight loss, mean placebo-subtracted diastolic changes were 2.0±1.5 with 15 mg sibutramine (NS vs placebo, 1.5±1.0 mmHg) and –0.9±1.4 mmHg (NS vs placebo) for 20 mg sibutramine. For >10% weight loss, mean

	placebo-subtracted changes were 1.7±2.2 and 1.0±1.8 mmHg, respectively (both NS vs placebo).
Quality and comments	…

Porter 2004	
Results	*Adverse events were significantly greater for patients under sibutramine treatment. 12.5% participants discontinued treatment as a result of 43 adverse events (2.0% with constipation, 2.0% with hypertension, 1.4% with tachycardia, 1.0% with headache, 1.0% with chest pain, 0.7% with insomnia, 0.7% with dizziness, 0.7% with haemorrhoidal or rectal events, 0.7% with rash, and 4.4% with miscellaneous events.* *Thirty-three serious adverse events were reported in 30 participants in the drug group, and 21 serious adverse events were reported in 18 participants in the non-drug group.*
Quality and comments	…

Redmon 2003 and 2005	
Results	*Dry mouth and constipation were reported by some participants whilst initiating the combination therapy, although these symptoms were not severe and did not require discontinuation of treatment.*
Quality and comments	…

Sanchez-Reyes 2004	
Results	*Twenty sibutramine patients experienced 39 adverse events, including increased BP in five patients. Besides alterations in BP, the most frequently occurring adverse events in the sibutramine group were hypoglycaemia (n=4) and constipation (n=3). Eighteen patients in the placebo group experienced 27 adverse events; the most frequently occurring events were hypoglycaemia (n=5), increased BP (n=4), upper respiratory tract infection (n=4), and dizziness (n=3).*
Quality and comments	…

Generalisability

Hainer 2005	
Country and setting	Czech Republic. Weight-reduction programme in obesity management centre.
Participants (included/excluded)	Participants were excluded if any of the following diseases were present: type 1 and type 2 diabetes mellitus; endocrine diseases; peptic ulcer; uncontrolled hypertension; cardiovascular, cerebrovascular, hepatic and renal diseases; psychiatric illnesses and eating disorders. Contraindications also included lactation and pregnancy; weight change >5 kg or the use of antiobesity drugs in the previous 6 months; administration of serotonin reuptake inhibitors or monoamine oxidase inhibitors as well as medications affecting body weight or contraindicated with the use of sibutramine.
Recruitment	Recruited from the obesity outpatient clinics
Intervention (mode and intensity)	*In monthly check-ups, a physician together with a psychologist and a dietitian assessed dietary and physical activity records and encouraged modifications in lifestyle according to cognitive behavioural modification techniques.*

Duration of active intervention	After the double-blind, placebo controlled 4-month phase, participants received either sibutramine (10 mg/day) or placebo. Subsequently, an open phase continued until month 12, in which sibutramine was administered to all participants.
Control (mode and intensity)	Same as treatment intervention, although with placebo.
Delivery of intervention/control (who)	Physician, psychologist and dietitian.
Dropout rates	16.25%
Treatment of dropouts (return to baseline, or last measurement?)	Not clear

Hauner 2004	
Country and setting	Primary care setting, general practice. Cologne-Dusseldorf, Germany.
Participants (included/excluded)	Participants were included if age was between 18 and 65 years, BMI between 30 and 40 kg/m^2, stable weight during the preceding 3 months (±2 kg), motivation and willingness to reduce weight and written informed consent for participation Participants were excluded if they had renal failure (serum creatinine > 2 mg/dl), hypercholesterolaemia (>160/95 mmHg, mean of three independent measurements), type 2 diabetes mellitus, coronary heart disease (CHD), clinically significant dysrhythmia, psychiatric diseases, childbearing potential without adequate contraception or use of medication that may alter appetite.
Recruitment	Participants were recruited in 33 general practices (general practitioners and family doctor internists).
Intervention (mode and intensity)	*All participants had a total number of 11 visits to the doctor's office.* *Diet: Individual dietary counselling for the first seven days. Second dietary counselling after 3 to 6 months for weight stabilising diet, and a third individual session held at the end of the study to develop weight regain prevention strategies, after discontinuation of drug.* *Educational sessions: during the first 4 weeks for 90 min.*
Duration of active intervention	*54 weeks*
Control (mode and intensity)	…
Delivery of intervention/control (who)	Trained dietitian, general practitioners and family doctor internists.
Dropout rates	*36.6% for sibutramine* *43% for placebo*
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis on all participants with at least one follow-up visit with weight measurement. LOCF technique was employed for the final analysis.

Kaukua 2004 (In O'Meara as Rissanen 1998)	
Country and setting	Finland. University research centre
Participants (included/excluded)	Participants were eligible for the study if treated by diet alone, had a relatively stable weight (<5 kg weight change in previous 3 months), and had no nephropathy, proliferative retinopathy, exudative masculopathy, or insulin deficiency (ketonuria or fasting C-peptide <0.3 mmol/l). Participants with significant illnesses such as uncontrolled hypertension, uncompensated heart failure, symptomatic coronary disease, and renal or hepatic failure were excluded.
Recruitment	From 11 Finnish primary medical care centres.
Intervention (mode and intensity)	See weight loss table

Duration of active intervention	12 months
Control (mode and intensity)	Placebo once daily and 700 kcal/day hypoenergetic diet for 12 months
Delivery of intervention/control (who)	N/R
Dropout rates	8% for the sibutramine group 11% for the placebo group.
Treatment of dropouts (return to baseline, or last measurement?)	Analysis were carried out in the completers population and in the ITT population.

McMahon 2002	
Country and setting	USA. Clinical research centre
Participants (included/excluded)	Participants had to have a history of hypertension that was controlled for ≥60 days preceding the screening visit with a constant dose of an ACE inhibitor, with or without a thiazide diuretic. The dose and nature of the medication used to control hypertension had to have been unchanged for ≥60 days preceding the screening visit. Patients were randomised if their hypertension was well controlled at each of three qualifying consecutive run-in visits, defined as a mean supine DBP ≤95 mmHg at each qualifying visit, with an overall difference of ≤10 mmHg between visits, without changes to the dose of the ACE inhibitor or thiazide diuretic. Exclusion criteria: increased BP secondary to concurrent medical condition or drug therapy; mean supine pulse rate >95 beats per min at baseline or mean supine DBP >95 mmHg at any run-in visit; clinically significant history of cardiac disease or any clinically significant abnormal cardiac condition other than hypertension; had been previously treated with sibutramine, or had gastric surgery to decrease obesity.
Recruitment	Not stated.
Intervention (mode and intensity)	As in weight loss table.
Duration of active intervention	52 weeks
Control (mode and intensity)	Placebo group given general advice regarding weight loss and 55.4% were on concomitant diuretic treatment.
Delivery of intervention/control (who)	Not clear.
Dropout rates	43% in the sibutramine group and 51% in the placebo group.
Treatment of dropouts (return to baseline, or last measurement?)	LOCF methodology was used in the intention-to-treat patient population (first analysis). Baseline data was not carried forward. A second analysis was an observed analysis that used only the actual data recorded for a patient; and the third analysis was on data for patients who completed the study.

McNulty 2003 (In O'Meara as Williams)	
Country and setting	Twenty-one primary and secondary care centres in England, Canada, France and Belgium.

Participants (included/excluded)	Inclusion criteria: type 2 diabetes (absence of ketonuria, rapid preceding weight loss, or need for insulin treatment), diabetes duration >6 months, BMI ≥27 kg/m^2, duration of metformin treatment of 3 months to 2 years, fasting serum glucose 7.0–15.0 mmol/l and age 25–70 years. Exclusion criteria encompassed the following: current or previous evidence of ischemic heart disease, heart failure, or stroke; seated pulse rate >100 beats per min; DBP >95 mmHg; total fasting serum cholesterol >7.8 mmol/l; fasting serum TAG >5.6 mmol/l; serum creatinine >120 µmol/l; serum liver enzymes or bilirubin levels that exceeded twice the upper limit of normal; weight change of >3 kg during the preceding 3 months; malignancy; and significant neurological or psychiatric disturbances, including alcohol or drug abuse. Excluded medications (within the previous 3 months) were anorectic agents, laxatives, beta-agonists (other than inhalers), cyproheptadine, phenothiazines, anti-depressants, anti-serotoninergics, barbiturates, antipsychotics, and oral corticosteroids. Antihypertensive and lipid-lowering drugs were permitted if treatment was stable for at least 3 months. Women were excluded if they were pregnant, lactating, or of childbearing potential while not taking adequate contraceptive precautions.
Recruitment	Suitable participants were identified from review of case notes and/or computerised clinic registers.
Intervention (mode and intensity)	*See weight loss table.*
Duration of active intervention	12 months
Control (mode and intensity)	Placebo once daily for 12 months.
Delivery of intervention/control (who)	Dietary advice for 4 weeks was given by dietitian and/or specialist nurse.
Dropout rates	There were 50 patients who withdrew prematurely (19 in the 15 mg/day sibutramine group, 13 in the 20 mg/day sibutramine group and 18 in the placebo group).
Treatment of dropouts (return to baseline, or last measurement?)	Analyses, performed by the Biostatistics Section, Knoll Limited, were based on the ITT populations using the LOCF.

Porter 2004	
Country and setting	USA. University weight management programme

Participants (included/excluded)	Included individuals were ≥18 years of age, willing to enrol in the KPWMP, willing and able to give informed consent, and had a BMI of ≥30 kg/m^2. Individuals with a BMI of 27 to 29.9 kg/m^2 were eligible for enrolment only if they had one or more of the following comorbidities: diabetes mellitus with or without drug therapy, hypertension treated with drug therapy, or hyperlipidaemia treated with drug therapy. Individuals were excluded if they had taken a prescription weight loss agent within 6 months; had a history of coronary heart disease, congestive heart failure, cardiac arrhythmia, or stroke; had uncontrolled hypertension (mean BP >145/95 mmHg, or isolated mean systolic BP >160 mmHg with diastolic BP <95 mmHg, or isolated DBP >95 mmHg with SBP <145 mmHg); a mean resting heart rate of greater than 100 beats per min; or one of the contraindications to sibutramine listed in the product labelling. Other exclusions included narrow-angle glaucoma, severe renal impairment, severe hepatic dysfunction, obesity of organic origin, seizures, other medical conditions that placed them at increased medical risk by participating in the study (as determined by the study physician), previous participation in the study, participation in KPWMP or any required American heart association classed within the past 6 months, and inability to read English. Individuals were also excluded if they were pregnant, planning a pregnancy during the study, or breastfeeding. Moreover, individuals taking: selective serotonine reuptake inhibitors, St John's wort, sumatripan succinate or related agents, ergotamine tartrate, lithium, fentanyl citrate, pentazocine, meperidine hydrochloride, dextromethorphan, tryptophan and cisapride
Recruitment	Individuals enrolled in the KPWMP.
Intervention (mode and intensity)	*Participants paid $100 for the programme consisting of five monitored care visits with a prevention specialist and two weight management seminars chosen from 20 possible seminars.* *Study visits for all patients occurred at baseline and at 3, 6, 9 and 12 months.*
Duration of active intervention	*12 months*
Control (mode and intensity)	No drug treatment although also enrolled in KPWMP
Delivery of intervention/control (who)	KPWMP was delivered by a physician
Dropout rates	*Not clear*
Treatment of dropouts (return to baseline, or last measurement?)	Last available recorded visit.

Redmon 2003 and 2005	
Country and setting	USA. Weight-loss programme at University research centre.
Participants (included/excluded)	*To be included, participants were required to have: age 30–70 years, diagnosis of type 2 diabetes with HbA$_{1c}$ 7.0–10.0%, BMI 27–50 kg/m^2, stable weight for the previous 3 months, and constant doses of any oral diabetes, hypertension, and lipid medications for at least 1 month. Participants were excluded if they had: current use or use in the previous 6 months of insulin, prior use of sibutramine, use of any weight loss product or participation in any formal weight loss programme in the previous month, significant abnormality on screening tests, history of heart disease or stroke, prior bariatric surgery, lactose intolerance, and any chronic disease or therapy that would make adherence to the study protocol difficult.*
Recruitment	Not clear.

Intervention (mode and intensity)	*Participants in both groups received individual counselling by a registered dietitian. At baseline, each subject's basal energy requirement was calculated, and resting energy expenditure was measured. Using these data and an estimate of the subject's typical activity level, the dietitian prescribed an individualised diet that would promote a 500–1000 kcal reduction in daily energy.*
Duration of active intervention	12 months, with 10 mg sibutramine daily with the option to increase to 15 mg daily after 6 months if BMI remained >27 kg/m^2 and LEDs providing 900–1300 kcal for seven consecutive days every 2 months. After year 1, the standard therapy group was crossed over to combination therapy for the second year of the study. The combination therapy group continued combination therapy in the second year and therefore received 2 years continuous therapy.
Control (mode and intensity)	Intervention as described in weight loss table, although with no sibutramine.
Delivery of intervention/control (who)	Individual counselling by registered dietitian.
Dropout rates	8% At year 2 the dropout in the combination group was 23%, whilst in the standard therapy group was 14%.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be last measurement.

Sanchez-Reyes 2004	
Country and setting	Mexico. Endocrinology service, general hospital.
Participants (included/excluded)	Eligible participants were adult (age range 24–65 years) overweight or obese (BMI >27 kg/m^2) patients with type 2 diabetes who had stable fasting plasma glucose levels (<140 mg/dl) and had been receiving glibenclamide for at least 2 weeks. *Patients were excluded if they had endocrine diseases other than type 2 diabetes, uncontrolled hypertension (BP >140/90 mmHg), an autoimmune disease, ischemic heart disease, arrhythmia, or psychosis. Also excluded were those requiring medications acting on the central nervous system, cathartics, thyroid hormone replacement, or diuretics. Pregnant or lactating women were excluded.*
Recruitment	Unclear.
Intervention (mode and intensity)	All patients received individually tailored dietary advice and were counselled by a nutritionist and an endocrinologist at the monthly clinic visits. In general, it was recommended that patients adhere to a diet consisting of 30 kcal/kg IBW, with 50% of energy from carbohydrate, 30% from lipids and 20% from protein. Patients received a list of recommended foods, portions, and combinations. Patients were also advised to walk for 30 min each day.
Duration of active intervention	12 months
Control (mode and intensity)	Same as treatment group, although with placebo.
Delivery of intervention/control (who)	Physician performed medical assessment and part of monthly check. All patients received individually tailored dietary advice and were counselled by a nutritionist and an endocrinologist at the monthly clinic visits.
Dropout rates	45.5%
Treatment of dropouts (return to baseline, or last measurement?)	LOCF methodology was used.

1.7 Surgical interventions

Throughout, used data from Clegg and Maggard reviews for SDs, mean weight change etc…
Detailed evidence tables have only been done for comparative studies, and not single arm studies. We have adapted the Technology Evaluation Centre evidence tables for single arm studies, as appropriate.
We would like to acknowledge the work of the teams on both the Colquitt Cochrane review and the TEC review, as we have been able to use their detailed data extractions in our modified review.

1.7.1 Key systematic reviews and guidelines

Colquitt Cochrane Review 2005

- Types of studies
    - RCTs comparing surgical interventions with other surgical interventions.
    - RCTs, controlled clinical trials and prospective cohort studies comparing surgical interventions with non-surgical treatment (medical management or no treatment) were included as few RCTS were anticipated.
    - Short-term weight loss is common, therefore studies were only included if they reported measurements after a minimum of 1 year.
- Types of participants
    - Adults aged ≥18 years with morbid obesity defined as BMI >40 kg/m^2 or BMI >35 kg/m^2 with serious comorbid disease, in whom previous non-surgical interventions have failed. Different classifications for morbid obesity, such as percentage excess weight, were converted to BMI to confirm eligibility.
- Types of intervention
    - Comparisons of surgical procedures, performed either as open procedures or laparoscopically, including vertical banded gastroplasty, horizontal gastroplasty, gastric banding, GBP or biliopancreatic diversion.
    - Surgical procedures vs usual care (no treatment or medical management, for example VLED).
- Excluded comparisons
    - Comparisons of variations of surgical techniques rather than different procedures.
    - Jejunoileal bypass procedures: no longer recommended in Europe and the USA due to unacceptably high morbidity and mortality associated with the procedure.
- Types of outcome measures
    - Main outcome measures
    - Studies were included if they reported one or more of the following outcomes after at least 12 months follow-up: measures of weight change, fat content (for example BMI) or fat distribution (for example WHR).
    - Quality of life, ideally measured using a validated instrument.
    - Obesity related co-morbidities (for example diabetes, hypertension).

Lefevre 2005 TEC review

- Study selection
    - Full-length articles published in peer-reviewed journals in the English language between 1985 and May 2005.
- Patient population of adults with morbid obesity, as defined by: BMI >40 kg/m^2, BMI >35 kg/m^2 and at least one serious medical comorbidity, OR similar measure of defining morbid obesity (e.g. more than100% above IBW).
    - Patients treated with one of the bariatric surgical procedures of interest (i.e., open GBP, laparoscopic adjustable gastric banding, biliopancreatic diversion, long-limb GBP).

- At least 1-year follow-up (except for short term adverse events, for which this criterion did not apply)
- Reports on at least one relevant outcome: weight loss adverse effects of surgery (early morbidity/mortality of procedure, long-term adverse effects due to altered GI anatomy and physiology).
- Study design is:
    - Comparative study with one or more comparisons of interest: open GBP vs laparoscopic adjustable gastric banding, or open GBP vs biliopancreatic diversion/long-limb GBP for patients with super-obesity, and includes at least 25 evaluable patients per treatment arm;
    - OR: Single-arm study that reports on outcomes of laparoscopic adjustable gastric banding, or biliopancreatic diversion/long-limb GBP for patients with super-obesity, and includes at least 100 evaluable patients that were treated with particular procedure.
- For procedures intended for super-obese patients (biliopancreatic diversion, long-limb GBP), studies were sought for this specific population. However, due to the lack of studies that focused exclusively on this population, inclusion criteria were not limited to super-obese populations for these procedures.

Maggard 2005 meta-analysis (used for summary statistics)

- Focused on studies that assessed surgery and used a concurrent comparison group. This category included RCTs, controlled clinical trials and cohort studies. A brief scan of the literature showed that these types of studies were rare. Therefore, also elected to include case series with ten or more patients, since these studies could be used to assess adverse events and could potentially augment the efficacy data from comparative studies.

1.7.2 Surgery vs non-surgical interventions

Weight loss

Andersen 1984 (in Clegg TA Andersen 1988) RCT	
Aim	To compare the weight reducing effect of diet and gastroplasty with that of diet alone in people who were severely obese
Participants	*People who were severely obese (≥60% overweight)* *Total 57 (60 randomised) – 50 F, 7 M. Median (range) age 35 years (21 to 53 years) surgery+diet (n=27), 33 years (18 to 53 years) diet (n=30). Median (range) body weight 120 kg (94 to 166 kg) surgery+diet, 115 kg (98 to 206 kg).*
Intervention	*Surgery: gastroplasty (Gomez method)* *Diet (500 kcal, 34 g protein): started on seventh day after surgery. Five daily meals of 50 g each and 2l of low-energy drinks (in 50 ml portions) between meals. Food endangering stoma passage were avoided. Vitamin and mineral supplements were also given.* *Other: received 'careful' verbal and written instructions before start of treatment. Seen at weekly intervals initially, then every 2 weeks after three months.* In the long term (up to 5 years), if weight was regained, advised to return to previously prescribed diets. *After cessation of the primary weight loss, invited to a weekly open-house session.*

Comparison	Two alternating diets used. Diet (341 kcal, 35 g protein): For 8 weeks, special formula taken with orange juice, vitamin and mineral supplement (as above) and 3 g potassium chloride. Diet (900 kcal): From 2 weeks, natural high-protein, low-fat, low-carbohydrate foods. Allowed to take diethylpropion (reduces appetite) maximum 35 mg three times per day, but urged to do so only if hunger prevented compliance with the diet. Diets stopped when failed to lose weight for 2 months. Other: received 'careful' verbal and written instructions before start of treatment. Seen at weekly intervals initially, then every 2 weeks after three months. Also included visits to outpatient clinics and groups meetings. Group meetings were to repeat and elaborate the instructions, to discuss diet experiences, and to offer support in case of faltering compliance. After cessation of weight loss, participants seen for dietetic counselling every three months. In the long term (up to 5 years), if weight was regained, advised to return to previously prescribed diets. After cessation of the primary weight loss, invited to a weekly open-house session.
Length of follow-up	*5 to 6 years*
Results	At 3 months, mean weight change (SD) was –20.0 (no SD) kg in the surgery group compared with –15.0 (no SD) kg in the diet group ($p<0.05$). At 6 months, mean weight change (SD) was –25.0 (no SD) kg in the surgery group compared with –21.0 (no SD) kg in the diet group (p=NS). At 12 months, mean weight change (SD) was –22.0 (15.5) kg in the surgery group compared with –18.0 (15.5) kg in the diet group. Mean weight change in the surgery group compared with diet was –4.0 (95% CI –12.2 to 4.2). At 18 months, mean weight change (SD) was –18.5 (no SD) kg in the surgery group compared with –10.5 (no SD) kg in the diet group (p=NS). At 24 months, mean weight change (SD) was –30.5 (20.3) kg in the surgery group compared with –8.0 (20.3) kg in the diet group. Mean weight change in the surgery group compared with diet was –3.50 (95% CI –38.2 to –6.9). The median (range) time to maximum weight loss was 9 months (3 to 24 months) in the surgery group and 9 months (3 to 21 months) in the diet group (p=NS). Median maximum weight change was –26.1 kg in the surgery group and –22.0 kg in the diet group (p=NS). Median weight regain in the surgery group at 12 months was +10 kg compared with +12.5 kg in the diet group (p=NS). At 18 months, the diet group had regained significantly more weight than the surgery group (+21.5 vs +10 kg, respectively, $p<0.05$). At 5 years, 30 (95% CI 14 to 50) % of the surgery group had achieved weight loss of 10 kg or more compared with 17 (95% CI 6 to 35) %. Median weight change in those who had lost ≥10 kg did not differ between groups (–18.2 vs –26.8 kg, p=NS). Cumulative success rate was higher in the surgery group (16 vs 3%, respectively, $p<0.05$). *Excess weight not reported.*
Quality and comments	*During the study period, two diet only participants had gastroplasty elsewhere after having regained all weight lost.* From CR 2005: randomisation and concealment unclear. ITT not done. Blinded assessment not done. *Some discrepancies in reviews and original papers.* *Sugerman: horizontal, unbanded Gp is a flawed operation, and is no longer performed.*
Sponsor details	*Foundation grants. Formula and supplements provided by Oluf Mork Bio-Chemie.*

Mingrone 2002 RCT	
Aim	To investigate the consequence of weight reduction treatment in the modification of CHD risk in severely obese people.

Participants	People who were severely obese (not defined?). Total 79 – 52F, 27M. Aged 30 to 45 years (not reported by group). Mean (SD) weight 125.3 (12.8) kg surgery F (*n*=31), 151.8 (17.1) kg surgery M (*n*=15), 121.6 (24.1) kg diet F (n=21), 147.3 (26.8) kg diet M (*n*=12).
Intervention	*Surgery: biliopancreatic diversion.*
Comparison	Diet: 20 kcal/kg FFM, 55% carbohydrate, 30% fat, 15% protein. Modified 6 monthly in line with DEXA FFM.
Length of follow-up	*12 months*
Results	Women: At 12 months, mean weight change (SD) was –35.1 (no SD) kg in the surgery group compared with –7.1 (no SD) kg in the diet group (no *p* value). Men: At 12 months, mean weight change (SD) was –52.1 (no SD) kg in the surgery group compared with –9.1 (no SD) kg in the diet group (no *p* value). Changes in the surgery group for both women and men were significantly different from baseline (*p*<0.0001), and changes in the diet were not significant. *Excess weight not reported.*
Quality and comments	*Not sure how comparable the groups were – no baseline comparison.* From CR 2005: randomisation and concealment unclear. ITT and blinded assessment unclear.
Sponsor details	*None reported.*

SOS Matched control cohort study (in Clegg TA)	
Aim	To examine the effects of weight loss in people with severe obesity
Participants	Obese (BMI ≥34 kg/m^2 for men, ≥38 kg/m^2 for women) adults *Total – sample size differs with publication of different outcomes.* *Weight loss/diabetes/BP (at 8 years):* *Number: total 483, surgical 251, control 232* *Age (mean): surgical 46 (SD 6) years, Control 47 (SD 6) years.* *Sex: Surgical 65.9% female, Control 65.9% female.* *BMI: Surgical 41.6 (SD 3.9) kg/m*^{2}*, Control BMI 41 (SD 4.7) kg/m*^{2}*.* *HRQL:* *Number: total 974, surgical 487, control 487* *Age (mean): surgical 46.6 (95% CI 46.1 to 47.1) years, control 47.7 (95% CI 47.2 to 48.3) years.* *Sex: surgical 67% female, control 67% female.* *Lipid disturbances:* *Number: total 1479, surgical 767, control 712* *Age: surgical 47 (SD 5.8) years, control 48.6 (SD 6.3) years.* *Sex: surgical 69% female, control 68% female.* *BMI: surgical BMI 42.1 (SD 4.3) kg/m*^{2}*, control 39.8 (SD 4.6) kg/m*^{2}*.* *Gallstones, gallbladder disease and pancreatitis:* *Number: total 2682, surgical 1422, control 1260.* *Age, men: surgical 47.3 (5.7) years, controls 48.4 (6.1) years,* p*=0.005; women: surgical 47.1 (5.9) years, controls 48.3 (6.3) years,* p*<0.001.* *Sex (M:F): surgical 468:954, controls 418:842.* *BMI, men: surgery 41.2 (4.7) kg/m*^{2}*, control 38.8 (4.7)* kg/m^2, p*<0.001; Women: surgery 42.8 (4.1) kg/m*^{2}*, controls 40.6 (4.4) kg/m*^{2}*,* p*<0.001.* *Medication use:* *Number: total 965, surgery 510, control 455.* *Mean age: surgery 47.1 (5.8) years, control 48.6 (6.1) years.* *Sex, % of men: surgery 31.0, control 31.0.* *Mean BMI: surgery 41.8 (4.1)* kg/m^2*, control 39.9 (4.6)* kg/m^2. *Medication for CVD (%): surgery 29.4, control 27.5* *Diabetes: surgery 6.3, control 4.6.*

Intervention	*Surgery: vertical banded gastroplasty or gastric banding or GBP.* *Other: customary obesity treatment of the site at which the surgery was performed.*
Comparison	Conventional treatment: customary obesity treatment of the site at which registered. Ranged from sophisticated lifestyle and behavioural interventions, to no treatment.
Length of follow-up	*Differs with publication of different outcomes. Details reported by outcome.*
Results	Weight (kg), surgical (*n*=1210) vs control (*n*=1099): Baseline: difference 7 kg (95% CI 5.7 to 8.3) kg. 24 months: difference –21 kg (95% CI –23 to –19) kg. Weight loss after 24 months: Surgical 28 kg (23%), control unchanged, *p*<0.001. Weight changes at 8 years (surgical n=232, control n=251): Baseline: surgical 120.4 (SD 16.0) kg, control 114.7 (SD 17.8) kg. 8 years: surgical 100.3 (SD 17.8) kg, control 115.4 (SD 19.2) kg. Difference in weight change between groups at 8 years: 20.7 kg (*p*<0.001). Relative weight change at 8 years: surgical =–16.3 (SD 12.3)%, control =0.9 (SD 10.8)%. Weight at 8 years: GBP 92 kg vs vertical banded gastroplasty 100 kg (*p*=NS) vs gastric banding Weight loss at 2 years for subgroup with biliary disease data: Men: surgery 29.4 (15.3) kg, 21.9 (10.0) %, controls 0.3 (9.5) kg, 0.1 (7.4) %, *p*<0.001. Women: surgery 28.0 (13.8) kg, 23.9 (10.7)%, controls 0.6 (8.6) kg, 0.3 (7.9) %, *p*<0.001. Relative weight change, mean (SD) for subgroup with medication data: 2 years: surgery –22.6 (10.6)%, control –0.3 (7.9)%. 6 years: surgery –16.2 (11.5)%, control 0.8 (9.6)%. At 24 months, mean weight change (SD) was –28.0 (15.0) kg in the surgery group compared with 0.5 (8.9) kg in the non-surgery group. Mean weight change in the surgery group compared with non-surgery was –28.50 (95% CI –29.75 to –27.25) kg. At 8 years, mean weight change (SD) was –20.0 (16.0) kg in the surgery group compared with 0.7 (12.0) kg in the non-surgery group. Mean weight change in the surgery group compared with non-surgery was –20.70 (95% CI –23.21 to –18.19) kg. At 10 years, mean % weight change (SD) was –16.1% (no SD reported) in the surgery group compared with +1.6% (12) in the non-surgery group. Difference was –16.3 (95% CI –17.6 to –14.9) kg. The fractions of participants who, after completing 10 years of the study, had a loss of less than 5% of their initial weight were 72.7% (control group), 8.8% (GBP subgroup), 13.8% (vertical banded gastroplasty subgroup), and 25.0% (banding subgroup). The fractions of participants achieving 20% weight loss or more over the 10-year period were 3.8% (control group), 73.5% (GBP subgroup), 35.2% (vertical banded gastroplasty subgroup), and 27.6% (banding subgroup). Excess weight not reported.

Quality and comments	From CR 2005: baseline differences between groups including for confounders (but these were adjusted for). Unclear as to whether groups comparable for disease progression. Outcome assessment not blinded. Dropouts and reasons unclear. At inclusion, surgical group were younger than controls ($p<0.001$), had a higher prevalence of hypertension ($p<0.05$) and were more often smokers (not significant). Also reports higher BMI ($p<0.001$), BP ($p<0.001$) and energy intake ($p<0.001$) in surgical patients. Added weight loss data from Sjostrom 2004 for 10-year time point
Sponsor details	*Swedish Medical Research Council. Hoffman-La Roche. Others including Volvo Research Foundation, Skandia Insurance.*

Other outcomes

Andersen 1984 (in Clegg TA Andersen 1988) RCT	
Results	*None reported.*
Quality and comments	…

Mingrone 2002 RCT	
Results	*No significant changes were seen in the diet groups for ratios of TC:HDL, or levels of TC, HDL, LDL, TAG, or glucose (FPG?).* *Significant improvements were seen for women in TC:HDL (–2.0,* $p<0.01$*), TC (–0.88 mmol/l,* $p<0.0001$*), LDL (–0.74 mmol/l,* $p<0.01$*) and TAG (–0.5 g/l,* $p<0.0001$*).* *Significant improvements were seen for men in TC:HDL (–3.7,* $p<0.0001$*), TC (–1.78 mmol/l,* $p<0.0001$*), HDL (+0.68 mmol/l,* $p<0.0001$*), LDL (–2.04 mmol/l,* $p<0.0001$*), and TAG (–1.33g/l,* $p<0.0001$*), and glucose (–1.41mmol/l,* $p<0.01$*).*
Quality and comments	…

SOS Matched control cohort study (in Clegg TA)	
Results	HRQL (mean; 95% CI): Current health perception: 'general health rating index/current health scale ' Baseline: surgery 26.9 (26.1 to 27.7); control 29.4 (28.5 to 30.2). 2 years: surgery 34.3 (33.4 to 35.1); control 30.2 (29.4 to 31.1). Psychosocial functioning – 'obesity-related psychological problems': Change by 2 years (mean, 95% CI): Surgery males –1.01 (–1.14 to –0.87), females –1.10 (–1.19 to –1.00); Control males –0.07 (–0.17 to 0.03) (p=0.001); females –0.16 (–0.22 to –0.09) ($p=0.001$). 'Sickness impact profile/social interaction' Change by 2 years (mean, 95% CI): Surgery males –3.3 (–5.0 to –1.5), females –5.2 (–6.5 to –4.0); Control males 1.5 (0.2 to 3.2) ($p=0.001$); females 1.2 (0.2 to 2.2) ($p=0.0001$). Mental well-being scales – 'mood adjective checklist': Change by 2 years (mean, 95% CI): Pleasantness/unpleasantness: surgery 0.21 (0.16 to 0.26); control –0.04 (–0.09 to 0.01) ($p=0.001$); Activation/deactivation: surgery 0.32 (0.27,0.37); control 0.00 (–0.04 to 0.05) ($p=0.001$); Calmness/tension: surgery 0.20 (0.15,0.26); control –0.01 (–0.06 to 0.04) ($p=0.001$). Hospital Anxiety and Depression scale

Change by 2 years (mean, 95% CI):
Anxiety: surgery –1.7 (–2.0 to –1.4); control –0.6 (–0.9 to –0.2) (*p*=0.0001);
Depression: surgery –2.2 (–2.5 to –1.9); control –0.4 (–0.6 to–0.1) (*p*=0.0001);
At 24 months: improvement in surgical vs controls on all HQRL measures (*p*<0.0001).
Changes in all HRQL measures significantly related to magnitude of weight loss.

Type 2 diabetes:
2-year unadjusted incidence: controls 4.7%, surgical 0.0% (*p*=0.0012).
8-year unadjusted incidence: controls 18.5%, surgical 3.6% (*p*=0.0001).
Adjusted odds ratios of developing diabetes, 8 years:
Completers (*n*=437) 0.17 (95% CI 0.08 to 0.38).
All (ITT) (*n*=611) 0.16 (95% CI 0.07 to 0.36).

Hypertension:
2-year unadjusted incidence: controls 9.9%, surgical 3.2% (*p*=0.032).
8 year unadjusted incidence controls 25.8%, surgical 26.4% (*p*=0.91).
Adjusted odds ratios of developing hypertension, 24 months:
Completers (*n*=257) 0.27 (95% CI 0.07 to 0.99).
All (ITT) (*n*=377) 0.27 (95% CI 0.09 to 0.76)
Adjusted odds ratios of developing hypertension, 8 years:
Completers (n=257) 1.05 (95% CI 0.58 to 1.89).
All (ITT) (n=377) 1.01 (95% CI 0.61 to 1.67).

Lipids:
Adjusted odds ratios at 24 months (95% CI):
Hypertriglyceridaemia 0.10 (0.04 to 0.25), *p*<0.001.
Hypo HDL-cholesterolaemia 0.28 (0.16 to 0.49), *p*<0.001.
Hypercholesterolaemia 1.24 (0.84 to 1.8), *p*=NS.
Relative risks for recovery from disease:
Hyperinsulinaemia (n=221) 1.4 (1.2 to 1.7), *p*<0.00001.
Hypertriglyceridaemia (n=314) 1.9 (1.5 to 2.4), *p*<0.00001.
Hypo HDL-cholesterolaemia (n=216) 1.7 (1.4 to 2.1), *p*<0.00001.
Hypercholesterolaemia (n=531) 1.2 (0.95 to 1.5), *p*=NS.

Biliary disease and pancreatitis; frequencies over 2 years (%), Fisher's exact test and odds ratios (OR) (95% CI) adjusted for age and BMI at baseline:
Cholelithiasis, men: surgery 4.0, controls 1.2, *p*=0.011, OR 4.2 (1.5 to 12.0); women: surgery 5.5, controls 4.5, p=0.328, OR 1.1 (0.7 to 1.8).
Cholecystitis, men: surgery 2.5, controls 0.7, *p*=0.058, OR 4.5 (1.2 to 17.1); women: surgery 3.3, controls 2.5, p=0.379, OR 1.4 (0.7, 2.5).
Cholecystectomy, men: surgery 3.4, controls 0.7, *p*=0.008, OR 5.4 (1.5 to 19.6); women: surgery 3.5, controls 2.3, *p*=0.191, OR 1.6 (0.9, 3.0).
Total biliary disease, men: surgery 4.1, controls 1.5, *p*=0.024, OR 3.5 (1.3 to 9.2); women: surgery 6.8, controls 5.3, *p*=0.223, OR 1.2 (0.8, 1.9).
Pancreatitis, men: surgery 1.1, controls 0.2, *p*=0.219, OR 3.6 (0.4 to 31.2); women: surgery 0.7, controls 0.4, *p*=0.514, OR 1.8 (0.4 to 7.6).

Proportion on CVD medication, risk ratio (95% CI adjusted to mean values of sex, age and BMI at baseline):
Participants on medication at baseline, *n*: surgery 150, control 125.
Proportion on medication at:
2 years, %: surgery 61.7, control 91.2, RR 0.69 (0.60 to 0.80), *p*<0.05.
6 years, %: surgery 64.7, control 86.4, RR 0.77 (0.67 to 0.88), *p*<0.05.
Participants not on medication at baseline, *n*: surgery 360, control 330.
Proportion on medication at:
2 years, %: surgery 3.1, control 10.1, RR 0.28 (0.14 to 0.56), *p*<0.05.
6 years, %: surgery 13.3, control 16.7, RR 0.80 (0.56 to 1.16).

Proportion on diabetes medication, risk ratio (95% CI adjusted to mean values of

	sex, age, and BMI at baseline): Participants on medication at baseline, *n*: surgery 32, control 21. Proportion on medication at: 2 years, %: surgery 56.2, control 100.0, RR 0.56 (0.41 to 0.76), *p*<0.05. 6 years, %: surgery 68.8, control 100.0, RR 0.71 (0.56 to 0.89), *p*<0.05. Participants not on medication at baseline, *n*: surgery 478, control 434. Proportion on medication at: 2 years, %: surgery 0.2, control 3.7, RR 0.08 (0.01 to 0.58), *p*<0.05. 6 years, %: surgery 2.1, control 11.3, RR 0.20 (0.10 to 0.38), *p*<0.05. At 10 years, mean energy intake at the time of inclusion in the intervention study was 2882 kcal/ day among the surgically treated participants, as compared with 2526 kcal/day among the controls. The baseline adjusted energy intake was significantly lower in the surgery group than in the control group over the 10-year period (–20.7 vs –1.0%, *p*<0.001). Similarly, the fraction of participants physically active during leisure time was higher in the surgery group over the 10-year period, and the fraction of those physically active during work time was higher in the surgery group for the first 6 years of the intervention. *The WC was reduced more in the surgery group than in the control group after 10 years (–10.1 vs 2.8%,* p*<0.001). Glucose and insulin levels increased in the control group (+18.7 and +12.3%), whereas substantial decreases were seen in the surgically treated group after 10 years of observation (–2.5 and –28.2%,* p*<0.001 compared with control for both outcomes). Similarly, changes in uric acid, TAG and HDL-cholesterol levels were more favourable in the surgically treated group than in the control group 10 years. SBP was not significantly different at 10 years (0.5 vs +4.4%,* p*=NS). DBP (–2.6 vs –2.0%,* p*<0.001) and TC (–5.4 vs –6.0%,* p*<0.05) were reduced by more in the surgery group than in the control group after 10 years. The pulse-pressure increase was less pronounced in the surgery group than in the control group after 10 years (+10.8 vs +18.0%,* p*<0.05).* *The incidence rates of hypertriglyceridaemia (OR 0.61,* p*=0.03), diabetes (OR 0.25,* p*<0.001), and hyperuricaemia (OR 0.49,* p*<0.001) were markedly lower in the surgically treated group than in the control group 10 years. The incidence of low HDL-cholesterol was not significantly different in the surgical group after 10 years. The incidence of hypertension and hypercholesterolaemia did not differ between the groups over 10-year periods.* *Recovery from hypertension (OR 1.68,* p*=0.02), diabetes (OR 3.45,* p*=0.001), hypertriglyceridaemia (OR 2.57,* p*<0.001), a low HDL-cholesterol level (OR 2.35,* p*=0.001), and hyperuricaemia (OR 2.37,* p*<0.001) was more frequent in the surgical group than in the control group at 10 years. The rates of recovery from hypercholesterolemia did not differ between the two groups after 10 years.*
Quality and comments	…

Complications

Andersen 1984 (in Clegg TA Andersen 1988) RCT	
Harms	*No surgery participants needed to be re-operated.* *Perioperative complications (gastroplasty only,* n*=27): subphrenic abscess 7%; atelectasis/pneumonia 4%; wound infection 4%.* *Later complications (gastroplasty [*n*=27] vs VLED [n=30]): thrombophlebitis (4 vs 0%); nausea (15 vs 7%); heartburn (11 vs 0%); ructus (1 vs 0%); pain projected to left shoulder (15 vs 0%); epigastric pain (22 vs 10%); outlet obstruction (4 vs 0%); vomiting (52 vs 0%,* p*<0.05); cholesystectomy (7 vs 0%); obstipation (26 vs 13%); orthostatic hypotension (7 vs 27%); dizziness (7 vs 17%); transient loss of hair (15 vs 10%); headache (11 vs 17%); fatigue (30 vs 53%); irritability and low spirits (0 vs 33%,* p*<0.05); gout (0 vs 3%); staple line rupture (4 vs 0%), ventral hernia (4 vs 0%); abortion (4 vs 0%).*

	Two (6%) VLED patients had gastroplasty elsewhere having regained all weight lost on diet.
Quality and comments	…

Mingrone 2002 RCT	
Harms	None reported.
Quality and comments	…

SOS Matched control cohort study (in Clegg TA)	
Harms	*Postoperative mortality (at 8 years): four (0.2%) deaths, three due to leakage detected too late and one due to a technical laparoscopic mistake.* *Perioperative complications: 13% experienced complications. Bleeding 0.9%, thrombo-embolic events 0.8%, wound complications 1.8%, abdominal infection 2.1%, pulmonary symptoms 6.2%, miscellaneous 4.8%.* *Re-operation: 2.2%.* At 10 years, five of the 2010 participants who underwent surgery (0.25%) died postoperatively.
Quality and comments	…

Generalisability

Andersen 1984 (in Clegg TA Andersen 1988) RCT	
Country and setting	Denmark. Hospital obesity clinic.
Participants (included/excluded)	*Included consecutive patients referred for surgery assessed for eligibility and asked for consent.* *Excluded if less than 60% overweight (three), not aged between 18–54 years (14), not attempted previous treatments (three), chronic bronchitis (one), alcohol or drugs abuse (six), ongoing obesity treatment (two), unwillingness to co-operate or occupational or geographic factors impeding participation (21). Of 78 eligible, 11 refused surgical and three refused non-surgical treatment, four dropped out before random assignment, two refused after random assignment to gastroplasty, gastroplasty could not be performed in one patient due to hepatomegly.*
Recruitment	From participants referred for surgery.
Randomisation	No details.
Intervention (mode and intensity)	*Seen at weekly intervals initially, then every 2 weeks after 3 months. Also invited to weekly meetings after cessation of weight loss.*
Comparison (mode and intensity)	Seen at weekly intervals initially, then every 2 weeks after 3 months. Also invited to weekly meetings after cessation of weight loss.
Delivery of intervention/comparison (who)	Group meetings lead by clinical dietitians.
Dropout rates	*2% surgery and 2% diet in 2-year study. Further 2% from surgery during 5 years follow-up.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only?

Mingrone 2002 RCT	
Country and setting	Italy. No details.

Participants (included/excluded)	Included if aged 30 to 45 years. Excluded if pregnant; history or diagnosis of diabetes, heart disease, hypertension, or other chronic diseases; hormone replacement therapy; chronic steroid therapy; a history of alcohol or drug abuse; and glucose intolerance, defined as a 2 h glucose level of >140 mg/dl after a 75 g oral glucose load and of stable weight (within ±2 kg, 6 months before testing).
Recruitment	N/R
Randomisation	N/R
Intervention (mode and intensity)	N/R
Comparison (mode and intensity)	N/R
Delivery of intervention/comparison (who)	N/R
Dropout rates	*0% overall*
Treatment of dropouts (return to baseline, or last measurement?)	No dropouts and no crossing assumed.

SOS Matched control cohort study (in Clegg TA)	
Country and setting	Sweden. Multi-centre, primary care-based.
Participants (included/excluded)	Included if aged 37–60 years, BMI 38 kg/m^2 for women and 34 kg/m^2 for men. Excluded if previous bariatric surgery, gastric surgery for other causes in last 6 years, serious health problems including active malignancy and recent MI, bulimic eating pattern, drug or alcohol abuse, psychological problems likely to lead to poor co-operation, regular use of cortisone or NSAIDs.
Recruitment	Recruited through mass media and primary healthcare centres, and participants could volunteer for conventional or surgical treatment.
Randomisation	N/A
Intervention (mode and intensity)	*Varied.*
Comparison (mode and intensity)	Varied.
Delivery of intervention/comparison (who)	Varied – care provided by registered centre. No details.
Dropout rates	*27% surgical, 33% control at 8 years. 25% surgical, 26% control at 10 years.*
Treatment of dropouts (return to baseline, or last measurement?)	**Not sure of follow-up values?

1.7.3 Restrictive surgery

1.7.3.1 Laparoscopic (adjustable) gastric banding vs GBP

Comparative studies

Weight loss

Biertho 2003 (in TEC) case control	
Aim	To compare the results of laparoscopic (adjustable) gastric banding (LAGB) and laparoscopic GBP.
Participants	Adults undergoing bariatric surgery Total 1261 – 997 F, 264 M. Mean (SD) age 41.7 (10.9) years LAGB (*n*=805), 40.2 (10.5) years laparoscopic GBP (*n*=456). Mean (SD) BMI (kg/m^2) 42.2 (4.9) LAGB, 49.4 (8.3) laparoscopic GBP.
Intervention	*Surgery: LAGB* *After the operation, followed in an outpatient clinic every 2 months for the first year, and then every 3 months for the following years. The gastric band was slowly inflated. Patients were evaluated every 3 months, and no inflation was done if a 1 kg weight loss had been noted in the past 3 months.*
Comparison	Surgery: Laparoscopic GBP After the operation, followed in an outpatient clinic every 3 months for the first year, and then every 6 months for the following years.
Length of follow-up	*18 months for key outcomes but TEC reported follow-up of 36.9 months?*
Results	% Excess weight loss (EWL)

Month	***3***	***5***	***12***	***18***
LAGB	*15*	*22*	*33*	*40*
Laparoscopic GBP	*36*	*52*	*67*	*75*

The EWL for patients in the laparoscopic GBP vs LABG groups at 12 months was 75 vs 37%, respectively, for patients with a BMI between 30 and 40 kg/m^2; 81 vs 40%, respectively, at 18 months for patients with a BMI between 40 and 50 kg/m2; and 69% vs 33%, respectively, at 18 months for patients with a BMI between 50 and 60 kg/m^2.

The weight loss analysis also showed an inverse correlation between preoperative weight and EWL: the heavier the patient, the smaller the EWL. This is illustrated by the inferior EWL for patients with a BMI between 50 and 60 kg/m^2 (69% in the bypass group and 33% in the LAGB group after 18 months) compared with patients with a BMI between 40 and 50 kg/m^2 (81 and 40%).

*In the laparoscopic GBP group, a super-super-obese group (BMI >60 kg/m^2) was available for analysis (*n*=40). In this group, the EWL was 36.1% at 3 months (*n*=35, 87.5%), 51.7% at 6 months (*n*=24, 60%), and 66.9% at 12 months (*n*=14, 35%).*

Quality and comments	*LGB group were significantly heavier than the LAGB group (135.4±26.3 kg vs 117±17.1 kg,* p*=0.0001). This difference was also expressed by a higher preoperative BMI (49.4±8.3 vs 42.2±4.9 kg/m^2,* p*=0.0001).* *Assessed by TEC: operations carried out in two different institutions in different countries, follow-up not reported, details of care not reported, ITT not done. Poor.*
Sponsor details	*N/R*

<table>
<tr><th colspan="2">Weber 2004 (in TEC) case control</th></tr>
<tr><td>Aim</td><td>To define whether LAGB or laparoscopic Roux-en-Y GBP (LGBP) represents the better approach to treat patients with morbid obesity.</td></tr>
<tr><td>Participants</td><td>Adults undergoing bariatric surgery at one institution.
Total 206 – 168 F, 38 M. Mean (SD) age 39.6 (10.1) years LAGB (n=103), 40.1 (9.9) years LGBP (n=103). Mean (SD) BMI (kg/m^2) 48.0 (6.3) LAGB, 47.8 (6.1) LGBP.
Excess (SD) weight (kg) 73.0 (17.9) LAGB, 72.3 (17.6) LGBP.</td></tr>
<tr><td>Intervention</td><td>*Surgery: LAGB*</td></tr>
<tr><td>Comparison</td><td>Surgery: LGBP</td></tr>
<tr><td>Length of follow-up</td><td>*24 months*</td></tr>
<tr><td>Results</td><td>Weight loss was significantly different between both groups in favour of the bypass procedure. Already after 1 month and thereafter at every time point of follow-up, 3, 6, 9, 12, 18 and 24 months, BMI values differed significantly between the groups ($p<0.02$, range <0.001–0.012).
<table>
<tr><th>Months</th><th>0</th><th>1</th><th>3</th><th>6</th><th>9</th><th>12</th><th>18</th><th>24</th></tr>
<tr><td>LAGB</td><td>48.0</td><td>46.0</td><td>43.6</td><td>42.0</td><td>40.1</td><td>39.0</td><td>36.7</td><td>36.8</td></tr>
<tr><td>LGBP</td><td>47.8</td><td>43.7</td><td>39.3</td><td>36.2</td><td>33.8</td><td>33.1</td><td>33.2</td><td>31.9</td></tr>
</table>
The mean BMI decreased in the bypass group from 47.8 to 31.9 kg/m^2, whereas in the banding group the decrease was from 48.0 to 36.8 kg/m^2.

Regarding % excessive weight loss, similar findings with a significant difference at every time point of follow-up favouring the bypass procedure were seen.
<table>
<tr><th>Months</th><th>0</th><th>1</th><th>3</th><th>6</th><th>9</th><th>12</th><th>18</th><th>24</th></tr>
<tr><td>LAGB</td><td>0</td><td>8.2</td><td>16.4</td><td>24.9</td><td>30.7</td><td>35.1</td><td>41.9</td><td>42.1</td></tr>
<tr><td>LGBP</td><td>0</td><td>15.0</td><td>32.8</td><td>44.0</td><td>52.0</td><td>54.8</td><td>55.0</td><td>54.0</td></tr>
</table>
*The %EWL after 24 months was 54.0% in the LAGB group vs 42.1% in the LGBP group (*p*<0.05, range <0.001–0.043). After 12 months, body composition was routinely measured with an impedance analysis showing a mean fat mass loss of 38.8% for the bypass group vs 26.6% for the banding patients (*p*<0.001).*</td></tr>
<tr><td>Quality and comments</td><td>*First 50 patients with LAGB or LGBP were excluded to avoid a learning curve bias. Assessed by TEC: details of follow-up not reported. ITT not done. Fair.*</td></tr>
<tr><td>Sponsor details</td><td>*None reported.*</td></tr>
</table>

Other outcomes

Biertho 2003 (in TEC) case control	
Results	*Postoperative stay after laparoscopic GBP was significantly less than after LAGB (3 vs 5 days,* p*<0.05), but this was probably related more to the differences in the health system in the two countries than to the operation itself.*
Quality and comments	…

Weber 2004 (in TEC) case control	
Results	*The prevalence of comorbidities, such as arterial hypertension (60 vs 52%,* p*=0.35), diabetes mellitus type II (44 vs 37%,* p*=0.21), and dyslipidaemia (62 vs 74%,* p*=0.06), was comparable in the 2 groups (LAGB vs LGBP) before surgery. The frequency of all these comorbidities decreased in the follow-up period, with one exception of dyslipidaemia in the banding patients. The prevalence of hypertension dropped from 52 to 13% in the bypass group, and from 60% to 18% in the banding group. Diabetes declined from 37 to 6%, and 44 to 18%, respectively, leading to a significantly lower frequency in the bypass patients (*p*=0.007) in the follow-up. Dyslipidaemia was significantly lower in the bypass group after follow-up, than in the banding group (*p*=0.001).*

Quality and comments	…

Complications

Biertho 2003 (in TEC) case control	
Harms	Mortality: LAGB 0%, 0.44% laparoscopic GBP in first 30 days (*p*=NS). Major intraoperative complications: LAGB 10 (1.3)% – bleeding 4, liver haematoma 3, oesophageal perforation 1, haemorrhage from gastroepiploic artery 1, gas embolism 1; laparoscopic GBP 9 (2.0%) – major leakage of gastrojejunal anastomosis 3, Roux limb too short 3, revision of gastric pouch because of haematoma 1, end-to-end anastomosis pulled through stomach 1, nasogastric tube stapled 1. Conversion: LAGB 24 (3.0%) – difficulties with obesity 10, technical difficulties 7, hepatomegaly 4, splenectomy for bleeding 1, oesophageal perforation 1, haemorrhage from gastroepiploic artery 1: laparoscopic GBP 9 (2.0%) – excessive intraabdominal obesity 2, hepatomegaly 2, Roux limb too short 2, leakage of gastrojejunal anastomosis 1, end-to-end anastomosis pulled through stomach 1, nasogastric tube stapled 1. Note: in the LAGB group, most conversions occurred during the introduction of the technique. When last 400 cases were considered, conversion rate fell to 2% (*n*=8). Early major postoperative complications: LAGB 14 (1.7%) – pneumonia 8, pulmonary embolism 2, port haematoma 2, acute abdomen 1, port infection 1; laparoscopic GBP 19 (4.2%) - leakage of gastrojejunal anastomosis 6, deep vein thrombosis 4, gastric dilatation 2, intraabdominal bleeding 2, fistula on Roux limb 1, intestinal bleeding 1, paresia left arm 1, pneumonia 1. Late major complications: LAGB 46 (5.8%); laparoscopic GBP 37 (8.1%); LAGB Port-a-Cath+tube 23 (2.9%); LAGB others 4 (0.5%); LAGB total 73 (9.1%).
Quality and comments	…

Weber 2004 (in TEC) case control	
Harms	There was one conversion to open surgery in the bypass group because of a staple device malfunction, whereas in the banding group no conversion was necessary. The operation time was significantly longer for the bypass procedure than for the gastric banding (190 vs 145 min; *p*<0.001). The hospital stay was also significantly longer for the bypass procedure (8.4 vs 3.3 days; *p*<0.001). There was zero mortality in either group. Morbidity was reported as early complications within 30 days after surgery and late complications thereafter. To compare the severity of the complications, rates of re-interventions were reported and divided further to surgical re-operation and endoscopic dilatation. Early complications: 21 cases in the bypass group and 18 in the banding group (*p*=0.36). Re-interventions, including endoscopic dilatation, due to early complications were performed in 11 cases in the bypass group and once in the banding group (*p*=0.003). Surgical re-operations were indicated in 7 bypass patients and in 1 banding patient (*p*=0.033). Early complications were: LGBP wound/port site infections 8, intra-abdominal abscess 1, bleeding 1, stenosis at gastrojejunostomy 4, internal herniation 2, leakage at gastrojejunostomy 2, small bowel perforation 1, bleeding in remnant stomach 1, pulmonary embolism 1; LAGB wound/port site infections 16, intra-abdominal abscess 1, bleeding 1. Late complications: occurred in 14 patients in the bypass group and in 45 in banding group. Re-interventions were undertaken in 9 bypass patients and 26 banding patients (*p*=0.001). Late complications were: LGBP band slippage/pouch formation 1, stenosis at gastrojejunostomy 5, internal herniation2, gastrogastric fistula 1, incisional hernia at trocar site 1, pancreatitis 1, perisplenic abscess 1,

	cellulitis abdominal wall 1; LAGB band slippage/pouch formation 37, with oesophageal dysmotility 25, band leakage 4, band penetration 2, primary failure 1, port site infection 1. All 26 banding patients required surgery. Seventeen patients with banding were converted to a bypass, whereas no patient with a bypass was switched to another procedure. Four patients had their band replaced due to leakage of the band system, three patients due to secondary failure with pouch dilatation and weight gain, and one required a band repositioning for primary band failure. One port replacement was done. Surgery was necessary in only four of nine patients treated with GBP (*p*<0.001). Five patients underwent endoscopic dilatation.
Quality and comments	…

Generalisability

Biertho 2003 (in TEC) case control	
Country and setting	US and Switzerland. Specialist centres?
Participants (included/excluded)	Inclusion criteria for LAGB were a BMI >40 kg/m^2, or a BMI >35 kg/m^2 with at least one obesity-related morbidity, and failure of previous medical treatment. Patients with a BMI above 50 kg/m^2 were usually considered for a GBP, performed by laparotomy. The main indications for laparoscopic GBP were a BMI >40 kg/m^2 or >35 kg/m^2 with associated comorbidities. Patients with a BMI above 60 kg/m^2 were usually considered for a laparoscopic biliopancreatic diversion.
Recruitment	From referrals?
Randomisation	N/A
Intervention (mode and intensity)	*LAGB with follow-up in an outpatient clinic every 2 months for the first year, and then every 3 months for the following years. The gastric band was slowly inflated. Patients were evaluated every 3 months, and no inflation was done if a 1 kg weight loss had been noted in the past 3 months.*
Comparison (mode and intensity)	laparoscopic GBP with follow-up in an outpatient clinic every 3 months for the first year, and then every 6 months for the following years.
Delivery of intervention/comparison (who)	N/R.
Dropout rates	*3% LAGB, 13% laparoscopic GBP at 12 months.*
Treatment of dropouts (return to baseline, or last measurement?)	N/R – results for completers only.

Weber 2004 (in TEC) case control	
Country and setting	Switzerland. University hospital.
Participants (included/excluded)	Included for bariatric surgery if BMI > 40 kg/m^2 or BMI > 35 kg/m^2 with comorbidities, history of obesity more than 5 years, failed conservative treatment of more than 2 years, and age between 18 and 60 years.
Recruitment	From clinic?
Randomisation	N/A
Intervention (mode and intensity)	*The choice for the type of surgery was based on the time when the operation was performed. In the first period of the study (from May 1995 until June 2000), preferentially performed laparoscopic banding procedures as bariatric operation. Based on the growing evidence progressively switched to LGBP after June 2000.*

Comparison (mode and intensity)	As above
Delivery of intervention/comparison (who)	Routine evaluation from MDT (nutritionist, endocrinologist, psychologist, surgeon) using standardised protocol.
Dropout rates	*Not clear.*
Treatment of dropouts (return to baseline, or last measurement?)	Not clear.

Laparoscopic (adjustable) gastric banding

Single arm studies

Table 1 Study characteristics and weight loss outcomes

Study	Mean age (years)	Mean BMI (kg/m^2)	% Male	Follow-up (months)	No. enter/eval	No. at follow-up (years) and weight loss outcome(s)					Prosp/Cons[§]	Pre-operative workup
						1	2	3	4	5		
Lap-Band™												
Angrisani 2001	38	44.1	20	48	1265	NR BMI –9.0	NR BMI –13.9	NR BMI –12.0	NR BMI –12.6	…	…	…
Angrisani 2003	37.8	43.7	19.0	72 (maximum)	1893	NR BMI –10.0	NR BMI –8.9	NR BMI –9.6	NR BMI –11.0	NR BMI –8.9	Cons	…
Belachew 1998	35.5	42.9	21	36	350	NR EWL 50% BMI –10.9	NR EWL 58% BMI –11.9	NR EWL 77% BMI –16.9	…	…	Cons	…
Belachew 2002	34	42	22	48 (min)	763/687	NR EWL 40% BMI –10	NR EWL 50% BMI –12	NR EWL 60% …	NR EWL 52% …	NR EWL 66% BMI –12	…	…
Busetto 2002	37.6	46.6	28	36	260	252 EWL 40% BMI –8.6	247 … BMI –9.6	250 EWL 43% BMI –9.6	…	…	Cons	Yes
Cadiere 2000	40	45	24	24	652	NR EWL 38% BMI –10	NR EWL 62% BMI –12	…	…	…	Cons	…
Chevallier 2002	40.2	43.8	12	24	400	168 EWL 42% BMI –9.5	33 EWL 53% BMI –11.1	…	…	…	Prosp; cons	Yes
Dargent 1999	39.4	43	16	36	500	270 EWL 56%	96 EWL 65%	19 EWL 64%	…	…	Cons	…
Dargent 2004	39.5	43.3	15.4	108 (maximum)	1180	696 EWL 49%	573 56% EWL	434 EWL 57%	321 EWL 57%	190 54% (at 6 years, 86, 49% EWL, at 7 years, 14, 50% EWL)	Cons	…
Favretti 2002	37.9	46.4	22	84	830/805	660 BMI –9.1	479 BMI –10.0	305 BMI –9.6	185 BMI –9.8	74 BMI –10.0	Cons	Yes

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[§] PROSP prospective study, CONS consecutive patients.

Study	Mean age (years)	Mean BMI (kg/m^2)	% Male	Follow-up (months)	No. enter/eval	No. at follow-up (years) and weight loss outcome(s)					Prosp/Cons§	Pre-operative workup
						1	2	3	4	5		
FDA data 2000	38.8	47.4	15	36	299	233 EWL 35% BMI –8.5	189 EWL 38% BMI –9.4	178 EWL 36% BMI –9.8	…	…	Prosp; cons	Yes
Frigg 2004	41	45	21	44 (mean)	295	243 EWL 40% BMI –8	200 EWL 46% BMI –10	155 47% EWL BMI –10	98 54% EWL BMI –11	…	Cons	…
Holloway 2004	NR	49	18	36 (maximum)	504	311 EWL 50% BMI –13	122 EWL 61% BMI –16	40 65% EWL BMI –16	…	…	Cons	Yes
Miller 1999	36	44	10	28 (mean)	166/156	NR BMI –10	NR BMI –14	NR BMI –16	…	…	Prosp; cons	Yes
O'Brien 2002	41	45	15	72	709	492 EWL 47% BMI –10	336 EWL 53% BMI –12	273 EWL 53% BMI –12	112 EWL 52% BMI –13	32 EWL 54% BMI –13 (at 7 years, 10, 54% EWL, and BMI –13)	Prosp; cons	Yes
Parikh 2005	43	55.3	30	36	180	158 EWL 35.3%	85 EWL 45.8%	31 49.5%	…	…	…	…
Spivak 2004	40	45.3	13	24 (maximum)	271	72 EWL 40% BMI –9	21 EWL 43% BMI –10.6	…	…	…	Cons	…
Vertruyen 2002	41	44	10	36 (mean)	543/521	NR EWL 38% BMI –10.8	NR EWL 61% BMI –12.7	NR EWL 62% BMI –13.9	NR EWL 58% BMI –12.6	NR EWL 53% BMI –12.8 (at 86 months, 52% EWL, and BMI –11.9)	Cons	Yes
Weiner 1999	35.2	47.8	11	24	184	112 EWL 58% BMI –15.8	53 EWL 87% BMI –19.2	…	…	…	…	…
Swedish adjustable gastric band												
Biertho 2005	43	42.4	22.8	39.6 (mean)	824	821 EWL 30%	744 EWL 42%	593 EWL 48%	380 EWL 52%	184 EWL 55%	Prosp; cons	…
Greenslade 2004	40.1	42.9	14	48 (maximum)	215	NR EWL 45% BMI –9.9	NR EWL 58% BMI –10.9	NR EWL 55% BMI –11.4	NR EWL 50% BMI –11.9	NR EWL 44%	Prosp; cons	Yes

Table 2 Adverse outcomes

Study	*n*	Perioperative complications (%)							Long-term complications (%)								
		Death	Perf	Conv	Throm	Card	Bleed	Wound	Reop	Rem	SI/Dil	Eros	Oesoph	Obstr	Port	Hern	GORD
Lap-Band™																	
Angrisani 2001	1265	0.6	0.4	1.7	0.2	0.2	0.4	–	3.2	0.6	5.2	1.9	–	–	4.3	–	–
Angrisani 2003	1893	0.3	…	3.1	…	…	…	…	…	0.9	…	1.1	4.8	…	4.1	…	…
Belachew 1998	350	0	0.3	1.4	0	–	–	0	13.4	2.6	13	–	–	–	–	–	–
Belachew 2002	763	0.1	0.6	1.3	–	–	0.1	0.1	11	3.1	8.0	0.9	–	–	2.5	0	–
Busetto 2002	260	0	0.8	4.2	–	…	4.6	…	4.2	1.9	12	0.8	–	–	29	–	–
Cadiere 2000	652	0.2	0.3	3.8	0	0.2	–	0	4.4	–	3.8	0.3	0.2	–	2.7	–	–
Chevallier 2002	400	0	1	3	0	1.8	–	–	8.8	5.8	8.5	0	–	–	7.5	0.5	–
Dargent 1999	500	0	0.2	1.9	–	–	–	0.6	5.2	1.4	5.0	0.6	–	–	–	–	–
Dargent 2004	1180	0.2	0.5	0.4	0.2	0.5	…	0.2	12.7	5.6	8.8	1.9	2.0	…	…	…	…
Favretti 2002	830	0	0.1	2.7	–	–	–	–	3.9	1.7	10	0.5	–	–	–	–	–
FDA data 2000	299	0	0.7	0.7	0.3	–	–	14	24	15	24	1.0	10	14	8.7	5.4	34
Frigg 2004	...	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…
Holloway 2004	504	0.2	1.8	0.2	…	0.2	…	…	…	2.6	5.6	0.4	…	…	8.5	…	…
Miller 1999	166	–	0.6	1.9	–	–	0.6	0.6	7.0	3.2	1.3	0.6	1.3	–	2.5	–	–
O'Brien 2002	709	0	0.3	1.0	0.3	0.7	–	3.4	19	1.7	13	2.8	–	–	3.6	–	–
Parikh 2005	180	0	…	…	…	…	…	0.5	0.5	…	…	…	…	1.0	1.0	…	…
Spivak 2004	271	…	…	1.1	0.4	0.7	0.4	…	…	…	1.8	…	6.6	1.8	7.3	…	…
Vertruyen 2002	543	–	1.3	1.1	0.2	0.4	0.2	–	5.9	2.6	4.6	0.9	–	–	2.8	–	–
Weiner 1999	184	0	–	0	–	–	0.5	–	5.4	1.6	2.2	1.1	–	2.2	3.2	–	–
Swedish adjustable gastric band																	
Biertho 2005	824	0.1	0.1	8.3	…	…	…	…	14.7	…	4.2	…	7.5	…	6.7	…	…
Greenslade 2004	215	–	–	–	–	–	–	–	–	1.9	0	1.4	…	…	7.5	…	…

Bleed, bleeding complications; Card, cardiopulmonary complications, e.g. MI, congestive heart failure, pneumonia, respiratory failure; Conv, conversion from laparoscopic to open procedure; Death, death within 30 days of operation; Eros, erosion of adjustable band through oesophageal/stomach wall, or erosion into other visceral organ; GORD,; Hern, abdominal wall hernia at incision or port site; Obstr, bowel obstruction resulting from procedure; Oesoph, oesophageal abnormalities; Perf, perforation of bowel and/or visceral organ, including splenic injury; Port, complications at the port access site, including infection, dysfunction, and/or revisions; Rem, removal of band; Reop, re-operation resulting from a complication of the original procedure; Sl/Dil, slippage of adjustable band or dilation of proximal GI tract; Throm, thromboembolic complication; Wound, wound complications, including infection and dehiscence.

1.7.4 Restrictive/malabsorptive surgery

1.7.4.1 ***GBP***

Comparative studies

See other sections for comparison with LAGB and duodenal switch-bileopancreatic diversion (DS-BPD)

1.7.4.2 ***GBP (open)***

Single arm studies

Table 3 Study characteristics and weight loss outcomes

Study	Mean age (years)	Mean BMI (kg/m^2)	% Male	Follow-up (months)	No. enter/eval	No. at follow-up (years) and weight loss outcome(s)					Prosp/Cons[5]	Pre-operative workup
						1	2	3	4	5		
Avinoah 1992	36.1 (*n*=200)	…	29 (*n*=200)	80 (mean)	450/200	102 EWL 69%	198 65% EWL	103 (25 to 72 months) 48% EWL	…	88 (73 to 96 months) EWL 56%	…	…
Balsiger 2000	42 (median)	49 (median)	25.7	48	191	113 BMI –18	88 BMI –19	72 BMI –17	55 BMI –16	…	Prosp; cons	Y
Csendes 2005	38.5	46	22.3	36 (maximum)	400	115 BMI –18.3	55 BMI –18.4	14 BMI –18.3	…	…	Prosp	Y
Oh 1997	32.5	45.18	13.4	48	194/193	93 EWL 69% BMI –18	48 EWL 71% BMI –18.5	31 EWL 70% BMI –18	14 EWL 55% BMI –16.5	…	Prosp; cons	..
Pories 1995	37.3	49.7	16.8	168	608	506 EWL 69%	…	…	…	317 EWL 58% (at 10 years, 158, 55% EWL, at 14 years, 10, 49% EWL)	…	Y
Schoepel	41.7	50.2	13.1	24 (maximum)	168/85	85 EWL 51%	85 EWL 55%	…	…	…	…	…
Torres 1983	34	…	10.7	24 (maximum)	300	300 –48.5 kg	300 –52.0 kg	…	…	…	Cons	Y

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[5] PROSP prospective study, CONS consecutive patients.

Table 4 Adverse outcomes

Study	*n*	Perioperative complications (%)								Long-term complications (%)							
		Death	Perf	Anas	Bleed	Obstr	Thromb	Card	Wound	Reop	Sten	Obstr	Ulcer	Nutr	N/V	Hern	Chol
Avinoah 1992	200	…	…	…	…	…	…	…	…	…	…	…	…	51% meat intolerance	…	…	…
Balsiger 2000	191	0.5	0.5	0.5	0.5	…	0.5	2.1	5.8	5	1	…	0.5	23% milk intolerance	4	17	0.5
Csendes 2005	400	0.5	…	2.5	0.75	0.25	…	…	1.25	…	…	2.0	…	…	…	10.2	…
Oh 1997	193	0	1.03	0	…	…	…	0.52	1.03	…	…	3.61	4.12	…	…	8.25	3.09
Pories 1995	608	1.5	2.5	3.0	…	…	…	…	14.6	2.8	…	…	…	40% vitamin B_{12} deficiency, 39% anaemia	…	23.9	11.4
Schoepel 2001	85	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…
Torres 1983	300			0.7	2			0.3	2	12							

Anas, complication at one of the anastomic sites (stenosis, stricture, leak, staple line failure); Bleed, bleeding complications; Card, cardiopulmonary complications, e.g. MI, congestive heart failure, pneumonia, respiratory failure; Death, death within 30 days of operation; Chol, cholecystitis requiring cholecystectomy; Hern, hernial complications; Nutr, nutritional complications; N/V, nausea and/or vomiting; Obstr, bowel obstruction resulting from procedure; Perf, perforation of bowel and/or visceral organ, including splenic injury; Reop, re-operation resulting from a complication of the original procedure; stenosis;

Throm, thromboembolic complication; Ulcer, stomal, pouch, limb, near site of procedure; Wound, wound complications, including infection, necrosis and dehiscence.

1.7.4.3 GBP (laparoscopic)

Single arm studies

Table 5 Study characteristics and weight loss outcomes

Study	Mean age (years)	Mean BMI (kg/m^2)	% Male	Follow-up (months)	No. enter/eval	No. at follow-up (years) and weight loss outcome(s)					Prosp/Cons[6]	Pre-op workup
						1	2	3	4	5		
Ballesta-Lopez 2005	38.7	44.4	21	30 (maximum)	600	NR EWL 66% BMI –13	NR EWL 69% BMI –13	…	…	…	Cons	…
Higa 2001	13–73 (range)	35–78 (range)	18	36	1500/1497	572 EWL 69%	51 EWL 69%	19 EWL 62%	…	…	Cons	…
Schauer 2000	42	48.32	29	31 (maximum)	275	101 EWL 68.8% BMI –16.75	19 EWL 83.2% BMI –20.86	…	…	…	Prosp; cons	Y
Schauer 2003	48	50.4	25	48	240/191	97 EWL 59.9% BMI –16.2	42 EWL 66.5% BMI –16.8	33 EWL 59.1% BMI –15.0	11 EWL 52.1% BMI –13.0	…	Prosp	Y
Wittgrove 2000	…	…	…	60 maximum	500	… EWL 77%	… EWL 81%	92 EWL 75%	36 EWL 75%	4 EWL 82%	Prosp; cons	Y

Table 6 Adverse outcomes

Study	*n*	Perioperative complications (%)									Long-term complications (%)							
		Death	Conv	Perf	Anas	Bleed	Obstr	Thromb	Card	Wound	Reop	Sten	Obstr	Ulcer	Nutr	N/V	Hern	Chol
Ballesta-Lopez 2005	600	1.1	0.5	0.3	3.8	1.6	…	…	0.1	0.1	1.8	0.1	0.6	1.2	…	…	…	0.6
Higa 2001	1497	0.2	1.3	0.3	0.7	0.8	0.2	0.2	0.1	0.1	0.1	5.6	…	0.8	…	…	2.5	2.1

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[6] PROSP prospective study, CONS consecutive patients.

Study	*n*	Perioperative complications (%)									Long-term complications (%)							
		Death	Conv	Perf	Anas	Bleed	Obstr	Thromb	Card	Wound	Reop	Sten	Obstr	Ulcer	Nutr	N/V	Hern	Chol
Schauer 2000	275	0.4	1.1	…	8.4	3.3	1.1	1.1	0	9.1	9.8	…	0.3	0.7	23.8	12	0.6	1.5
Schauer 2003	191	0.5	1.6	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…
Wittgrove 2000	500	0	…	…	2.2	0.8	…	…	1.4	5	0.03	1.6	0.6	…	…	…	…	…

Anas, complication at one of the anastomic sites (stenosis, stricture, leak, staple line failure); Bleed, bleeding complications; Card, cardiopulmonary complications, e.g. MI, congestive heart failure, pneumonia, respiratory failure; Conv, conversion from laparotomy to open; Death, death within 30 days of operation; Chol, cholecystitis requiring cholecycstectomy; Hern, hernial complications; Nutr, nutritional complications; N/V, nausea and/or vomiting; Obstr, bowel obstruction resulting from procedure; Perf, perforation of bowel and/or visceral organ, including splenic injury; Reop, re-operation resulting from a complication of the original procedure; Sten, stenosis; Throm, thromboembolic complication; Ulcer, stomal, pouch, limb, near site of procedure; Wound, wound complications, including infection, necrosis and dehiscence.

1.7.4.4 Laparoscopic vs open GBP

Comparative studies

Weight loss

Lujan 2004 RCT	
Aim	To compare the results of open vs laparoscopic GBP in the treatment of severe obesity.
Participants	People who were severely obese (BMI >40 kg/m^2) without coexisting pathological disorders) or who were obese (BMI >35 kg/m^2) with coexisting pathological disorders. Total 104 – 81 F, 23 M. Mean (range) age 37 (18–64) years laparoscopic GBP (*n*=53), 38 (20–63) years open GBP (*n*=51). Mean (range) weight 130.70 (92–208) kg laparoscopic GBP, 137.57 (97–214) kg open GBP.
Intervention	*laparoscopic GBP*
Comparison	Open GBP
Length of follow-up	*36 months*
Results	*No statistical analysis of weight loss. From graph, laparoscopic and open GBP appeared to perform very similarly over time (36 months, mean follow-up 23 months) (described as 'similar' by the authors).* BMI (kg/m^2; estimated from figure), *p*=NS. 3 months: Laparoscopic 41, Open 47. 6 months: Laparoscopic 36, Open 41. 12 months: Laparoscopic 33, Open 37. 18 months: Laparoscopic 31, Open 36. 24 months: Laparoscopic 32, Open 35. 36 months: Laparoscopic 31, Open 35.5. (FROM CR)
Quality and comments	Blinded assessment not reported. ITT not stated, but probably as 0% loss to follow-up, and no mention of crossing groups.
Sponsor details	*None reported.*

Nguyen 2001 (in Clegg TA) RCT	
Aim	To compare outcomes, quality of life, and costs of laparoscopic and open GBP.
Participants	People who were severely obese (40>BMI (kg/m^2)<60). Total 155 – 139 F, 16 M. Mean (SD) age 40 (8) years laparoscopic GBP (*n*=79), 42 (9) years open GBP (*n*=76). Mean (SD) weight 131.1 (17.2) kg laparoscopic GBP 134.3 (20.0) kg open GBP.
Intervention	Laparoscopic GBP: Other: Pre-operative and post-operative antibiotics, antiembolic stockings and sequential pneumatic compression devices. Postoperative pulmonary care incentive spirometry and deep breathing exercises. Patient controlled analgesia using intravenous morphine.
Comparison	*Open GBP:* *Other: as above*
Length of follow-up	Up to 12 months
Results	*No weight loss data suitable to add to analysis.* Percentage excess body weight loss (not ITT): 3 months laparoscopic GBP (*n*=60) 37±1%; open GBP (*n*=56) 32±10% (*p*=0.01) 6 months laparoscopic GBP (*n*=45) 54±14%; open GBP (*n*=44) 45±12% (*p*=0.01) 12 months laparoscopic GBP (*n*=29) 68±15%; open GBP (*n*=25) 62±14% (*p*=0.07)

Quality and comments	From Clegg TA QA: blinded assessment not done.
Sponsor details	*None reported.*

Sundbom 2004 RCT	
Aim	To determine whether patients derive significant benefit from hand-assisted laparoscopic GBP in comparison to open surgery.
Participants	People who were referred for surgery? Total 50 – 45 F, 5 M. Median (range) age 37 (19 to 54) years laparoscopic GBP (*n*=25), 38 (24 to 54) years open GBP (*n*=25). Median (range) BMI (kg/m^2) 44 (36 to 54) laparoscopic GBP, 45 (34 to 54) open GBP.
Intervention	*Laparoscopic GBP: Roux-en-Y. Cholecystectomy done through a slightly enlarged incision for the hand-assisted device. Also, fenestration of an incidentally discovered large liver cyst was done in another patient.* *Other: antibiotic prophylaxis and thromboprophylaxis. Seen at outpatient clinic after 4–6 weeks. Also at 6 and 12 months.*
Comparison	Open GBP: Roux-en-Y Other: as above
Length of follow-up	*12 months*
Results	*At 4 to 6 weeks after surgery, median weight change was –13 kg in both groups. At 12 months, weight change was similar in both groups, –39 (–23 to –57) and –41 (–26 to –57) kg after hand-assisted and open surgery respectively. Accordingly, the reduction in BMI was 15 units, to 29 and 30 kg/m^2 respectively.*
Quality and comments	*Blinded assessment done. Sample size achieved (minimum 21 in each group). ITT done.* *Could not add weight loss to analysis as no SDs.*
Sponsor details	*None reported.*

Westling 2001 (in HTA) RCT	
Aim	To compare laparoscopic and open Roux-en-Y GBP with regard to postoperative pain, hospital stay, sick-leave, weight loss and complications.
Participants	*People who were severely obese (BMI >40, or BMI >35 kg/m^2 in the presence of significant comorbidity).* *Total 51 – 48 F, 3 M. Mean (SD) age 36 (9) years overall. Mean (SD) BMI (kg/m^2)42 (4) overall. Randomised* n=30 *laparoscopic GBP (including conversions), and 21 to open GBP.*
Intervention	Laparoscopic GBP: Roux-en-Y Other: antibiotic prophylaxis with intravenous cefuroxime and metronidazole, thromboprophylaxis with enoxaparine or preoperative dextron. Advice from specially trained nurse for advice and regular checks from dietitians and internists.
Comparison	*Open GBP: Roux-en-Y* *Other: as above*
Length of follow-up	12 months
Results	Mean BMI (1 year): laparoscopy 27±4 kg/m^2; open 30.6±4 kg/m^2. Mean change in BMI (1 year): laparoscopy 14±3 kg/m^2; open 13±3 kg/m^2 (*p*=NS).
Quality and comments	Baseline BMI was lower in the laparoscopic GBP group compared with the open GBP group (mean (SD) 41 (4) vs 44 (4) kg/m^2, *p*<0.05). From Clegg TA QA: proper sampling and blind assessment classified as substandard or incomplete, sample size not reported. *Not able to add weight loss to analysis.* *Sugerman: complication rate for laparoscopic GBP higher than other studies. Poss due to 'learning curve' affect. Laparoscopic GBP is classified as 'one of the most technically difficult of all laparoscopic procedures'. Also number of cases was 'profoundly lower' than most of the published observational studies.*

Sponsor details	None reported.

Other outcomes

Lujan 2004 RCT	
Results	*Mean operating time was 186.4 (125–290) min in the laparoscopic GBP group and 201.7 (129–310) min in the open GBP group (*p*<0.05).* *Mean hospital stay was 5.2 (1–13) days in the laparoscopic GBP group and 7.9 (2–28) days in the open GBP group (*p*<0.05)*
Quality and comments	…

Nguyen 2001 (in Clegg TA) RCT	
Results	Operative outcomes Operative time (min): laparoscopic 225±40, open 19±41, *p*<0.001; Estimated blood loss (ml); laparoscopic 137±79, open 395±284, *p*<0.001; Proportion requiring intensive care unit stay: laparoscopic 7.6%, open 21.1%, *p*=0.03; Median length of hospital stay (days): laparoscopic 3 (IQR 1), open 4 (IQR 2), *p*<0.001; Proportion requiring re-operation: laparoscopic 7.6%, open 6.6%, *p*=NS; Return to activities of daily living (days): laparoscopic 8.4±8.6, open 17.7±19.1, p<0.001; Return to work (days): laparoscopic 32.2±19.8, open 46.1±20.6, *p*=0.02; Intraoperative transfusion: laparoscopic 0, open 3.9% Conversion from laparoscopic to open: 2 (2.5%) due to failure of circular stapler; inability to insufflate abdomen safely. Quality of Life (not ITT) SF-36 Scores (mean ± SD) (pre-operative laparoscopic *n*=70, open *n*=73; 3 months laparoscopic *n*=54, open *n*=42) Physical functioning: pre-operative laparoscopic 46.5 (21.3), open 40.0 (24.4), *p*=NS; 1 month laparoscopic 60.9 (24.7), open 46.3 (24.7), *p*<0.05; 3 months laparoscopic 80.2 (19.1), open 67.8 (26.6), *p*=NS; US Norms 84.2 (23.3). Role-physical: pre-operative laparoscopic 47.2 (40.2), open 37.5 (37.9), *p*=NS; 1 month laparoscopic 29.7 (39.2), open 18.5 (32.3), *p*=NS; 3 months laparoscopic 80.7 (32.5), open 76.8 (33.3), *p*=NS; US Norms 81.0 (34.0) Bodily pain: pre-operative laparoscopic 51.0 (22.7), open 48.7 (24.1), *p*=NS; 1 month laparoscopic 59.2 (21.5), open 45.1 (24.4), *p*<0.05; 3 months laparoscopic 75.1 (24.7), open 68.1 (25.6), *p*=NS; US Norms 75.2 (23.7) General health: pre-operative laparoscopic 54.5 (21.6), open 52.9 (22.3), *p*=NS; 1 month laparoscopic 71.3 (18.0), open 64.0 (18.1), *p*<0.05; 3 months laparoscopic 77.2 (15.7), open 72.4 (16.5), *p*=NS; US Norms 72.0 (20.3) Vitality : pre-operative laparoscopic 38.5 (20.0), open 36.6 (19.9), *p*=NS; 1 month laparoscopic 45.4 (20.5), open 39.1 (18.9), *p*=NS; 3 months laparoscopic 65.8 (17.7), open 73.1 (95.2), *p*=NS; US Norms 60.9 (21.0) Social functioning: pre-operative laparoscopic 64.4 (26.3), open 61.6 (29.5), *p*=NS; 1 month laparoscopic 67.6 (24.5), open 51.9 (29.1), *p*<0.05; 3 months laparoscopic 87.3 (17.9), open 74.1 (30.0), *p*=NS; US Norms 83.3 (22.7) Role-emotional: pre-operative laparoscopic 49.1 (24.4), open 45.5 (27.2), *p*=NS; 1 month laparoscopic 78.5 (28.2), open 69.5 (33.5), *p*=NS; 3 months laparoscopic 83.0 (29.6), open 74.6 (40.7), *p*=NS; US Norms 81.3 (33.0) Mental health: pre-operative laparoscopic 73.0 (15.1), open 71.9 (17.3), *p*=NS; 1 month laparoscopic 76.8 (17.4), open 70.8 (19.4), *p*=NS; 3 months laparoscopic 82.9 (14.2), open 75.0 (19.2), *p*=NS; US Norms 74.7 (18.1) Morrehead-Ardelt Quality of Life scores (score of 0 =same as before, + score

	=positive changes, – score =negative change) (3 months laparoscopic *n*=47, open *n*=36; 6 months laparoscopic *n*=34, open *n*=28). Self-esteem (score range –1 to +1): 3 month laparoscopic 0.81 (0.3), open 0.73 (0.32) (p=NS); 6 months laparoscopic 0.84 (0.27), open 0.80 (0.28) (*p*=NS). Physical (score range –0.5 to +0.5): 3 month laparoscopic 0.48 (0.40), open 0.46 (0.44) (p=NS); 6 months laparoscopic 0.37 (0.17), open 0.34 (0.18) (*p*=NS). Social (score range –0.5 to +0.5): 3 month laparoscopic 0.31 (0.19), open 0.24 (0.21) (p=NS); 6 months laparoscopic 0.33 (0.19), open 0.29 (0.21) (*p*=NS). Labour (score range –0.5 to +0.5): 3 month laparoscopic 0.24 (0.19), open 0.13 (0.29) (p<0.05); 6 months laparoscopic 0.28 (0.21), open 0.21 (0.27) (*p*=NS). Sexual (score range –0.5 to +0.5): 3 month laparoscopic 0.20 (0.21), open 0.09 (0.24) (p<0.05); 6 months laparoscopic 0.26 (0.20), open 0.19 (0.26) (*p*=NS). Costs (mean $ ± SD) Direct costs: laparoscopic 7478 (2802); open 7,440 (4,661) (*p*=NS). Operative costs: laparoscopic 4922 (1927); open 3591 (1000) (p<0.01) Operative time and supplies: laparoscopic 4098 (1,538); open 2,788 (674) (*p*<0.01) Post-anaesthesia: laparoscopic 504 (487); open 525 (382) (*p*=NS) Hospital service costs: laparoscopic 2,519 (1,712); open 3,742 (3,978) (*p*=0.02) Diagnostic :laparoscopic 467(170); open 609 (402) (*p*<0.01) Nursing: laparoscopic 1,201 (821); open 1,975 (2,773) (*p*=0.03) Pharmaceutical: laparoscopic 418 (232); open 579 (413) (*p*<0.01) Therapeutic: laparoscopic 97 (249); open 146 (430) (*p*=NS) Other: laparoscopic 268 (213); open 423 (443) (*p*<0.01) Indirect costs: laparoscopic 6645 (2437); open 6,765 (4,077) (*p*=NS). Total costs: laparoscopic 14,087 (5237); open 14,098 (8,527) (*p*=NS).
Quality and comments	…

Sundbom 2004 RCT	
Results	*Post-operatively, all patients spent the first night after surgery in the surgical ward. Patient-controlled analgesia was satisfactory in all patients, and the amount of morphine required during the first 3 days after operation was similar for both procedures (Table 2). The systemic inflammatory response, measured by the C-reactive protein level, did not differ between the groups. Median length of hospital stay was 6 days in both groups.* *At 1-month follow-up (4 to 6 weeks), total sick leave, analysed in 40 patients, was 30 (15–59) and 37 (19–95) days after hand-assisted laparoscopic and open GBP respectively. The remaining ten patients were retired or on long-term sick leave.*
Quality and comments	…

Westling 2001 (in HTA) RCT	
Results	Pain – morphine dose (mg±sd): laparoscopy (*n*=29) 98 ±71.5) (*p*=NS); laparoscopy: conversions excluded (*n*=22) 69±46.4 (*p*<0.005); open (*n*=21) 140±90. Hospital stay (days): laparoscopy (n=29+) 4.5±1.2 (*p*=NS); laparoscopy: conversions excluded (*n*=22) 4±0.8 (*p*=0.025); open (n=21) 6±3.8. Sick leave (wks): laparoscopy (n=24+*) 3.9±2.1 (*p*=NS); laparoscopy: conversions excluded (*n*=18*) 2.8±1.8 (*p*=0.025); open (n=14*) 5±3.3 (**n* excludes people receiving pensions or who are unemployed). (*patient with malignant hyperthermia excluded) No correlation between pre-operative BMI and amount of morphine used post-operatively, length of stay or sick leave (no results reported). Patient satisfaction (1 year) All patients – 92% very satisfied, 8% satisfied. No difference between groups (no results reported).

Quality and comments	…

Complications

Lujan 2004 RCT	
Harms	Laparoscopic GBP: conversion to laparotomy necessary in four patients (8%) due to extreme hepatomegaly, portal hypertension secondary to hepatic cirrhosis discovered during the operation, anaesthetic problems (hypercapnia), and splenic lesion during dissection of the angle of His. All the conversions occurred in the first 20 patients. Open GBP: intraoperative complications in four patients (8%): three splenectomies and one splenic vein tear requiring suture. Three patients died post-operatively, two in the laparoscopic GBP group, one case not related with the surgical procedure and one in the open GBP group. Early complications (<30 days): Twelve patients (22.6%) of the laparoscopic GBP group vs 15 patients (29.4%) of the open GBP group, with no significant differences. Of note in the laparoscopic GBP group were two asymptomatic leaks of the gastro-entero-anastomosis, diagnosed during a control intestinal transit performed in the immediate postoperative period. A further transit was performed at 6 days, with no evidence of leaks, and a liquid diet was started, with good patient progress. Two patients developed intra-abdominal bleeding revealed by blood in the drains, without haemodynamic repercussions or need for transfusion, which ceased spontaneously, probably because of bleeding of the gastric dissection line. Two patients presented with an upper GI haemorrhage, 1 requiring blood transfusion, with bleeding at the gastrojejunal anastomosis, which sclerosed with upper GI endoscopy. Another patient presented with a lower GI haemorrhage with no haemodynamic repercussions or need for transfusion, probably due to bleeding of the entero-anastomosis. Another patient presented with a stenosis of the gastro-entero-anastomosis, which required endoscopic dilatation. Four patients in the open GBP group presented with a subphrenic abscess, which was drained by radiological puncture. The origin of these abscesses is unclear, as all the patients presented with a normal GI transit; it cannot be ruled out that the origin was due to leaks occurring in the late postoperative period. Three had an upper GI haemorrhage, which evolved favourably with medical treatment without the need for transfusion, and 1 patient died of broncho-aspiration in the re-operation for evisceration secondary to coughing on the second postoperative day. Late complications (>30 days): 11% of the laparoscopic GBP group compared with 24% of the open GBP group, with statistically significant differences ($p<0.05$). Of note in the laparoscopic GBP group was a sudden death on postoperative day 32 due to a possible pulmonary thrombo-embolism (no autopsy) and three intestinal obstructions: one resolved with medical treatment and two requiring surgery: one was caused by a hernia through the mesocolon. Another patient presented with an internal hernia between the mesocolon and the mesentery of the small intestine (Peterson's space), which caused an obstruction of the alimentary loop leading to perforation of the gastrojejunal anastomosis with acute peritonitis. Undergoing surgery, the patient presented with multiorgan failure in the postoperative period and died at 48 h. In the open GBP group there was a subphrenic abscess, which was drained by radiological puncture, and an intestinal obstruction due to adhesions, which was operated on 8 months after surgery. The differences observed between the two groups are due to the presence of ten abdominal wall hernias in the open GBP group, three receiving surgery and seven awaiting operation.
Quality and comments	…

Nguyen 2001 (in Clegg TA) RCT	
Harms	*Complications* *Major complications: total laparoscopic 6 (7.6%), open 7 (9.2%) (p=0.78); anastomotic leak laparoscopic 1, open 1; gastric pouch outlet obstruction laparoscopic 0, open 1; hypopharyngeal perforation laparoscopic 1, open 0; jejunojejunostomy obstruction laparoscopic 3, open 0; pulmonary embolism laparoscopic 0, open 1; respiratory failure laparoscopic 0, open 1; GI bleeding laparoscopic 1, open 0; wound infection laparoscopic 0, open 2; retained laparotomy sponge laparoscopic 0, open 1.* *Minor complications: total laparoscopic 6 (7.6%), open 9 (11.8%)* (p=*0.42); GI ileus laparoscopic 1, open 0;* C. difficile *colitis laparoscopic 1, open 0; gastrogastric fistula laparoscopic 0, open 1; asymptomatic leak laparoscopic 0, open 1; GI bleeding laparoscopic 2, open 0; wound infection laparoscopic 1, open 6; deep venous thrombosis laparoscopic 1, open 1.* *Late complications: total laparoscopic 15 (18.9%), open 12 (15.8%)* (p=*0.52); anastomotic stricture laparoscopic 9, open 2; prolonged nausea/vomiting laparoscopic 1, open 2; small bowel obstruction laparoscopic 1, open 0; cholelithiasis laparoscopic 3, open 0; ventral hernia laparoscopic 0, open 6,* p=*0.01); anaemia laparoscopic 0, open 2; protein–energy malnutrition laparoscopic 1, open 0.* *125*
Quality and comments	…

Sundbom 2004 RCT	
Harms	One woman in the hand-assisted group experienced tachycardia, fever and general deterioration, and a contrast study revealed evidence of leakage at the gastrojejunostomy. Leakage near the gastrojejunostomy was confirmed at laparotomy and large-bore drains were placed. She made an uneventful recovery after a 2-day stay in the intensive care unit and was discharged after 14 days in hospital. There were no other re-operations. Respiratory symptoms that required prolonged antibiotic treatment and physiotherapy occurred in eight patients in the hand-assisted and five in the open group. No clinical deep venous thrombosis, pulmonary embolism or wound dehiscence was noted. One patient in each group received two units of blood because of postoperative anaemia. All patients tolerated solids at discharge. There were no deaths within the first 30 days after operation. One-month follow-up Eighteen patients complained of various grades of dysphagia. Gastroscopy revealed a narrow anastomosis in six patients, two in the hand-assisted group and four in the open group. All patients had successful balloon dilatation and no stomal ulcers were seen. One patient in each group had a wound infection with pus and four had abnormal secretions, all of whom were treated conservatively. One-year results All patients were taking regular supplements of vitamin B_{12} and multivitamins. Iron was given to all women, but two were anaemic and required intensive treatment. One patient in the open group had a symptomatic incisional hernia. Three patients in each group had required short-term treatment with a proton pump inhibitor. Gastroscopy revealed a small stomal ulcer in one patient in the open group. One patient died 11 months after operation from metastatic breast cancer. She received oncological treatment and conventional terminal care, which were not affected by her previous Roux-en-Y GBP.
Quality and comments	…

Westling 2001 (in HTA) RCT	
Harms	*Surgical outcomes* *Conversions: 7 (23%) of laparoscopic patients were converted to open due to either bleeding (n=4) or other operative concerns (n=3).* *Duration (min): laparoscopy (n=30) 245 (135–390); open (n=21) 100 (70–150).* *Preoperative bleeding (ml): laparoscopy (n=30) 250 (50–1500); open (n=21) 300 (200–500).* *Complications* *Deaths: one laparoscopy patient from malignant hyperthermia (family history).* *GI symptoms (dumping/vomiting/diarrhoea): 5% of all patients.* *Incisional hernia: one laparoscopy patient.* *6 (20%) laparoscopy patients without conversion re-operated: returned to hospital emergency department median 4 weeks (1–5 weeks) post-operation due to colicky pain and vomiting due to narrow stricture of tunnel through mesocolon (n=5), and to herniated Roux limb (n=1). Restriction was removed (n=5) or Roux limb closely adherent to pancreas and excluded stomach (n=1).* *One open suffered leakage due to failure of hand-sewn part.* *One laparoscopy had a small embolus.* *Jejunal ulcers: three laparoscopy, two open (p=NS)* *Stricture in gastrojejunostomy: one laparoscopic treated by endoscopic dilation.* *Superficial wound infection: three open.* *Readmission for unexplained fever (1), pneumonia (1), epigastric pain and/ or vomiting with normal gastroscopy (2).*
Quality and comments	…

Generalisability

Lujan 2004 RCT	
Country and setting	Spain. Department of surgery?
Participants (included/excluded)	Included if BMI >40 kg/m^2 without coexisting pathological disorders or BMI >35 kg/m^2 with coexisting pathological disorders. No exclusion criteria reported.
Recruitment	N/R
Randomisation	No details other than computer generated numbers in sealed, opaque, numbered envelopes.
Intervention (mode and intensity)	*Seen post-operatively at 15 days, then 3, 6, 12, 18, 24 months. Annually thereafter.*
Comparison (mode and intensity)	As above.
Delivery of intervention/comparison (who)	N/R
Dropout rates	*0%?*
Treatment of dropouts (return to baseline, or last measurement?)	N/R.

Nguyen 2001 (in Clegg TA) RCT	
Country and setting	USA. Department of surgery?

Participants (included/excluded)	Included all patients evaluated for surgical treatment of morbid obesity with BMI 40 to 60 kg/m^2, aged 21–60 years, failed previous non-surgical treatment. Excluded if previous obesity surgery, previous gastric surgery, large abdominal ventral hernia, history of venous thrombosis/ pulmonary embolism, severe cardiovascular, respiratory, hepatic or renal disease.
Recruitment	From clinic (all referrals).
Randomisation	Stratified by BMI (40 to 49, 50 to 60 kg/m^2).
Intervention (mode and intensity)	Assessed in outpatient clinic postoperatively at 7 days and at 1, 3, 6 and 12 months post-surgery and annually thereafter.
Comparison (mode and intensity)	As above
Delivery of intervention/comparison (who)	N/R
Dropout rates	People who withdrew consent or did not undergo GBP were excluded from the analysis. Nineteen eligible participants did not undergo randomisation; 13 requested laparoscopic GBP and six requested open GBP; two randomised to GBP were excluded after randomisation (one withdrew consent, one needed splenectomy).
Treatment of dropouts (return to baseline, or last measurement?)	ITT done – no details reported.

Sundbom 2004 RCT	
Country and setting	Sweden. Department of surgery?
Participants (included/excluded)	No details reported, other than not undergone previous bariatric surgery.
Recruitment	From hospital metabolic unit, but no details.
Randomisation	Stratified by sex.
Intervention (mode and intensity)	*Seen at outpatient clinic after 4–6 weeks. Also at 6 and 12 months.*
Comparison (mode and intensity)	As above.
Delivery of intervention/comparison (who)	Seen at 6 and 12 months by an internist and dietitian.
Dropout rates	*0% overall, but one woman died 11 months after the operation due to metastatic breast cancer.*
Treatment of dropouts (return to baseline, or last measurement?)	ITT done, no details but minimal dropout. Exclusion of protocol violations (cholecystectomy and liver cyst fenestration) did not alter the results substantially.

Westling 2001 (in HTA) RCT	
Country and setting	Sweden. Department of surgery?
Participants (included/excluded)	*Included if people with BMI >40 kg/m^2 or BMI >35 kg/m^2 with significant comorbidity; failed in various supervised non-surgical long term weight loss programs within hospital; fully informed of operation and consequences.* *Excluded 70 patients prior to randomisation as they were unsuitable for laparoscopy (n=21), had gallstones (n=7), or were scheduled for Roux-en-Y GBP as a revisional procedure (n=42).*
Recruitment	N/R
Randomisation	*Blocked 60% to laparoscopic GBP and 40% to open due to presupposed need for conversions. Stratified by gender, but not BMI.*

Intervention (mode and intensity)	*Seen at 4–6 weeks and 12 months after operation. Also encouraged to contact a specially trained nurse in-between scheduled appointments for advice on upcoming problems. Regular checks and support from dietitians and internists also given.*
Comparison (mode and intensity)	As above.
Delivery of intervention/comparison (who)	Specially trained nurse acted as contact after surgery, and dietitians and internists gave regular checks and support.
Dropout rates	*0%*
Treatment of dropouts (return to baseline, or last measurement?)	100% of participants were included.

1.7.5 Malabsorptive/restrictive surgery

Weight loss

Deveney 2004 (TEC) observational study	
Aim	To compared weight loss (expressed as percentage of EWL) after 1 and 2 years in patients who underwent open Roux-en-Y GBP or DS-BPD performed by the same surgeons at one institution.
Participants	People who underwent open Roux-en-Y GBP or DS-BPD. Total 350 – 273 F, 77 M. Mean (SD) BMI DS-BPD 59 (11) DS-BPD (*n*=113), 55 (11) Roux-en-Y GBP, (*n*=237). Mean (SD) age 46 (10) years DS-BPD, 44 (11) years Roux-en-Y GBP.
Intervention	*Surgery: DS-BPD (open and laparoscopic)* *No further details of additional treatment.*
Comparison	Surgery: Roux en Y GBP (open and laparoscopic) No further details of additional treatment.
Length of follow-up	*24 months*
Results	*Change in body weight in kg was not reported.* *Only results for patients with 1- and 2-year follow-ups were reported.*

	DS-BPD (n=36)	*Roux-en-Y GBP (n=57)*
Mean age (years)	*44*	*45*
Mean (SD) BMI (kg/m^2)	*64 (9.5)*	*59 (10.9)*
Mean % EWL at 12 months	*53 (11)*	*54 (16)*
Mean % EWL at 24 months	*63 (21)*	*67 (18)*

	Statistically significant differences reported for baseline BMI only, and not for mean EWL at 12 or 24 months.
Quality and comments	*Baseline differences in BMI (heavier in DS-BPD group,* p*<0.05) and higher rates of diabetes (41 vs 30%,* p*<0.005) and hypertension (67 vs 56%,* p*<0.005) in the DS-BPD group.* *Retrospective review of records from patient database.*
Sponsor details	*None reported.*

Other outcomes

Deveney 2004 (TEC) observational study	
Results	*None reported.*
Quality and comments	…

Complications

Deveney 2004 (TEC) observational study	
Harms	

	DS-BPD (n=113)	***Roux-en-Y GBP (n=237)***
Mean length of stay (days)	*8.7*	*5.9*
Wound infection	*25 (22%)*	*47 (20%)*
Postoperative anastomotic leak	*7(6%)*	*8 (3%)*
Mortality	*1 (0.9%)*	*2 (0.8%)*

	Rates were similar apart from a higher length of stay for DS-BPD (*p*<0.05).
Quality and comments	…

Generalisability

Deveney 2004 (TEC) observational study	
Country and setting	USA. University centre?
Participants (included/excluded)	Included if underwent DS-BPD or roux-en-Y GBP between January 2000 and March 2003. Excluded if had previous failed bariatric procedures.
Recruitment	Retrieved records from database. Procedure chosen by surgeon and/or patient.
Randomisation	N/A
Intervention (mode and intensity)	*No details*
Comparison (mode and intensity)	No details.
Delivery of intervention/comparison (who)	No details.
Dropout rates	*68% DS-BPD, 76% Roux-en-Y GBP at 24 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

*1.7.5.1 **Duodenal switch (BPD)***

Single arm studies

Table 7 Study characteristics and weight loss outcomes

Study	Mean age (years)	Mean BMI (kg/m^2)	% Male	Follow-up (months)	No enter/eval	No. at follow-up (years) and weight loss outcome(s)					Prosp/Cons[7]	Pre-operative workup
						1	2	3	4	5		
Anthone 2003	42.3	52.3	21.7	60 (maximum)	701	333 EWL 69% BMI –20.3	NR	71 EWL 73% BMI –21.3	NR	50 EWL 66% BMI –20.3	Prosp; cons	Yes
Biron 2004	38	48.4	21.5	94.8 (mean)	997	NR	NR	NR	NR	997 BMI –17.1 (not reported at specific time point)	Cons	…
Guedea 2004	38	54	15	67.9 (mean)	150/74	74 EWL 68% BMI –20	74 EWL 75% BMI –23	…	…	55 EWL 70% BMI –21	Cons	…
Hess 1998	39	50	22	18 (maximum)	440	NR EWL 74%	NR EWL 78%	NR EWL 77%	NR EWL 75%	NR EWL 73%	Cons	…
Marinari 2004	38	47	28.3	>60	858	…	800 EWL 67%	…	738 EWL 67%	659 (6 year) EWL 68%	…	…
Slater 2004	45	43	18	48 (maximum)	376	170 EWL 48%	59 EWL 68%	37 EWL 59%	28 EWL 59%	…	Cons	…
Totte 1999	35.8	48.8	20	36 (maximum)	180	118 EWL 57% BMI –16.8	…	72 EWL 70% BMI –20.0	…	…	Cons	…

Hess also reported rates of EWL of 70, 68, 70, 74 and 87% at 6, 7, 8, 9 and 10 years follow-up, respectively.

Table 8 Adverse outcomes

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[7] PROSP prospective study, CONS consecutive patients.

Study	***n***	**Perioperative complications (%)**									**Long-term complications (%)**							
		Death	**Perf**	**Leak**	**Bleed**	**Sten**	**SBO**	**Throm**	**Card**	**Wound**	**Reop**	**Sten**	**Obstr**	**Ulcer**	**Nutr**	**N/V**	**Hern**	**Chol**
Anthone 2003	701	1.4	…	0.7	…	…	…	…	…	…	5.7	…	…	…	…	…	…	…
Biron 2004	997	1.0	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…
Guedea 2004	74 (384)	0	…	2.7	…	…	…	…	…	6.8	2.7	4.1	…	10.8	…	…	33.8	…
Hess 1998	440	0.5	0.9	3.8	0.5	…	-	1.3	0.5	-	3.9	-	2.8	-	-	-	-	-
Marinari 2004	858	…	…	0.1	…	…	…	0.1	…	…	6.3	…	…	…	…	…	1.7	…
Slater 2004	Reported on nutritional outcomes, not complications	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…
Totte 1999	180	0	-	1.1	-	…	-	1.1	-	5	3.9	-	1.1	11	1.1	-	18	-

Bleed, bleeding complications; Card, cardiopulmonary complications, e.g. MI, CHF, pneumonia, respiratory failure; Chol, cholycystectomy; Death, death within 30 days of operation; Hern, abdominal wall hernia at incision or port site; Leak, anastomitic leak; N/V, chronic nausea and/or vomiting, moderate or severe; Nutr, nutritional deficiencies, including vitamin deficiencies; Obstr, bowel obstruction resulting from procedure; Perf, perforation of bowel and/or visceral organ, including splenic injury; Reop, re-operation resulting from a complication of the original procedure; SBO, small bowel obstruction; Sten, stenosis; Throm, thromboembolic complication; Ulcer, mucosal ulceration occurring at or near site of procedure; Wound, wound complications, including infection and dehiscence.

1.7.6 Staged surgery

Detailed evidence tables were not needed for this section, as appropriate levels of detail are provided in the Narrative.

1.7.7 Competencies, training, and volume

Detailed evidence tables were not needed for this section, as appropriate levels of detail are provided in the Narrative.

1.7.8 Interventions in a UK clinical setting

Weight loss

Taylor 2003	
Aim	To compare the efficacy of an energy prescription diet with usual care (healthy eating diet)
Participants	Overweight (no definition) adults referred to a outpatient dietetic clinic. Total 53 – 18 M, 35 F. Mean (SD) age 48.9 (14.5) years diet (*n*=27), 44.5 (14.7) years healthy eating (*n*=26). Mean (SD) BMI (kg/m^2) 37.2 (9.0) diet, 37.0 (5.2) healthy eating.
Intervention	*Diet: 500 kcal/day deficit diet. No revisions made during study period.* *Seen at four sessions with a dietitian held at four weekly intervals up to week 12.*
Comparison	Healthy eating: based on Balance of Good Health. Seen as in intervention group.
Length of follow-up	*12 weeks*
Results	*At 4 weeks, mean (SD) weight change in kg was –1.7 (2.3) in the diet group, and –1.9 (2.5) in the control group. Mean weight change in the intervention group compared with control was 0.2 (95% CI –1.1 to 1.5).* *At 12 weeks, mean (SD) weight change in kg was –2.70 (3.8) in the diet group, and –3.1 (3.6) in the control group. Mean weight change in the intervention group compared with control was 0.4 (95% CI –1.7 to 2.4).*
Quality and comments	*Small, underpowered (needed 686 for 80% power) study. Quasi randomised (alternate allocation), but no further details. Blinded assessment not done. High dropout rate (almost 50%).*
Sponsor details	*None reported.*

Moore 2003	
Aim	To evaluate a training programme intended to improve the management of obesity, delivered to general practice teams.
Participants	General practices invited consecutive attending obese (BMI ≥30 kg/m^2) adults aged 16 to 64 years to participate. Total 843 – 220 M, 623 F. Mean (SD) age 48.4 (10.9) years intervention (*n*=415), 48.8 (12.2) years control (*n*=428). Mean (SD) BMI (kg/m^2) 37.0 (5.7) intervention, 36.9 (5.8) control.
Intervention	*4.5 h training programme promoting an obesity management model included* *Training: educational strategy was based on a previous nutrition training programme. All GPs and practice nurses to attend all three sessions.* *Model approach: incorporated best evidence and was perceived to be brief enough that primary care staff could deliver it to their patients. The training covered information on the clinical benefit of weight loss and effective treatment options, including reduction of dietary energy intake, increased physical activity, and pharmaceutical intervention.* *Organisation: seeing patients regularly (about every 2 weeks) until they had lost 10% of their original body weight and then less regularly (about every one to 2 months) for maintenance of weight over a sustained period. Current and target weight and dietary and activity targets were to be recorded in the patients' records to facilitate continuity of support across practice teams. Practices devised individualised weight management protocols based on the model.* *Diet: prescription of a moderate energy deficit diet was advocated. Diet sheets and supporting written resources facilitated the dietary prescription to patients.*
Comparison	Usual care
Length of follow-up	*18 months*

Results	*At 12 months, there was no difference between the intervention and control group patients with regard to weight (mean weight change +0.3 kg intervention vs 0.7 kg control,* p*=0.5).*
Quality and comments	*Cluster RCT, so contamination minimal. Randomisation done by statistician team, so assumed to be concealed allocation. Clustering accounted for. Results for completers only.*
Sponsor details	*NHS Executive (Northern and Yorkshire)*

Other outcomes

Taylor 2003	
Results	*No difference in mean satisfaction scores were seen between the groups (3.9 diet vs 3.6 healthy eating, no* p *value reported).*
Quality and comments	Satisfaction measured using a visual analogue scale of 1–5. No mention of whether validated scheme.

Moore 2003	
Results	*Patients in trained practices consulted, on average, on two more occasions than patients in control practices in the year after the delivery of the training. Trained practices were more likely to discuss weight (OR 2.0,* p*=0.003), and the records of patients from trained practices were more likely to include weight (OR 2.0,* p*= 0.004), target weight (13.6,* p*=0.001) and dietary targets (4.5,* p*=0.02).*
Quality and comments	…

Harms

Taylor 2003	
Harms	None reported.
Quality and comments	

Moore 2003	
Harms	None reported.
Quality and comments	

Generalisability

Taylor 2003	
Country and setting	UK. Hospital outpatient dietetic clinic.
Participants (included/excluded)	Included if overweight adults referred to clinic over a 12-month period.
Recruitment	Consecutive referrals.
Randomisation	Alternate allocation
Intervention (mode and intensity)	*Seen at four sessions with a dietitian held at four weekly intervals up to week 12.*
Duration of active intervention	12 weeks
Comparison (mode and intensity)	As above
Delivery of intervention/comparison (who)	Dietitian
Dropout rates	*41% diet, 58% healthy eating at 12 weeks.*

Treatment of dropouts (return to baseline, or last measurement?)	N/R

Moore 2003	
Country and setting	UK. Primary care.
Participants (included/excluded)	Included adults with BMI ≥30 kg/m^2, aged 16 to 64 years. No exclusion criteria reported.
Recruitment	From consecutive attendees at a general practice.
Randomisation	Informed by practice and patient level characteristics.
Intervention (mode and intensity)	*Three 90 min sessions, intended to be delivered at intervals of no less than one week and no more than 2 weeks apart, to the 22 intervention practices* *Practitioners saw patients regularly (about every 2 weeks) until they had lost 10% of their original body weight and then less regularly (about every one to 2 months) for maintenance of weight over a sustained period*
Duration of active intervention	18 months, but training only during first 6 weeks maximum
Comparison (mode and intensity)	Usual care
Delivery of intervention/comparison (who)	Training by four dietitians trained in the standardised delivery of the training who then delivered the programme to small group, multidisciplinary general practice teams. Patient care by GPs and practice nurses.
Dropout rates	*38% intervention, 36% control at 18 months.*
Treatment of dropouts (return to baseline, or last measurement?)	Results for completers only.

1.7.9 Barriers and attitudes to the management of overweight and obesity in the clinical setting

Detailed evidence tables were not needed for this section, as appropriate levels of detail are provided in the Narrative.

1.7.10 Role of professionally organised therapies in the management of overweight and obesity

The evidence review was based on one systematic review only. No additional primary studies were identified.

1.7.11 Effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for people who are overweight and obese

Weight loss

Pritchard 1999 (in HTA) RCT	
Aim	To study the clinical and cost outcomes of providing nutritional counselling to people with one or more of the following conditions: overweight, hypertension, type 2 diabetes.
Participants	Men and women aged between 25 and 65 years with either hypertension, type 2 diabetes or were overweight (BMI >25 kg/m^2). 273 total – 198F, 75M. 199 participants were aged <50 years. Mean weight (kg) 91.7 in the dietitian led intervention group (*n*=92), 85.5 in the doctor and dietitian led intervention group (*n*=88), 89.1 in the control group (*n*=90). Majority were from disadvantaged socio-economic groups (58% most disadvantaged quartile and 20% more disadvantaged quartile).
Intervention (including details of diet)	*Counselling focused on principles of good nutrition and exercise and addressed problem areas in lifestyle and dietary patterns. Counselled on food, shopping, cooking, food selection, meal planning, exercise programmes. Advised to complete food records and diet history. Advised to reduce total energy intake and to reduce energy intake from fat to ≤30% (carbohydrate ≥50% and protein 20%). Discouraged from smoking and to have two or more alcohol-free days per week, with two or fewer alcoholic standard drinks for women and four for men.* *In the doctor and dietitian group, as well as counselling above, participants were seen by the GP at baseline and saw same GP on two other occasions during the 12 months for 5 min each time to encourage and monitor the participant.*
Control	Received results of initial screening and advised to discuss queries with the GP at appointment. Received usual care (including monitoring, advice and prescriptions) from GP but no dietitian counselling. Mailed to re-attend at 12 months.
Length of follow-up	*12 months*
Results	Only 12-month outcomes reported. In an intention to treat analysis, the doctor/dietitian group lost 6.7 kg or 7.3% of screening weight compared with the control group (95% CI 6.5 to 8.3) while the dietitian group lost 5.6 kg or 6.6 (95% CI 5.8 to 7.6)%. The doctor/dietitian group lost 1.1 kg or 0.7% more weight than the dietitian group but this was not statistically significant (95% CI - 0.42 to 1.82).

Quality and comments	*Control groups halved. ITT analysis done. Blinded assessment not done. Real possibility of disclosure of allocation, although some attempt made at concealment.*

Other outcomes

Pritchard 1999 (in HTA) RCT	
Results	*No effect was found on the subsequent use of medication between the intervention groups and control.* *The cost of an additional kg weight loss was AUS$9.76 in the doctor and dietitian group compared with AUS$7.30 in the dietitian group.*
Quality and comments	…

Reported Harms

Pritchard 1999 (in HTA) RCT	
Harms	None reported.
Quality and comments	…

Generalisability

Pritchard 1999 (in HTA) RCT	
Country and setting	Australia. University group general practice, in lower socioeconomic suburb.
Participants (included/excluded)	Included if aged between 25 and 65 years. Also if BMI >25 kg/m^2, or screened BP >140/90 mmHg and recorded BP >140/90 mmHg at least twice in medical records, history of type 2 diabetes. Excluded if mentally ill, intellectually handicapped, terminally ill, acutely ill, pregnant or participating in other health education programmes.
Recruitment	Participants were screened opportunistically when attending the GP. People with recorded diagnosis of overweight, hypertension or type 2 diabetes in their patient notes were invited to participate. People who appeared to be overweight on presentation at reception were also invited to participate.
Intervention (mode and intensity)	*Intervention lasted 12 months. Contacted seven times (baseline then six times by dietitian over 12 months). Also supplemented with baseline contact with GP and 25 min sessions with the GP in the doctor and dietitian group.*
Control (mode and intensity)	Contacted twice (baseline and 12 months).
Delivery of intervention/control (who)	Initial screening and counselling done by dietitian. Dietitian invited those allocated to the dietitian group to participate. GP invited those allocated to the doctor and dietitian group, after screening by the dietitian. Mailed invite to attend for final measurement in control group.
Dropout rates	*45% dietitian group, 29% doctor and dietitian group, and 29% control at 12 months. (As reported in original paper, not HTA.) Dropouts were significantly higher in the dietitian group (p=0.022) than either the doctor and dietitian group or the control.*
Treatment of dropouts (return to baseline, or last measurement?)	If missing data, the last measurement recorded was taken to populate subsequent data values.

Contents

Appendix 16

1 Excluded studies

1.1 Measures other than body mass index

References were excluded from this review because they did not evaluate the utility of the measure of interest compared with body mass index (BMI), but compared with some other measure of overweight or obesity. For a full list of excluded references, please contact the Methods Team.

1.2 Measures and morbidity in ethnic populations

Study	Source	Reason for exclusion
Chambers JC, Eda S, Bassett P et al. (2001) C-reactive protein, insulin resistance, central obesity, and coronary heart disease risk in Indian Asians from the United Kingdom compared with European whites. *Circulation* 104(2):145–150.	Experts	Assesses the relationship between C-reactive protein, not anthropometric measures.
Despres JP, Lemieux I, Prud'homme D (2001) Treatment of obesity: need to focus on high risk abdominally obese patients. *British Medical Journal* 322(7288):716–20.	Experts	Not focused on ethic differences.
Farooqi A, Nagra D, Edgar T, Khunti K (2000) Attitudes to lifestyle risk factors for coronary heart disease amongst South Asians in Leicester: a focus group study. *Family Practice* 17:293–97.	Searches	Qualitative study of knowledge and attitudes of coronary heart disease risk factors. Not assessment.
Forouhi NG, Sattar N, McKeigue PM (2001) Relation of C-reactive protein to body fat distribution and features of the metabolic syndrome in Europeans and South Asians. *International Journal of Obesity and Related Metabolic Disorders* 25(9):1327–31.	Experts	Assesses the relationship between C-reactive protein, and anthropometric measures – not a routinely measured marker.
Han TS, Feskens EJ, Lean ME, Seidell JC (1998) Associations of body composition with type 2 diabetes mellitus. *Diabetic Medicine* 15(2):129–35. Han TS, Lean ME, Seidell JC (1996) Waist circumference remains useful predictor of coronary heart disease. *British Medical Journal* 312(7040):1227–28. Han TS, McNeill G, Seidell JC, Lean ME (1997) Predicting intra-abdominal fatness from anthropometric measures: the influence of stature. *International Journal of Obesity and Related Metabolic Disorders* 21(7):587–93. Han TS, van Leer EM, Seidell JC, Lean ME (1995) Waist circumference action levels in the identification of cardiovascular risk factors: prevalence study in a random sample. *British Medical Journal* 311(7017):1401–405. Han TS, van Leer EM, Seidell JC, Lean ME (1996) Waist circumference as a screening tool for cardiovascular risk factors: evaluation of receiver operating characteristics (ROC). *Obesity Research* 4(6):533–47.	Experts	Discusses the use of waist circumference and the effect of different cut-offs. Effect of ethnic difference not explored.

Study	Source	Reason for exclusion
Lean ME, Han TS, Deurenberg P (1996) Predicting body composition by densitometry from simple anthropometric measurements. *American Journal of Clinical Nutrition* 63(1):4–14. Lean ME, Han TS, Morrison CE (1995) Waist circumference as a measure for indicating need for weight management. *British Medical Journal* 311(6998):158–61. Lean ME, Han TS, Seidell JC (1998) Impairment of health and quality of life in people with large waist circumference. *Lancet* 351(9106):853–56.	Experts	Discusses the use of waist circumference and the effect of different cut-offs, or equations. Effect of ethnic difference not explored.
Malina RM, Huang YC, Brown KH (1995) Subcutaneous adipose tissue distribution in adolescent girls of four ethnic groups. *International Journal of Obesity and Related Metabolic Disorders* 19 (11):793–97.	Searches	Investigated subcutaneous adipose tissue distribution in adolescents of four ethnic groups in the USA. However, 327 out of the 498 of the sample were Mexicans, the Asian sample was 63 and almost exclusively Filipino, and the Black sample was only 27. Generalisability of the sample to the UK population was therefore extremely limited.
Misra A, Arora N, Mondal S (2001) Relation between plasma leptin and anthropometric and metabolic covariates in lean and obese diabetic and hyperlipidaemic Asian Northern Indian subjects. *Diabetes, Nutrition and Metabolism* 14(1):18–26.	Searches	Plasma leptin and obesity – not routinely measured.
Misra A, Wasir JS, Pandey RM (2005) An evaluation of candidate definitions of the metabolic syndrome in adult Asian Indians. *Diabetes Care* 28(2):398–403.	Searches	Assesses the effect of different definitions for metabolic syndrome in Asian Indians.
Misra A, Wasir JS, Vikram NK (2005) Carbohydrate diets, postprandial hyperlipidaemia, abdominal obesity and Asian Indians: a recipe for atherogenic disaster. *Indian Journal of Medical Research* 121(1):5–8.	Searches	Narrative review.
Pomerleau J, McKeigue PM, Chaturvedi N (1999) Factors associated with obesity in South Asian, Afro-Caribbean and European women. *International Journal of Obesity and Related Metabolic Disorders* 23(1):25–33.	Searches	Assessed the association between different anthropometric measures and other social factors.
Rosengren A, Hawken S, Ounpuu S et al. (2004) Association of psychosocial risk factors with risk of acute myocardial infarction in 11119 cases and 13648 controls from 52 countries (the INTERHEART study): case–control study. *Lancet* 364 (9438):953–62.	Experts	Assesses the effects of psychosocial risk factors associated with myocardial infarction across countries. Not relevant to review (INTERHEART).
Sattar N, Clark P, Holmes A, Lean ME, Walker I, Greer IA (2001) Antenatal waist circumference and hypertension risk. *Obstetrics and Gynecology* 97 (2):268–71.	Searches	Waist circumference in pregnant women. No ethnic differences explored.
Sattar N, Tan CE, Han TS et al. (1998) Associations of indices of adiposity with atherogenic lipoprotein subfractions. *International Journal of Obesity and Related Metabolic Disorders* 22(5):432–9.	Searches	To assess the association of indices of adiposity with cardiovascular risk factors. No ethnic differences explored.
Seidell JC, Han TS, Feskens EJ, Lean ME (1997) Narrow hips and broad waist circumferences independently contribute to increased risk of non-insulin-dependent diabetes mellitus. *Journal of Internal Medicine* 242(5):401–6.	Searches	Describes the body shape of people with non-insulin-dependent diabetes mellitus, but no ethnic difference explored

Study	Source	Reason for exclusion
Tillin T, Forouhi N, Johnston DG, McKeigue PM, Chaturvedi N, Godsland IF (2005) Metabolic syndrome and coronary heart disease in South Asians, African-Caribbeans and white Europeans: a UK population-based cross-sectional study. *Diabetologia* 48(4):649–56.	Experts	Assesses the effect of different definitions for metabolic syndrome in different ethnic groups.
Valsamakis G, Chetty R, Anwar A, Banerjee AK, Barnett A, Kumar S (2004) Association of simple anthropometric measures of obesity with visceral fat and the metabolic syndrome in male Caucasian and Indo-Asian subjects. *Diabetic Medicine* 21(12):1339–45.	Experts	Assess the usefulness of waist circumference, but does not compare different cut-offs between White and Indo-Asian men.
Vikram NK, Misra A, Dwivedi M et al. (2003) Correlations of C-reactive protein levels with anthropometric profile, percentage of body fat and lipids in healthy adolescents and young adults in urban North India. *Atherosclerosis* 168(2):305–313.	Experts	Assesses the relationship between C-reactive protein levels and obesity. Not a routinely measured marker.
Vikram NK, Misra A, Pandey RM, Dwivedi M, Luthra K (2004) Adiponectin, insulin resistance, and C-reactive protein in postpubertal Asian Indian adolescents. *Metabolism: Clinical and Experimental* 53(10):1336–41.	Experts	To compare serum adiponectin levels and obesity. Not routinely measured.
Widjaja A, Stratton IM, Horn R, Holman RR, Turner R, Brabant G (1997) UKPDS 20: Plasma leptin, obesity, and plasma insulin in type 2 diabetic subjects. *Journal of Clinical Endocrinology and Metabolism* 82(2):	Searches	Evaluates the association between leptin and BMI in different ethnic groups. Leptin is not a routinely measured plasma marker.
Wong W, Stuff JE, Butte NF, Smith EO, Ellis KJ (2000) Estimation of body fat in Caucasian and African-American girls: total-body electrical conductivity methodology versus a four-component model. *International Journal of Obesity and Related Metabolic Disorders* 24(9):1200–206.	Searches	Compared two research methods of estimating body fat in White and African American girls. It did not explore ethnicity differences in associations between commonly used proxy indicators of obesity and total body fat
Yusuf S, Hawken S, Ounpuu S et al. (2004) Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case–control study. *Lancet* 364(9438):937–52.	Experts	Assesses the effects of potentially modifiable risk factors associated with myocardial infarction across countries. Not relevant to review (INTERHEART).

1.3 Diet interventions

Study	Source	Reason for exclusion
Ahrens RA, Hower M, Best AM (2003) Effects of weight reduction interventions by community pharmacists. *Journal of the American Pharmacists Association* 43(5):583–9.	Searches	Not 52-week follow-up.
Allison DB, Gadbury G, Schwartz LG et al. (2003) A novel soy-based meal replacement formula for weight loss among obese individuals: a randomized controlled clinical trial. *European Journal of Clinical Nutrition* 57(4):514–22.	Searches	Not 52-week follow-up.
Arvidsson E, Viguerie N, Andersson I, Verdich C, Langin D, Arner P (2003) Effects of different hypocaloric diets on protein secretion from adipose tissue of obese women. *Diabetes* 53(8):1966–71.	Searches	Not 52-week follow-up.
Ash S, Reeves MM, Yeo S, Morrison G, Carey D, Capra S (2003) Effect of intensive dietetic interventions on weight and glycaemic control in overweight men with type II diabetes: a randomised trial. *International Journal of Obesity and Related Metabolic Disorders* 27(7):797–802.	Searches	Aimed to assess the effectiveness of intensive, innovative methods for implementing isoenergetic dietary prescriptions on weight management and glycaemic control in men with type 2 diabetes. Compared liquid meal replacements, prepared meals provided, self-prepared and selected meals, but all had the same balance of 50% of energy from carbohydrate and 30% from fat. Weight change for all men only, not by different intervention group.
Ashley JM, St Jeor ST, Perumean-Chaney S, Schrage J, Bovee V (2001) Meal replacements in weight intervention. *Obesity Research* 9(Suppl 4):S312–20.	Searches	Evaluates two comparable diets, but uses MR in one group. MR not clinical interventio
Bacon L, Keim NL, Van Loan MD et al. (2002) Evaluating a 'non-diet' wellness intervention for improvement of metabolic fitness, psychological well-being and eating and activity behaviors. *International Journal of Obesity and Related Metabolic Disorders* 26(6):854–65.	Searches	Compared behavioural therapy (BT), diet and physical activity (PA) with BT only. Added to PA review.
Barnard ND, Scialli AR, Turner-McGrievy G, Lanou AJ (2004) Acceptability of a low-fat vegan diet compares favorably to a step II diet in a randomized, controlled trial. *Journal of Cardiopulmonary Rehabilitation* 24(4):229–35.	PH cross-reference	Not 52-week follow-up.
Bouche C, Rizkalla SW, Luo J et al. (2002) Five-week, low-glycemic index diet decreases total fat mass and improves plasma lipid profile in moderately overweight nondiabetic men. *Diabetes Care* 25(5):822–8.	Searches	Not 52-week follow-up.

Study	Source	Reason for exclusion
Bray GA, Lovejoy JC, Most-Windhauser M et al. (2002) A 9-mo randomized clinical trial comparing fat-substituted and fat-reduced diets in healthy obese men: the Ole Study. *American Journal of Clinical Nutrition* 76(5):928–34.	Searches	Not 52-week follow-up.
Brehm BJ, Seeley RJ, Daniels SR, D'Alessio DA (2003) A randomized trial comparing a very low carbohydrate diet and a calorie-restricted low fat diet on body weight and cardiovascular risk factors in healthy women. *Journal of Clinical Endocrinology and Metabolism* 88(4):1617–23.	Searches	Not 52-week follow-up.
Clifton PM, Noakes M, Keogh JB (2004) Very low-fat (12%) and high monounsaturated fat (35%) diets do not differentially affect abdominal fat loss in overweight, nondiabetic women. *Journal of Nutrition* 134(7):1741–5.	Searches	Not 52-week follow-up.
Conceicao de Oliveira M, Sichieri R, Sanchez MA (2003) Weight loss associated with a daily intake of three apples or three pears among overweight women. *Nutrition* 19(3):253–6.	Searches	Not 52-week follow-up.
Cox KL, Burke V, Morton AR, Beilin LJ, Puddey IB (2003) The independent and combined effects of 16 weeks of vigorous exercise and energy restriction on body mass and composition in free-living overweight men – a randomized controlled trial. *Metabolism: Clinical and Experimental* 52(1):107–115.	Searches	Not 52-week follow-up.
Deibert P, Konig D, Schmidt-Trucksaess A et al. (2004) Weight loss without losing muscle mass in pre-obese and obese subjects induced by a high-soy-protein diet. *International Journal of Obesity and Related Metabolic Disorders* 28(10):1349–52.	Searches	Not 52-week follow-up.
Ditschuneit HH, Flechtner-Mors M (2001) Value of structured meals for weight management: risk factors and long-term weight maintenance. *Obesity Research* 9(Suppl 4):S284–9.	Searches	Not 52 week intervention. Only randomised for 3 months, then single arm trial.
Djuric Z, Lababidi S, Heilbrun LK, Depper JB, Poore KM, Uhley VE (2002) Effect of low-fat and/or low-energy diets on anthropometric measures in participants of the women's diet study. *Journal of the American College of Nutrition* 21(1):38–46.	Searches	Not 52-week follow-up
Dzator JA, Hendrie D, Burke V et al. (2004) A randomized trial of interactive group sessions achieved greater improvements in nutrition and physical activity at a tiny increase in cost. *Journal of Clinical Epidemiology* 57(6):610–19.	Searches	Change in weight (kg) not reported.

Study	Source	Reason for exclusion
Ebbeling CB, Leidig MM, Sinclair KB, Hangen JP, Ludwig DS (2003) A reduced-glycemic load diet in the treatment of adolescent obesity. *Archives of Pediatrics and Adolescent Medicine* 157(8):773–9.	Searches	Not adults – adolescents aged 13 to 21 years.
Fagerberg B, Wiklund O, Agewall S, Camejo G, Wikstrand RJ (1996) Multifactorial treatment of hypertensive men at high cardiovascular risk and low-density lipoprotein cholesterol affinity to human arterial proteoglycans. *European Journal of Clinical Investigation* 26(11):960–65.	Agency for Healthcare Research and Quality (AHRQ)	Intervention was multifaceted – included diet, use of lipid-lowering agents, smoking cessation programme. Excluded as smoking cessation could affect weight change (NHS Health Technology Assessment Project [HTA] exclusion).
Fernandez de la Puebla RA, Fuentes F, Perez-Martinez P et al. (2003) A reduction in dietary saturated fat decreases body fat content in overweight, hypercholesterolemic males. *Nutrition Metabolism and Cardiovascular Diseases* 13(5):273–7.	Searches	Not 52-week follow-up.
Gerhard GT, Ahmann A, Meeuws K, McMurry MP, Duell PB, Connor WE (2004) Effects of a low-fat diet compared with those of a high-monounsaturated fat diet on body weight, plasma lipids and lipoproteins, and glycemic control in type 2 diabetes. *American Journal of Clinical Nutrition* 80(3):668–73.	Searches	Not 52-week follow-up.
Hays NP, Starling RD, Liu X et al. (2004) Effects of an ad libitum low-fat, high-carbohydrate diet on body weight, body composition, and fat distribution in older men and women: a randomized controlled trial. *Archives of Internal Medicine* 164(2):210–7.	Searches	Not 52-week follow-up.
Jen KL, Djuric Z, DiLaura NM et al. (2004) Improvement of metabolism among obese breast cancer survivors in differing weight loss regimens. *Obesity Research* 12(2):306–312.	Searches	Compared Weight Watchers (diet and meetings), individual counselling (no details of dietary or other content), Weight Watchers and counselling, and control. Not diet alone.
Joseph LJ, Trappe TA, Farrell PA et al. (2001) Short-term moderate weight loss and resistance training do not affect insulin-stimulated glucose disposal in postmenopausal women. *Diabetes Care* 24 (11):1863–9.	Searches	Not 52-week follow-up.
Kirk SF, Harvey EL, McConnon A et al. (2003) A randomised trial of an Internet weight control resource: the UK Weight Control Trial [ISRCTN58621669].*[BMC Health Services Research* 3(1):19.	Searches	Study protocol – not results.
Knowler WC, Barrett-Connor E, Fowler SE (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 346(6):393–403.	Searches and Guidance Development Group (GDG)	DPP study excluded as aim not weight loss, and no direct comparison of lifestyle, but lifestyle plus placebo.

Study	Source	Reason for exclusion
Krotkiewski M (2001) Value of VLCD supplementation with medium chain triglycerides. *International Journal of Obesity and Related Metabolic Disorders* 25(9):1393–1400.	Searches	Not 52-week follow-up.
Landers P, Wolfe MM, Glore S, Guild R, Phillips L (2002) Effect of weight loss plans on body composition and diet duration. *Journal of the Oklahoma State Medical Association* 95(5):329–31.	Searches	Not 52-week follow-up.
Landry N, Bergeron N, Archer R et al. (2003) Whole-body fat oxidation rate and plasma triacylglycerol concentrations in men consuming an ad libitum high-carbohydrate or low-carbohydrate diet. *American Journal of Clinical Nutrition* 77(3):580–6.	Searches	Not 52-week follow-up.
Lantz H, Peltonen M, Agren L, Torgerson JS (2003) Intermittent versus on-demand use of a very low calorie diet: a randomized 2-year clinical trial. *Journal of Internal Medicine* 253(4):463–71.	Searches	Compared intermittent and regular use of short-term diets, not type of diet.
Lantz H, Peltonen M, Agren L, Torgerson JS (2003) A dietary and behavioural programme for the treatment of obesity. A 4-year clinical trial and a long-term posttreatment follow-up. *Journal of Internal Medicine* 254(3):272–9.	Searches	See included trial: Torgerson 1997.
Lean ME, Han TS, Prvan T, Richmond PR, Avenell A (1997) Weight loss with high and low carbohydrate 1200 kcal diets in free living women. *European Journal of Clinical Nutrition* 51(4):243–8.	CR Pirozzo	Not 12-month outcomes.
Leslie WS, Lean ME, Baillie HM, Hankey CR (2002) Weight management: a comparison of existing dietary approaches in a work-site setting. *International Journal of Obesity and Related Metabolic Disorders* 26(11):1469–75.	Searches	Not 52-week follow-up.
Lovejoy JC, Bray GA, Lefevre M et al. (2003) Consumption of a controlled low-fat diet containing olestra for 9 months improves health risk factors in conjunction with weight loss in obese men: The Ole Study. *International Journal of Obesity* 27(10):1242–9.	Searches	Not 52-week follow-up.
Meckling KA, O'Sullivan C, Saari D (2004) Comparison of a low-fat diet to a low-carbohydrate diet on weight loss, body composition, and risk factors for diabetes and cardiovascular disease in free-living, overweight men and women. *Journal of Clinical Endocrinology and Metabolism* 89(6):2717–23.	Searches	Not 52-week follow-up.

Study	**Source**	**Reason for exclusion**
Miyashita Y, Koide N, Ohtsuka M et al. (2004) Beneficial effect of low carbohydrate in low calorie diets on visceral fat reduction in type 2 diabetic patients with obesity. *Diabetes Research and Clinical Practice* 65:235–41.	Submitted evidence and searches	Not 52-week follow-up.
Nieman DC, Brock DW, Butterworth D, Utter AC, Nieman CC (2002) Reducing diet and/or exercise training decreases the lipid and lipoprotein risk factors of moderately obese women. *Journal of the American College of Nutrition* 21(4):344–50.	Searches	Not 52-week follow-up.
Noakes M, Foster PR, Keogh JB, Clifton PM (2004) Meal replacements are as effective as structured weight-loss diets for treating obesity in adults with features of metabolic syndrome. *Journal of Nutrition* 134(8):1894–9.	Searches	Not 52-week follow-up.
Parker B, Noakes M, Luscombe N, Clifton P (2002) Effect of a high-protein, high-monounsaturated fat weight loss diet on glycemic control and lipid levels in type 2 diabetes. *Diabetes Care* 25(3):425–30.	Searches	Not 52-week follow-up.
Pelkman CL, Fishell VK, Maddox DH et al. (2004) Effects of moderate-fat (from monounsaturated fat) and low-fat weight-loss diets on the serum lipid profile in overweight and obese men and women. *American Journal of Clinical Nutrition* 79(2):204–212.	Searches	Not 52-week follow-up.
Piers LS, Walker KZ, Stoney RM, Soares MJ, O'Dea K (2003) Substitution of saturated with monounsaturated fat in a 4-week diet affects body weight and composition of overweight and obese men. *British Journal of Nutrition* 90(3):717–27.	Searches	Not 52-week follow-up.
Poston WSC, Haddock CK, Pinkston MM, Pace P, Karakoc ND, Reeves RS, Foreyt JP. (2005) Weight loss with meal replacement and meal replacement plus snacks: a randomized trial. International Journal of Obesity 29 (9):1107-14.	Stakeholder	Not 52-week follow-up.
Poppitt SD, Keogh GF, Prentice AM et al. (2002) Long-term effects of ad libitum low-fat, high-carbohydrate diets on body weight and serum lipids in overweight subjects with metabolic syndrome. *American Journal of Clinical Nutrition* 75(1):11–20.	Searches	Not 52-week follow-up.
Ricci TA, Heymsfield SB, Pierson RN Jr, Stahl T, Chowdhury HA, Shapses SA (2001) Moderate energy restriction increases bone resorption in obese postmenopausal women. *American Journal of Clinical Nutrition* 73(2):347–52.	Searches	Not 52-week follow-up.

Study	Source	Reason for exclusion
Rolland-Cachera MF, Thibault H, Souberbielle JC et al. (2004) Massive obesity in adolescents: dietary interventions and behaviours associated with weight regain at 2 y follow-up. *International Journal of Obesity and Related Metabolic Disorders* 28(4):514–9.	Searches	Not adults – children aged 11 to 16 years
Ross R, Janssen I, Dawson J et al. (2004) Exercise-induced reduction in obesity and insulin resistance in women: a randomized controlled trial. *Obesity Research* 12(5):789–98.	Searches	Not 52-week follow-up.
Roy HJ, Most MM, Sparti A et al. (2002) Effect on body weight of replacing dietary fat with olestra for two or ten weeks in healthy men and women. *Journal of the American College of Nutrition* 21(3):259–67.	Searches	Not 52-week follow-up.
Saris WHM (2001) Very low calorie diets and sustained weight loss. *Obesity Research* 9(4):	Searches	Narrative review.
Sondike SB, Copperman N, Jacobson MS (2003) Effects of a low-carbohydrate diet on weight loss and cardiovascular risk factor in overweight adolescents. *Journal of Pediatrics* 142(3):253–8.	Searches	Not adults – children aged 12 to 18 years.
St Onge MP, Bourque C, Jones PJ, Ross R, Parsons WE (2003) Medium- versus long-chain triglycerides for 27 days increases fat oxidation and energy expenditure without resulting in changes in body composition in overweight women. *International Journal of Obesity and Related Metabolic Disorders* 27(1):95–102.	Searches	Not 52-week follow-up.
St Onge MP, Jones PJ (2003) Greater rise in fat oxidation with medium-chain triglyceride consumption relative to long-chain triglyceride is associated with lower initial body weight and greater loss of subcutaneous adipose tissue. *International Journal of Obesity and Related Metabolic Disorders* 27(12):1565–71.	Searches	Not 52-week follow-up.
St Onge MP, Ross R, Parsons WD, Jones PJ (2003) Medium-chain triglycerides increase energy expenditure and decrease adiposity in overweight men. *Obesity Research* 11(3):395–402.	Searches	Not 52 week follow-up
Stamets K, Taylor DS, Kunselman A, Demers LM, Pelkman CL, Legro RS (2004) A randomized trial of the effects of two types of short-term hypocaloric diets on weight loss in women with polycystic ovary syndrome. *Fertility and Sterility* 81(3):630–37.	Searches	Not 52-week follow-up.

Study	**Source**	**Reason for exclusion**
Taylor FC, Irons LJ, Finn P, Summerbell CD (2003) Controlled clinical trial of two weight reducing diets in a NHS hospital dietetic outpatient clinic – a pilot study [erratum appears in *Journal of Human Nutrition and Dietetics* (2003) 16(3):215]. *Journal of Human Nutrition and Dietetics* 16(2):85–87.	Searches	Not 52-week follow-up.
Tsai AG, Wadden TA (2005) Systematic review: an evaluation of major commercial weight loss programs in the United States. *Annals of Internal Medicine* 142(1):56–66.	Searches	Systematic review of commercial weight loss programmes available and evaluated only in the USA.
Volek JS, Sharman MJ, Love DM (200) Body composition and hormonal responses to a carbohydrate-restricted diet. *Metabolism: Clinical and Experimental* 51(7):864–70.	Searches	Not overweight participants – normal weight men only (not defined).
Volek JS, Sharman MJ, Gomez AL et al. (2004) Comparison of a very low-carbohydrate and low-fat diet on fasting lipids, LDL subclasses, insulin resistance, and postprandial lipemic responses in overweight women. *Journal of the American College of Nutrition* 23(2):177–84.	Submitted evidence	Not 52-week follow-up.
West JA, de Looy AE (2001) Weight loss in overweight subjects following low-sucrose or sucrose-containing diets. *International Journal of Obesity and Related Metabolic Disorders* 25(8):1122–8.	Searches	Not 52 week follow-up.
Wien MA, Sabate JM, Ikle DN, Cole SE, Kandeel FR. Almonds vs complex carbohydrates in a weight reduction program [erratum appears in *International Journal of Obesity and Related Metabolic Disorders* (2004) 28(3):459]. *International Journal of Obesity and Related Metabolic Disorders* 27(11):1365–72.	Searches	Not 52 week follow-up
Womble LG, Wadden TA, McGuckin BG, Sargent SL, Rothman RA, Krauthamer-Ewing ES (2004) A randomized controlled trial of a commercial internet weight loss program. *Obesity Research* 12(6):1011–8.	Searches	Compared low-energy diets but intervention arm had Internet support – not clinical setting.
Yancy WS Jr, Olsen MK, Guyton JR, Bakst RP, Westman EC (2004) A low-carbohydrate, ketogenic diet versus a low-fat diet to treat obesity and hyperlipidemia: a randomized, controlled trial. *Annals of Internal Medicine* 140(10):769–77.	Searches	Not 52-week follow-up.
Yip I, Go VL, DeShields S et al. (2001) Liquid meal replacements and glycemic control in obese type 2 diabetes patients. *Obesity Research* 9(Suppl 4):S341–7.	Searches	Not 52-week follow-up.

1.4 Behaviour therapy (with or without diet)

Study	Source	Reason for exclusion
Bacon L, Keim NL, Van Loan MD et al. (2002) Evaluating a 'non-diet' wellness intervention for improvement of metabolic fitness, psychological well-being and eating and activity behaviors. *International Journal of Obesity and Related Metabolic Disorders* 26 (6):854–65.	Searches	Compared BT, diet and PA with BT only. In PA review.
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S (2003) Physical activity and nutrition programs for couples: a randomized controlled trial. *Journal of Clinical Epidemiology* 5(5):421–32.	Searches	Weight (in kg) not reported.
Dalle GR, Todesco T, Banderali A, Guardini S (2004) Cognitive-behavioural guided self-help for obesity: a preliminary research. *Eating and Weight Disorders* 9(1):69–76.	Searches	Not 52-week follow-up.
Dallow CB, Anderson J (2003) Using self-efficacy and a transtheoretical model to develop a physical activity intervention for obese women. *American Journal of Health Promotion* 17(6):373–81.	Searches	Not 52-week follow-up.
Dzator JA, Hendrie D, Burke V et al. (2004) A randomized trial of interactive group sessions achieved greater improvements in nutrition and physical activity at a tiny increase in cost. *Journal of Clinical Epidemiology* 57(6):610–19.	Searches	Weight (in kg) not reported.
Fagerberg B, Wiklund O, Agewall S, Camejo G, Wikstrand RJ (1996) Multifactorial treatment of hypertensive men at high cardiovascular risk and low-density lipoprotein cholesterol affinity to human arterial proteoglycans. *European Journal of Clinical Investigation* 26(11):960–65.	AHRQ	Intervention included smoking cessation, which may have had an effect on weight change.
Gorin AA, Le Grange D, Stone AA (2003) Effectiveness of spouse involvement in cognitive behavioral therapy for binge eating disorder. *International Journal of Eating Disorders* 33(4):421–33.	Searches	Participants were women with binge eating disorder.
Harvey-Berino J, Pintauro SJ, Gold EC (2002) The feasibility of using Internet support for the maintenance of weight loss. *Behavior Modification* 26(1):103–116.	Searches	Compared diet, BT and PA with different levels of support for maintenance – in non-clinical settings review.
Harvey-Berino J, Pintauro S, Buzzell P, Gold EC (2004) Effect of internet support on the long-term maintenance of weight loss. *Obesity Research* 12 (2):320–29.	Searches	Compared diet, BT and PA with different levels of support for maintenance – in non-clinical settings review.
Heshka S, Anderson JW, Atkinson RL et al. (2004) Weight loss with self-help compared with a structured commercial program: a randomized trial. *Journal of the American Medical Association* 289(14):1792–8.	Searches	Compared self-help with a commercial programme. Not clinical setting.
Hoeger KM, Kochman L, Wixom N, Craig K, Miller RK, Guzick DS (2004) A randomized, 48-week, placebo-controlled trial of intensive lifestyle modification and/or metformin therapy in overweight women with polycystic ovary syndrome: a pilot study. *Fertility and Sterility* 82(2):421–9.	Searches	Compared diet, PA and possible BT with metformin or placebo, and placebo only.
Jeffery RW, Wing RR, Sherwood NE, Tate DF (2003) Physical activity and weight loss: does prescribing higher physical activity goals improve outcome? *American Journal of Clinical Nutrition* 78(4):684–9.	Searches	Compared different levels of PA and BT.

Study	Source	Reason for exclusion
Jeffery RW, Sherwood NE, Brelje K et al. (2003) Mail and phone interventions for weight loss in a managed-care setting: Weigh-To-Be one-year outcomes. *International Journal of Obesity and Related Metabolic Disorders* 27(12):1584–92.	Searches	Compared mail or telephone delivery of intervention – non-clinical setting.
Jenkins I, Djuric Z, Darga L, DiLaura NM, Magnan M, Hryniuk WM (2003) Relationship of psychiatric diagnosis and weight loss maintenance in obese breast cancer survivors. *Obesity Research* 11(11):1369–75.	Searches	Individualised counselling – not BT.
Kajaste S, Brander PE, Telakivi T, Partinen M, Mustajoki P (2004) A cognitive-behavioral weight reduction program in the treatment of obstructive sleep apnea syndrome with or without initial nasal CPAP: a randomized study. *Sleep Medicine* 5(2):125–31.	Searches	Comparison of nasal continuous positive airway pressure (CPAP), not weight loss intervention.
Keele-Smith R, Leon T (2003) Evaluation of individually tailored interventions on exercise adherence. *Western Journal of Nursing Research* 25(6):623–40, 2003.	Searches	Not 52-week follow-up.
Kenardy J, Mensch M, Bowen K, Green B, Walton J (2002) Group therapy for binge eating in Type 2 diabetes: a randomized trial. *Diabetic Medicine* 19(3):234–9.	Rubak	Not 52-week follow-up. Participants with binge eating disorder.
Kerr D, Miles P (2004) The 12 month findings of using a commercial very low calorie diet (VLCD) weight-loss programme for patients with Type 2 diabetes who have unsuccessfully reduced weight despite following all first line interventions.	Submitted evidence	No published papers (checked April 2005).
Kirk SF, Harvey EL, McConnon A et al. (2003) A randomised trial of an Internet weight control resource: the UK Weight Control Trial [ISRCTN58621669]. *BMC Health Services Research* 3(1):19.	Searches	Trial protocol, not results.
Knowler WC, Barrett-Connor E, Fowler SE et al. (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 346(6):393–403.	AHRQ, ICSI	Compared diet and BT and PA with metformin or placebo
Krummel DA, Semmens E, Boury J, Gordon PM, Larkin KT (2004) Stages of change for weight management in postpartum women. *Journal of the American Dietetic Association* 104(7):1102–108.	Searches	Not results of the randomised controlled trial (RCT):
Lindstrom J, Louheranta A, Mannelin M et al. (2003) The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. *Diabetes Care* 26(12):3230–6.	Searches	In combined review – Finnish Diabetes Prevention Study.
Littrell KH, Hilligoss NM, Kirshner CD, Petty RG, Johnson CG (2003) The effects of an educational intervention on antipsychotic-induced weight gain. *Journal of Nursing Scholarship* 35(3):237–41.	Searches	Not BMI ≥28 kg/m^2.
Mayer-Davis EJ, D'Antonio AM, Smith SM et al. (2004) Pounds off with empowerment (POWER): a clinical trial of weight management strategies for black and white adults with diabetes who live in medically underserved rural communities. *American Journal of Public Health* 94(10):1736–42.	Searches	Compared diet, PA and BT using two forms of delivery with control (information).
Moore H, Summerbell CD, Greenwood DC et al. (2003) Improving management of obesity in primary care: cluster randomised trial. *British Medical Journal* 327(7423):1085.	Searches	Intervention aimed at healthcare professionals.

Study	Source	Reason for exclusion
O'Toole ML, Sawicki MA, Artal R (2003) Structured diet and physical activity prevent postpartum weight retention. *Journal of Women's Health* 12(10):991–8.	Searches	Compares structured individualised programme on diet and PA with group sessions, and self-directed weight loss (information with no additional contact).
Oldroyd JC, Unwin NC, White M, Imrie K, Mathers JC, Alberti KG (2001) Randomised controlled trial evaluating the effectiveness of behavioural interventions to modify cardiovascular risk factors in men and women with impaired glucose tolerance: outcomes at 6 months. *Diabetes Research and Clinical Practice* 52(1):29–43.	Shaw CR	Not 52-week follow-up.
Painot D, Jotterand S, Kammer A, Fossati M, Golay A (2001) Simultaneous nutritional cognitive–behavioural therapy in obese patients. *Patient Education and Counseling* 42(1):47–52.	Shaw CR	Not 52-week follow-up.
Park TL, Perri MG, Rodrigue JR (2003) Minimal intervention programs for weight loss in heart transplant candidates: a preliminary examination. *Progress in Transplantation* 13 (4):284–8.	Searches	Not 52-week follow-up.
Raynor HA, Jeffery RW, Tate DF, Wing RR (2004) Relationship between changes in food group variety, dietary intake, and weight during obesity treatment. *International Journal of Obesity and Related Metabolic Disorders* 28(6):813–20.	Searches	Compared BT and diet with different levels PA. In PA review.
Read A, Ramwell H, Storer H, Webber J (2004) A primary care intervention programme for obesity and coronary heart disease risk factor reduction. *British Journal of General Practice* 54(501):272–8.	PH *cross*-reference	Not RCT.
Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD (2001) Individual versus group therapy for obesity: effects of matching participants to their treatment preferences. *Journal of Consulting and Clinical Psychology* 69(4):717–21.	Searches	Not 52-week follow-up.
Sartorio A, Lafortuna CL, Marinone PG, Tavani A, La Vecchia C, Bosetti C (2003) Short-term effects of two integrated, non-pharmacological body weight reduction programs on coronary heart disease risk factors in young obese patients. *Diabetes, Nutrition and Metabolism* 16(4):262–5.	Searches	Not 52-week follow-up.
Simkin-Silverman LR, Wing RR, Boraz MA, Kuller LH (2003) Lifestyle intervention can prevent weight gain during menopause: results from a 5-year randomized clinical trial. *Annals of Behavioral Medicine* 26(3):212–20.	Searches	Earlier publications from the same trial excluded from the HTA. Not BMI ≥28 kg/m^2.
Tate DF, Jackvony EH, Wing RR (2003) Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. *Journal of the American Medical Association* 289(14):1833–6.	Searches	Compared diet, BT and PA with different levels of support – basic Internet vs. e-counselling. Non-clinical setting
Womble LG, Wadden TA, McGuckin BG, Sargent SL, Rothman RA, Krauthamer-Ewing ES (2004) A randomized controlled trial of a commercial internet weight loss program. *Obesity Research* 12(6):1011–18.	Searches	Compared diet, BT and PA with different levels of support – manual vs. Internet site. Non-clinical setting.

Study	Source	Reason for exclusion
Yeh MC, Rodriguez E, Nawaz H, Gonzalez M, Nakamoto D, Katz DL (2003) Technical skills for weight loss: 2-y follow-up results of a randomized trial. *International Journal of Obesity and Related Metabolic Disorders* 27(12):1500–506.	Searches	Compared skills-based BT therapy with BT counselling – no details of techniques used in counselling – excluded.
Yu CM, Li LS, Ho HH, Lau CP (2003) Long-term changes in exercise capacity, quality of life, body anthropometry, and lipid profiles after a cardiac rehabilitation program in obese patients with coronary heart disease. *American Journal of Cardiology* 91(3):321–5.	Searches	Not BMI ≥28 kg/m^2.

1.5 Physical activity (alone or in combination with diet or behaviour therapy)

Study	Source	Reason for exclusion
Aggel-Leijssen DP, Saris WH, Hul GB, Van Baak MA (2001) Short-term effects of weight loss with or without low-intensity exercise training on fat metabolism in obese men. *American Journal of Clinical Nutrition* 73(3):523–31.	Shaw CR	Not 52-week follow-up.
Aggel-Leijssen DP, Saris WH, Homan M, Van Baak MA (2001) The effect of exercise training on beta-adrenergic stimulation of fat metabolism in obese men. *International Journal of Obesity and Related Metabolic Disorders* 25(1):16–23.	Shaw CR	Not 52 week follow-up.
Aggel-Leijssen DP, Saris WH, Wagenmakers AJ, Senden JM, Van Baak MA (2002) Effect of exercise training at different intensities on fat metabolism of obese men. *Journal of Applied Physiology* 92(3):1300–309.	Searches	Not 52-week follow-up.
Allen JK (1996) Coronary risk factor modification in women after coronary artery bypass surgery. *Nursing Research* 45(5):260–65.	AHRQ	Intervention included smoking cessation, which may have had an effect on weight change.
Andersen RE, Franckowiak SC, Bartlett SJ, Fontaine KR (2002) Physiologic changes after diet combined with structured aerobic exercise or lifestyle activity. *Metabolism: Clinical and Experimental* 51(12):1528–33.	Searches (PH cross-reference)	Not 52-week follow-up.
Balkestein EJ, Aggel-Leijssen DP, Van Baak MA, Struijker-Boudier HA, Van Bortel LM (1999) The effect of weight loss with or without exercise training on large artery compliance in healthy obese men. *Journal of Hypertension* 17(12 Pt 2):1831–5.	Shaw CR	Not 52-week follow-up.
Baughman K, Logue E, Sutton K, Capers C, Jarjoura D, Smucker W (2003) Biopsychosocial characteristics of overweight and obese primary care patients: do psychosocial and behavior factors mediate sociodemographic effects? *Preventive Medicine* 37(2):129–37.	Searches	Not RCT. Checked for published RCT results.

Study	Source	Reason for exclusion
Brach JS, VanSwearingen JM, FitzGerald SJ, Storti KL, Kriska AM (2004) The relationship among physical activity, obesity, and physical function in community-dwelling older women. *Preventive Medicine* 39(1):74–80.	Searches	Reported 14-year follow-up from RCT Results not reported by group, but for whole cohort only.
Brankston GN, Mitchell BF, Ryan EA, Okun NB (2004) Resistance exercise decreases the need for insulin in overweight women with gestational diabetes mellitus. *American Journal of Obstetrics and Gynecology* 190(1):188–93.	Searches	Not 52-week follow-up.
Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S (2003) Physical activity and nutrition programs for couples: a randomized controlled trial. *Journal of Clinical Epidemiology* 56(5):421–32.	Searches	Change in weight (kg) not reported.
Cox KL, Burke V, Morton AR, Beilin LJ, Puddey IB (2003) The independent and combined effects of 16 weeks of vigorous exercise and energy restriction on body mass and composition in free-living overweight men – a randomized controlled trial. *Metabolism: Clinical and Experimental* 52(1):107–115.	Shaw CR	Weight loss not reported.
Cox KL, Burke V, Morton AR, Beilin LJ, Puddey IB (2004) Independent and additive effects of energy restriction and exercise on glucose and insulin concentrations in sedentary overweight men. *American Journal of Clinical Nutrition* 80(2):308–316.	Searches	Not 52-week follow-up.
Cox KL, Puddey IB, Morton AR, Burke V, Beilin LJ, McAleer M (1996) Exercise and weight control in sedentary overweight men: effects on clinic and ambulatory blood pressure. *Journal of Hypertension* 14(6):779–90.	Searches	Not 52-week follow-up.
Deibert P, Konig D, Schmidt-Trucksaess A et al. (2004) Weight loss without losing muscle mass in pre-obese and obese subjects induced by a high-soy-protein diet. *International Journal of Obesity and Related Metabolic Disorders* 28(10):1349–52.	Searches	Not 52-week follow-up.
Dunn AL, Garcia ME, Marcus BH, Kampert JB, Kohl HW, Blair SN (1998) Six-month physical activity and fitness changes in Project Active, a randomized trial. *Medicine and Science in Sports and Exercise* 30(7):1076–83.	Morgan	Not 52-week follow-up. No weight outcomes.
Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HW III, Blair SN (1999) Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness: a randomized trial. *Journal of the American Medical Association* 281(4):327–34.	Searches	Not required to be overweight.
Dzator JA, Hendrie D, Burke V et al. (2004) A randomized trial of interactive group sessions achieved greater improvements in nutrition and physical activity at a tiny increase in cost. *Journal of Clinical Epidemiology* 57(6):610–19.	Searches	Change in weight (kg) not reported.
Esposito K, Giugliano F, Di Palo C et al. (2004) Effect of lifestyle changes on erectile dysfunction in obese men: a randomized controlled trial. *Journal of the American Medical Association* 29 (24):2978–84.	Searches	No details of level of PA.
Esposito K, Pontillo A, Di Palo C et al. (2003) Effect of weight loss and lifestyle changes on vascular inflammatory markers in obese women: a randomized trial. *Journal of the American Medical Association* 289(14):1799–1804.	Searches	No details of level of PA.

Study	**Source**	**Reason for exclusion**
Fagerberg B, Wiklund O, Agewall S, Camejo G, Wikstrand RJ (1996) Multifactorial treatment of hypertensive men at high cardiovascular risk and low-density lipoprotein cholesterol affinity to human arterial proteoglycans. *European Journal of Clinical Investigation* 26(11):960–65.	AHRQ	Intervention included smoking cessation, which may have had an effect on weight change.
Fox KR (2004) Impact assessment of Body Magic, Slimming World's physical activity promotion campaign.	Submitted evidence	Survey, not RCT.
Gillett PA & Eisenman PA (1987) The effect of intensity controlled aerobic dance exercise on aerobic capacity of middle-aged, overweight women. *Research in Nursing and Health* 10(6):383–90.	Searches	Not 52-week follow-up.
Gordon NF, Scott CB, Levine BD (1997) Comparison of single versus multiple lifestyle interventions: are the antihypertensive effects of exercise training and diet-induced weight loss additive? *American Journal of Cardiology* 79(6):763–7.	Shaw CR	Not 52-week follow-up.
Grant S, Todd K, Aitchison TC, Kelly P, Stoddart D (2004) The effects of a 12-week group exercise programme on physiological and psychological variables and function in overweight women. *Public Health* 11(1):31–42.	Searches	Not 52-week follow-up.
Harland J, White M, Drinkwater C, Chinn D, Farr L, Howel D (1999) The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *British Medical Journal* 319 (7213):828–32.	Morgan	No details of baseline BMI status. Participants did not have to be overweight.
Hays NP, Starling RD, Liu X et al. (2004) Effects of an ad libitum low-fat, high-carbohydrate diet on body weight, body composition, and fat distribution in older men and women: a randomized controlled trial. *Archives of Internal Medicine* 164(2):210–17.	Searches	Not 52 week follow-up
Hellenius ML, de Faire U, Berglund B, Hamsten A, Krakau I (1993) Diet and exercise are equally effective in reducing risk for cardiovascular disease. Results of a randomized controlled study in men with slightly to moderately raised cardiovascular risk factors. *Atherosclerosis* 103(1):81–91.	Shaw CR	Not 52-week follow-up.
Heshka S, Anderson JW, Atkinson RL et al. (2003) Weight loss with self-help compared with a structured commercial program: a randomized trial. *Journal of the American Medical Association* 289(14):1792–8.	Searches	Non-clinical setting
Jakicic JM, Wing RR, Butler BA, Robertson RJ (1995) Prescribing exercise in multiple short bouts versus one continuous bout: effects on adherence, cardiorespiratory fitness, and weight loss in overweight women. *International Journal of Obesity and Related Metabolic Disorders* 19(12):893–901.	Searches	Not 52-week follow-up.
Janssen I, Fortier A, Hudson R, Ross R (2002) Effects of an energy-restrictive diet with or without exercise on abdominal fat, intermuscular fat, and metabolic risk factors in obese women. *Diabetes Care* 25(3):431–8.	Shaw CR	Not 52-week follow-up.
Jen KL, Djuric Z, DiLaura NM (2004) Improvement of metabolism among obese breast cancer survivors in differing weight loss regimens. *Obesity Research* 12(2):306–312.	Searches	No detail of PA.
Kaplan RM, Hartwell SL, Wilson DK, Wallace JP (1987) Effects of diet and exercise interventions on control and quality of life in non-insulin-dependent diabetes mellitus. *Journal of General Internal Medicine* 2(4):220–8.	Avenell HTA	Not overweight or obese requirement

Study	**Source**	**Reason for exclusion**
Keele-Smith R, Leon T (2003) Evaluation of individually tailored interventions on exercise adherence. *Western Journal of Nursing Research* 25(6):623–40.	Searches	Not 52-week follow-up
Kiernan M, King AC, Stefanick ML, Killen JD (2001) Men gain additional psychological benefits by adding exercise to a weight-loss program. *Obesity Research* 9(12):770–77.	Shaw CR	Part of Wood 1991 trial.
Knowler WC, Barrett-Connor E, Fowler SE et al. (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 346(6):393–403.	Shaw CR	Compared lifestyle intervention with standard BT and placebo or standard BT and metformin.
Kostis JB, Wilson AC, Shindler DM, Cosgrove NM, Lacy CR (2002) Persistence of normotension after discontinuation of lifestyle intervention in the trial of TONE Trial of Nonpharmacologic Interventions in the Elderly. *American Journal of Hypertension* 15(8):732–4.	AHRQ	Part of the TONE study included in the HTA diet, BT, PA vs. control review.
Krummel DA, Semmens E, Boury J, Gordon PM, Larkin KT (2004) Stages of change for weight management in postpartum women. *Journal of the American Dietetic Association* 104(7):1102–108.	Searches	Not results of the RCT. Not published yet (April 2005)
Kumanyika SK, Espeland MA, Bahnson JL et al. (2002). Ethnic comparison of weight loss in the Trial of Nonpharmacologic Interventions in the Elderly. *Obesity Research* 10(2):96–106.	AHRQ	Part of the TONE study included in the HTA diet, BT, PA vs. control review.
Laitinen JH, Ahola IE, Sarkkinen ES, Winberg RL, Harmaakorpi-Iivonen PA, Uusitupa MI (1993) Impact of intensified dietary therapy on energy and nutrient intakes and fatty acid composition of serum lipids in patients with recently diagnosed non-insulin-dependent diabetes mellitus. *Journal of the American Dietetic Association* 93(3):276–83.	HTA	No requirement for participants to be overweight.
Lamb SE, Bartlett HP, Ashley A, Bird W (2002) Can lay-led walking programmes increase physical activity in middle aged adults? A randomised controlled trial. *Journal of Epidemiology and Community Health* 56(4):246–52.	Morgan	Not BMI ≥28 kg/m^2.
Lejeune MP, Aggel-Leijssen DP, Van Baak MA, Westerterp-Plantenga MS (2003) Effects of dietary restraint vs exercise during weight maintenance in obese men. *European Journal of Clinical Nutrition* 57(10):1338–44.	Searches	Results shown graphically only. Also, most analysis not by group.
Leutholtz BC, Keyser RE, Heusner WW, Wendt VE, Rosen L (1995) Exercise training and severe caloric restriction: effect on lean body mass in the obese. *Archives of Physical Medicine and Rehabilitation* 76(1):65–70.	Searches	Not 52-week follow-up.
JM Manning, CR Dooly-Manning, K White et al. (1991) Effects of a resistive training program on lipoprotein – lipid levels in obese women. *Medicine and Science in Sports and Exercise* 23(11):1222–6.	Shaw CR	Not 52-week follow-up.
Marcus BH, Stanton AL (1993) Evaluation of relapse prevention and reinforcement interventions to promote exercise adherence in sedentary females. *Research Quarterly for Exercise and Sport* 64(4):447–52.	Morgan	Not 52-week follow-up.
McAuley E, Courneya KS, Rudolph DL, Lox CL (1994) Enhancing exercise adherence in middle-aged males and females. *Preventive Medicine* 23(4):498–506.	Morgan	Not 52-week follow-up.

Study	Source	Reason for exclusion
Melanson K, Gootman J, Myrdal A, Kline G, Rippe JM (2003) Weight loss and total lipid profile changes in overweight women consuming beef or chicken as the primary protein source. *Nutrition* 19(5):409–414.	Searches	Not 52-week follow-up.
Munsch S, Biedert E, Keller U (2003) Evaluation of a lifestyle change programme for the treatment of obesity in general practice. *Swiss Medical Weekly* 133(9/10):148–54.	Searches	No details of PA reported – other than increased
Neumark-Sztainer D, Kaufmann NA, Berry EM (1995) Physical activity within a community-based weight control program: program evaluation and predictors of success. *Public Health Reviews* 23(3):237–51.	Shaw CR	Excluded from HTA as not 52-week follow-up.
Nieman DC, Nehlsen-Cannarella SL, Henson DA et al. (1998) Immune response to exercise training and/or energy restriction in obese women. *Medicine and Science in Sports and Exercise* 30(5):679–86	Shaw CR	Not 52-week follow-up.
O'Toole ML, Sawicki MA, Artal R (2003) Structured diet and physical activity prevent postpartum weight retention. *Journal of Women's Health* 12(10):991–8.	Searches	Participants were women in the first year post-partum.
Okura T, Nakata Y, Tanaka K (2003) Effects of exercise intensity on physical fitness and risk factors for coronary heart disease. *Obesity Research* 11(9):1131–9.	Searches	Not 52-week follow-up.
Phenix A (1990) *A one year follow-up of a weight loss study comparing behavioural techniques, nutrition information and exercise*. PhD thesis: California School of Professional Psychology, Fresno.	Avenell HTA	Unpublished PhD thesis only.
Pinto BM, Friedman R, Marcus BH, Kelley H, Tennstedt S, Gillman MW (2002) Effects of a computer-based, telephone-counseling system on physical activity. *American Journal of Preventive Medicine* 23(2):113–20.	PH cross-reference	Not 52-week follow-up.
Raz I, Hauser E, Bursztyn M (1994) Moderate exercise improves glucose metabolism in uncontrolled elderly patients with non-insulin-dependent diabetes mellitus. *Israeli Journal of Medical Science* 30(10):766–70.	Shaw CR	Not 52-week follow-up.
Robertson MC, Devlin N, Gardner MM, Campbell AJ (2001) Effectiveness and economic evaluation of a nurse delivered home exercise programme to prevent falls. 1: Randomised controlled trial. *British Medical Journal* 322(7288):697–701. Robertson MC, Gardner MM, Devlin N, McGee R, Campbell AJ (2001) Effectiveness and economic evaluation of a nurse delivered home exercise programme to prevent falls. 2: Controlled trial in multiple centres. *British Medical Journal* 322(7288):701–704.	Morgan	No weight outcomes.
Ross R, Rissanen J, Pedwell H, Clifford J, Shragge P (1996) Influence of diet and exercise on skeletal muscle and visceral adipose tissue in men. *Journal of Applied Physiology* 81(6):2445–55.	Shaw CR	Not 52-week follow-up.
Ross R, Janssen I, Dawson J et al. (2004) Exercise-induced reduction in obesity and insulin resistance in women: a randomized controlled trial. *Obesity Research* 12(5):789–98.	Searches	Not 52-week follow-up.
Sartorio A, Lafortuna CL, Marinone PG, Tavani A, La Vecchia C, Bosetti C (2003) Short-term effects of two integrated, non-pharmacological body weight reduction programs on coronary heart disease risk factors in young obese patients. *Diabetes, Nutrition and Metabolism* 16(4):262–5.	Searches	Not 52-week follow-up.

Study	**Source**	**Reason for exclusion**
Sartorio A, Lafortuna CL, Massarini M, Galvani C (2003) Effects of different training protocols on exercise performance during a short-term body weight reduction programme in severely obese patients. *Eating and Weight Disorders* 8(1):36–43.	Searches	Not 52-week follow-up.
Sartorio A, Maffiuletti NA, Agosti F, Marinone PG, Ottolini S, Lafortuna CL (2004) Body mass reduction markedly improves muscle performance and body composition in obese females aged 61–75 years: comparison between the effects exerted by energy-restricted diet plus moderate aerobic-strength training alone or associated with rGH or nandrolone undecanoate. *European Journal of Endocrinology* 150(4):511–15.	Searches	Not 52-week follow-up.
Schmitz KH, Jensen MD, Kugler KC, Jeffery RW, Leon AS (2003) Strength training for obesity prevention in midlife women. *International Journal of Obesity and Related Metabolic Disorders* 27(3):326–33.	Searches	Not 52-week follow-up.
Schwartz RS (1987) The independent effects of dietary weight loss and aerobic training on high density lipoproteins and apolipoprotein A-I concentrations in obese men. *Metabolism: Clinical and Experimental* 36(2):165–71.	Shaw CR	Not 52-week follow-up.
Schwartz RS, Jaeger LF, Veith RC, Lakshminarayan S (1990) The effect of diet or exercise on plasma norepinephrine kinetics in moderately obese young men. *International Journal of Obesity* 14(1):1–11.	Shaw CR	Not 52-week follow-up.
Simkin-Silverman LR, Wing RR, Boraz MA, Kuller LH (2003) Lifestyle intervention can prevent weight gain during menopause: results from a 5-year randomized clinical trial. *Annals of Behavioral Medicine* 26(3):212–20.	Searches	Not BMI ≥28 kg/m^2. Mean BMI was 25 kg/m^2.
Simons-Morton DG (2001) Effects of physical activity counseling in primary care: The activity counseling trial: A randomized controlled trial. *Journal of the American Medical Association* 286(6): 677–87.	Hillsdon CR	No weight outcomes.
Slentz CA, Duscha BD, Johnson JL et al. (2004) Effects of the amount of exercise on body weight, body composition, and measures of central obesity: STRRIDE – a randomized controlled study. *Archives of Internal Medicine* 164(1):31–9.	Searches	Not 52-week follow-up.
Stefanick ML, Mackey S, Sheehan M, Ellsworth N, Haskell WL, Wood PD (1998) Effects of diet and exercise in men and postmenopausal women with low levels of HDL cholesterol and high levels of LDL cholesterol. *New England Journal of Medicine* 339(1):12–20.	Shaw CR	Excluded from HTA as BMI not ≥28 kg/m^2.
Stensel DJ, Brooke-Wavell K, Hardman AE, Jones PR, Norgan NG (1994) The influence of a 1-year programme of brisk walking on endurance fitness and body composition in previously sedentary men aged 42–59 years. *European Journal of Applied Physiology and Occupational Physiology* 68(6):531–7.	Shaw CR	Not BMI ≥28 kg/m^2.
Stevens W, Hillsdon M, Thorogood M, McArdle D (1998) Cost-effectiveness of a primary care based physical activity intervention in 45–74 year old men and women: a randomised controlled trial. *British Journal of Sports Medicine* 32(3):236–41.	Morgan	No weight outcomes. Not 52-week follow-up.

Study	Source	Reason for exclusion
Svendsen OL, Hassager C, Christiansen C (1993) Effect of an energy-restrictive diet, with or without exercise, on lean tissue mass, resting metabolic rate, cardiovascular risk factors, and bone in overweight postmenopausal women. *American Journal of Medicine* 95(2):131–40.	Shaw CR	Not 52-week follow-up.
Tate DF, Jackvony EH, Wing RR (2003) Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. *Journal of the American Medical Association* 289(14):1833–6.	Searches	Compared diet, BT and PA with different levels of support – non-clinical setting.
Taylor AH, Doust J, Webborn N (1998) Randomised controlled trial to examine the effects of a GP exercise referral programme in Hailsham, East Sussex, on modifiable coronary heart disease risk factors. *Journal of Epidemiology Community Health* 52(9):595–601.	Morgan	No weight outcomes (BMI only, skinfold thicknesses). Not 52-week follow-up. Not overweight only.
Thong FS, Hudson R, Ross R, Janssen I, Graham TE (2000) Plasma leptin in moderately obese men: independent effects of weight loss and aerobic exercise. *American Journal of Physiology* 279(2):E307–313.	Shaw CR	Not 52-week follow-up.
Utter AC, Whitcomb DC, Nieman DC, Butterworth DE, Vermillion SS (2000) Effects of exercise training on gallbladder function in an obese female population. *Medicine and Science in Sports and Exercise* 32(1):41–5.	Shaw CR	Not 52-week follow-up.
Wadden TA, Vogt RA, Andersen RE et al. (1997) Exercise in the treatment of obesity: effects of four interventions on body composition, resting energy expenditure, appetite, and mood. *Journal of Consulting and Clinical Psychology* 65(2):269–77.	Shaw CR	Excluded from HTA as not 52 week follow-up
Wallace MB, Mills BD, Browning CL (1997) Effects of cross-training on markers of insulin resistance/hyperinsulinemia. *Medicine and Science in Sports and Exercise* 29(9):1170–5.	Searches	Not 52-week follow-up.
Whatley JE, Gillespie WJ, Honig J, Walsh MJ, Blackburn AL, Blackburn GL (1994) Does the amount of endurance exercise in combination with weight training and a very-low-energy diet affect resting metabolic rate and body composition? *American Journal of Clinical Nutrition* 59(5):1088–92.	Shaw CR	Not 52-week follow-up.
Whelton PK, Appel LJ, Espeland MA et al. (1998) Sodium reduction and weight loss in the treatment of hypertension in older persons: a randomized controlled trial of nonpharmacologic interventions in the elderly (TONE). TONE Collaborative Research Group. *Journal of the American Medical Association* 279(11):839–46.	AHRQ	Included in HTA diet, BT, PA vs. control (TONE).
Wirth A, Diehm C, Hanel W, Welte J, Vogel I (1985) Training-induced changes in serum lipids, fat tolerance, and adipose tissue metabolism in patients with hypertriglyceridemia. *Atherosclerosis* 54(3):263–71.	Shaw CR	Not 52-week follow-up.
Yancy WS Jr, Olsen MK, Guyton JR, Bakst RP, Westman EC (2003) A low-carbohydrate, ketogenic diet versus a low-fat diet to treat obesity and hyperlipidemia: a randomized, controlled trial. *Annals of Internal Medicine* 140(10):769–77.	Searches	Not 52-week follow-up.
You T, Berman DM, Ryan AS, Nicklas BJ (2004) Effects of hypocaloric diet and exercise training on inflammation and adipocyte lipolysis in obese postmenopausal women [erratum appears in *Journal of Clinical Endocrinology and Metabolism* 2004;89(6):2972]. *Journal of Clinical Endocrinology and Metabolism* 89(4):1739–46.	Searches	Not 52-week follow-up.

Study	**Source**	**Reason for exclusion**
Yu CM, Li LS, Ho HH, Lau CP (2003) Long-term changes in exercise capacity, quality of life, body anthropometry, and lipid profiles after a cardiac rehabilitation program in obese patients with coronary heart disease. *American Journal of Cardiology* 91(3):321–5.	Searches	Not BMI ≥28 kg/m^2.

1.6 Pharmacological interventions

1.6.1 Orlistat

Study	Source	Reason for exclusion
Bloch KV, Salles GF, Muxfeldt ES, Da Rocha N (2003) Orlistat in hypertensive overweight/obese patients: results of a randomized clinical trial. *Journal of Hypertension* 21(11):2159–65.	Norris CR	Not 52-week follow-up (adults).
Bonnici F (2002) Effect of orlistat on glycemic control and body weight in overweight or obese South African patients with type 2 diabetes. *Diabetes* 51(Suppl 2):1692.	Norris CR	Not 52-week follow-up (adults).
Deerchanawong C (2001) Effect of treatment with orlistat in overweight or obese Thai patients with type 2 diabetes. *Diabetes* 50(Suppl 2):A433	Norris CR	Not 52-week follow-up (adults).
Derosa G, Mugellini A, Ciccarelli L, Rinaldi A, Fogari R (2002) Effects of orlistat, simvastatin, and orlistat + simvastatin in obese patients with hypercholesterolemia: A randomized, open-label trial. *Current Therapeutic Research, Clinical and Experimental* 42:621–33.	Searches	Compared diet + orlistat with diet + simvastatin, and diet + orlistat + simvastatin. No placebo control group.
Derosa G, Cicero AFG, Murdolo G, Ciccarelli L, Fogari R (2004) Comparison of metabolic effects of orlistat and sibutramine treatment in Type 2 diabetic obese patients. *Diabetes, Nutrition and Metabolism* 17(4):222–9.	Searches	No weight outcome (kg) reported. Only change in BMI reported.
Derosa G, Cicero AF, Murdolo G et al. (2005) Efficacy and safety comparative evaluation of orlistat and sibutramine treatment in hypertensive obese patients. *Diabetes Obesity and Metabolism* 7(1):47–55.	Derosa publication search	No control group. Direct comparison of orlistat and sibutramine in people with hypertension.
Dixon et al.(2004) Evaluation of the association between health-related utility and obesity in hospital treated subjects. ISPOR 2004. Anonymous. Anonymous.10-2004.	Submitted evidence	Economic evaluation – conference presentation. No publications found – June 2005
J Erdmann, F Lippl, G Klose, V Schusdziarra (2004) Cholesterol lowering effect of dietary weight loss and orlistat treatment – efficacy and limitations. *Alimentary Pharmacology and Therapeutics* 19(11):1173–1179, 2004.	Searches	Not 52-week follow-up (adults).

Study	Source	Reason for exclusion
Guy-Grand B, Gin H, Valensi P, Crouin P, Eschwege E (2001) Differential weight loss in orlistat treated obese and overweight patients with various comorbidities. *International Journal of Obesity*:S93.	Norris CR	Not 52-week follow-up. (adults)
Hakim Z, Wolf A, Garrison LP (2002) Estimating the effect of changes in body mass index on health state preferences. *Pharmacoeconomics* 20(6):393–404.	Submitted evidence	Economic evaluation – used to cross-reference. No additional references found.
Halpern A, Mancini MC, Suplicy H et al. (2003) Latin-American trial of orlistat for weight loss and improvement in glycaemic profile in obese diabetic patients. *Diabetes, Obesity and Metabolism* 5:180–8.	Norris CR	Not 52-week follow-up (adults).
Hanefeld M, Sachse G (2002) The effects of orlistat on body weight and glycaemic control in overweight patients with type 2 diabetes: a randomized, placebo-controlled trial. *Diabetes, Obesity and Metabolism* 4(6):415–23.	Searches	Not 52-week follow-up. Four-week pre-treatment (weeks –4 to 0) with 48-week treatment phase (weeks 1 to 48).
Hawkins F, Duran S, Vilardell E et al. (2000) Orlistat promotes glycemic control and other cardiovascular risk factors lowering in obese patients with type 2 diabetes. Randomised clinical trial. *Diabetologia* 43:658	Norris CR	Not 52-week follow-up (adults).
Hsieh C, Wang P, Liu R et al. (2005) Orlistat for obesity: benefits beyond weight loss. *Diabetes Research and Clinical Practice* 67(1):78–83.	Searches	No weight outcome (kg) reported.
Jayagopal V, Kilpatrick ES, Holding S, Jennings PE, Atkin SA (2004) Orlistat and metformin are equally beneficial in reducing hyperandrogenaemia in polycystic ovary syndrome.	Submitted evidence	Not 52-week follow-up (adults).
Kelley DE, Kuller LH, McKolanis TM, Harper P, Kalhan S (2004) Effects of moderate weight loss and orlistat on insulin resistance, regional adiposity, and fatty acids in type 2 diabetes. *Diabetes Care* 27(1):33–40.	Norris CR	Not 52-week follow-up (adults).
Lucas CP, Boldrin MN, Reaven GM (2003) Effect of orlistat added to diet (30% of calories from fat) on plasma lipids, glucose, and insulin in obese patients with hypercholesterolemia. *American Journal of Cardiology* 91(8):961–64.	Searches	Subset of participants in five RCTs. No details of which trials were reported.

Study	**Source**	**Reason for exclusion**
Mathus-Vliegen EM, Van Ierland-Van Leeuwen ML, Terpstra A (2004) Lipase inhibition by orlistat: effects on gall-bladder kinetics and cholecystokinin release in obesity. *Alimentary Pharmacology and Therapeutics* 19(5):601–611.	Searches	Designed as an observational study, only part of a full RCT – no references found.
McEwan P (2004) Evaluation of the cost-utility of orlistat in the UK ISPOR 2004. Anonymous. Anonymous. 10-2004.	Submitted evidence	Economic evaluation – poster only.
Mendoza Guadarrama LG, Lopez Alvarenga JC, Castillo Martinez L et al. (2000) Orlistat reduces visceral fat independent of weight changes in obese diabetics type 2. *International Journal of Obesity* 24(Suppl 1):S167.	Norris CR	Not 52-week follow-up (adults).
Muls E, Kolanowski J, Scheen A, Van Gaal L, ObelHyx Study Group (2001) The effects of orlistat on weight and on serum lipids in obese patients with hypercholesterolemia: a randomized, double-blind, placebo-controlled, multicentre study. *International Journal of Obesity and Related Metabolic Disorders* 25(11):1713–21.	Searches	Not 52-week follow-up (adults).
National Institute of Child Health and Human Development (NICHD) (2003) Safety and efficacy of Xenical in children and adolescents with obesity-related diseases. *ClinicalTrials.gov*.	Searches	Study currently recruiting? Checked for publications, but no references found.
Prentice A, Jebb S, Blskett A, Corner A (2004) A patient support programme for orlistat: analysis of adherence and weight loss. *International Journal of Obesity* 28(Suppl 1):S28.	Submitted evidence	Abstract only. No publications found – June 2005.
Rissanen A (2004) Effect of orlistat in the prevention of weight gain and in long-term weight maintenance in abdominally obese patients after a very low calorie diet (VLCD) (Final study report).	Submitted evidence	Retrospective analysis of two trials (Sjostrom 1998; Rossner 2000), both in HTA.
Serrano Rios M, Armero F, Genis M (2001) Orlistat efficacy on weight loss in overweight or obese patients with type 2 diabetes mellitus. Diabetes 50(Suppl 1):A131.	Norris CR	Not 52-week follow-up (adults).
Sjostrom CD, Peltonen M, Wedel H, Sjostrom L (2000) Differentiated long-term effects of intentional weight loss on diabetes and hypertension. *Hypertension* 36(1):20–25.	Searches	In HTAs as Sjostrom 1998.

Study	Source	Reason for exclusion
Tiikkainen M, Bergholm R, Rissanen A et al. (2004) Effects of equal weight loss with orlistat and placebo on body fat and serum fatty acid composition and insulin resistance in obese women. *American Journal of Clinical Nutrition* 79(1):22–30.	Searches	Not 52-week follow-up (adults).
Tong PC, Lee ZS, Sea MM et al. (2002). The effect of orlistat-induced weight loss, without concomitant hypocaloric diet, on cardiovascular risk factors and insulin sensitivity in young obese Chinese subjects with or without type 2 diabetes. *Archives of Internal Medicine* 162(21):2428–35.	Searches	Not RCT (adults aged 18 to 50 years).
Vlassov VV (2001) Weight reduction for reducing mortality in obesity and overweight. In Vlassov VV*, Weight reduction for reducing mortality in obesity and overweight. The Cochrane Database of Systematic Reviews: Protocols 2001 Issue 3.* John Wiley & Sons, Ltd Chichester, UK.	Searches	Cochrane protocol only.
Wadden TA, Berkowitz RI, Womble LG, Sarwer DB, Arnold ME, Steinberg CM (2000) Effects of sibutramine plus orlistat in obese women following 1 year of treatment by sibutramine alone: a placebo-controlled trial. *Obesity Research* 8(6):431–437.	HTA	Excluded from orlistat review as continuation study of sibutramine RCT, with 16-week trial of add-on orlistat.
Wang Y, Liu C, Liu Y (2003) Orlistat for adjutant treatment of fatty type 2 diabetes mellitus in 32 patients. *Chinese Journal of New Drugs* 22(11):651–3.	Norris CR	Not 52-week follow-up (adults).
Wirth A, Platon J (2001) Effect of orlistat on body weight and co-morbidities in clinical practice: The xxl-Primary Health Care Observational Trial. *International Journal of Obesity* 25:O62.	Submitted evidence	No published references found – June 2005.
Wirth A (2004) Sustained weight reduction after cessation of obesity treatment with Sibutramine. *Deutsche Medizininische Wochenschrift* 129(18):1002–5.	Submitted evidence	Not RCT – post-marketing surveillance assumed to be adults (mean age 48 years).
Zoss I, Piec G, Horber FF (2002) Impact of orlistat therapy on weight reduction in morbidly obese patients after implantation of the Swedish adjustable gastric band. *Obesity Surgery* 12(1):	Searches	Not RCT.

1.6.2 Sibutramine

Study	Source	Reason for exclusion
Apfelbaum M, Vague P, Ziegler O, Hanotin C, Thomas F, Leutenegger E (1999) Long-term maintenance of weight loss after a very-low-calorie diet: a randomized blinded trial of the efficacy and tolerability of sibutramine. *American Journal of Medicine* 106(2):179–84.	Submitted evidence	In HTA.
Ara R, Brennan A (2004) Economic evaluation of sibutramine for the treatment of obesity in adults without other co-morbidities in the UK Anonymous. Anonymous. Sheffield: ScHARR, University of Sheffield. 1-49. From Abbott.	Submitted evidence	Economic evaluation – used to cross-reference clinical effectiveness. Of five possible trials, one excluded as German post marketing surveillance reports (see Scholze), and others to be scanned for inclusion (Hauner, James, Smith, Wirth).
Arterburn DE, Crane PK, Veenstra DL (2004) The efficacy and safety of sibutramine for weight loss: a systematic review. *Archives of Internal Medicine* 164(9):994–1003.	Searches	Systematic review – used to cross-reference (adults only). Of five possible 52 week trials, one included in TA (Apfelbaum), and others to be scanned for inclusion (Hauner,[1] James, McNulty, Smith).
Bach DS, Rissanen AM, Mendel CM et al. (1999) Absence of cardiac valve dysfunction in obese patients treated with sibutramine. *Obesity Research* 7(4):363–9.	Submitted evidence	Not 52-week follow-up (adults).
Barkeling B, Elfhag K, Rooth P, Rossner S (2003) Short-term effects of sibutramine (Reductil) on appetite and eating behaviour and the long-term therapeutic outcome. *International Journal of Obesity and Related Metabolic Disorders* 27(6):693–700.	Submitted evidence	Not 52-week follow-up (adults).
Birkenfeld AL, Schroeder C, Boschmann M et al. (2002) Paradoxical effect of sibutramine on autonomic cardiovascular regulation. *Circulation* 106(19):2459–65.	Submitted evidence	Not 52-week follow-up (adults).
Bray GA, Blackburn GL, Ferguson JM et al. (1999) Sibutramine produces dose-related weight loss. *Obesity Research* 7(2):189–98.	Submitted evidence	Not 52-week follow-up (adults).
Brennan A, Ara R, Sterz R, Matiba B, Bergemann R (2004) Cost-utility analysis of sibutramine for the treatment of obese adults without other co-morbidities in Germany. *International Journal of Obesity*	Submitted evidence	No published references found (June 2005).

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[1] Hauner 2000 is a conference presentation of Hauner 2004.

Study	Source	Reason for exclusion
Canadian Coordinating Office for Health Technology Assessment (2001) Sibutramine. *Emerging Drug List.*	Searches	Summary of evidence – no clear referencing.
Cuellar GE, Ruiz AM, Monsalve MC, Berber A (2000) Six-month treatment of obesity with sibutramine 15 mg; a double-blind, placebo-controlled monocenter clinical trial in a Hispanic population. *Obesity Research* 8(1):71–82.	Submitted evidence	Not 52-week follow-up (adults).
Derosa G, Cicero GAF, Murdolo G, Ciccarelli L, Fogari R (2004) Comparison of metabolic effects of orlistat and sibutramine treatment in Type 2 diabetic obese patients. *Diabetes, Nutrition and Metabolism* 17(4):222–9.	Searches	No weight outcomes, only BMI.
Dujovne CA, Zavoral JH, Rowe E, Mendel CM, Sibutramine Study Group (2001) Effects of sibutramine on body weight and serum lipids: a double-blind, randomized, placebo-controlled study in 322 overweight and obese patients with dyslipidemia. *American Heart Journal* 142(3):489–97.	Submitted evidence	Not 52-week follow-up. (adults)
Fanghanel G, Cortinas L, Sanchez L-Reyes, Berber A (2000) Clinical trial of the use of sibutramine for the treatment of patients suffering essential obesity. *International Journal of Obesity and Related Metabolic Disorders* 24(2):144–150. Fanghanel G, Cortinas L, Sanchez L-Reyes, Berber A (2001) Second phase of a double-blind study clinical trial on Sibutramine for the treatment of patients suffering essential obesity: 6 months after treatment cross-over. *International Journal of Obesity and Related Metabolic Disorders* 25(5):741–7.	Searches, submitted evidence	Not 52-week follow-up (adults)/
Faria AN, Ribeiro Filho FF, Lerario DD, Kohlmann N, Ferreira SR, Zanella MT (2002) Effects of sibutramine on the treatment of obesity in patients with arterial hypertension. *Arquivos Brasileiros de Cardiologia* 78(2):172–180.	Submitted evidence	Not 52-week follow-up (adults).
Finer N, Bloom SR, Frost GS, Banks LM, Griffiths J (2000) Sibutramine is effective for weight loss and diabetic control in obesity with type 2 diabetes: a randomised, double-blind, placebo-controlled study. *Diabetes, Obesity and Metabolism* 2(2):105–112.	Submitted evidence	Not 52-week follow-up (adults).

Study	Source	Reason for exclusion
Fujioka K, Seaton TB, Rowe E et al. (2000) Weight loss with sibutramine improves glycaemic control and other metabolic parameters in obese patients with type 2 diabetes mellitus. *Diabetes, Obesity and Metabolism* 2(3):175–87.	Submitted evidence	Not 52-week follow-up (adults).
Gokcel A, Karakose H, Ertorer EM, Tanaci N, Tutuncu NB, Guvener N (2001) Effects of sibutramine in obese female subjects with type 2 diabetes and poor blood glucose control. *Diabetes Care* 24(11):1957–60.	Searches, submitted evidence	Not 52-week follow-up (adults).
Griffiths J, Bloom SR, Finer N, Banks LM, Romanac FM (1995) Body compositional changes following weight loss induced by sibutramine. *International Journal of Obesity and Related Metabolic Disorders* 19:144.	Submitted evidence	Not 52-week follow-up (adults).
Hadden 2001	Searches, submitted evidence	In HTA as James 2000
Hanotin C, Thomas F, Jones SP, Leutenegger E, Drouin P (1998) Efficacy and tolerability of sibutramine in obese patients: A dose-ranging study. *International Journal of Obesity* 22(1):32–8.	Searches, submitted evidence	Not 52-week follow-up (adults).
Hansen DL, Toubro S, Stock MJ, Macdonald IA, Astrup A (1999) The effect of sibutramine on energy expenditure and appetite during chronic treatment without dietary restriction. *International Journal of Obesity and Related Metabolic Disorders* 23(10):1016–24.	Submitted evidence	Not 52-week follow-up (adults).
Hayman LL (2004) Toward evidence-based practice. (Commentary on) Behavior therapy and sibutramine for the treatment of adolescent obesity: a randomized controlled trial. *MCN: The American Journal of Maternal/Child Nursing* 29(1):68.	Searches	Evidence update – no appropriate references.
Hazenberg BP (2000) Randomized, double-blind, placebo-controlled, multicenter study of sibutramine in obese hypertensive patients. *Cardiology* 94(3):152–8.	Submitted evidence	Not 52-week follow-up (adults).

Study	Source	Reason for exclusion
Hwu CM, Hung YJ, Kuo CS, Pei D, Jeng CY, Ho LT (2003) Sibutramine treatment enhances weight loss and reduces waist circumference in obese Chinese type 2 diabetic patients. *Journal of Parenteral and Enteral Nutrition* 27(1):S12–3.	Searches	Conference abstract only. No published references found (June 2005).
James WP, Astrup A, Finer N et al. (2000) Effect of sibutramine on weight maintenance after weight loss: a randomised trial. STORM Study Group. Sibutramine Trial of Obesity Reduction and Maintenance. *Lancet* 356(9248):2119–25.	Searches, submitted evidence	In HTA as James 1999.
Kaukua JK, Pekkarinen TA, Rissanen AM (2004) Health-related quality of life in a randomised placebo-controlled trial of sibutramine in obese patients with type II diabetes. *International Journal of Obesity and Related Metabolic Disorders* 28(4):600–605.	Searches	In HTA as Rissanen 1998.
Li QF, Li R, Luo R, Wang ZH et al. (2002) Sibutramine capsules for treatment of simple obesity. *Chinese Journal of New Drugs and Clinical Remedies* 21(7):401–4.	Searches	Chinese language.
McMahon FG, Fujioka K, Singh BN et al. (2000) Efficacy and safety of sibutramine in obese white and African American patients with hypertension: a 1-year, double-blind, placebo-controlled, multicenter trial. *Archives of Internal Medicine* 160(14):2185–91.	Submitted evidence	In HTA.
McNulty SJ, Ur E, Williams G, Multicenter Sibutramine Study Group (2003) A randomized trial of sibutramine in the management of obese type 2 diabetic patients treated with metformin. *Diabetes Care* 26(1):125–31.	Searches, submitted evidence	In HTA as Williams 1999.
Norris SL, Zhang X, Avenell A et al. (2004) Efficacy of pharmacotherapy for weight loss in adults with type 2 diabetes mellitus: a meta-analysis. *Archives of Internal Medicine* 164(13):1395–1404.	Submitted evidence	Will use Norris CR to cross-reference.
Scholze J (2002) Sibutramine in clinical practice – a PMS-study with positive effects on blood pressure and metabolic parameters. *Deutsche Medizinische Wochenschrift* 127(12):606–610.	Submitted evidence	Not RCT (assumed to be adults only).

Study	Source	Reason for exclusion
Seagle HM, Bessesen DH, Hill JO (1998) Effects of sibutramine on resting metabolic rate and weight loss in overweight women. *Obesity Research* 6(2):115–21.	Submitted evidence	Not 52-week follow-up (adults).
Serrano M-Rios, Melchionda N, Moreno-Carretero E, Spanish Investigators (2002) Role of sibutramine in the treatment of obese Type 2 diabetic patients receiving sulphonylurea therapy. *Diabetic Medicine* 19(2):119–24.	Submitted evidence	Not 52-week follow-up (adults).
Sircar AR, Kumar A, Lal M (2001) Clinical evaluation of sibutramine in obese type 2 diabetic patients refractory to dietary management. *Journal of the Association of Physicians of India* 49:885–8.	Submitted evidence	Not 52-week follow-up (adults).
Smith IG, Goulder MA, on behalf of the Members of the Sibutramine Clinical Study (2001) Randomized placebo-controlled trial of long-term treatment with sibutramine in mild to moderate obesity. *Journal of Family Practice* 50(6):505–512.	Searches	In HTA as Smith 1994.
Sramek JJ, Leibowitz MT, Weinstein SP et al. (2002) Efficacy and safety of sibutramine for weight loss in obese patients with hypertension well controlled by beta-adrenergic blocking agents: a placebo-controlled, double-blind, randomised trial. *Journal of Human Hypertension* 16(1):13–19.	Submitted evidence	Not 52-week follow-up (adults).
Tankova T, Dakovska G, Lazarova M, Dakovska L, Kirilov G, Koev D (2003) Sibutramine in the treatment of obesity in type 2 diabetic patients. *Endocrinologia* 8(4):257–65.	Submitted evidence	Not 52-week follow-up (adults).
Toubro S, Hansen DL, Hilsted JC, Porsborg PA, Astrup AV (2001) The effect of sibutramine for the maintenance of weight loss: A randomised, clinical, controlled study. *Ugeskrift for Laeger* 163(21):2935–40.	Searches	Danish publication of the STORM trial (see James 2000).
Vargas R, McMahon FG, Jain AK (1994) Effects of Sibutramine (S) vs Placebo (P) in NIDDM. *Clinical Pharmacology and Theraputics* 55:188.	Submitted evidence	Not 52-week follow-up (adults).

Study	Source	Reason for exclusion
Vlassov VV (2005) Weight reduction for reducing mortality in obesity and overweight. Cochrane collaboration. Anonymous. Online.	Searches	Cochrane protocol only.
Warren E, Brennan A, Akehurst R (2004) Cost-effectiveness of sibutramine in the treatment of obesity. *Medical Decision Making* 24(1):9–19.	Searches, submitted evidence	Economic evaluation – used to cross reference clinical effectiveness. Two trials to be scanned (James 2000; Smith 2001)
Weintraub M, Rubio A, Golik A, Byrne L, Scheinbaum ML (1991) Sibutramine in weight control: a dose-ranging, efficacy study. *Clinical Pharmacology and Therapeutics* 50(3):330–7.	Submitted evidence	Not 52-week follow-up (adults).
Wirth A, Krause J (2001) Long-term weight loss with sibutramine: a randomized controlled trial. *Journal of the American Medical Association* 11:1331–9.	Searches	Not 52-week follow-up (adults).
Yanovski JA, Yanovski SZ (2003) Treatment of pediatric and adolescent obesity. *Journal of the American Medical Association* 14:1851–3.	Searches	Editorial on Berkowitz. Used for discussion and limitations.
Zannad F, Gille B, Grentzinger A et al. (2002) Effects of sibutramine on ventricular dimensions and heart valves in obese patients during weight reduction. *American Heart Journal* 144(3):508–515.	Submitted evidence	Not 52-week follow-up (adults).

1.7 Surgical interventions

Study	Source	Reason for exclusion
American Diabetes Association Position Statement, 2002.	Searches	Position statement. No additional references.
American Gastroenterological Association Guidelines, 2002.	Searches	Guideline recommendations. No additional references.
Agren G, Naslund I. (1989) A prospective randomized comparison of vertical banded gastroplasty (VBG), loop gastric bypass (GBY) and gastric banding (GB). *International Journal of Obesity* 13:595.	CR	RCT of vertical banded gastroplasty (VBG).
Allgood P (2001) Surgical interventions for morbid obesity. STEER Reports. Online.	Searches	Rapid, systematic review. No additional references.
Andersen T, Backer OG, Astrup A, Quaade F (1987) Horizontal or vertical banded gastroplasty after pretreatment with very-low-calorie formula diet: a randomized trial. *International Journal of Obesity* 11(3):295–304.	Clegg TA	RCT comparing horizontal and vertical gastric banding.
Angus LDG, Cottam DR, Gorecki PJ, Mourello R, Ortega RE, Adamski J (2003) DRG, costs and reimbursement following Roux-en-y gastric bypass: an economic appraisal. *Obesity Surgery* 000:000. [115]	Searches	Retrospective study. Some health economic data.
Anonymous (2005) Surgical treatment for morbid obesity. *Evidence Based Practice* 8(2):1–2.	Searches	Commentary on Buchwald review. No additional references.
Anonymous (2004) Study finds large cost variation for laparoscopic gastric bypass. *OR Manager* 20(7):1. [33]	Searches	Benchmarking study. Some health economic data.
Anonymous (2004) AORN bariatric surgery guideline. *AORN Journal* 79(5):1026–52.	Searches	Guideline recommendations. No additional references.
Ashy AR, Merdad AA (1998) A prospective study comparing vertical banded gastroplasty versus laparoscopic adjustable gastric banding in the treatment of morbid and super-obesity. *International Surgery* 83(2):108–110.	Buchwald review	Excluded from Clegg TA as not RCT.
Barrow C (2002) Roux-en-Y gastric bypass for morbid obesity. Surgical option in bariatric surgery in the treatment of obesity. *AORN Journal* 76(4):593–604.	Searches	Narrative review. No additional references.

Study	**Source**	**Reason for exclusion**
Basque Office for Health Technology Assessment and Health Department (2003) Bariatric surgery for the treatment of morbid obesity – Systematic review. Online.	Searches	Systematic review. No additional references.
Blanco-Engert R, Weiner S, Pomhoff I, Matkowitz R, Weiner RA (2003) Outcome after laparoscopic adjustable gastric banding, using the Lap-Band and the Heliogast band: a prospective randomized study. *Obesity Surgery* 13(5):776–9. [39]	Searches	Compares two different types of bands (Lap-Band vs. Heliogast), not different surgical techniques. Checked for published Blanco-Engert references (abstract only cited). No references found.
Buchwald H, Avidor Y, Braunwald E et al. (2004) Bariatric surgery: A systematic review and meta-analysis. *Journal of the American Medical Association* 292(14):13.	Searches	Systematic review and meta-analysis. Used for cross-referencing and comparison. Added Mingrone 2002 for assessment.
Canadian Coordinating Office for Health Technology Assessment (2003) Laparoscopic adjustable gastric banding for clinically severe obesity. CCOHTA. [95]	Searches	Scoping search for HTA No additional references.
Comite d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT) (2004) Laparoscopic adjustable gastric banding – systematic review, expert panel (project). HTA. [97]	Searches	Recommendations only, full text only available in French. No references.
Chapman AE, Kiroff G, Game P et al. (2004) Adjustable gastric banding in the treatment of obesity: A systematic literature review. *Surgery* 135:326–51.	Searches	Systematic review. No additional references.
Chen J, McGregor M (2004) The gastric banding procedure: an evaluation. Online.	Searches	Technology assessment. No additional references. Some health economic data.
Choban PS, Flancbaum L (2002) The effect of Roux limb lengths on outcome after Roux-en-Y gastric bypass: a prospective, randomized clinical trial. *Obesity Surgery* 12(4):540–5. [70]	Searches	RCT of different Roux limb lengths on weight loss. Not a comparison of different surgical procedures.
Cegaina V (2002) Erratum: Gastric pacing as therapy for morbid obesity: Preliminary results (*Obesity Surgery* 2002;12[Suppl 1]:14S). *Obesity Surgery* 12(3):	Searches	Report of gastric pacing.
Clegg A, Colquitt J, Sidhu M, Royle P, Walker A (2003) Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. *International Journal of Obesity*.	Searches	Published version of technology assessment evidence review.

Study	Source	Reason for exclusion
Cooney RN, Bryant P, Haluck R, Rodgers M, Lowery M (2001) The impact of a clinical pathway for gastric bypass surgery on resource utilization. *Journal of Surgical Research*	Searches	Not RCT of surgery. No additional references. Some health economic data.
Cooney RN, Haluck RS, Ku J et al. (2003) Analysis of cost outliers after gastric bypass surgery: What can we learn? *Obesity Surgery*	Searches	Not RCT of surgery. No additional references. Some health economic data.
Cottam DR, Schaefer PA, Shaftan GW, Velcu L, Angus LDG (2002) Effect of surgically-induced weight loss on leukocyte indicators of chronic inflammation in morbid obesity. *Obesity Surgery* 12(3):	Searches	Not RCT. No additional references.
Craig BM, Tseng DS (2002) Cost-effectiveness of gastric bypass for severe obesity (Provisional record). [delete?] *American Journal of Medicine*	Searches	Cost-effectiveness study.
Danish Obesity Project (1979) Randomised trial of jejunoileal bypass versus medical treatment in morbid obesity. The Danish Obesity Project. *Lancet* 2(8155):1255–8.	Clegg TA	Excluded as surgical procedure was jejunoileal bypass, which is no longer performed.
Davila-Cervantes A, Borunda D, Dominguez-Cherit G et al. (2002) Open versus laparoscopic vertical banded gastroplasty: a randomized controlled double blind trial. *Obesity Surgery* 12(6):812–8. [61]	Searches	RCT of laparoscopic vs. open VBG.
DeMaria EJ, Schweitzer MA, Kellum JM, Meador J, Wolfe L, Sugerman HJ (2002) Hand-assisted laparoscopic gastric bypass does not improve outcome and increases costs when compared to open gastric bypass for the surgical treatment of obesity (DARE structured abstract). *Surgical Endoscopy and Other Interventional Techniques* 16:1452–5.	Searches	Not RCT No additional references. Some cost data.
Deveney CW, MacCabee D, Marlink K, Welker K, Davis J, McConnell DB (2004) Roux-en-Y divided gastric bypass results in the same weight loss as duodenal switch for morbid obesity. *American Journal of Surgery* 187(5):.	Searches	Not RCT. No additional references.
Fernandez AZ Jr, DeMaria EJ, Tichansky DS et al. (2004) Multivariate analysis of risk factors for death following gastric bypass for treatment of morbid obesity. *Annals of Surgery* 239(5):698–702.	Searches	No weight outcomes.
Flodmark E-C, Lissau I, Moreno LA, Pietrobelli A, Widhalm K. New insights into the field of children and adolescents' obesity: The European perspective. *International Journal of Obesity* 28(10):	Searches	Narrative review on children and adolescents.

Study	Source	Reason for exclusion
Gallagher SF, Banasiak M, Gonzalvo JP et al. (2003) The impact of bariatric surgery on the veterans administration healthcare system: A cost analysis. *Obesity Surgery* 13(2):245–8. [122]	Searches	Cost analysis using retrospective data, not RCT.
Gonzalez R, Lin E, Venkatesh KR, Bowers SP, Smith CD (2003) Gastrojejunostomy during laparoscopic gastric bypass: analysis of 3 techniques (Provisional record). *Archives of Surgery*	Searches	Not RCT. Added Nguyen 2001 for assessment.
Greenberg I, Perna F, Kaplan M, Sullivan MA (2005) Behavioral and psychological factors in the assessment and treatment of obesity surgery patients. *Obesity Research* 13(2):244–9.	Searches	Recommendations on assessment for surgery.
Hell E, Miller KA, Moorehead MK, Norman S (2000) Evaluation of health status and quality of life after bariatric surgery: comparison of standard Roux-en-Y gastric bypass, vertical banded gastroplasty and laparoscopic adjustable silicone gastric banding. *Obesity Surgery* 10(3):214–9.	TEC 2005	Case series with <150 participants.
Health Technology Board for Scotland (HTBS) (2002) *The use of surgery for the morbidly obese*. 2002. [111]	Searches	Comments on NICE guidance, not new reviews. Comments on surgery not reported.
Horgan S, Holterman MJ, Jacobsen GR et al. (2005) Laparoscopic adjustable gastric banding for the treatment of adolescent morbid obesity in the United States: A safe alternative to gastric bypass. *Journal of Pediatric Surgery* 40(1):	Searches	Not adults.
Inge TH, Garcia V, Daniels S et al. (2004) Multidisciplinary approach to the adolescent bariatric surgical patient. *Journal of Pediatric Surgery* 39(3):	Searches	Not adults.
Kaur H, Hyder ML, WS Poston C (2003) Childhood overweight: an expanding problem. *Treatments in Endocrinology* 2(6):.	Searches	Not adults.
Lee WJ, Huang MT, Wang W, Lin CM, Chen TC, Lai IR (2004) Effects of obesity surgery on the metabolic syndrome. *Archives of Surgery* 139(10):1088–92.	Searches	Not RCT. No additional references.
Malaysian Health Technology Assessment Unit (MHTAU) (2004) Management of obesity in childhood. Online.	Searches	Not adults.
Mathus-Vliegen EM, Tygat GN (2002) Gastro-oesophageal reflux in obese subjects: influence of overweight, weight loss and chronic gastric balloon distension. *Scandinavian Journal of Gastroenterology* 37(11):1246–52. [59]	Searches	RCT of gastric balloons.

Study	Source	Reason for exclusion
Mathus-Vliegen EM, van Weeren M, van Eerten PV (2003) Loss of function and obesity: the impact of untreated obesity, weight loss, chronic gastric balloon distension. *Digestion* 68(2/3):161–8. [37].	Searches	RCT of gastric balloons.
MSAC Medical Services Advisory Committee (2003) Laparoscopic adjustable gastric banding for morbid obesity. Online. http://www.msac.gov.au/pdfs/reports/msacref14.pdf	Searches	Evidence review. Checked Weiner 2001 for assessment.
Muscelli E, Mingrone G, Camastra S et al. (2005) Effect of weight loss on insulin resistance in surgically treated obese patients. *American Journal of Medicine* 118(1):	Searches	Not RCT. No additional references.
Nguyen NT, Lee SL, Goldman C et al. (2001) Comparison of pulmonary function and postoperative pain after laparoscopic versus open gastric bypass: a randomized trial. *Journal of the American College of Surgery* 192(4):469–76.	Searches	Not 12-month follow-up. No weight outcomes. No additional references.
Nguyen NT, Ho HS, Fleming NW et al. (2002) Cardiac function during laparoscopic vs open gastric bypass: A randomized comparison. *Surgical Endoscopy* 16(1):78–83. [52]	Searches	Not 12-month follow-up. No weight outcomes. No additional references.
Nguyen NT, Braley S, Fleming NW, Lambourne L, Rivers R, Wolfe BM (2003) Comparison of postoperative hepatic function after laparoscopic versus open gastric bypass. *American Journal of Surgery* 186(1):40–44. [26]	Searches	Not 12-month follow-up. No weight outcomes. No additional references.
Nguyen NT, Cronan M, Braley S, Rivers R, Wolfe BM (2003) Duplex ultrasound assessment of femoral venous flow during laparoscopic and open gastric bypass. *Surgical Endoscopy* 17(2):285–90. [29]	Searches	Not 12-month follow-up. No weight outcomes. No additional references.
Nilsell K, Thorne A, Sjostedt S, Apelman J, Pettersson N (2001) Prospective randomised comparison of adjustable gastric banding and vertical banded gastroplasty for morbid obesity. *European Journal of Surgery* 167(7):504–509.	Clegg TA	RCT of adjustable vs. VBG
Norris SL, Zhang X, Avenell A et al. (2005) Long-term non-pharmacologic weight loss interventions for adults with type 2 diabetes. *The Cochrane Database of Systematic Reviews*, Issue 2. John Wiley & Sons, Ltd: Chichester.	Searches	Surgical interventions excluded from review.
Pereira JA, Claro BM, Pareja JC et al. (2003) Restored insulin inhibition on insulin secretion in nondiabetic severely obese patients after weight loss induced by bariatric surgery. *International Journal of Obesity* 27(4):1.	Searches	Not RCT. No additional references.

Study	**Source**	**Reason for exclusion**
Ponson AE, Janssen CIM, Klinkenbijl GJH (2002) Laparoscopic adjustable gastric banding: A prospective comparison of two commonly used bands. *Obesity Surgery* 12(4):	Searches	Compares two different types of bands (Swedish Adjustable Gastric Band vs. Lap-Band), not different surgical techniques. No additional references.
Potteiger CE, Paragi PR, Inverso NA et al. (2004) Bariatric surgery: Shedding the monetary weight of prescription costs in the managed care arena. *Obesity Surgery*	Searches	Not RCT, Some cost data.
Sabbioni M-EE (2002) Intermediate results of health related quality of life after vertical banded gastroplasty. *International Journal of Obesity and Related Metabolic Disorders* 26(2):277–80. [21]	Searches	Not RCT, no additional references.
Sjostrom CD, Peltonen M, Wedel H, Sjostrom L (2000) Differentiated long-term effects of intentional weight loss on diabetes and hypertension. *Hypertension* 36(1):20–5.	Submitted evidence	Review, mainly of Swedish Obese Subjects (SOS) study.
Smith SC, Edwards CB, Goodman GN, Halversen RC, Simper SC (2004) Open vs laparoscopic Roux-en-Y gastric bypass: comparison of operative morbidity and mortality. *Obesity Surgery* 14(1):73–6.	Searches	Weight outcomes only at 6, 12 months, not at minimum 24 months as required.
Stanford A, Glascock JM, Eid GM (2003) Laparoscopic Roux-En-Y gastric bypass in morbidly obese adolescents. *Journal of Pediatric Surgery* 38(3):1.	Searches	Not adults.
Stoeckli R, Chanda R, Langer I, Keller U (2004) Changes of body weight and plasma ghrelin levels after gastric banding and gastric bypass. *Obesity Research* 12(2):346–50.	CR 2005	Cohort study <150 participants
Strauss RS, Bradley LJ, Brolin RE (2001) Gastric bypass surgery in adolescents with morbid obesity. *Journal of Pediatrics* 138(4):499–504. [150]	Searches	Not adults.
Strauss RS (2002) Gastric bypass surgery in adolescents with morbid obesity. *Nutrition in Clinical Practice* 17(1):43. [134]	Searches	Not adults.
Suter M, Giusti V, Worreth M, Heraief E, Calmes J-M (2005) Laparoscopic gastric banding: A prospective, randomized study comparing the Lapband and the SAGB: Early results. *Annals of Surgery* 241(1):	Searches	Compares two different types of bands (Swedish Adjustable Gastric Band vs. Lap-Band), not different surgical techniques. No additional references.

Study	Source	Reason for exclusion
Swedish Council on Technology Assessment in Health Care (SBU) (2004) Gastric pacing (gastric electrical stimulation) for the treatment of obesity – early assessment briefs (Alert). Online.	Searches	Gastric pacing review.
Thorne A, Lonnqvist F, Apelman J, Hellers G, Arner P (2002) A pilot study of long-term effects of a novel obesity treatment: omentectomy in connection with adjustable gastric banding. *International Journal of Obesity and Related Metabolic Disorders* 26(2):193–9. [48]	Searches	Compares adjustable gastric banding with or without omentectomy.
Tolonen P, Victorzon M (2003) Quality of life following laparoscopic adjustable gastric banding – The Swedish Band and the Moorehead–Ardelt questionnaire. *Obesity Surgery* 13(3):1.	Searches	Not RCT. No additional references.
VATAP Bariatric surgery: summary of INAHTA reviews (2005) Online.	Searches	Evidence review. No additional references.
Vlassov VV (2005) Weight reduction for reducing mortality in obesity and overweight. Cochrane collaboration. Online.	Searches	Protocol only.
von Mach MA, Stoeckli R, Bilz S, Kraenzlin M, Langer I, Keller U (2004) Changes in bone mineral content after surgical treatment of morbid obesity. *Metabolism: Clinical and Experimental* 53(7):918–21.	CR 2005	Cohort study <150 participants.
Weiner R, Bockhorn H, Rosenthal R, Wagner D (2001) A prospective randomized trial of different laparoscopic gastric banding techniques for morbid obesity. *Surgical Endoscopy* 15(1):63–8.	Medical Services Advisory Committee (MSAC)	Excluded from Clegg TA.
Weiss HG, Nehoda H, Labeck B et al. (2002) Adjustable gastric and esophagogastric banding: a randomized clinical trial. *Obesity Surgery* 12(4):573–8. [49]	Searches	Gastric banding vs. oesophagogastric banding.
Widhalm K, Dietrich S, Prager G (2004) Adjustable gastric banding surgery in morbidly obese adolescents: Experiences with eight patients. *International Journal of Obesity* 28(Suppl 3):	Searches	Not adults.
Zengin K, Taskin M, Sakoglu N, Salihoglu Z, Demiroluk S, Uzun H (2002) Systemic inflammatory response after laparoscopic and open application of adjustable banding for morbidly obese patients. *Obesity Surgery* 12(2):	Searches	No mention of randomisation. No additional references.
Zoss I, Piec G, Horber FF (2005) Impact of orlistat therapy on weight reduction in morbidly obese patients after implantation of the Swedish adjustable gastric band. *Obesity Surgery* 12	Searches	Not RCT. No additional references.

1.7.1 Open and laparoscopic gastric bypass single arm studies

Study	Reason for exclusion
Arteaga JR, Huerta S, Livingston EH (2002) Management of gastrojejunal anastomotic leaks after Roux-en-Y gastric bypass. *American Surgeon* 68(12):1061–5.	Weight loss not reported.
Brolin RE, Bradley LJ, Wilson AC, Cody RP (2000) Lipid risk profile and weight stability after gastric restrictive operations for morbid obesity. *Journal of Gastrointestinal Surgery* 4(5):464–9.	Outcomes not reported by type of surgery.
Carrasquilla C, English WJ, Esposito P, Gianos J (2004) Total stapled, total intra-abdominal (TSTI) laparoscopic Roux-en-Y gastric bypass: one leak in 1000 cases. *Obesity Surgery* 14(5):613–7.	Not 24-months follow-up.
Demaria EJ, Sugerman HJ, Kellum JM, Meador JG, Wolfe LG (2002) Results of 281 consecutive total laparoscopic Roux-en-Y gastric bypasses to treat morbid obesity. *Annals of Surgery* 235(5):640–45.	Not 24-months follow-up.
Faintuch J, Matsuda M, Cruz ME (2004). Severe protein–calorie malnutrition after bariatric procedures. *Obesity Surgery* 14(2):175–81.	Not 150 participants.
Fernandez AZ Jr, DeMaria EJ, Tichansky DS et al. (2004) Multivariate analysis of risk factors for death following gastric bypass for treatment of morbid obesity. *Annals of Surgery* 239(5):698.	Laparoscopic vs. open study.
Frezza EE, Ikramuddin S, Gourash W et al. (2002) Symptomatic improvement in gastroesophageal reflux disease (GORD) following laparoscopic Roux-en-Y gastric bypass. *Surgical Endoscopy* 16(7):1027–31.	Laparoscopic gastic bypass, not 24-months follow-up.
Hedenbro JL, Frederiksen SG (2002) Fully stapled gastric bypass with isolated pouch and terminal anastomosis: 1–3 year results. *Obesity Surgery* 12(4):546–50.	Not standard Roux-en-Y gastic bypass.
Jones KB Jr (1998) Roux-en-Y gastric bypass: an effective antireflux procedure in the less than morbidly obese. *Obesity Surgery* 8(1):35–8.	Not 150 participants.
MacLean LD, Rhode BM, Nohr CW (2000) Late outcome of isolated gastric bypass. *Annals of Surgery* 231(4):524–8.	Not standard Roux-en-Y gastic bypass.
Murphy K, McCracken JD, Ozment KL (1980) Gastric bypass for obesity. Results of a community hospital series. *American Journal of Surgery* 140(6):747–50.	Only 47 patients had Roux-en-Y gastic bypass.
Obeid F, Falvo A, Dabideen H, Stocks J, Moore M, Wright M (2005) Open Roux-en-Y gastric bypass in 925 patients without mortality. *American Journal of Surgery* 189(3):352–6.	Not 24 months follow-up.
Parikh MS, Shen R, Weiner M, Siegel N, Ren CJ (2005) Laparoscopic bariatric surgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. *Obesity Surgery* 15(6):858–63.	Not 150 patients for laparoscopic gastic bypass.

Study	**Reason for exclusion**
Raftopoulos I, Ercole J, Udekwu AO, Luketich JD, Courcoulas AP (2005) Outcomes of Roux-en-Y gastric bypass stratified by a body mass index of 70 kg/m^2: a comparative analysis of 825 procedures. *Journal of Gastrointestinal Surgery* 9(1):44–52.	Compared open *and* laparoscopic procedures in people who were severely obese or superobese.
Raftopoulos Y, Gatti GG, Luketich JD, Courcoulas AP (2005) Advanced age and sex as predictors of adverse outcomes following gastric bypass surgery. *Journal of the Society of Laparoendoscopic Surgeons* 9(3):272–6.	Weight loss not reported.
Smith SC, Edwards CB, Goodman GN (1997) Symptomatic and clinical improvement in morbidly obese patients with gastroesophageal reflux disease following Roux-en-Y gastric bypass. *Obesity Surgery* 7(6):479–84.	Weight loss not reported for gastric bypass group alone.
Smith SC, Edwards CB, Goodman GN, Halversen RC, Simper SC (2004) Open vs laparoscopic Roux-en-Y gastric bypass: comparison of operative morbidity and mortality. *Obesity Surgery* 14(1):73–6.	Open vs. laparoscopic.
Warde-Kamar J, Rogers M, Flancbaum L, Laferrere B (2004) Calorie intake and meal patterns up to 4 years after Roux-en-Y gastric bypass surgery. *Obesity Surgery* 14(8):1070–9.	Excluded as only 69 participants out of 360 invited.

1.8 Interventions in a UK clinical setting

Study	Source	Reason for exclusion
Mhurchu CN, Margetts BM, Speller V (1998) Randomized clinical trial comparing the effectiveness of two dietary interventions for patients with hyperlipidaemia. *Clinical Science* 95(4): 479–87.	Searches	No requirement to be overweight or obese. Baseline BMI <28 kg/m^2.
Barrett P, Finer N, Fisher C, Boyle G (1999) Evaluation of a multimodality treatment programme for weight management at the Luton and Dunstable Hospital NHS Trust. *Journal of Human Nutrition and Dietetics* 12(Suppl 1): 43–52.	Searches	No control group.
Bowerman S (2001	Non-clinical review	Non-UK study.
Cadman L, Wiles R (1996) Short report. Nutrition advice in primary care: evaluation of practice nurse nutrition training programmes. *Journal of Human Nutrition and Dietetics* 9(2):147–56.	Searches	No control group.
Collins et al. 1999	Searches	All parameters for inclusion were met, except the presence of control or comparison group.
Cooper CA, de Looy AE, Conry MA (1979) Efficiency of energy-reduced diets in the treatment of obesity by dietitians. *Proceedings of the Nutrition Society* 38(1):7A.	Searches	No control group.
Deforche B, Bourdeaudhuij ID, Tanghe A, Hills AP, Bode PD (2004) Changes in physical activity and psychosocial determinants of physical activity in children and adolescents treated for obesity. *Patient Education and Counseling* 55(3):407–415.	Searches	All parameters for inclusion were met, except the presence of control or comparison group.
Drummond S, Kirk T (1998) The effect of different types of dietary advice on body composition in a group of Scottish men. *Journal of Human Nutrition and Dietetics* 11(6):473–85.	Searches	Normal to moderately overweight men only. Baseline BMI <28 kg/m^2.
Drummond S (2000) Obesity in primary care. *Primary Health Care* 10(5):43–9.	Searches	Narrative review.
Drummond S, Dixon K, Griffin J, De Looy A (2004)Weight loss on an energy-restricted, low-fat, sugar-containing diet in overweight sedentary men. *International Journal of Food Science and Nutrition* 55(4):279–90.	Searches	No control group.
Eley Morris S, Lean MEJ, Hankey CR, Hunter C (1999) Who gets what treatment for obesity? A survey of GPs in Scotland. *European Journal of Clinical Nutrition* 53(2):S44–8.	Searches	Survey.

Study	Source	Reason for exclusion
Elgar FJ, Roberts C, Moore L, Tudor-Smith C (2005) Behaviour, physical activity and weight problems in adolescents in Wales. *Public Health* 119(6):518–24.	Searches	Cohort study, also all parameters for inclusion were met, except the presence of control or comparison group
Fletcher AM (1982) The nutritionist as the primary care provider in a team approach to obesity. *Journal of the American Dietetic Association* 80(3):253–5.	Searches	Non-UK descriptive paper.
Foster A, Brereton P, Foster A, Brereton P (1978) Professional flab fighting at district level. *Health and Social Service Journal* 88(4621):1416–7.	Searches	No control group.
Frühbeck G, Diez CA, Gómez AJ, Cienfuegos J (2003) Management of overweight and obese adults: Comment. *British Medical Journal* 326(7380):102–3.	Searches	Not study report (letter).
Fuller TL, Milburn K Backet, Hopton JL (2003) Healthy eating: the views of general practitioners and patients in Scotland. *American Journal of Clinical Nutrition* 77(4)(Suppl):S1043–7.	Searches	Qualitative study.
Garrow J (1976) Obesity clinic. 1. Who works there and why. *Nursing Times* 72(2):78–9. Garrow J (1976) Obesity clinic. 2. Treatment of refractory patients. *Nursing Times* 72(3):116–7.	Searches	No control group.
Green SM, Passway TJ (1998) Focus on nutrition. Management of obesity in the primary care setting. *British Journal of Community Nursing* 3(5):244–9.	Searches	Narrative review.
Green SM, McCoubrie M, Cullingham C (2000) Practice nurses' and health visitors' knowledge of obesity assessment and management. *Journal of Human Nutrition and Dietetics* 13(6):413–23.	Searches	Survey.
Grignard S, Pierre B Jean, Michel B, Philippe M, Chantal V (2003) Characteristics of adolescent attempts to manage overweight. *Patient Education and Counseling* 51)2):183–9.	Searches	Cohort study, also all parameters for inclusion were met, except the presence of control or comparison group.
Hankey CR, Rumley A, Lowe G-DO, Woodward M, Lean MEJ (1997) Moderate weight reduction improves red cell aggregation and factor VII activity in overweight subjects. *International Journal of Obesity* 21(8):644–50.	Searches	No control group.
Hankey CR (2002) Weight change after myocardial infarction: Statistical perspectives for future study. *Journal of Human Nutrition and Dietetics* 15(6):439–44,	Searches	See Leslie WS, 2004

Study	Source	Reason for exclusion
Hankey CR, Eley S, Leslie WS, Hunter CM, Lean MEJ (2004) Eating habits, beliefs, attitudes and knowledge among health professionals regarding the links between obesity, nutrition and health. *Public Health Nutrition* 7(2):337–43.	Searches	Survey.
Harland J, White M, Drinkwater C, Chinn D, Farr L, Howel D (1999) The Newcastle exercise project: A randomised controlled trial of methods to promote physical activity in primary care. *British Medical Journal* 319(7213): 828–32.	Searches	No requirement for participants to be overweight or obese. No weight outcomes reported.
Harland P-SE, Watson MJ, Ashworth L (1997) The effect of metabolic programming on atherosclerosis and obesity risk factors in UK adolescents living in poor socioeconomic areas. *Annals of the N Y Academy of Sciences* 817:361–4.	Searches	Study to determine associations between metabolic consequences and birth weight.
Harvey EL, Summerbell CD, Kirk SF et al. (2002) Dietitians' views of overweight and obese people and reported management practices. *Journal of Human Nutrition and Dietetics* 15(5):331–47.	Searches	Survey.
Hillsdon M, Thorogood M, White I, Foster C (2002) Advising people to take more exercise is ineffective: A randomized controlled trial of physical activity promotion in primary care. *International Journal of Epidemiology* 31(4):808–815.	Non-clinical review	No baseline BMI reported and no requirement to be overweight or obese.
Hudson A (2004) Fighting fat: who slims wins. *Primary Health Care* 14(3):12–4.	Searches	No control group. Report of counterweight.
Hughes J, Todorovic V, Kemp H (1999) 'The Sugar Buddies': An intervention programme for 'obese' patients with poorly controlled diabetes. *Journal of Human Nutrition and Dietetics* 12(Suppl 1):71–8.	Searches	No control group.
Hughes J, Martin S (1999) The Department of Health's project to evaluate weight management services. *Journal of Human Nutrition and Dietetics* 12(Suppl 1):1–8.	Searches	Report of Department of Health survey.
Jayagopal V, Kilpatrick ES, Holding S, Jennings PE, Atkin SL (2005) Orlistat is as beneficial as metformin in the treatment of polycystic ovarian syndrome. *Journal of Clinical Endocrinology and Metabolism* 90(2):729–33.	Searches	Compared orlistat and metformin for polycystic ovarian syndrome.
Kenny C (2001) Primary care prevention of cardiovascular disease in diabetes. *Practical Diabetes International* 18(6):212–6.	Searches	Narrative review.
Keppie B, Lyon A (1999) Evaluation of weight management services provided by dietitians within a community trust. *Journal of Human Nutrition and Dietetics* 12(Supp 1): 53–60.	Searches	No control group.

Study	Source	Reason for exclusion
King S, Gibney M (1999) Dietary advice to reduce fat intake is more successful when it does not restrict habitual eating patterns. *Journal of the American Dietetic Association* 99(6): 685–9.	Searches	Conducted in Ireland, not UK
Kirk SFL (2003)	Searches	Not results of intervention, methods paper.
Kirk T, Crombie N, Cursiter M (2000) Promotion of dietary carbohydrate as an approach to weight maintenance after initial weight loss: a pilot study. *Journal of Human Nutrition and Dietetics* 13(4):277–85.	Searches	No control group.
Koliopoulos G, Wood PL, Papanikou E, Creatsas G (2005) Body mass index extremes in a British adolescent gynecology clinic. *Journal of Pediatric and Adolescent Gynecology* 18(3):163–6.	Searches	Retrospective case-series.
Lamb SE, Bartlett HP, Ashley A, Bird W (2002) Can lay-led walking programmes increase physical activity in middle aged adults? A randomised controlled trial. *Journal of Epidemiology and Community Health* 56(4): 246–52.	Searches	No requirement to be overweight or obese. Baseline BMI <28 kg/m^2.
Leslie WS, Lean MEJ, Baillie HM, Hankey CR (2002) Weight management: A comparison of existing dietary approaches in a work-site setting. *International Journal of Obesity* 26(11): 1469–75.	Searches	In non-clinical review.
Leslie WS, Hankey CR, Matthews D, Currall JEP, Lean MEJ (2004) A transferable programme of nutritional counselling for rehabilitation following myocardial infarction: A randomised controlled study. *European Journal of Clinical Nutrition* 58(5): 778–86).	Searches	No requirement to be overweight or obese. Baseline BMI <28 kg/m^2.
Little P (1998) GP documentation of obesity: what does it achieve? *British Journal of General Practice* 48(426):890–4.	Searches	No control group.
Marshall D, McConkey R, Moore G (2003) Obesity in people with intellectual disabilities: the impact of nurse-led health screenings and health promotion activities. *Journal of Advanced Nursing* 41(2):147–53.	Searches	No control group.
Martell R (20040 Childhood obesity 'is everyone's problem'. *Physiotherapy Frontline* 10(12):23–5.	Searches	Information brochure.
Martin C, Woolf-May K (1999) The retrospective evaluation of a general practitioner exercise prescription programme. *Journal of Human Nutrition and Dietetics* 12(Suppl 1): 32–42.	Searches	Not 12 weeks.
Maryon-Davis A (2005) Weight management in primary care: how can it be made more effective? *Proceedings of the Nutrition Society* 64(1):97–103.	Searches	Narrative review.

Study	**Source**	**Reason for exclusion**
McArdle S (2004) Running an obesity management clinic. *Practice Nurse* 27(10):38.	Searches	Narrative review.
Mercer SW, Tessier S, Mercer SW, Tessier S (2001) A qualitative study of general practitioners' and practice nurses' attitudes to obesity management in primary care. *Health Bulletin (Edinburgh)* 59(4):248–53.	Searches	Survey.
Munnelly P, Feehan S (2002) An obesity clinic model. *Proceedings of the Nutrition Society* 61(1):9–10.	Searches	No control group.
Murphy C, Simkins M, Helowicz R (1999) Diabetes exercise project. *Journal of Human Nutrition and Dietetics* 12(Suppl 1):79–90).	Searches	Relevant to non-clinical review on people with co-morbidities.
Nupponen R, Laukkanen R (1998) How to develop a group curriculum: developing an exercise programme for overweight adults. *Patient Education and Counseling* 33(Suppl 1):S77–85.	Searches	Non-UK study. No control group.
Ogden J, Bandara I, Cohen H et al. (2001) General practitioners' and patients' models of obesity: Whose problem is it? *Patient Education and Counseling* 44(3):227–33.	Searches	Survey.
Oldroyd JC, Unwin NC, White M, Imrie K, Mathers JC, Alberti KG (2001) Randomised controlled trial evaluating the effectiveness of behavioural interventions to modify cardiovascular risk factors in men and women with impaired glucose tolerance: outcomes at 6 months. *Diabetes Research and Clinical Practice* 52(1):29–4.	Searches	Focus on improving cardiovascular risk factors, not main aim of weight loss. No requirement for participants to be overweight, but mean BMI ≥28 kg/m^2.
Owen TA (2004) Weight in Wales. *Nutrition Bulletin* 29(2):85–91.	Searches	Survey.
Pike H (2004) Welsh pharmacist tackling obesity with weight reduction support clinic. *Pharmaceutical Journal* 272(7292):383–87	Searches	No control group.
Pill R, Stott NCN, Rollnick SR, Rees M (1998) A randomized controlled trial of an intervention designed to improve the care given in general practice to Type II diabetic patients: Patient outcomes and professional ability to change behaviour. *Family Practice* 15(3): 229–35.	Searches	No baseline BMI reported and no requirement to be overweight or obese.
Prentice A (2004)	Searches	No control group. Abstract only.
Raaff CA (2005) A preliminary investigation into the use of multimedia to enhance dietetic management of overweight and obese children: multimedia design for child–dietitian consultations. *Nutrition Bulletin* 30(2):126–31.	Searches	Appears to be case series.

Study	Source	Reason for exclusion
Rayner M, Ziebland S (1999) Process evaluation of a research workshop and follow-up support to help practitioners from 13 weight management projects to carry out evaluations. *Journal of Human Nutrition and Dietetics* 12(Supp 1): 9–19.	Searches	Process evaluation of research workshop.
Read S (2004)	Searches	No control group.
Reed B, Jackson J, Harborne J, Roberts R (1999) Study to evaluate the effect of dietary advice and the role of exercise in obese women who are trying to lose weight. *Journal of Human Nutrition and Dietetics* 12(Suppl 1):61–70.	Searches	Not evaluation of defined intervention, but retrospective review of factors that influenced weight loss.
Roberts A, Ashley G (1999) What are the characteristics of overweight and obese patients who achieve weight loss and what factors are most helpful? A quantitative and qualitative study of patients and interventions in a rural general practice. *Journal of Human Nutrition and Dietetics* 12(Suppl 1):20–27.	Searches	Not evaluation of defined intervention, but retrospective review of factors that influenced weight loss.
Rudolf MCJ, Sahota P (2004) WATCH IT. A community based approach for the treatment of childhood obesity: a pilot study. *International Journal of Obesity and Metabolic Disorders*		Children
Sleath C (1999) Can clinically significant weight loss be achieved and sustained? An evaluation of a general practice based weight control clinic. *Journal of Human Nutrition and Dietetics* 12(Suppl 1): 28–31.	Searches	No control group.
Stensel DJ (1994)	Searches	No requirement to be overweight or obese. Baseline BMI <28 kg/m^2.
Stevens W, Hillsdon M, Thorogood M, McArdle D, Eaton CB (1998) Cost-effectiveness of a primary care based physical activity intervention in 45–74 year old men and women: A randomised controlled trial. *British Journal of Sports Medicine* 32(3): 236–41.	Searches	No weight outcomes. No requirement to be overweight or obese.
Taylor AH, Doust J, Webborn N (1998) Randomised controlled trial to examine the effects of a GP exercise referral programme in Hailsham, East Sussex, on modifiable coronary heart disease risk factors. *Journal of Epidemiology and Community Health* 52(9): 595–601.	Searches	No requirement to be overweight or obese. Baseline BMI <28 kg/m^2.
Tessier S, Morris SE, Lean ME (2000) The demand and supply of nutritional advice and guidance in Scottish family planning services. *British Journal of Family Planning* 26(2):97–99.	Searches	Survey.
Thompson RL, Thomas DE (2000) A cross-sectional survey of the opinions on weight loss treatments of adult obese patients attending a dietetic clinic. *International Journal of Obesity and Related Metabolic Disorders* 24(2):164–70.	Searches	Survey.

Study	Source	Reason for exclusion
Tod AM, Lacey A (2004) Overweight and obesity: helping clients to take action. *British Journal of Community Nursing* 9(2):59–66.	Searches	Qualitative study.
Treasure JL, Katzman M, Schmidt U, Troop N, Todd G, De Silva P (1999) Engagement and outcome in the treatment of bulimia nervosa: First phase of a sequential design comparing motivation enhancement therapy and cognitive behavioural therapy. *Behaviour Research and Therapy* 37(5): 405–18.	Dunn review	People with bulimia.
Turner S (2005) Promoting healthy lifestyles for people with learning disabilities: a survey of provider organisations. *British Journal of Learning Disabilities* 24(4):138–44.	Searches	Survey.
Viner R, Nicholls D, Viner R, Nicholls D (2005) Managing obesity in secondary care: a personal practice. *Archives of Disease in Childhood* 90(4):385–90.	Searches	Literature review/expert opinion.
Watch it – An NHS Community Service for obese children.	Submitted evidence	Information brochure. No experimental study was conducted.
Wells MB, Turner S, Martin DM, Roy A (1997) Health gain through screening – coronary heart disease and stroke: developing primary health care services for people with intellectual disability. *Journal of Intellectual and Developmental Disabilities* 22(4):251–63.	Searches	Describes the results of a screening programme.
West JA, De Looy AE (2001) Weight loss in overweight subjects following low-sucrose or sucrose-containing diets. *International Journal of Obesity* 25(8):1122–8.	Searches	Not 12 weeks.
Williams J, Sultan M (1999) Evaluation of an Asian women's healthy eating and exercise group. *Journal of Human Nutrition and Dietetics 12*(Suppl 1):91–8).	Searches	No control group.

1.9 Barriers and attitudes to the management of overweight and obesity in the clinical setting

Study	**Reason for exclusion**
Adolfsson B et al (2002) Treating obesity: a qualitative evaluation of a lifestyle intervention for weight reduction. *Health Education Journal* 61:244–58.	Not UK-based.
Andersen et al. (1998)	Participants were not overweight or obese.
Banning M (2005) Obesity. The management of obesity: the role of the specialist nurse. *British Journal of Nursing* 14(3):139–44.	Literature review.
Drummond S (2000) Address the weighty problem of obesity. *Practice Nurse* 20:146–9.	Literature review.
Farooqi A, Nagra D, Edgar T, Khunti K (2000) Attitudes to lifestyle risk factors for coronary heart disease amongst South Asians in Leicester: a focus group study. *Family Practice* 17(4):293–7.	Not relevant to weight management.
Fuller TL, Backett-Milburn K, Hopton JL (2003) Healthy eating: the views of general practitioners and patients in Scotland. *American Journal of Clinical Nutrition* 77(4 Suppl):S1043–7.	Not relevant to weight management.
Green (1998)	Literature review.
Heyes T, Long S, Mathers N (2004) Preconception care: practice and beliefs of primary care workers. *Family Practice* 21(1):22–7.	Not relevant to weight management.
Hunt P, Pearson D (2001) Motivating change. *Nursing Standard* 16(2):45–52.	Literature review.
Ingledew, Sullivan (2002)	Adolescents were recruited in Germany.
John J, Ziebland S (2004) Reported barriers to eating more fruit and vegetables before and after participation in a randomized controlled trial: a qualitative study. *Health Education Research* 19(2):165–74.	Not relevant to weight management.
John J, Yudkin P, Neil H (2003) Does Stage of Change predict outcome in a primary-care intervention to encourage an increase in fruit and vegetable consumption? *Health Education Research* 18(4):429–38.	Not relevant to weight management.
Lloyd et al. (1995)	Included subjects that were overweight and subjects with normal weight, and no stratification of weight results was performed.

Study	**Reason for exclusion**
Nigg CR (1999) Stages of change across ten health risk behaviors for older adults. Gerontologist 39(4):473–82.	Not UK-based.
Prochaska JO (1994) Stages of change and decisional balance for 12 problem behaviors. *Health Psychology* 13:39–46.	Not relevant to weight management.
Salmon et al. Reducing sedentary behaviour and increasing physical activity among 10-year-old children: Overview and process evaluation of the 'Switch-Play' intervention. *Health Promotion International* 20:7–17.	Not UK-based.
Sutton K, Logue E, Jarjoura D, Baughman K, Smucker W, Capers C (2003) Assessing dietary and exercise stage of change to optimize weight loss interventions. *Obesity Research* 11(5):641–52.	Not UK-based.
Taylor et al. 2004	Not UK-based
Thompson RL, Thomas DE (2000) A cross-sectional survey of the opinions on weight loss treatments of adult obese patients attending a dietetic clinic. *International Journal of Obesity and Related Metabolic Disorders* 24(2):164–70.	No barriers were reported in this study.
Turner 1996	Participants were not overweight or obese.
Wallace PG, Brennan PJ, Haines AP (1987) Are general practitioners doing enough to promote healthy lifestyle? Findings of the Medical Research Council's general practice research framework study on lifestyle and health. *British Medical Journal (Clinical Research Ed.)* 294(6577):940–2.	Participants were not overweight. Promotion of health lifestyle.
Williams, Sultan	Not relevant to clinical practice.

1.10 Effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for people who are overweight and obese

Study	Reason for exclusion
Albright CL (2000) Incorporating physical activity advice into primary care: Physician- delivered advice within the Activity Counseling Trial. *American Journal of Preventive Medicine* vol 2000;Apr-234	Participants were not obese/overweight.
Ammerman AS, Keyserling TC, Atwood JR, Hosking JD, Zayed H, Krasny C (2003) A randomized controlled trial of a public health nurse directed treatment program for rural patients with high blood cholesterol. *Preventive Medicine* 36(3):340–51.	Not a brief intervention.
Ammerman AS, Lindquist CH, Hersey J (2002) The efficacy of behavioral interventions to modify dietary fat and fruit and vegetable intake: A review of the evidence. *Preventive Medicine* 35:25–41.	Not relevant.
Ashley JM, St Jeor ST, Schrage JP et al. (2001) Weight control in the physician's office. *Archives of Internal Medicine* 161(13):1599–1604.	Not relevant to KCQ.
Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EHA (1997) Dietary intervention in primary care practice: the Eating Patterns Study. *American Journal of Public Health* 87:610–616.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
Black DR, Coe WC, Friesen JG, Wurzmann AG (1984) Minimal interventions for weight control: a cost-effective alternative. *Addictive Behavior* 9(3):279–85.	Less than12-month study.
Bull FC, Jamrozik K, Blanksby BA (1999) Tailored advice on exercise – Does it make a difference. *American Journal of Preventive Medicine* 16(3):230–9.	BMI values were only reported at month 1.
Burke BL (2004) The emerging evidence base for motivational interviewing: a meta-analytic and qualitative inquiry. *Journal of Cognitive Psychotherapy* (Special Issue: Motivational Interviewing: Theory, Research, and Practice)	Narrative review.
Conn Vicki, Valentine J, Cooper H (2002) Interventions to increase physical activity among aging adults: A meta-analysis. *Annals of Behavioral Medicine* 24(3): 190–200.	Participants were not overweight/obese
Dowell AC, Ocheran JJ, Hilton SR et al. (1996) Prevention in practice: Results of a 2-year follow-up of routine health promotion interventions in general practice. *Family Practice* 13(4):357–62.	Also included participants that were not overweight or obese.
Drummond S, Kirk T (1999) Assessment of advice to reduce dietary fat and non-milk extrinsic sugar in a free-living male population. *Public Health Nutrition* 2(2):187–97.	Weight and BMI values were only reported at baseline.

Dubbert PM (2002) Physical activity and exercise: Recent advances and current challenges. *Journal of Consulting and Clinical Psychology* (Special Issue: Behavioral medicine and clinical health psychology).	Participants were not obese/overweight.
Dunn C, Deroo L, Rivara FP (2001) The use of brief interventions adapted from motivational interviewing across behavioral domains: A systematic review. *Addiction* 96:1770-2.	Not relevant systematic review. References checked.
Fulton JE, Garg M, Galuska DA, Rattay KT, Caspersen CJ (2004) Public health and clinical recommendations for physical activity and physical fitness: special focus on overweight youth. *Sports Medicine* 2004; 34(9):581–99.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
Goldstein MG (2004) Multiple behavioral risk factor interventions in primary care: summary of research evidence. *American Journal of Preventive Medicine* (Special Issue: Addressing Multiple Behavioral Risk Factors in Primary Care).	Literature review. References checked.
Halbert JA, Silagy CA, Finucane PM, Withers RT, Hamdorf PA (2000) Physical activity and cardiovascular risk factors: Effect of advice from an exercise specialist in Australian general practice. *Medical Journal of Australia* 173(2):85–7.	Not relevant to KCQ.
Hebert JR, Ebbeling CB, Ockene IS et al. (1999) A dietitian-delivered group nutrition program leads to reductions in dietary fat, serum cholesterol, and body weight: the Worcester Area Trial for Counseling in Hyperlipidemia (WATCH). *Journal of the American Dietetic Association* 99:544–52.	6 weeks study.
Hensrud DD (2004) Tackling obesity in a 15 minute office visit. Physicians can start patients on an effective weight-loss program, despite time constraints 115(1): 95–61.	Not RCT.
Hilton S, Doherty S, Kendrick T, Kerry S, Rink E, Steptoe A Promotion of healthy behaviour among adults at increased risk of coronary heart disease in general practice: methodology and baseline data from the Change of Heart study. *Health Education*	Not a brief intervention as nurse contacted patients via telephone in between counselling sessions.
Gerda J, Martin BW (2005) Implementation and effectiveness of a primary care based physical activity counselling scheme. *Patient Education and Counseling* 2(1):16–34.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
King AC (2002) Harnessing motivational forces in the promotion of physical activity: The Community Health Advice by Telephone (CHAT) project. *Health Education Research*	Not relevant to KCQ.
Leslie WS, Hankey CR, Matthews D, Currall JE, Lean ME (2004) A transferable programme of nutritional counselling for rehabilitation following myocardial infarction: a randomised controlled study. *European Journal of Clinical Nutrition* 58:778–86.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.

Little P, Kelly J, Barnett J, Dorward M, Margetts B, Warm D (2004) Randomised controlled factorial trial of dietary advice for patients with a single high blood pressure reading in primary care. *British Medical Journal* 328(7447):1054–7.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
Logue E, Sutton K, Jarjoura D et al. (2005) Transtheoretical model – chronic disease care for obesity in primary care: a randomized trial. *Obesity Research* 13(5):917–27.	Not a brief intervention.
Loreto et al. (2003)	Exclusively for participants with type 2 diabetes. Aim other than to assess effectiveness of a brief intervention in weight loss in obese/overweight individuals.
Massari A, Point C, Truffe P, Chatellier G, Simon A, Menard J (1995) A randomised trial comparing 2 different educational interventions for teaching diet in 300 subjects having a high cardiovascular risk. *Archives des Maladies du Coeur et des Vaisseaux*	Language other than English.
Mengham LH, Morris BF, Palmer CR, White AJS (1999) Is intensive dietetic intervention effective for overweight patients with diabetes mellitus? A randomised controlled study in a general practice. *Practical Diabetes International* 16:5–8.	Not a brief intervention.
Moore H, Summerbell CD, Greenwood DC et al. (2003) Improving management of obesity in primary care: Cluster randomised trial. *British Medical Journal* 327(7423):1085–8.	Not a brief intervention.
Naylor PJ (1999) Comparison of stage-matched and unmatched interventions to promote exercise behaviour in the primary care setting. *Health Education Research*	Participants were not obese/overweight.
Nemet et al. (2005) Short- and long-term beneficial effects of a combined dietary-behavioral-physical activity intervention for the treatment of childhood obesity. *Pediatrics* 115	3-month study.
Nicholas L, Pond D, Roberts D-CK The effectiveness of nutrition counselling by Australian General Practitioners. *European Journal of Clinical Nutrition* 59(Suppl 1):S140–6.	Not RCT.
Ockene IS, Hebert JR, Ockene JK et al. (1999) Effect of physician-delivered nutrition counseling training and an office-support program on saturated fat intake, weight, and serum lipid measurements in a hyperlipidemic population: Worcester area trial for counseling in hyperlipidemia (WATCH). *Archives of Internal Medicine* 159(7):725–31.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
Olivarius N-DF, Palmvig B, Andreasen AH, Thorgersen JT, Hundrup C (2005) An educational model for improving diet counselling in primary care: A case study of the creative use of doctors' own diet, their attitudes to it and to nutritional counselling of their patients with diabetes. *Patient Education and Counseling* 58(2):199–202.	Not relevant to KCQ.

Olsen J, Willaing I, Ladelund S, Jorgensen T, Gundgaard J, Sorensen J (2005) Cost-effectiveness of nutritional counseling for obese patients and patients at risk of ischemic heart disease. *International Journal of Technology Assessment in Health Care* 2005; 21(2):194–202	Not a brief intervention.
Petrella RJ (2003) Can primary care doctors prescribe exercise to improve fitness? The Step Test Exercise Prescription (STEP) Project. *American Journal of Preventive Medicine*	Being overweight/obese was not part of inclusion criteria.
Pignone MP (2003) Counseling to promote a healthy diet in adults: A summary of the evidence for the U.S Preventive Services Task Force. *American Journal of Preventive Medicine*	Studies that included only obese/overweight subjects were excluded from this review.
Pronk NP (2004) Addressing multiple behavioral risk factors in primary care: a synthesis of current knowledge and stakeholder dialogue sessions. *American Journal of Preventive Medicine* (Special Issue: Addressing multiple behavioral risk factors in primary care	Not relevant to KCQ.
Reed B, Jackson J, Harborne J, Roberts R (1999) Study to evaluate the effect of dietary advice and the role of exercise in obese women who are trying to lose weight. *Journal of Human Nutrition and Dietetics* 12(Suppl 1):61–70.	Retrospective analysis.
Roderick P, Ruddock V, Hunt P, Miller G (1997) A randomized trial to evaluate the effectiveness of dietary advice by practice nurses in lowering diet-related coronary heart disease risk. *British Journal of General Practice* 47(414):7–12.	Not a brief intervention.
Simkin-Silverman LR (20050 Predictors of weight control advice in primary care practices: Patient health and psychosocial characteristics. *Preventive Medicine*	Not a brief intervention.
Simkin-Silverman LR, Wing RR (1997) Management of obesity in primary care 5(6):603–612.	Not clear length of follow-up.
Simons-Morton DG (2001) Effects of physical activity counseling in primary care: The Activity Counseling Trial: A randomized controlled trial. *Journal of the American Medical Association*	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
Smith DE, Heckemeyer CM, Kratt PP, Mason DA (1997) Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM A pilot study. *Diabetes Care* 20:52–4.	Not relevant to KCQ.
Staten LK (2004) Provider Counseling, Health Education, and Community Health Workers: The Arizona WISEWOMAN Project. *Journal of Women's Health*	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.

Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S (1999) Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: Randomised trial. *British Medical Journal* 319(7215):943–7.	No weight values were reported at the assessments.
Steptoe A, Kerry S, Rink E, Hilton S (2001) The impact of behavioral counseling on stage of change in fat intake, physical activity, and cigarette smoking in adults at increased risk of coronary heart disease. *American Journal of Public Health* 91:265–9. [77]	No subgroup analysis for subjects with overweight/obesity or normal weight.
Traeden UI, Holm L, Sandstrom B, Andersen PK, Jarden M (1998) Effectiveness of a dietary intervention strategy in general practice: effects on blood lipids, health and well-being. *Public Health Nutrition* 1(4):273–81.	Not an RCT.
Van der Veen J, Bakx C, Van den Hoogen H et al. (2002) Stage-matched nutrition guidance for patients at elevated risk for cardiovascular disease: A randomized intervention study in family practice. *Journal of Family Practice* 51(9):751–8.	Aim other than to assess effectiveness of a brief intervention in weight loss/maintenance in obese/overweight individuals.
Van der Bij AK (2002) Effectiveness of physical activity interventions for older adults. *American Journal of Preventive Medicine*	Participants were not obese/overweight.
Whitlock EP (2002) Evaluating primary care behavioral counseling interventions: An evidence-based approach. *American Journal of Preventive Medicine*	Literature review.
Willaing I, Ladelund S, Jorgensen T, Simonsen T, Nielsen LM (2004) Nutritional counselling in primary health care: A randomized comparison of an intervention by general practitioner or dietician. *European Journal of Cardiovascular Prevention and Rehabilitation* 11(6):513–20	Not a brief intervention.
Wolf AM, Conaway MR, Crowther JQ et al. (2004) Translating lifestyle intervention to practice in obese patients with type 2 diabetes: Improving Control with Activity and Nutrition (ICAN) study. *Diabetes Care* 27(7):1570–6	Not a brief intervention.
Woollard J, Beilin L, Lord T, Puddey I, MacAdam D, Rouse I (1995) A controlled trial of nurse counselling on lifestyle change for hypertensives treated in general practice: Preliminary results. *Clinical and Experimental Pharmacology and Physiology* 22(6/7):466–8.	Not a brief intervention.
Woollard J, Burke V, Beilin LJ, Verheijden M, Bulsara MK (2003) Effects of a general practice-based intervention on diet, body mass index and blood lipids in patients at cardiovascular risk. *Journal of Cardiovascular Risk* 10:31–40.	Being overweight/ obese was not part of inclusion criteria.

2 Update searches and papers considered

Reference	Reason for exclusion
Abate N, Chandalia M, Snell PG, Grundy SM, Abate N, Chandalia M *et al*. Adipose tissue metabolites and insulin resistance in nondiabetic Asian Indian men. *J.Clin.Endocrinol.Metab* 2004;89:2750-5.	Not considered to affect evidence statements…
Acarturk TO, Wachtman G, Heil B, Landecker A, Courcoulas AP, Manders EK *et al*. Panniculectomy as an adjuvant to bariatric surgery. [Review] [21 refs]. *Ann.Plast.Surg.* 2004;53:360-6.	Reviewed the use of panniculectomy as adjuvant. Not technique of weight loss surgery.
Acheson KJ,.Acheson KJ. Carbohydrate and weight control: where do we stand?. [Review] [70 refs]. *Curr.Opin.Clin.Nutr.Metab Care* 2004;7:485-92.	Narrative review
Adami GF, Ramberti G, Weiss A, Carlini F, Murelli F, Scopinaro N. Quality of life in obese subjects following biliopancreatic diversion. *Behavioral Medicine.* 2005;31:53-60.	Not effectiveness of weight loss surgery. Mean EWL not reported.
Alvarado R, Alami RS, Hsu G, Safadi BY, Sanchez BR, Morton JM *et al*. The impact of preoperative weight loss in patients undergoing laparoscopic Roux-en-Y gastric bypass. *Obesity Surgery.* 2005;15:1282-6.	Less than 150 participants.
Ames GE, Perri MG, Fox LD, Fallon EA, De Braganza N, Murawski ME *et al*. Changing weight-loss expectations: a randomized pilot study. *Eat.* 2005;6:259-69.	Added in relevant Update section
Anderson JW, Luan J, Hoie LH, Anderson JW, Luan J, Hoie LH. Structured weight-loss programs: meta-analysis of weight loss at 24 weeks and assessment of effects of intervention intensity. [Review] [75 refs]. *Adv.Ther.* 2004;21:61-75.	Effects at 24 weeks, not 12 months
Angrisani L, Favretti F, Furbetta F, Iuppa A, Doldi SB, Paganelli M *et al*. Italian Group for Lap-Band System: results of multicenter study on patients with BMI < or =35 kg/m2. *Obes.Surg.* 2004;14:415-8.	Added detail in relevant Update section
Ardern CI, Janssen I, Ross R, Katzmarzyk PT, Ardern CI, Janssen I *et al*. Development of health-related waist circumference thresholds within BMI categories. *Obes.Res.* 2004;12:1094-103.	Not considered to affect evidence statements…
Armitage CJ. Evidence That Implementation Intentions Reduce Dietary Fat Intake: A Randomized Trial. *Health Psychology.* 2004;23:319-23.	Not 52 week follow-up
Aucott L, Poobalan A, Smith WC, Avenell A, Jung R, Broom J *et al*. Weight loss in obese diabetic and non-diabetic individuals and long-term diabetes outcomes--a systematic review. [Review] [17 refs]. *Diabetes Obes.Metab* 2004;6 :85-94.	Systematic review.

Reference	Reason for exclusion
Aude YW, Agatston AS, Lopez JF, Lieberman EH, Almon M, Hansen M *et al*. The National Cholesterol Education Program diet vs a diet lower in carbohydrates and higher in protein and monounsaturated fat: a randomized trial. *Arch.Intern.Med.* 2004;164:2141-6.	Not 52 week follow-up
Azizi F, Esmaillzadeh A, Mirmiran P, Ainy E, Azizi F, Esmaillzadeh A *et al*. Is there an independent association between waist-to-hip ratio and cardiovascular risk factors in overweight and obese women? *Int.J.Cardiol.* 2005;101 :39-46.	Not considered to affect evidence statements…
Beck-da-Silva L, Higginson L, Fraser M, Williams K, Haddad H, Beck-da-Silva L *et al*. Effect of Orlistat in obese patients with heart failure: a pilot study. *Congest.Heart Fail.* 2005;11:118-23.	Not 52 week follow-up
Bennett P. Obesity, diabetes and VLCDs. Primary and secondary care partnership model to treat obesity. *British Journal of Diabetes & Vascular Disease.* 2004;4:328-30.	Description of service, not evaluation.
Berne C, the Orlistat ST, Berne C, the Orlistat ST. A randomized study of orlistat in combination with a weight management programme in obese patients with Type 2 diabetes treated with metformin. *Diabet.Med.* 2005;22:612-8.	Absolute weight change not reported.
Bhat DS, Yajnik CS, Sayyad MG, Raut KN, Lubree HG, Rege SS *et al*. Body fat measurement in Indian men: Comparison of three methods based on a two-compartment model. *International Journal of Obesity.* 2005;29:842-8.	Not considered to affect evidence statements…
Bigaard J, Frederiksen K, Tjonneland A, Thomsen BL, Overvad K, Heitmann BL *et al*. Waist and hip circumferences and all-cause mortality: Usefulness of the waist-to-hip ratio? *International Journal of Obesity.* 2004;28:741-7.	Not considered to affect evidence statements…
Birkenfeld AL, Schroeder C, Pischon T, Tank J, Luft FC, Sharma AM *et al*. Paradoxical effect of sibutramine on autonomic cardiovascular regulation in obese hypertensive patients--sibutramine and blood pressure. *Clin.Auton.Res.* 2005;15:200-6.	Not 52 week follow-up
Birketvedt GS, Shimshi M, Erling T, Florholmen J, Birketvedt GS, Shimshi M *et al*. Experiences with three different fiber supplements in weight reduction. *Med.Sci.Monit.* 2005;11:I5-I8.	Effectiveness of fibre supplements.
Blair SN, LaMonte MJ, Nichaman MZ, Blair SN, LaMonte MJ, Nichaman MZ. The evolution of physical activity recommendations: how much is enough?. [Review] [62 refs]. *Am.J.Clin.Nutr.* 2004;79:913S-20S.	Narrative review.

Reference	Reason for exclusion
Borg P, Fogelholm M, Kukkonen-Harjula K. Food selection and eating behaviour during weight maintenance intervention and 2-y follow-up in obese men. *International Journal of Obesity.* 2004;28:1548-54.	Observational follow-up study from RCT
Brandsma LL. Physician and patient attitudes toward obesity. *Eating Disorders.* 2005;13:1-211.	Not UK based
Branson R, Potoczna N, Brunotte R, Piec G, Ricklin T, Steffen R *et al*. Impact of age, sex and body mass index on outcomes at four years after gastric banding. *Obesity Surgery.* 2005;15:834-42.	Added detail in relevant Update section
Cabioglu MT, Ergene N, Cabioglu MT, Ergene N. Electroacupuncture therapy for weight loss reduces serum total cholesterol, triglycerides, and LDL cholesterol levels in obese women. *Am.J.Chin.Med.* 2005;33:525-33.	Not included therapy
Camerini G, Marinari GM, Adami GF, Scopinaro N. Preoperative resting energy expenditure does not predict weight loss and maintenance after vertical banded gastroplasty. *Obesity Surgery.* 2005;15:809-12.	Less than 150 participants.
Carels RA DLDOCHR. Education on the glycemic index of foods fails to improve treatment outcomes in a behavioral weight loss program. *Eat.* 2005;6:145-50.	Compared effectiveness of different education programmes (with/without GI component), rather than different diets.
Chapman MJ, Craven MJ, Chadwick DD. Fighting fit? An evaluation of health practitioner input to improve healthy living and reduce obesity for adults with learning disabilities. *Journal of Intellectual Disabilities.* 2005;9:131-44.	Not RCT
Chopra M, Darnton-Hill I, Chopra M, Darnton-Hill I. Tobacco and obesity epidemics: not so different after all?. [Review] [23 refs]. *BMJ* 2004;328:1558-60.	Narrative review
Christou NV, Jarand J, Sylvestre JL, McLean APH. Analysis of the Incidence and Risk Factors for Wound Infections in Open Bariatric Surgery. *Obesity Surgery.* 2004;14:16-22.	Wound infection in the immediate period after surgery, not weight loss.
Cikim AS, Ozbey N, Orhan Y. Relationship between cardiovascular risk indicators and types of obesity in overweight and obese women. *Journal of International Medical Research.* 2004;32:268-73.	Not considered to affect evidence statements…
Coffey CS, Steiner D, Baker BA, Allison DB, Coffey CS, Steiner D *et al*. A randomized double-blind placebo-controlled clinical trial of a product containing ephedrine, caffeine, and other ingredients from herbal sources for treatment of overweight and obesity in the absence of lifestyle treatment. *Int.J.Obes.Relat Metab Disord.* 2004;28:1411-9.	OTC herbal product

Reference	Reason for exclusion
Collet D, Rault A, Sa C, Larroude D, Masson B. Laparoscopic adjustable gastric banding results after 2 years with two different band types. *Obesity Surgery.* 2005;15:853-7.	Comparison of different lap bands.
Cook NR KSCJWPToHPCRG. Dose-response of sodium excretion and blood pressure change among overweight, nonhypertensive adults in a 3-year dietary intervention study. *J.Hum.Hypertens.* 2005;19:47-54.	TOHP II paper
Crowe TC,.Crowe TC. Safety of low-carbohydrate diets. [Review] [70 refs]. *Obes.Rev.* 2005;6:235-45.	Narrative review
Dalle Grave R, Calugi S, Magri F, Cuzzolaro M, Dall AE, Lucchin L *et al*. Weight Loss Expectations in Obese Patients Seeking Treatment at Medical Centers. *Obesity Research, Dec 2004, vol.12., no.12., p.2005 2012., eISSN.: 1550.8528., ISSN.: 1071.7323.Publisher.: North American Assn.for the Study of Obesity (NAASO.), US, http.://www.naaso.org.* 2004.	Refer to CPHE review on Behaviour Change for evidence (to be published)
Dargent J. Esophageal dilatation after laparoscopic adjustable gastric banding: Definition and strategy. *Obesity Surgery.* 2005;15:843-8.	No mean EWL reported.
Day P. What is the evidence for the safety and effectiveness of surgical and non-surgical interventions for patients with morbid obesity? 2005.	Technical review – similar conclusions re evidence base
de Zwaan M, Mitchell JE, Crosby RD, Mussell MP, Raymond NC, Specker SM *et al*. Short-Term Cognitive Behavioral Treatment Does Not Improve Outcome of a Comprehensive Very-Low-Calorie Diet Program in Obese Women With Binge Eating Disorder. *Behavior Therapy, Win.2005, vol.36., no.1, p.89.99., ISSN.: 0005.7894.Publisher.: Assn.for the Advancement.of Behavior Therapy, US, http.://www.aabt.org.* 2005.	Not 52 week follow-up. Also involved treatment of BED.
Deforche B, De B, I, Tanghe A, Debode P, Hills AP, Bouckaert J *et al*. Post-treatment phone contact: a weight maintenance strategy in obese youngsters. *Int.J.Obes.Relat Metab Disord.* 2005;29:543-6.	Children/adolescents, not adults
Dolan K,.Fielding G. Bilio pancreatic diversion following failure of laparoscopic adjustable gastric banding. *Surgical Endoscopy.* 2004;18:60-3.	Only subset of 85 patients who had band removed.
Douketis JD, Paradis G, Keller H, Martineau C, Douketis JD, Paradis G *et al*. Canadian guidelines for body weight classification in adults: application in clinical practice to screen for overweight and obesity and to assess disease risk. *ECMAJ., Can.* 2005;172:995-8.	Guidelines, used for cross reference
Due A, Toubro S, Stender S, Skov AR, Astrup A, Due A *et al*. The effect of diets high in protein or carbohydrate on inflammatory markers in overweight subjects. *Diabetes Obes.Metab* 2005;7:223-9.	Not 52 week follow-up.

Reference	Reason for exclusion
Dunstan DW DRO. Home-based resistance training is not sufficient to maintain improved glycemic control following supervised training in older individuals with type 2 diabetes. *Diabetes Care* 2005;28:3-9.	Added in relevant Update searches,
Ebbeling CB LMSKS-SLFHLD. Effects of an ad libitum low-glycemic load diet on cardiovascular disease risk factors in obese young adults. *The American journal of clinical nutrition* 2005;81:976-82.	Not added, as compares different diets in combination with activity and behavioural interventions. Small study, with limited detail on interventions. Would not change evidence statements or recommendations.
Elfhag K,.Rossner S. Who succeeds in maintaining weight loss? A conceptual review of factors associated with weight loss maintenance and weight regain. *Obesity Reviews.* 2005;6:67-85.	Refer to CPHE review on Behaviour Change for evidence (to be published)
Ellis Gardner R,.Hausenblas HA. Understanding Exercise and Diet Motivation in Overweight Women Enrolled in a Weight-Loss Program: A Prospective Study Using the Theory of Planned Behavior. *Journal of Applied Social Psychology, Jul.2004, vol.34., no.7., p.1353.1370., ISSN.: 0021.9029.Publisher.: Bellwether.Publishing., US, http.://www.bellpub.com.* 2004.	Refer to CPHE review on Behaviour Change for evidence (to be published)
Esmaillzadeh A, Mirmiran P, Azizi F, Esmaillzadeh A, Mirmiran P, Azizi F. Waist-to-hip ratio is a better screening measure for cardiovascular risk factors than other anthropometric indicators in Tehranian adult men. *Int.J.Obes.Relat Metab Disord.* 2004;28:1325-32.	Not considered to affect evidence statements…
Farmer SR, Auwerx J, Farmer SR, Auwerx J. Adipose tissue: new therapeutic targets from molecular and genetic studies--IASO Stock Conference 2003 report. [Review] [24 refs]. *Obes.Rev.* 2004;5:189-96.	Not relevant
Fatouros IG, Tournis S, Leontsini D, Jamurtas AZ, Sxina M, Thomakos P *et al*. Leptin and adiponectin responses in overweight inactive elderly following resistance training and detraining are intensity related. *Journal of Clinical Endocrinology & Metabolism.* 2005;90:5970-7.	No requirement for participants to be overweight/obese.
Feigenbaum A, Pasternak S, Zusk E, Sarid M, Vinker S, Feigenbaum A *et al*. Influence of intense multidisciplinary follow-up and orlistat on weight reduction in a primary care setting. *BMC Fam.Pract.* 2005;6:5.	Not RCT
Ferreira I, Snijder MB, Twisk JWR, Van M, Kemper HCG, Seidell JC *et al*. Central fat mass versus peripheral fat and lean mass: Opposite (adverse versus favorable) associations with arterial stiffness? The Amsterdam growth and health longitudinal study. *Journal of Clinical Endocrinology & Metabolism.* 2004;89:2632-9.	Not considered to affect evidence statements…

Reference	Reason for exclusion
Focht BC, Rejeski WJ, Ambrosius WT, Katula JA, Messier SP, Focht BC *et al*. Exercise, self-efficacy, and mobility performance in overweight and obese older adults with knee osteoarthritis. *Arthritis Rheum.* 2005;53:659-65.	Messier 2004 paper
Foster GD, Phelan S, Wadden TA, Gill D, Ermold J, Didie E *et al*. Promoting more modest weight losses: a pilot study. *Obes.Res.* 2004;12:1271-7.	Not RCT
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Ghosh A, Bose K, Chakravarti S, Chaudhuri AB, Chattopadhyay J, Dasgupta G *et al*. Central obesity and coronary risk factors. *J.R.Soc.Health* 2004;124:86-90.	Not considered to affect evidence statements…
Go MR, Muscarella IIP, Needleman BJ, Cook CH, Melvin WS. Endoscopic management of stomal stenosis after Roux-en-Y gastric bypass. *Surgical Endoscopy.* 2004;18:56-9.	Weight outcomes not reported.
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Reference	Reason for exclusion
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Hsu C, Hwang K, Chao C, Chang H, Chou P. Electroacupuncture in obese women: a randomized, controlled pilot study. *J.Womens Health (Larchmt.)* 2005;14:434-40.	Not relevant
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Reference	Reason for exclusion
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Linde JA, Jeffery RW, Finch EA, Ng DM, Rothman AJ. Are Unrealistic Weight Loss Goals Associated with Outcomes for Overweight Women? *Obesity Research, Mar.2004, vol.12., no.3, p.569.576., eISSN.: 1550.8528., ISSN.: 1071.7323.Publisher.: North American Assn.for the Study of Obesity (NAASO.), US, http.://www.naaso.org.* 2004.	Not clinical setting. Comparison of mail/phone interventions.
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Reference	Reason for exclusion
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Raja C, Hansen R, Baber R, Allen B. Hip girth as a predictor of abdominal adiposity in postmenopausal women. *Nutrition.* 1909;#2004:772-7.	Not considered to affect evidence statements…
Razak F, Anand S, Vuksan V, Davis B, Jacobs R, Teo KK *et al*. Ethnic differences in the relationships between obesity and glucose-metabolic abnormalities: a cross-sectional population-based study. *Int.J.Obes.* 2005;29:656-67.	Not considered to affect evidence statements…
Rolls BJ, Roe LS, Beach AM, Kris-Etherton PM, Rolls BJ, Roe LS *et al*. Provision of foods differing in energy density affects long-term weight loss. *Obes.Res.* 2005;13:1052-60.	Not able to assign to dietary category. Also no details of behavioural or activity intervention.
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Reference	Reason for exclusion
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Santos IA, Stein R, Fuchs SC, Duncan BB, Ribeiro JP, Kroeff LR *et al*. Aerobic exercise and submaximal functional capacity in overweight pregnant women: a randomized trial.[see comment]. *Obstet.Gynecol.* 2005;106:243-9.	Pregnant women, not 52 week follow-up.
Sari R, Balci MK, Cakir M, Altunbas H, Karayalcin U. Comparison of efficacy of sibutramine or orlistat versus their combination in obese women. *Endocrine Research.* 2004;30:159-67.	Not 52 week follow-up.
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Shuhaiber J,.Vitello J. Is Gastric Bypass Associated with More Complications in Patients Weighing >500 lb (>227 kg)? *Obesity Surgery.* 2004;14:43-6.	Less than 150 participants.
Simkin-Silverman LR GKKWWLB. Predictors of weight control advice in primary care practices: patient health and psychosocial characteristics. *Prev.Med.* 2005;40:71-82.	Refer to CPHE review on Behaviour Change for evidence (to be published)
Singh KD, Dhillon JK, Arora A, Gill BS, Singh KD, Dhillon JK *et al*. Receiver operating characteristic curve analysis of BMI and percentage body fat in type 2 diabetics of Punjab. *Indian J.Physiol Pharmacol.* 2004;48:73-80.	Not considered to affect evidence statements…
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Spivak H, Hewitt MF, Onn A, Half EE. Weight loss and improvement of obesity-related illness in 500 U.S. patients following laparoscopic adjustable gastric banding procedure. *American Journal of Surgery.* 2005;189:27-32.	Added detail in relevant Update section

Reference	Reason for exclusion
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Tudor-Locke C, Bell RC, Myers AM, Harris SB, Ecclestone NA, Lauzon N *et al*. Controlled outcome evaluation of the First Step Program: a daily physical activity intervention for individuals with type II diabetes. *Int.J.Obes.Relat Metab Disord.* 2004;28:113-9.	No requirement for participants to be overweight.
Vage V, Berstad A, Solhaug JH, Viste A. Cardiovascular risk factors in obese patients treated with jejunoileal bypass operation: A 25-year follow-up study. *Scandinavian Journal of Gastroenterology.* 2005;40:90-5.	Less than 150 participants.
Van Gool CH, Penninx BWJH, Kempen GIJM, Rejeski WJ, Miller GD, Van E *et al*. Effects of exercise adherence on physical function among overweight older adults with knee osteoarthritis. *Arthritis Care & Research.* 2005;53:24-32.	From Messier 2004 study.
Van Hout G, Verschure SKM, Van H. Psychosocial predictors of success following bariatric surgery. *Obesity Surgery.* 2005;15:552-60.	Narrative (although described as systematic) review of psychosocial factors and bariatric surgery.
Wadden TA, Berkowitz RI, Womble LG, Sarwer DB, Phelan S, Cato RK *et al*. Randomized trial of lifestyle modification and pharmacotherapy for obesity. *New England Journal of Medicine.* 2005;353:2111-20.	Added in relevant Update section.
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Wang Y, Rimm EB, Stampfer MJ, Willett WC, Hu FB. Comparison of abdominal adiposity and overall obesity in predicting risk of type 2 diabetes among men. *Am.J.Clin.Nutr.* 2005;81:555-63.	Not considered to affect evidence statements…
Watkins BM, Montgomery KF, Ahroni JH, Erlitz MD, Abrams RE, Scurlock JE *et al*. Adjustable gastric banding in an ambulatory surgery center. *Obes.Surg.* 2005; 15:1045-9.	Not 24 month follow-up
Wei QL,.Liu ZC. Treatment of simple obesity with auricular acupuncture, body acupuncture and combination of auricular and body acupuncture. *Zhongguo Linchuang Kangfu.* 2004;8:4357-9.	Not available
White S, Brooks E, Jurikova L, Stubbs RS. Long-term outcomes after gastric bypass. *Obesity Surgery.* 2005;15:155-63.	Added detail in relevant Update section

Reference	Reason for exclusion
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Wilkinson JR, Summerbell CD, Macknight N, Bailey K, Chappel DB. Use of surgery to aid weight reduction - Experience of two regions of Northern England: A database study. *International Journal of Obesity.* 2004;29:4-207.	Not effectiveness report, but variation in service provision.
Xu WH, Matthews CE, Xiang YB, Zheng W, Ruan ZX, Cheng JR *et al*. Effect of adiposity and fat distribution on endometrial cancer risk in Shanghai women. *Am.J.Epidemiol.* 2005;161:939-47.	Not considered to affect evidence statements…
Yalcin BM, Sahin EM, Yalcin E. Which anthropometric measurements is most closely related to elevated blood pressure? *Family Practice.* 2005;22:541-7.	Not considered to affect evidence statements…
Yeh WT, Chang HY, Yeh CJ, Tsai KS, Chen HJ, Pan WH *et al*. Do centrally obese Chinese with normal BMI have increased risk of metabolic disorders? *Int.J.Obes.* 2005;29:818-25.	Not considered to affect evidence statements…
Zemel MB, Thompson W, Milstead A, Morris K, Campbell P, Zemel MB *et al*. Calcium and dairy acceleration of weight and fat loss during energy restriction in obese adults. *Obes.Res.* 2004;12:582-90.	Not 52 week follow-up.
Zhang W, Mason EE, Renquist KE, Zimmerman MB, Contributors IBSR, Zhang W *et al*. Factors influencing survival following surgical treatment of obesity. *Obes.Surg.* 2005;15:43-50.	No weight outcomes reported.
Zhang X, Shu XO, Gao YT, Yang G, Matthews CE, Li Q *et al*. Anthropometric predictors of coronary heart disease in Chinese women. *Int.J.Obes.Relat Metab Disord.* 2004;28:734-40.	Not considered to affect evidence statements…
Zingmond DS, McGory ML, Ko CY. Hospitalization before and after gastric bypass surgery. *JAMA.* 1918; 294:18-1924.	No weight outcomes reported.

Appendix 17

3 Summary estimates for interventions

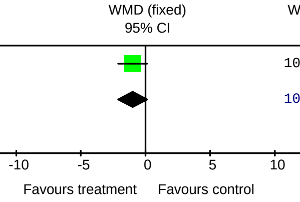
Please note all the summary statistics have been checked by a consultant statistician for accuracy.

3.1 *Dietary interventions*

Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 01 Weight change in kg at 3 months

Study	600kcal/low fat diet		Usual care		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
HOT 1999	51	-2.70(3.40)	51	-1.70(2.30)	100.00	-1.00 [-2.13, 0.13]
Total (95% CI)	51		51		100.00	-1.00 [-2.13, 0.13]

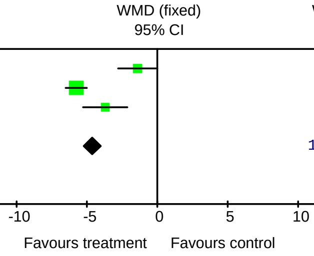
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.74 (P = 0.08)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 02 Weight change in kg at 6 months

Study	600kcal/low fat diet		Usual care		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
HOT 1999	51	-3.20(4.30)	51	-1.80(2.70)	19.09	-1.40 [-2.79, -0.01]
HPT 1990	112	-5.58(2.86)	119	0.18(2.95)	66.04	-5.76 [-6.51, -5.01]
TAIM 1992	89	-4.40(6.60)	90	-0.70(3.79)	14.87	-3.70 [-5.28, -2.12]
Total (95% CI)	252		260		100.00	-4.62 [-5.23, -4.01]

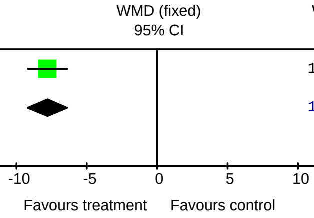
Test for heterogeneity: Chi² = 30.71, df = 2 (P < 0.00001), I² = 93.5%
Test for overall effect: Z = 14.87 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 03 Weight change in kg at 7 months

Study	600kcal/low fat diet		Usual care		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Wood 1988	42	-7.60(3.90)	42	0.20(2.50)	100.00	-7.80 [-9.20, -6.40]
Total (95% CI)	42		42		100.00	-7.80 [-9.20, -6.40]

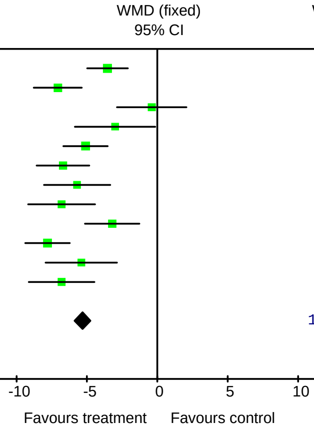
Test for heterogeneity: not applicable
Test for overall effect: Z = 10.91 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 04 Weight change in kg at 12 months

Study	600kcal/low fat diet		Usual care		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
DISH 1985	67	-4.00(5.00)	77	-0.46(3.60)	15.18	-3.54 [-4.98, -2.10]
Frey-Hewitt 1990	36	-6.68(3.94)	41	0.38(3.66)	10.85	-7.06 [-8.77, -5.35]
HOT 1999	51	-1.70(6.40)	51	-1.30(6.28)	5.22	-0.40 [-2.86, 2.06]
Hankey 2001	25	-0.60(5.30)	25	2.40(5.00)	3.87	-3.00 [-5.86, -0.14]
ODES 1995	52	-4.00(5.05)	43	1.10(2.62)	12.65	-5.10 [-6.68, -3.52]
Pritchard 1997	18	-6.40(3.30)	19	0.30(2.40)	9.05	-6.70 [-8.57, -4.83]
Pritchard 1999 Dietn	88	-5.10(7.36)	45	0.60(6.08)	5.72	-5.70 [-8.05, -3.35]
Pritchard 1999 Dn&Dr	92	-6.20(7.67)	45	0.60(6.08)	5.63	-6.80 [-9.17, -4.43]
TAIM 1992	57	-3.70(6.79)	61	-0.50(3.12)	8.49	-3.20 [-5.13, -1.27]
Wood 1988	42	-7.20(3.70)	42	0.60(3.70)	12.61	-7.80 [-9.38, -6.22]
Wood 1991 F	31	-4.10(5.50)	39	1.30(5.20)	4.93	-5.40 [-7.93, -2.87]
Wood 1991 M	40	-5.10(5.80)	40	1.70(4.80)	5.80	-6.80 [-9.13, -4.47]
Total (95% CI)	599		528		100.00	-5.32 [-5.88, -4.75]

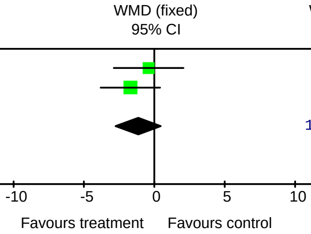
Test for heterogeneity: Chi² = 47.13, df = 11 (P < 0.00001), I² = 76.7%
Test for overall effect: Z = 18.54 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 05 Weight change in kg at 18 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
HOT 1999	51	-1.80(6.42)	51	-1.40(6.31)	42.19	-0.40 [-2.87, 2.07]
TAIM 1992	57	-2.70(7.55)	61	-1.00(3.12)	57.81	-1.70 [-3.81, 0.41]
Total (95% CI)	108		112		100.00	-1.15 [-2.76, 0.45]

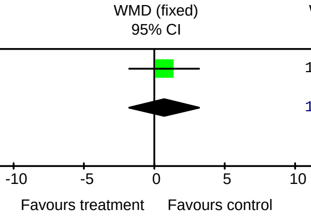
Test for heterogeneity: Chi² = 0.61, df = 1 (P = 0.43), I² = 0%
Test for overall effect: Z = 1.41 (P = 0.16)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 06 Weight change in kg at 30 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
HOT 1999	51	-1.30(6.28)	51	-2.00(6.48)	100.00	0.70 [-1.78, 3.18]
Total (95% CI)	51		51		100.00	0.70 [-1.78, 3.18]

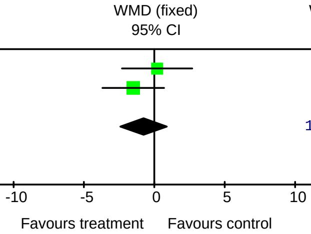
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.55 (P = 0.58)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 07 Weight change in kg at 24 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
HOT 1999	51	-1.70(6.40)	51	-1.90(6.45)	43.58	0.20 [-2.29, 2.69]
TAIM 1992	57	-1.90(7.55)	61	-0.40(3.91)	56.42	-1.50 [-3.69, 0.69]
Total (95% CI)	108		112		100.00	-0.76 [-2.41, 0.89]

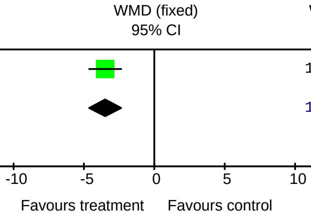
Test for heterogeneity: Chi² = 1.01, df = 1 (P = 0.32), I² = 0.7%
Test for overall effect: Z = 0.90 (P = 0.37)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 08 Weight change in kg at 36 months

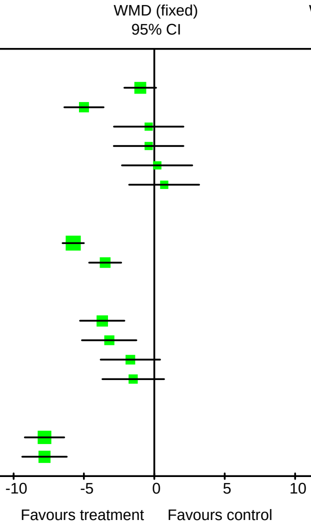
Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
HPT 1990	117	-1.63(4.43)	113	1.86(4.36)	100.00	-3.49 [-4.63, -2.35]
Total (95% CI)	117		113		100.00	-3.49 [-4.63, -2.35]

Test for heterogeneity: not applicable
Test for overall effect: Z = 6.02 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 09 Weight change in kg over time

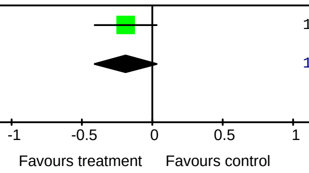
Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
01 HOT 1990						
HOT 3 months	51	-2.70(3.40)	51	-1.70(2.30)	40.29	-1.00 [-2.13, 0.13]
HOT 6 months	51	-3.20(4.30)	51	1.80(2.70)	26.33	-5.00 [-6.39, -3.61]
HOT 12 months	51	-1.70(6.40)	51	-1.30(6.28)	8.44	-0.40 [-2.86, 2.06]
HOT 18 months	51	-1.80(6.42)	51	-1.40(6.31)	8.38	-0.40 [-2.87, 2.07]
HOT 24 months	51	-1.70(6.40)	51	-1.90(6.45)	8.22	0.20 [-2.29, 2.69]
HOT 30 months	51	-1.30(6.28)	51	-2.00(6.48)	8.34	0.70 [-1.78, 3.18]
02 HPT 1990						
HPT 6 months	112	-5.58(2.86)	119	0.18(2.95)	69.68	-5.76 [-6.51, -5.01]
HPT 36 months	117	-1.63(4.43)	113	1.86(4.36)	30.32	-3.49 [-4.63, -2.35]
03 TAIM 1992						
TAIM 6 months	89	-4.40(6.60)	90	-0.70(3.79)	36.38	-3.70 [-5.28, -2.12]
TAIM 12 months	57	-3.70(6.79)	61	-0.50(3.12)	24.38	-3.20 [-5.13, -1.27]
TAIM 18 months	57	-2.70(7.55)	61	-1.00(3.12)	20.36	-1.70 [-3.81, 0.41]
TAIM 24 months	57	-1.90(7.55)	61	-0.40(3.91)	18.88	-1.50 [-3.69, 0.69]
04 Wood 1988						
Wood 7 months	42	-7.60(3.90)	42	0.20(2.50)	56.06	-7.80 [-9.20, -6.40]
Wood 12 months	42	-7.20(3.70)	42	0.60(3.70)	43.94	-7.80 [-9.38, -6.22]



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 10 Change in TC mmol/l at 7 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Wood 1988	42	-0.40(0.55)	42	-0.21(0.48)	100.00	-0.19 [-0.41, 0.03]
Total (95% CI)	42		42		100.00	-0.19 [-0.41, 0.03]

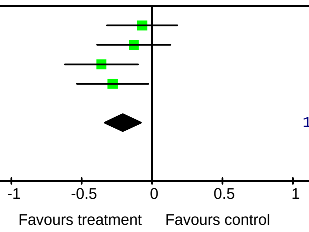
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.69 (P = 0.09)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 11 Change in TC mmol/l at 12 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
ODES 1995	52	-0.23(0.65)	43	-0.16(0.59)	26.23	-0.07 [-0.32, 0.18]
Wood 1988	42	-0.36(0.56)	42	-0.23(0.65)	24.28	-0.13 [-0.39, 0.13]
Wood 1991 F	31	-0.39(0.61)	39	-0.03(0.47)	24.08	-0.36 [-0.62, -0.10]
Wood 1991 M	40	-0.42(0.51)	40	-0.14(0.64)	25.41	-0.28 [-0.53, -0.03]
Total (95% CI)	165		164		100.00	-0.21 [-0.34, -0.08]

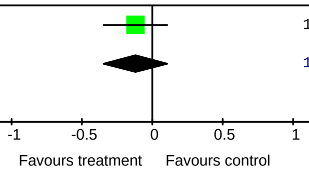
Test for heterogeneity: Chi² = 3.14, df = 3 (P = 0.37), I² = 4.4%
Test for overall effect: Z = 3.19 (P = 0.001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 12 Change in LDLC mmol/l at 7 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Wood 1988	42	-0.27(0.59)	42	-0.15(0.46)	100.00	-0.12 [-0.35, 0.11]
Total (95% CI)	42		42		100.00	-0.12 [-0.35, 0.11]

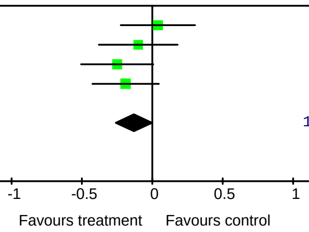
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.04 (P = 0.30)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 13 Change in LDLC mmol/l at 12 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
ODES 1995	52	-0.18(0.72)	43	-0.22(0.59)	23.88	0.04 [-0.22, 0.30]
Wood 1988	42	-0.31(0.64)	42	-0.21(0.67)	21.10	-0.10 [-0.38, 0.18]
Wood 1991 F	31	-0.28(0.63)	39	-0.03(0.41)	25.20	-0.25 [-0.51, 0.01]
Wood 1991 M	40	-0.39(0.48)	40	-0.20(0.59)	29.82	-0.19 [-0.43, 0.05]
Total (95% CI)	165		164		100.00	-0.13 [-0.26, 0.00]

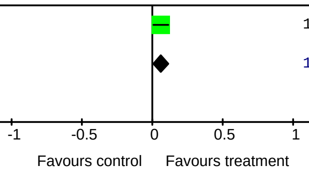
Test for heterogeneity: Chi² = 2.73, df = 3 (P = 0.43), I² = 0%
Test for overall effect: Z = 2.00 (P = 0.05)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 14 Change in HDLC mmol/l at 7 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Wood 1988	41	0.06(0.14)	41	0.00(0.10)	100.00	0.06 [0.01, 0.11]
Total (95% CI)	41		41		100.00	0.06 [0.01, 0.11]

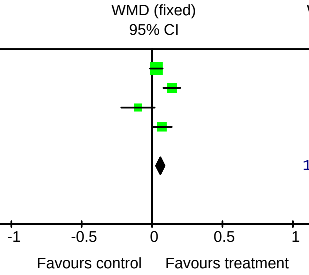
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.23 (P = 0.03)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 15 Change in HDLC mmol/l at 12 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	52	0.05(0.12)	43	0.02(0.10)	47.85	0.03 [-0.01, 0.07]
Wood 1988	41	0.12(0.16)	41	-0.02(0.11)	26.51	0.14 [0.08, 0.20]
Wood 1991 F	31	-0.15(0.26)	39	-0.05(0.24)	6.67	-0.10 [-0.22, 0.02]
Wood 1991 M	40	0.02(0.17)	40	-0.05(0.15)	18.97	0.07 [0.00, 0.14]
Total (95% CI)	164		163		100.00	0.06 [0.03, 0.09]

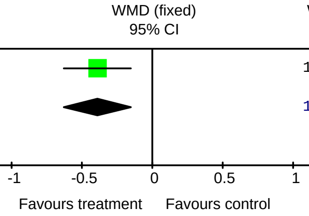
Test for heterogeneity: Chi² = 15.79, df = 3 (P = 0.001), I² = 81.0%
Test for overall effect: Z = 3.72 (P = 0.0002)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 16 Change in TG mmol/l at 7 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-0.40(0.60)	42	-0.01(0.51)	100.00	-0.39 [-0.63, -0.15]
Total (95% CI)	42		42		100.00	-0.39 [-0.63, -0.15]

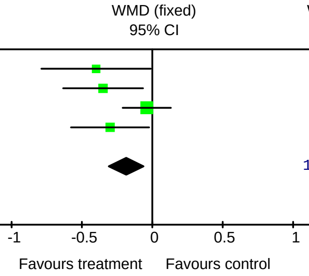
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.21 (P = 0.001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 17 Change in TG mmol/l at 12 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	52	-0.23(1.01)	43	0.17(0.92)	10.04	-0.40 [-0.79, -0.01]
Wood 1988	42	-0.27(0.72)	42	0.08(0.60)	18.86	-0.35 [-0.63, -0.07]
Wood 1991 F	31	0.09(0.36)	39	0.13(0.37)	51.30	-0.04 [-0.21, 0.13]
Wood 1991 M	40	-0.12(0.59)	40	0.18(0.67)	19.80	-0.30 [-0.58, -0.02]
Total (95% CI)	165		164		100.00	-0.19 [-0.31, -0.06]

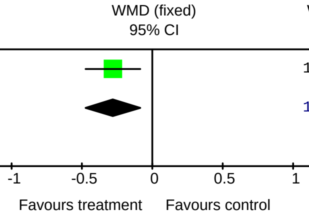
Test for heterogeneity: Chi² = 5.88, df = 3 (P = 0.12), I² = 48.9%
Test for overall effect: Z = 2.96 (P = 0.003)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 18 Change in FPG mmol/l at 12 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	52	-0.21(0.50)	43	0.07(0.46)	100.00	-0.28 [-0.47, -0.09]
Total (95% CI)	52		43		100.00	-0.28 [-0.47, -0.09]

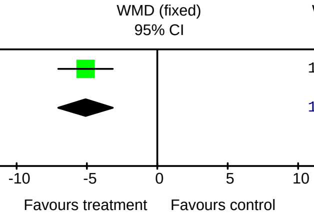
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.84 (P = 0.005)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 19 Change in SBP mmHg at 6 months

Study or sub-category	600kcal/low fat diet N	600kcal/low fat diet Mean (SD)	Usual care N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
HPT 1990	112	-6.90(7.41)	121	-1.80(7.70)	100.00	-5.10 [-7.04, -3.16]
Total (95% CI)	112		121		100.00	-5.10 [-7.04, -3.16]

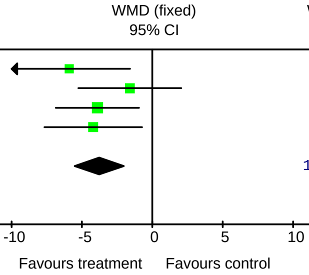
Test for heterogeneity: not applicable
Test for overall effect: Z = 5.15 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 20 Change in SBP mmHg at 12 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
ODES 1995	52	-6.40(10.10)	43	-0.50(11.15)	16.44	-5.90 [-10.22, -1.58]
Wood 1988	38	-5.70(7.90)	35	-4.10(8.00)	22.99	-1.60 [-5.25, 2.05]
Wood 1991 F	31	-4.10(6.00)	39	-0.20(6.60)	35.02	-3.90 [-6.86, -0.94]
Wood 1991 M	40	-4.10(8.10)	40	0.10(7.70)	25.55	-4.20 [-7.66, -0.74]
Total (95% CI)	161		157		100.00	-3.78 [-5.53, -2.03]

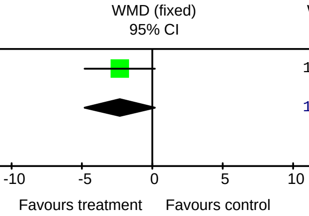
Test for heterogeneity: Chi² = 2.36, df = 3 (P = 0.50), I² = 0%
Test for overall effect: Z = 4.23 (P < 0.0001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 21 Change in SBP mmHg at 36 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
HPT 1990	117	-5.00(9.73)	115	-2.69(9.65)	100.00	-2.31 [-4.80, 0.18]
Total (95% CI)	117		115		100.00	-2.31 [-4.80, 0.18]

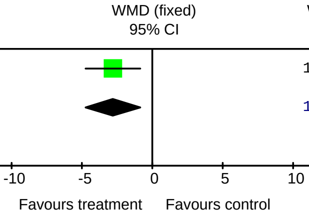
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.82 (P = 0.07)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 22 Change in DBP mmHg at 6 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
HPT 1990	112	-5.30(7.41)	121	-2.50(7.70)	100.00	-2.80 [-4.74, -0.86]
Total (95% CI)	112		121		100.00	-2.80 [-4.74, -0.86]

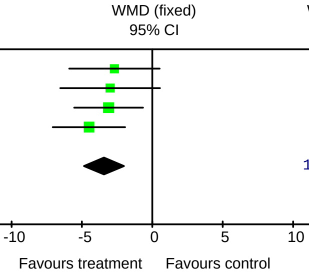
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.83 (P = 0.005)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 23 Change in DBP mmHg at 12 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
ODES 1995	52	-3.40(7.21)	43	-0.70(8.52)	19.56	-2.70 [-5.91, 0.51]
Wood 1988	38	-5.60(7.30)	35	-2.60(8.10)	16.04	-3.00 [-6.55, 0.55]
Wood 1991 F	31	-2.20(5.10)	39	0.90(5.30)	33.72	-3.10 [-5.55, -0.65]
Wood 1991 M	40	-2.40(6.60)	40	2.10(5.00)	30.68	-4.50 [-7.07, -1.93]
Total (95% CI)	161		157		100.00	-3.44 [-4.86, -2.01]

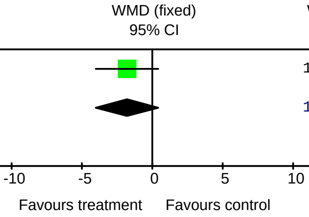
Test for heterogeneity: Chi² = 0.99, df = 3 (P = 0.80), I² = 0%
Test for overall effect: Z = 4.74 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 01 600kcal day deficit or low fat diet vs usual care
Outcome: 24 Change in DBP mmHg at 36 months

Study		600kcal/low fat diet		Usual care	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
HPT 1990	117	-4.20(8.65)	115	-2.40(8.58)	100.00	-1.80 [-4.02, 0.42]
Total (95% CI)	117		115		100.00	-1.80 [-4.02, 0.42]

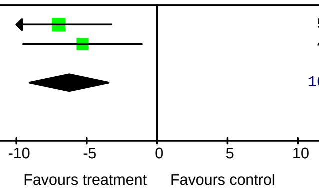
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.59 (P = 0.11)



Review: DIET Analyses for adults
Comparison: 02 Low calorie diet (1000-1600kcal/day) vs usual care
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Usual care Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
de Waard 1993 N'and	28	-5.50(7.50)	24	1.50(6.30)		55.78	-7.00 [-10.75, -3.25]
de Waard 1993 Pol	27	-5.90(7.60)	15	-0.60(6.10)		44.22	-5.30 [-9.51, -1.09]
Total (95% CI)	55		39			100.00	-6.25 [-9.05, -3.45]

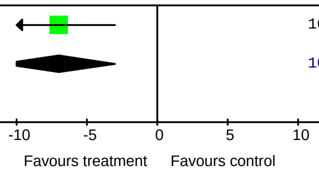
Test for heterogeneity: Chi² = 0.35, df = 1 (P = 0.55), I² = 0%
Test for overall effect: Z = 4.37 (P < 0.0001)



Review: DIET Analyses for adults
Comparison: 02 Low calorie diet (1000-1600kcal/day) vs usual care
Outcome: 02 Weight change in kg at 24 months

Study or sub-category	N	LCD Mean (SD)	N	Usual care Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
de Waard 1993 N'and	25	-5.00(7.30)	21	2.00(6.50)		100.00	-7.00 [-10.99, -3.01]
Total (95% CI)	25		21			100.00	-7.00 [-10.99, -3.01]

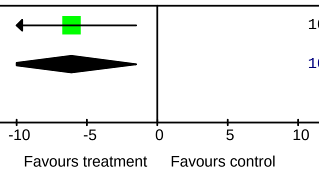
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.44 (P = 0.0006)



Review: DIET Analyses for adults
Comparison: 02 Low calorie diet (1000-1600kcal/day) vs usual care
Outcome: 03 Weight change in kg at 36 months

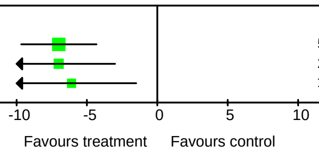
Study or sub-category	N	LCD Mean (SD)	N	Usual care Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
de Waard 1993 N'and	18	-5.00(7.30)	15	1.10(6.20)		100.00	-6.10 [-10.71, -1.49]
Total (95% CI)	18		15			100.00	-6.10 [-10.71, -1.49]

Test for heterogeneity: not applicable
Test for overall effect: Z = 2.60 (P = 0.009)



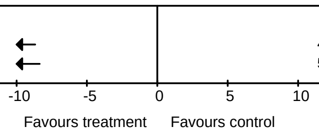
Review: DIET Analyses for adults
Comparison: 02 Low calorie diet (1000-1600kcal/day) vs usual care
Outcome: 04 Weight change in kg over time

Study or sub-category	N	LCD Mean (SD)	N	Usual care Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 de Waard 1993							
de Waard 12 months	281	-5.50(7.50)	24	1.50(6.30)		56.08	-7.00 [-9.67, -4.33]
de Waard 24 months	25	-5.00(7.30)	21	2.00(6.50)		25.09	-7.00 [-10.99, -3.01]
de Waard 36 months	18	-5.00(7.30)	15	1.10(6.20)		18.82	-6.10 [-10.71, -1.49]



Review: DIET Analyses for adults
Comparison: 03 Very low calorie diet (<1000kcal/day) vs usual care
Outcome: 01 Weight change in kg over time

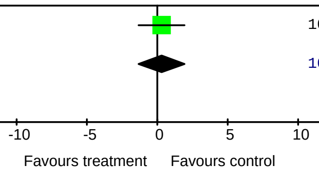
Study or sub-category	N	VLCD Mean (SD)	N	Usual care Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Stenius-Aarniala 2000							
Stenius-Aa 14 weeks	19	-14.20(9.93)	19	-0.30(6.00)		48.20	-13.90 [-19.12, -8.68]
Stenius-Aa 12 months	19	-11.10(9.06)	19	2.30(6.57)		51.80	-13.40 [-18.43, -8.37]



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 01 Weight change in kg at 2 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.50(3.80)	40	-3.80(3.60)		100.00	0.30 [-1.32, 1.92]
Total (95% CI)	40		40			100.00	0.30 [-1.32, 1.92]

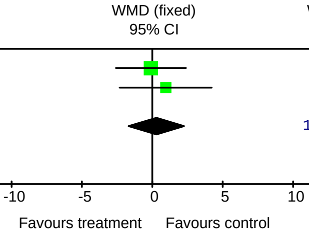
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.36 (P = 0.72)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 02 Weight change in kg at 6 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.50(5.60)	40	-3.40(5.70)	63.51	-0.10 [-2.58, 2.38]
Shah 1996	35	-3.95(7.03)	39	-4.90(7.30)	36.49	0.95 [-2.32, 4.22]
Total (95% CI)	75		79		100.00	0.28 [-1.69, 2.26]

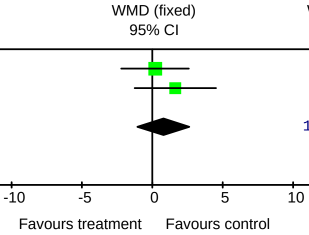
Test for heterogeneity: Chi² = 0.25, df = 1 (P = 0.62), I² = 0%
Test for overall effect: Z = 0.28 (P = 0.78)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.00(4.90)	40	-3.20(6.00)	59.13	0.20 [-2.20, 2.60]
Shah 1996	36	-0.82(6.15)	39	-2.45(6.61)	40.87	1.63 [-1.26, 4.52]
Total (95% CI)	76		79		100.00	0.78 [-1.06, 2.63]

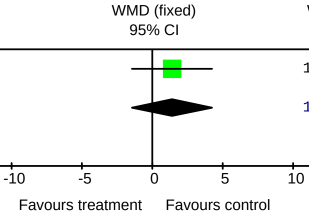
Test for heterogeneity: Chi² = 0.56, df = 1 (P = 0.46), I² = 0%
Test for overall effect: Z = 0.83 (P = 0.40)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 04 Weight change in kg at 18 months

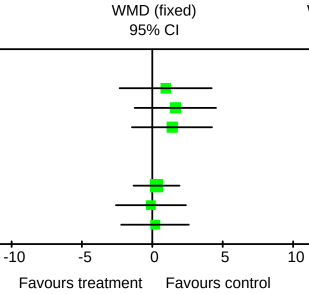
Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Shah 1996	35	1.80(6.42)	39	0.40(6.03)	100.00	1.40 [-1.45, 4.25]
Total (95% CI)	35		39		100.00	1.40 [-1.45, 4.25]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.96 (P = 0.34)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 05 Weight change in kg over time

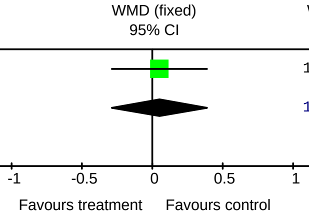
Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Shah 1996						
Shah 6 months	35	-3.95(7.03)	39	-4.90(7.30)	27.80	0.95 [-2.32, 4.22]
Shah 12 months	36	-0.82(6.15)	39	-2.45(6.61)	35.58	1.63 [-1.26, 4.52]
Shah 18 months	35	1.80(6.42)	39	0.40(6.03)	36.61	1.40 [-1.45, 4.25]
02 Dansinger 2005						
Dansinger 2 months	40	-3.50(3.80)	40	-3.80(3.60)	53.03	0.30 [-1.32, 1.92]
Dansinger 6 months	40	-3.50(5.60)	40	-3.40(5.70)	22.76	-0.10 [-2.58, 2.38]
Dansinger 12 months	40	-3.00(4.90)	40	-3.20(6.00)	24.21	0.20 [-2.20, 2.60]



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 06 Change in TC mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.21(0.62)	40	-0.26(0.90)	100.00	0.05 [-0.29, 0.39]
Total (95% CI)	40		40		100.00	0.05 [-0.29, 0.39]

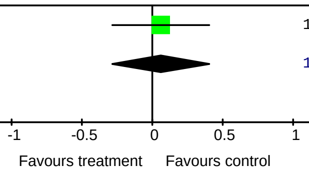
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.29 (P = 0.77)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 07 Change in LDLC mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.24(0.69)	40	-0.30(0.87)		100.00	0.06 [-0.28, 0.40]
Total (95% CI)	40		40			100.00	0.06 [-0.28, 0.40]

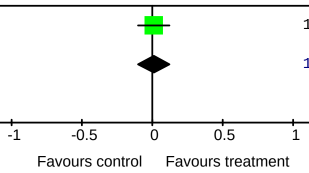
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.34 (P = 0.73)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 08 Change in HDLC mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.09(0.25)	40	0.08(0.26)		100.00	0.01 [-0.10, 0.12]
Total (95% CI)	40		40			100.00	0.01 [-0.10, 0.12]

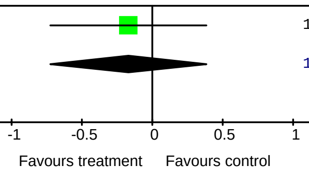
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.18 (P = 0.86)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 09 Change in TG mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.14(0.69)	40	0.03(1.65)		100.00	-0.17 [-0.72, 0.38]
Total (95% CI)	40		40			100.00	-0.17 [-0.72, 0.38]

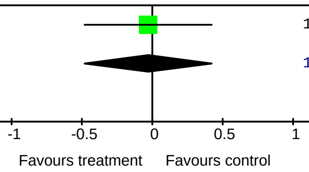
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.60 (P = 0.55)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 10 Change in FPG mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.26(1.06)	40	-0.23(1.00)		100.00	-0.03 [-0.48, 0.42]
Total (95% CI)	40		40			100.00	-0.03 [-0.48, 0.42]

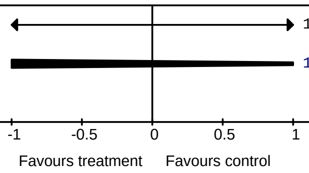
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.13 (P = 0.90)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 11 Change in DBP mmHg at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-2.70(13.00)	40	1.40(15.00)		100.00	-4.10 [-10.25, 2.05]
Total (95% CI)	40		40			100.00	-4.10 [-10.25, 2.05]

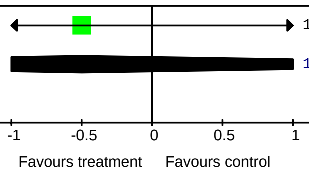
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.31 (P = 0.19)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 12 Change in SBP mmHg at 12 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.70(6.40)	40	-1.20(9.50)		100.00	-0.50 [-4.05, 3.05]
Total (95% CI)	40		40			100.00	-0.50 [-4.05, 3.05]

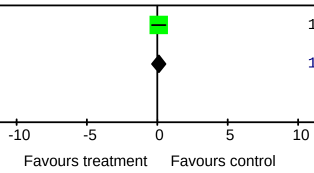
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.28 (P = 0.78)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 13 Change in TC mmol/l at 2 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.38(1.08)	40	-0.48(1.08)		100.00	0.10 [-0.37, 0.57]
Total (95% CI)	40		40			100.00	0.10 [-0.37, 0.57]

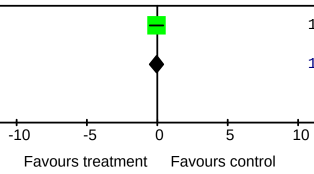
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.41 (P = 0.68)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 14 Change in TC mmol/l at 6 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.21(1.08)	40	-0.16(1.08)		100.00	-0.05 [-0.52, 0.42]
Total (95% CI)	40		40			100.00	-0.05 [-0.52, 0.42]

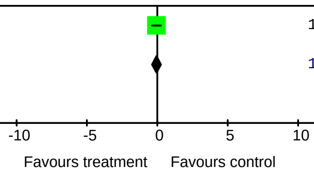
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.21 (P = 0.84)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 15 Change in LDLC mmol/l at 2 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.31(0.74)	40	-0.25(0.74)		100.00	-0.06 [-0.38, 0.26]
Total (95% CI)	40		40			100.00	-0.06 [-0.38, 0.26]

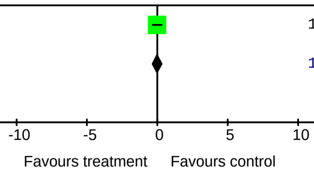
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.36 (P = 0.72)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 16 Change in LDLC mmol/l at 6 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.18(0.74)	40	-0.17(0.74)		100.00	-0.01 [-0.33, 0.31]
Total (95% CI)	40		40			100.00	-0.01 [-0.33, 0.31]

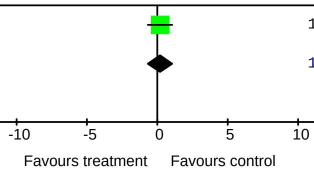
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.06 (P = 0.95)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 17 Change in FPG mmol/l at 2 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.31(1.98)	40	-0.50(1.98)		100.00	0.19 [-0.68, 1.06]
Total (95% CI)	40		40			100.00	0.19 [-0.68, 1.06]

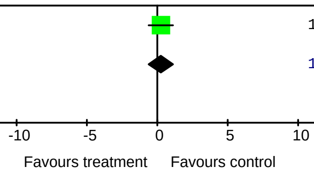
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.43 (P = 0.67)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 18 Change in FPG mmol/l at 6 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.21(1.98)	40	-0.46(1.98)		100.00	0.25 [-0.62, 1.12]
Total (95% CI)	40		40			100.00	0.25 [-0.62, 1.12]

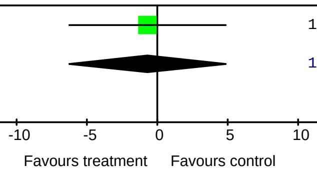
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.56 (P = 0.57)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 19 Change in SBP mmHg at 2 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.80(12.70)	40	-4.10(12.70)		100.00	-0.70 [-6.27, 4.87]
Total (95% CI)	40		40			100.00	-0.70 [-6.27, 4.87]

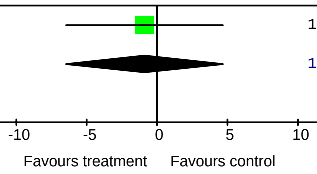
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.25 (P = 0.81)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 20 Change in SBP mmHg at 6 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.80(12.70)	40	-3.90(12.70)		100.00	-0.90 [-6.47, 4.67]
Total (95% CI)	40		40			100.00	-0.90 [-6.47, 4.67]

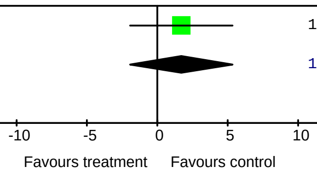
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.32 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 21 Change in DBP mmHg at 2 months

Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.10(8.30)	40	-4.80(8.30)		100.00	1.70 [-1.94, 5.34]
Total (95% CI)	40		40			100.00	1.70 [-1.94, 5.34]

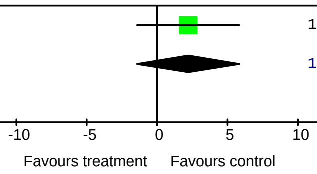
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.92 (P = 0.36)



Review: DIET Analyses for adults
Comparison: 04 Low calorie diet (1000-1600kcal/day) vs 600kcal/day deficit or low fat
Outcome: 22 Change in DBP mmHg at 6 months

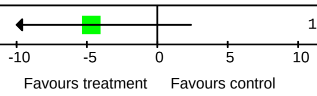
Study or sub-category	N	LCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.80(8.30)	40	-4.00(8.30)		100.00	2.20 [-1.44, 5.84]
Total (95% CI)	40		40			100.00	2.20 [-1.44, 5.84]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.19 (P = 0.24)



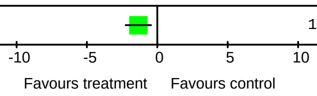
Review: DIET Analyses for adults
Comparison: 05 Very low calorie diet (<1000kcal/day) vs 600kcal day deficit or low fat
Outcome: 01 Weight change in kg at 24 months

Study or sub-category	N	VLCD Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Simonen 2000	10	-6.70(7.81)	6	-2.00(6.48)		100.00	-4.70 [-11.79, 2.39]



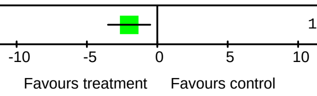
Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 01 Weight change in kg at 1 month

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Viegener 1990	31	-3.72(1.65)	32	-2.37(2.00)		100.00	-1.35 [-2.25, -0.45]



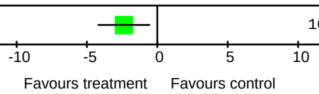
Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 02 Weight change in kg at 2 months

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Viegener 1990	31	-5.91(2.88)	32	-3.91(3.19)		100.00	-2.00 [-3.50, -0.50]



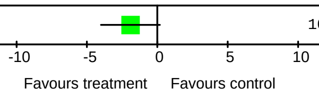
Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 03 Weight change in kg at 3 months

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Viegener 1990	31	-7.88(3.17)	32	-5.51(4.12)	100.00	-2.37 [-4.18, -0.56]



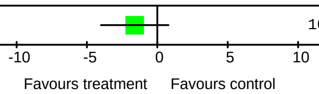
Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 04 Weight change in kg at 4 months

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Viegener 1990	31	-8.89(3.78)	32	-6.98(4.67)	100.00	-1.91 [-4.00, 0.18]



Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 05 Weight change in kg at 5 months

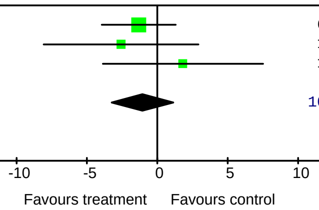
Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Viegener 1990	31	-9.63(4.44)	32	-8.02(5.23)	100.00	-1.61 [-4.00, 0.78]



Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 06 Weight change in kg at 6 months

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Viegener 1990	31	-10.19(5.06)	32	-8.87(5.56)	69.44	-1.32 [-3.94, 1.30]
Wing 6 months conc	11	-4.05(7.06)	12	-1.47(6.33)	15.81	-2.58 [-8.08, 2.92]
Wing 6 months space	12	-1.31(6.29)	9	-3.12(6.80)	14.75	1.81 [-3.88, 7.50]
Total (95% CI)	54		53		100.00	-1.06 [-3.24, 1.13]

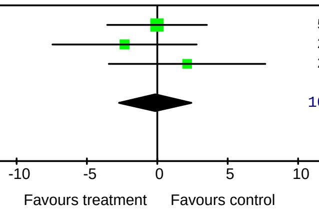
Test for heterogeneity: Chi² = 1.31, df = 2 (P = 0.52), I² = 0%
Test for overall effect: Z = 0.95 (P = 0.34)



Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 07 Weight change in kg at 12 months

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Viegener 1990	30	-8.97(6.72)	30	-8.95(7.26)	53.09	-0.02 [-3.56, 3.52]
Wing 6 months conc	11	-1.95(6.47)	12	0.38(6.02)	25.37	-2.33 [-7.45, 2.79]
Wing 6 months space	12	-0.58(6.08)	9	-2.69(6.68)	21.54	2.11 [-3.45, 7.67]
Total (95% CI)	53		51		100.00	-0.15 [-2.73, 2.43]

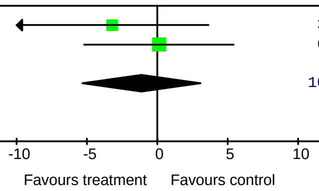
Test for heterogeneity: Chi² = 1.34, df = 2 (P = 0.51), I² = 0%
Test for overall effect: Z = 0.11 (P = 0.91)



Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 08 Weight change in kg at 18 months

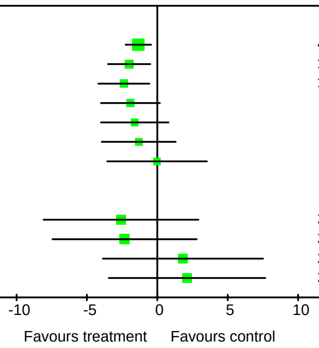
Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Pavlou 1989 1ga	18	-12.40(9.42)	10	-9.19(8.52)	37.56	-3.21 [-10.05, 3.63]
Pavlou 1989 1hb	16	-3.45(6.89)	11	-3.57(6.93)	62.44	0.12 [-5.19, 5.43]
Total (95% CI)	34		21		100.00	-1.13 [-5.32, 3.06]

Test for heterogeneity: Chi² = 0.57, df = 1 (P = 0.45), I² = 0%
Test for overall effect: Z = 0.53 (P = 0.60)



Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 09 Weight change in kg over time

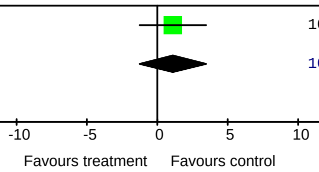
Study or sub-category	VLCD N	VLCD Mean (SD)	LCD N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Viegener 1990						
Viegener 1 month	31	-3.72(1.65)	32	-2.37(2.00)	47.05	-1.35 [-2.25, -0.45]
Viegener 2 months	31	-5.91(2.88)	32	-3.91(3.19)	17.10	-2.00 [-3.50, -0.50]
Viegener 3 months	31	-7.88(3.17)	32	-5.51(4.12)	11.72	-2.37 [-4.18, -0.56]
Viegener 4 months	31	-8.89(3.78)	32	-6.98(4.67)	8.76	-1.91 [-4.00, 0.18]
Viegener 5 months	31	-9.63(4.44)	32	-8.02(5.23)	6.72	-1.61 [-4.00, 0.78]
Viegener 6 months	31	-10.19(5.06)	32	-8.87(5.56)	5.59	-1.32 [-3.94, 1.30]
Viegener 12 months	30	-8.97(6.72)	30	-8.95(7.26)	3.07	-0.02 [-3.56, 3.52]
02 Wing 1984						
Wing 6 months conc	11	-4.05(7.06)	12	-1.47(6.33)	24.60	-2.58 [-8.08, 2.92]
Wing 12 months conc	11	-1.95(6.47)	12	0.38(6.02)	28.36	-2.33 [-7.45, 2.79]
Wing 6 months space	12	-1.31(6.29)	9	-3.12(6.80)	22.95	1.81 [-3.88, 7.50]
Wing 12 months space	12	-0.58(6.08)	9	-2.69(6.68)	24.08	2.11 [-3.45, 7.67]



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 01 Weight change in kg at 1 month

Study or sub-category	Low fat N	Low fat Mean (SD)	Other N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Baron 1986	68	-2.80(6.71)	63	-3.90(7.02)	100.00	1.10 [-1.26, 3.46]
Total (95% CI)	68		63		100.00	1.10 [-1.26, 3.46]

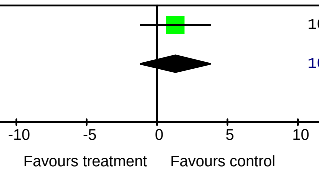
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.92 (P = 0.36)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 02 Weight change in kg at 3 months

Study or sub-category	Low fat N	Low fat Mean (SD)	Other N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Baron 1986	66	-3.70(6.96)	63	-5.00(7.33)	100.00	1.30 [-1.17, 3.77]
Total (95% CI)	66		63		100.00	1.30 [-1.17, 3.77]

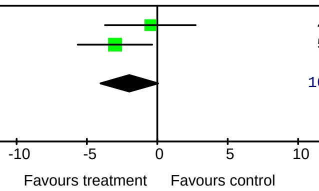
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.03 (P = 0.30)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 03 Weight change in kg at 4 months

Study or sub-category	Low fat N	Low fat Mean (SD)	Other N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-7.40(4.00)	13	-6.90(4.70)	40.20	-0.50 [-3.72, 2.72]
Pascale 1995 NIDDM	15	-7.70(3.60)	16	-4.70(3.90)	59.80	-3.00 [-5.64, -0.36]
Total (95% CI)	31		29		100.00	-1.99 [-4.04, 0.05]

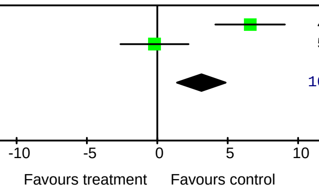
Test for heterogeneity: Chi² = 1.38, df = 1 (P = 0.24), I² = 27.8%
Test for overall effect: Z = 1.92 (P = 0.06)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 04 Weight change in kg at 6 months

Study or sub-category	Low fat N	Low fat Mean (SD)	Other N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Harvey-Berino 1998	28	-5.20(4.60)	29	-11.80(4.90)	48.92	6.60 [4.13, 9.07]
McManus 2001	23	-5.10(4.60)	31	-4.90(4.30)	51.08	-0.20 [-2.61, 2.21]
Total (95% CI)	51		60		100.00	3.13 [1.40, 4.85]

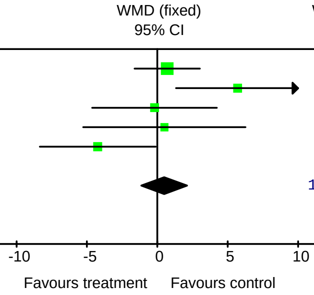
Test for heterogeneity: Chi² = 14.92, df = 1 (P = 0.0001), I² = 93.3%
Test for overall effect: Z = 3.55 (P = 0.0004)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 05 Weight change in kg at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Baron 1986	61	-1.60(6.37)	59	-2.30(6.57)	49.14	0.70 [-1.62, 3.02]
Harvey-Berino 1998	26	-3.00(6.76)	22	-8.70(8.38)	13.87	5.70 [1.34, 10.06]
McManus 2001	13	-5.00(7.30)	27	-4.80(5.20)	13.46	-0.20 [-4.63, 4.23]
Pascale 1995 FH	16	-3.00(8.40)	13	-3.50(7.40)	7.96	0.50 [-5.26, 6.26]
Pascale 1995 NIDDM	15	-5.20(7.30)	16	-0.96(3.70)	15.57	-4.24 [-8.36, -0.12]
Total (95% CI)	131		137		100.00	0.49 [-1.14, 2.11]

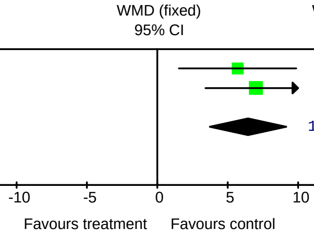
Test for heterogeneity: Chi² = 10.68, df = 4 (P = 0.03), I² = 62.6%
Test for overall effect: Z = 0.59 (P = 0.56)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 06 Weight change in kg at 18 months

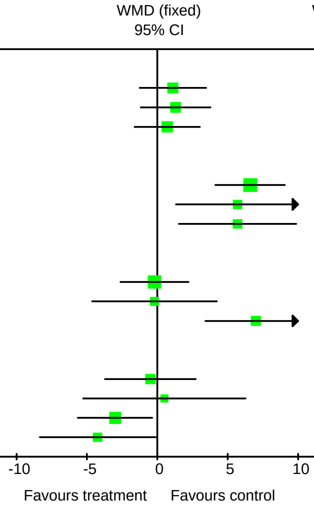
Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Harvey-Berino 1998	26	-1.80(6.42)	22	-7.50(8.04)	42.47	5.70 [1.53, 9.87]
McManus 2001	30	2.90(7.70)	31	-4.10(6.50)	57.53	7.00 [3.42, 10.58]
Total (95% CI)	56		53		100.00	6.45 [3.73, 9.16]

Test for heterogeneity: Chi² = 0.21, df = 1 (P = 0.64), I² = 0%
Test for overall effect: Z = 4.65 (P < 0.00001)



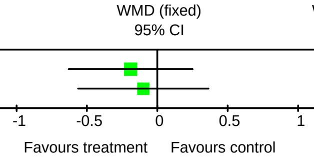
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 07 Weight change in kg over time

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Baron 1986						
Baron 1 month	68	-2.80(6.71)	63	-3.90(7.02)	33.96	1.10 [-1.26, 3.46]
Baron 3 months	66	-3.70(6.96)	63	-5.00(7.33)	30.92	1.30 [-1.17, 3.77]
Baron 12 months	61	-1.60(6.37)	59	-2.30(6.57)	35.12	0.70 [-1.62, 3.02]
02 Harvey-Berino 1998						
Harvey-Berino 6m	28	-5.20(4.60)	29	-11.80(4.90)	59.88	6.60 [4.13, 9.07]
Harvey-Berino 12m	26	-3.00(6.76)	22	-8.70(8.38)	19.16	5.70 [1.34, 10.06]
Harvey-Berino 18m	26	-1.80(6.42)	22	-7.50(8.04)	20.96	5.70 [1.53, 9.87]
03 McManus 2001						
McManus 6 months	23	-5.10(4.60)	31	-4.90(4.30)	57.10	-0.20 [-2.61, 2.21]
McManus 12 months	13	-5.00(7.30)	27	-4.80(5.20)	16.97	-0.20 [-4.63, 4.23]
McManus 18 months	30	2.90(7.70)	31	-4.10(6.50)	25.93	7.00 [3.42, 10.58]
04 Pascale 1995						
Pascale FH 4m	16	-7.40(4.00)	13	-6.90(4.70)	29.30	-0.50 [-3.72, 2.72]
Pascale FH 12m	16	-3.00(8.40)	13	-3.50(7.40)	9.17	0.50 [-5.26, 6.26]
Pascale NIDDM 4m	15	-7.70(3.60)	16	-4.70(3.90)	43.58	-3.00 [-5.64, -0.36]
Pascale NIDDM 12m	15	-5.20(7.30)	16	-0.96(3.70)	17.94	-4.24 [-8.36, -0.12]



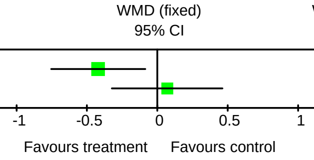
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 08 Change in TC mmol/l at 4 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.42(0.65)	13	-0.23(0.56)	52.53	-0.19 [-0.63, 0.25]
Pascale 1995 NIDDM	15	-0.33(0.70)	16	-0.23(0.61)	47.47	-0.10 [-0.56, 0.36]



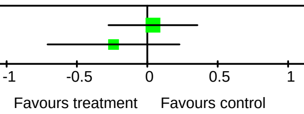
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 09 Change in TC mmol/l at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.18(0.28)	13	0.24(0.56)	58.02	-0.42 [-0.75, -0.09]
Pascale 1995 NIDDM	15	0.15(0.59)	16	0.08(0.52)	41.98	0.07 [-0.32, 0.46]



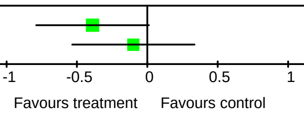
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 10 Change in LDLC mmol/l at 4 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	15	-0.02(0.46)	13	-0.06(0.39)	68.83	0.04 [-0.27, 0.35]
Pascale 1995 NIDDM	15	-0.27(0.72)	13	-0.03(0.54)	31.17	-0.24 [-0.71, 0.23]



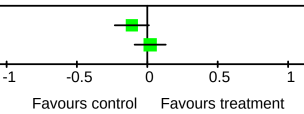
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 11 Change in LDLC mmol/l at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	15	-0.08(0.60)	13	0.31(0.48)	54.05	-0.39 [-0.79, 0.01]
Pascale 1995 NIDDM	15	0.02(0.59)	13	0.12(0.58)	45.95	-0.10 [-0.53, 0.33]



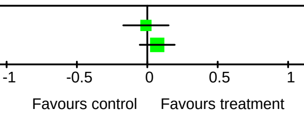
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 12 Change in HDLC mmol/l at 4 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.25(0.20)	13	-0.14(0.13)	45.34	-0.11 [-0.23, 0.01]
Pascale 1995 NIDDM	15	-0.12(0.17)	16	-0.14(0.14)	54.66	0.02 [-0.09, 0.13]



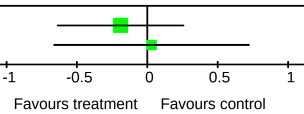
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 13 Change in HDLC mmol/l at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.13(0.22)	13	-0.12(0.22)	37.19	-0.01 [-0.17, 0.15]
Pascale 1995 NIDDM	15	-0.05(0.21)	16	-0.12(0.13)	62.81	0.07 [-0.05, 0.19]



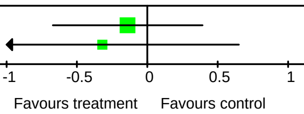
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 14 Change in TG mmol/l at 4 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.25(0.82)	13	-0.06(0.36)	70.50	-0.19 [-0.64, 0.26]
Pascale 1995 NIDDM	15	-0.24(1.24)	16	-0.27(0.59)	29.50	0.03 [-0.66, 0.72]



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 15 Change in TG mmol/l at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.03(0.99)	13	0.11(0.40)	76.92	-0.14 [-0.67, 0.39]
Pascale 1995 NIDDM	15	-0.16(1.79)	16	0.16(0.71)	23.08	-0.32 [-1.29, 0.65]

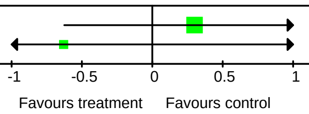


Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 16 3Change in FPG mmol/l at 4 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.36(0.83)	13	-0.32(0.59)	94.85	-0.04 [-0.56, 0.48]
Pascale 1995 NIDDM	15	-2.85(2.24)	16	-2.80(3.90)	5.15	-0.05 [-2.27, 2.17]

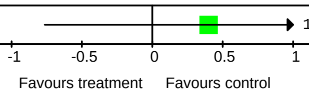
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 17 Change in FPG mmol/l at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Pascale 1995 FH	16	-0.38(1.70)	13	-0.68(0.74)		82.61	0.30 [-0.63, 1.23]
Pascale 1995 NIDDM	15	-1.11(3.42)	16	-0.48(2.11)		17.39	-0.63 [-2.65, 1.39]



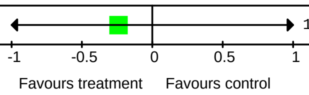
Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 18 Change in %HbA1c at 4 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Pascale 1995 NIDDM	15	-0.70(1.50)	16	-1.10(1.80)		100.00	0.40 [-0.76, 1.56]



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 19 Change in %HbA1c at 12 months

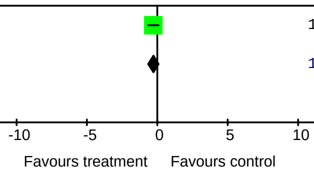
Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Pascale 1995 NIDDM	15	-0.03(1.90)	16	0.21(1.70)		100.00	-0.24 [-1.51, 1.03]



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 20 Change in TC in mmol/l at 1 month

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	68	-0.42(1.08)	63	-0.14(1.08)		100.00	-0.28 [-0.65, 0.09]
Total (95% CI)	68		63			100.00	-0.28 [-0.65, 0.09]

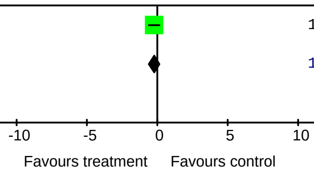
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.48 (P = 0.14)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 21 Change in TC in mmol/l at 3 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	66	-0.10(1.08)	63	0.13(1.08)		100.00	-0.23 [-0.60, 0.14]
Total (95% CI)	66		63			100.00	-0.23 [-0.60, 0.14]

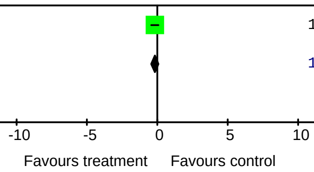
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.21 (P = 0.23)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 22 Change in LDLC mmol/l at 1 month

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	68	-0.05(0.74)	62	0.12(0.74)		100.00	-0.17 [-0.42, 0.08]
Total (95% CI)	68		62			100.00	-0.17 [-0.42, 0.08]

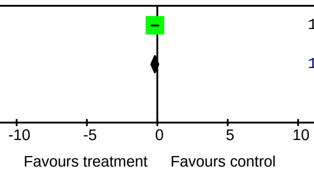
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.31 (P = 0.19)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 23 Change in LDLC mmol/l at 3 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	65	0.15(0.74)	63	0.32(0.74)		100.00	-0.17 [-0.43, 0.09]
Total (95% CI)	65		63			100.00	-0.17 [-0.43, 0.09]

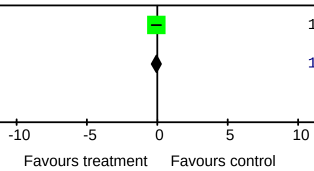
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.30 (P = 0.19)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 24 Change in TG mmol/l at 1 month

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	66	-0.29(0.96)	61	-0.22(0.96)		100.00	-0.07 [-0.40, 0.26]
Total (95% CI)	66		61			100.00	-0.07 [-0.40, 0.26]

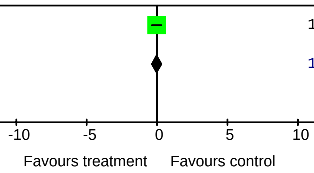
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.41 (P = 0.68)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 25 Change in TG mmol/l at 3 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	66	-0.19(0.96)	63	-0.16(0.96)		100.00	-0.03 [-0.36, 0.30]
Total (95% CI)	66		63			100.00	-0.03 [-0.36, 0.30]

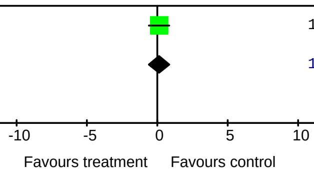
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.18 (P = 0.86)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 26 Change in FPG mmol/l at 1 month

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	58	-0.06(1.98)	56	-0.18(1.98)		100.00	0.12 [-0.61, 0.85]
Total (95% CI)	58		56			100.00	0.12 [-0.61, 0.85]

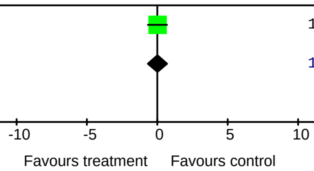
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.32 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 07 Low fat diet vs other weight reducing diets
Outcome: 27 Change in FPG mmol/l at 3 months

Study or sub-category	N	Low fat Mean (SD)	N	Other Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Baron 1986	66	-0.18(1.98)	63	-0.19(1.98)		100.00	0.01 [-0.67, 0.69]
Total (95% CI)	66		63			100.00	0.01 [-0.67, 0.69]

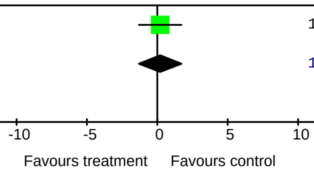
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.03 (P = 0.98)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 01 Weight change in kg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.60(3.30)	40	-3.80(3.60)		100.00	0.20 [-1.31, 1.71]
Total (95% CI)	40		40			100.00	0.20 [-1.31, 1.71]

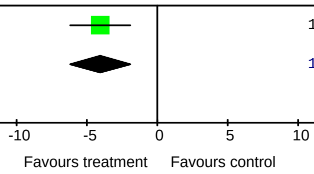
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.26 (P = 0.80)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 02 Weight change in kg at 3 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Foster 2003	33	-6.71(4.94)	30	-2.65(3.64)		100.00	-4.06 [-6.19, -1.93]
Total (95% CI)	33		30			100.00	-4.06 [-6.19, -1.93]

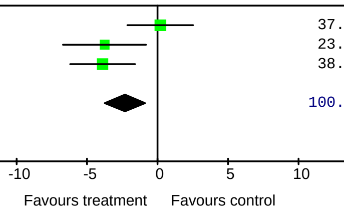
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.74 (P = 0.0002)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 03 Weight change in kg at 6 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.20(4.90)	40	-3.40(5.70)	37.74	0.20 [-2.13, 2.53]
Foster 2003	33	-6.91(6.42)	30	-3.15(5.50)	23.61	-3.76 [-6.70, -0.82]
Stern 2004	64	-5.70(8.60)	68	-1.80(3.90)	38.65	-3.90 [-6.20, -1.60]
Total (95% CI)	137		138		100.00	-2.32 [-3.75, -0.89]

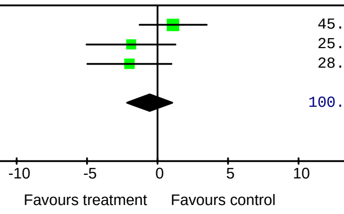
Test for heterogeneity: Chi² = 7.22, df = 2 (P = 0.03), I² = 72.3%
Test for overall effect: Z = 3.18 (P = 0.001)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 04 Weight change in kg at 12 months

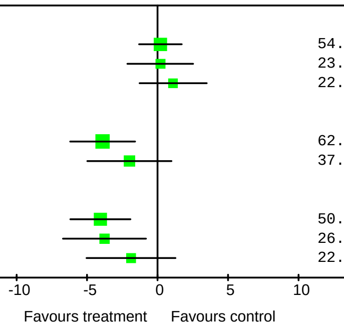
Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-2.10(4.80)	40	-3.20(6.00)	45.40	1.10 [-1.28, 3.48]
Foster 2003	33	-4.34(6.61)	30	-2.46(6.19)	25.76	-1.88 [-5.04, 1.28]
Stern 2004	62	-5.10(8.70)	64	-3.10(8.40)	28.84	-2.00 [-4.99, 0.99]
Total (95% CI)	135		134		100.00	-0.56 [-2.17, 1.04]

Test for heterogeneity: Chi² = 3.43, df = 2 (P = 0.18), I² = 41.7%
Test for overall effect: Z = 0.69 (P = 0.49)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 05 Weight change in kg over time

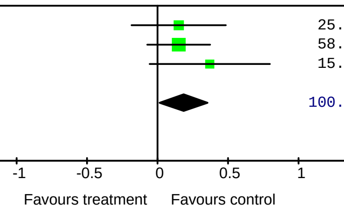
Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Dansinger 2005						
Dansinger 2 months	40	-3.60(3.30)	40	-3.80(3.60)	54.76	0.20 [-1.31, 1.71]
Dansinger 6 months	40	-3.20(4.90)	40	-3.40(5.70)	23.12	0.20 [-2.13, 2.53]
Dansinger 12 months	40	-2.10(4.80)	40	-3.20(6.00)	22.12	1.10 [-1.28, 3.48]
02 Stern 2004						
Stern 6 months	64	-5.70(8.60)	68	-1.80(3.90)	62.75	-3.90 [-6.20, -1.60]
Stern 12 months	62	-5.10(8.70)	64	-3.10(8.40)	37.25	-2.00 [-4.99, 0.99]
03 Foster 2003						
Foster 3 months	33	-6.71(4.94)	30	-2.65(3.64)	50.57	-4.06 [-6.19, -1.93]
Foster 6 months	33	-6.91(6.42)	30	-3.15(5.50)	26.46	-3.76 [-6.70, -0.82]
Foster 12 months	33	-4.34(6.61)	30	-2.46(6.19)	22.96	-1.88 [-5.04, 1.28]



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 06 Change in TC mmol/l at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.11(0.59)	40	-0.26(0.90)	25.94	0.15 [-0.18, 0.48]
Foster 2003	33	0.01(0.50)	30	-0.14(0.40)	58.17	0.15 [-0.07, 0.37]
Stern 2004	44	0.16(1.11)	43	-0.21(0.91)	15.89	0.37 [-0.06, 0.80]
Total (95% CI)	117		113		100.00	0.18 [0.02, 0.35]

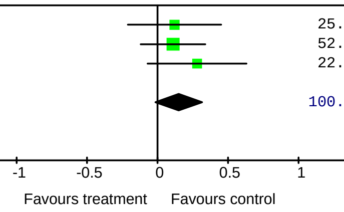
Test for heterogeneity: Chi² = 0.86, df = 2 (P = 0.65), I² = 0%
Test for overall effect: Z = 2.13 (P = 0.03)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 07 Change in LDLC mmol/l at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.18(0.62)	40	-0.30(0.87)	25.17	0.12 [-0.21, 0.45]
Foster 2003	33	0.01(0.55)	30	-0.10(0.37)	52.31	0.11 [-0.12, 0.34]
Stern 2004	44	0.18(0.91)	43	-0.10(0.75)	22.51	0.28 [-0.07, 0.63]
Total (95% CI)	117		113		100.00	0.15 [-0.02, 0.32]

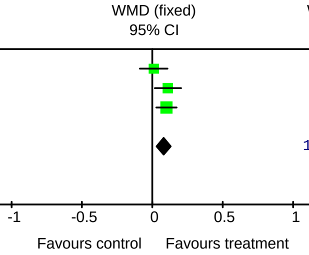
Test for heterogeneity: Chi² = 0.68, df = 2 (P = 0.71), I² = 0%
Test for overall effect: Z = 1.78 (P = 0.08)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 08 Change in HDLC mmol/l at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.09(0.18)	40	0.08(0.26)	25.09	0.01 [-0.09, 0.11]
Foster 2003	33	0.13(0.23)	30	0.02(0.14)	27.80	0.11 [0.02, 0.20]
Stern 2004	44	-0.03(0.18)	43	-0.13(0.16)	47.11	0.10 [0.03, 0.17]
Total (95% CI)	117		113		100.00	0.08 [0.03, 0.13]

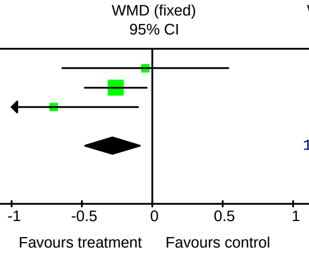
Test for heterogeneity: Chi² = 2.66, df = 2 (P = 0.26), I² = 24.8%
Test for overall effect: Z = 3.20 (P = 0.001)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 09 Change in TG mmol/l at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.02(0.94)	40	0.03(1.65)	10.91	-0.05 [-0.64, 0.54]
Foster 2003	33	-0.25(0.34)	30	0.01(0.52)	78.57	-0.26 [-0.48, -0.04]
Stern 2004	44	-0.65(1.78)	43	0.05(0.96)	10.52	-0.70 [-1.30, -0.10]
Total (95% CI)	117		113		100.00	-0.28 [-0.48, -0.09]

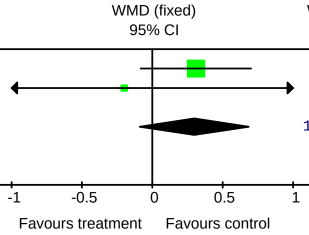
Test for heterogeneity: Chi² = 2.51, df = 2 (P = 0.29), I² = 20.2%
Test for overall effect: Z = 2.86 (P = 0.004)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 10 Change in FPG mmol/l at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.08(0.77)	40	-0.23(1.00)	97.68	0.31 [-0.08, 0.70]
Stern 2004	44	-0.53(6.06)	43	-0.33(6.01)	2.32	-0.20 [-2.74, 2.34]
Total (95% CI)	84		83		100.00	0.30 [-0.09, 0.68]

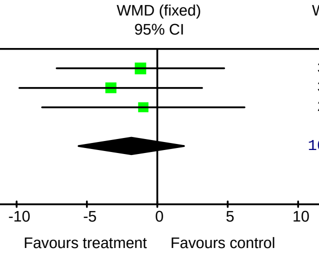
Test for heterogeneity: Chi² = 0.15, df = 1 (P = 0.70), I² = 0%
Test for overall effect: Z = 1.51 (P = 0.13)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 11 Change in SBP mmHg at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.20(12.00)	40	1.40(15.00)	39.54	-1.20 [-7.15, 4.75]
Foster 2003	33	-1.21(11.33)	30	2.10(14.55)	33.32	-3.31 [-9.79, 3.17]
Stern 2004	44	1.00(19.00)	43	2.00(15.00)	27.14	-1.00 [-8.18, 6.18]
Total (95% CI)	117		113		100.00	-1.85 [-5.59, 1.89]

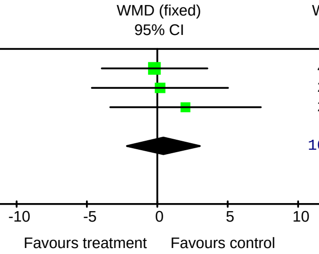
Test for heterogeneity: Chi² = 0.29, df = 2 (P = 0.86), I² = 0%
Test for overall effect: Z = 0.97 (P = 0.33)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 12 Change in DBP mmHg at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	600kcal/low fat N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.40(7.50)	40	-1.20(9.50)	47.76	-0.20 [-3.95, 3.55]
Foster 2003	33	-2.76(9.25)	30	-2.95(10.24)	28.73	0.19 [-4.65, 5.03]
Stern 2004	44	3.00(15.00)	43	1.00(10.00)	23.51	2.00 [-3.35, 7.35]
Total (95% CI)	117		113		100.00	0.43 [-2.16, 3.02]

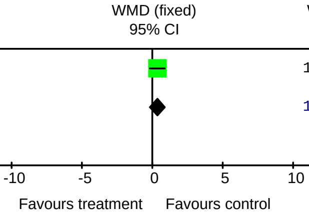
Test for heterogeneity: Chi² = 0.45, df = 2 (P = 0.80), I² = 0%
Test for overall effect: Z = 0.32 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 13 Change in TC mmol/l at 3 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Foster 2003	33	0.09(1.08)	30	-0.27(1.08)	100.00	0.36 [-0.17, 0.89]
Total (95% CI)	33		30		100.00	0.36 [-0.17, 0.89]

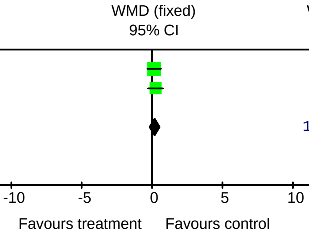
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.32 (P = 0.19)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 14 Change in TC mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.02(1.08)	40	-0.16(1.08)	56.00	0.14 [-0.33, 0.61]
Foster 2003	33	0.12(1.08)	30	-0.12(1.08)	44.00	0.24 [-0.29, 0.77]
Total (95% CI)	73		70		100.00	0.18 [-0.17, 0.54]

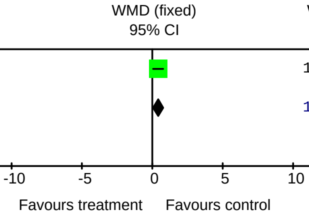
Test for heterogeneity: Chi² = 0.08, df = 1 (P = 0.78), I² = 0%
Test for overall effect: Z = 1.02 (P = 0.31)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 15 Change in LDLC mmol/l at 3 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Foster 2003	33	0.18(0.74)	30	-0.23(0.74)	100.00	0.41 [0.04, 0.78]
Total (95% CI)	33		30		100.00	0.41 [0.04, 0.78]

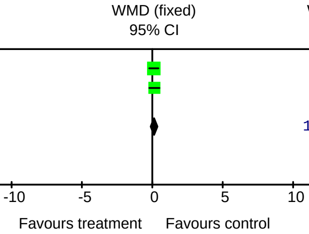
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.20 (P = 0.03)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 16 Change in LDLC mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.07(0.74)	40	-0.17(0.74)	56.00	0.10 [-0.22, 0.42]
Foster 2003	33	0.09(0.74)	30	-0.05(0.74)	44.00	0.14 [-0.23, 0.51]
Total (95% CI)	73		70		100.00	0.12 [-0.13, 0.36]

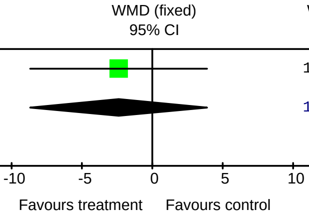
Test for heterogeneity: Chi² = 0.03, df = 1 (P = 0.87), I² = 0%
Test for overall effect: Z = 0.95 (P = 0.34)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 17 Change in SBP mmHg at 3 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Foster 2003	33	-3.13(12.70)	30	-0.74(12.70)	100.00	-2.39 [-8.67, 3.89]
Total (95% CI)	33		30		100.00	-2.39 [-8.67, 3.89]

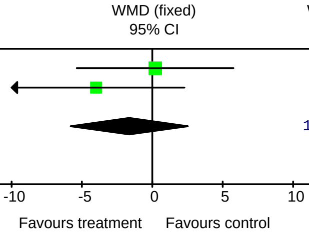
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.75 (P = 0.46)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 18 Change in SBP mmHg at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.70(12.70)	40	-3.90(12.70)	56.00	0.20 [-5.37, 5.77]
Foster 2003	33	-2.77(12.70)	30	1.23(12.70)	44.00	-4.00 [-10.28, 2.28]
Total (95% CI)	73		70		100.00	-1.65 [-5.81, 2.52]

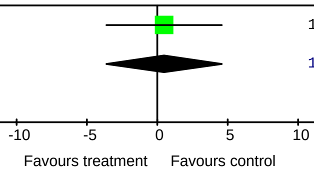
Test for heterogeneity: Chi² = 0.96, df = 1 (P = 0.33), I² = 0%
Test for overall effect: Z = 0.78 (P = 0.44)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 19 Change in DBP mmHg at 3 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Foster 2003	33	-2.24(8.30)	30	-2.72(8.30)		100.00	0.48 [-3.62, 4.58]
Total (95% CI)	33		30			100.00	0.48 [-3.62, 4.58]

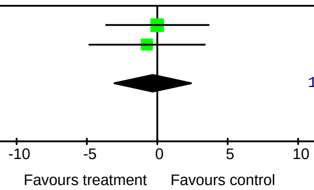
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.23 (P = 0.82)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 20 Change in DBP mmHg at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.00(8.30)	40	-4.00(8.30)		56.00	0.00 [-3.64, 3.64]
Foster 2003	33	-2.98(8.30)	30	-2.25(8.30)		44.00	-0.73 [-4.83, 3.37]
Total (95% CI)	73		70			100.00	-0.32 [-3.04, 2.40]

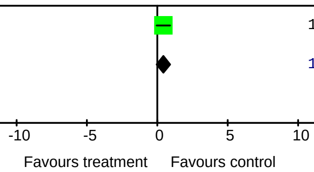
Test for heterogeneity: Chi² = 0.07, df = 1 (P = 0.79), I² = 0%
Test for overall effect: Z = 0.23 (P = 0.82)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 21 Change in TC mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.05(1.08)	40	-0.48(1.08)		100.00	0.43 [-0.04, 0.90]
Total (95% CI)	40		40			100.00	0.43 [-0.04, 0.90]

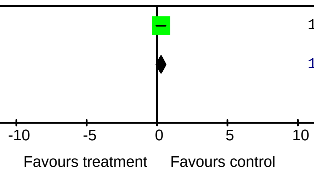
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.78 (P = 0.07)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 22 Change in LDLC mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.03(0.74)	40	-0.25(0.74)		100.00	0.28 [-0.04, 0.60]
Total (95% CI)	40		40			100.00	0.28 [-0.04, 0.60]

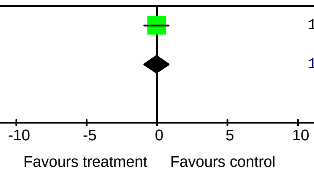
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.69 (P = 0.09)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 23 Change in FPG mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.54(1.98)	40	-0.50(1.98)		100.00	-0.04 [-0.91, 0.83]
Total (95% CI)	40		40			100.00	-0.04 [-0.91, 0.83]

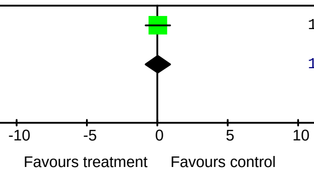
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.09 (P = 0.93)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 24 Change in FPG mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.43(1.98)	40	-0.46(1.98)		100.00	0.03 [-0.84, 0.90]
Total (95% CI)	40		40			100.00	0.03 [-0.84, 0.90]

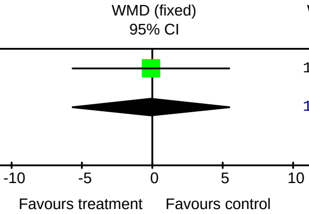
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.07 (P = 0.95)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 25 Change in SBP mmHg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.20(12.70)	40	-4.10(12.70)	100.00	-0.10 [-5.67, 5.47]
Total (95% CI)	40		40		100.00	-0.10 [-5.67, 5.47]

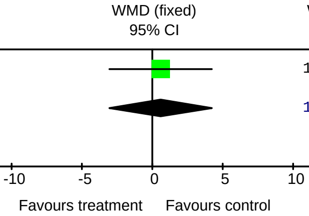
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.04 (P = 0.97)



Review: DIET Analyses for adults
Comparison: 08 Protein sparing modified fast vs 600kcal day deficit or low fat
Outcome: 26 Change in DBP mmHg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	600kcal/low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.20(8.30)	40	-4.80(8.30)	100.00	0.60 [-3.04, 4.24]
Total (95% CI)	40		40		100.00	0.60 [-3.04, 4.24]

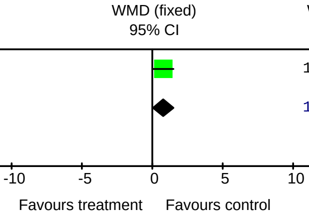
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.32 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 01 Weight change in kg at 1 week

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wadden 1994	28	-0.67(1.54)	21	-1.45(1.05)	100.00	0.78 [0.05, 1.51]
Total (95% CI)	28		21		100.00	0.78 [0.05, 1.51]

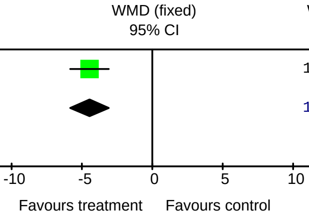
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.11 (P = 0.04)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 02 Weight change in kg at 5 weeks

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wadden 1994	28	-8.51(2.37)	21	-4.05(2.47)	100.00	-4.46 [-5.83, -3.09]
Total (95% CI)	28		21		100.00	-4.46 [-5.83, -3.09]

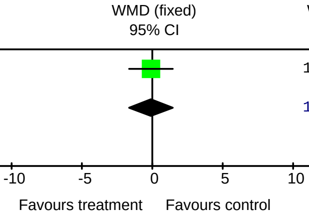
Test for heterogeneity: not applicable
Test for overall effect: Z = 6.36 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 03 Weight change in kg at 8 weeks

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.60(3.30)	40	-3.50(3.80)	100.00	-0.10 [-1.66, 1.46]
Total (95% CI)	40		40		100.00	-0.10 [-1.66, 1.46]

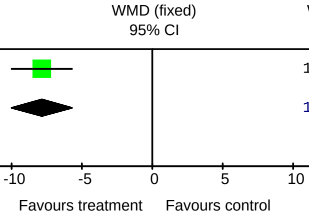
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.13 (P = 0.90)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 04 Weight change in kg at 9 weeks

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wadden 1994	28	-13.29(4.02)	21	-5.44(3.61)	100.00	-7.85 [-10.00, -5.71]
Total (95% CI)	28		21		100.00	-7.85 [-10.00, -5.71]

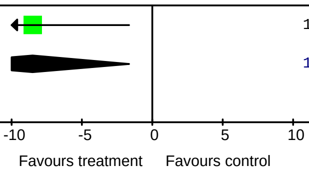
Test for heterogeneity: not applicable
Test for overall effect: Z = 7.17 (P < 0.00001)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 05 Weight change in kg at 5 months

Study or sub-category	PSMF N	PSMF Mean (SD)	LCD N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1991	17	-18.60(11.18)	16	-10.10(8.77)	100.00	-8.50 [-15.33, -1.67]
Total (95% CI)	17		16		100.00	-8.50 [-15.33, -1.67]

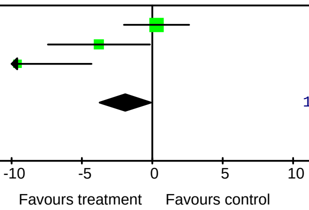
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.44 (P = 0.01)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 06 Weight change in kg at 6 months

Study or sub-category	PSMF N	PSMF Mean (SD)	LCD N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.20(4.90)	40	-3.50(5.60)	62.56	0.30 [-2.01, 2.61]
Wadden 1989	31	-16.80(6.68)	22	-13.00(6.57)	25.46	-3.80 [-7.41, -0.19]
Wadden 1994	26	-21.45(9.63)	17	-11.86(7.89)	11.98	-9.59 [-14.86, -4.32]
Total (95% CI)	97		79		100.00	-1.93 [-3.75, -0.10]

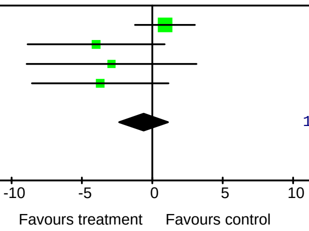
Test for heterogeneity: Chi² = 12.74, df = 2 (P = 0.002), I² = 84.3%
Test for overall effect: Z = 2.07 (P = 0.04)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 07 Weight change in kg at 12 months

Study or sub-category	PSMF N	PSMF Mean (SD)	LCD N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-2.10(4.80)	40	-3.00(4.90)	66.38	0.90 [-1.23, 3.03]
Wadden 1989	25	-10.60(8.00)	22	-6.60(8.91)	12.66	-4.00 [-8.87, 0.87]
Wadden 1994	23	-17.33(9.86)	17	-14.43(9.46)	8.23	-2.90 [-8.94, 3.14]
Wing 1994	41	-14.20(10.30)	38	-10.50(11.60)	12.74	-3.70 [-8.55, 1.15]
Total (95% CI)	129		117		100.00	-0.62 [-2.35, 1.11]

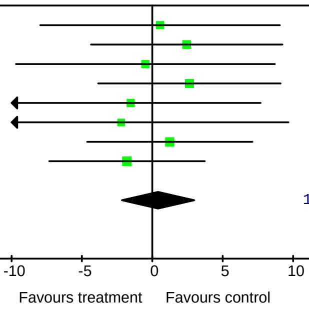
Test for heterogeneity: Chi² = 5.91, df = 3 (P = 0.12), I² = 49.3%
Test for overall effect: Z = 0.70 (P = 0.48)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 08 Weight change in kg at 18 months

Study or sub-category	PSMF N	PSMF Mean (SD)	LCD N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Pavlou 1989 1ca	16	-8.64(8.36)	5	-9.19(8.52)	9.09	0.55 [-7.97, 9.07]
Pavlou 1989 1db	16	-1.13(6.23)	5	-3.57(6.93)	14.27	2.44 [-4.36, 9.24]
Pavlou 1989 1ea	10	-9.68(8.65)	5	-9.19(8.52)	7.80	-0.49 [-9.68, 8.70]
Pavlou 1989 1fb	13	-0.93(6.18)	6	-3.57(6.93)	15.69	2.64 [-3.84, 9.12]
Pavlou 1989 2a	5	-7.29(7.98)	6	-5.75(7.54)	7.73	-1.54 [-10.78, 7.70]
Pavlou 1989 2b	5	-14.04(9.89)	5	-11.83(9.26)	4.68	-2.21 [-14.09, 9.67]
Wadden 1994	21	-10.94(9.97)	16	-12.18(8.23)	19.15	1.24 [-4.63, 7.11]
Wing 1991	17	-8.60(9.20)	16	-6.80(6.90)	21.59	-1.80 [-7.33, 3.73]
Total (95% CI)	103		64		100.00	0.40 [-2.17, 2.97]

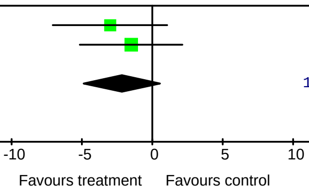
Test for heterogeneity: Chi² = 1.88, df = 7 (P = 0.97), I² = 0%
Test for overall effect: Z = 0.31 (P = 0.76)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 09 Weight change in kg at 24 months

Study or sub-category	PSMF N	PSMF Mean (SD)	LCD N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 1997	58	-9.20(13.00)	55	-6.20(8.70)	44.68	-3.00 [-7.06, 1.06]
Wing 1994	36	-7.20(8.00)	37	-5.70(7.90)	55.32	-1.50 [-5.15, 2.15]
Total (95% CI)	94		92		100.00	-2.17 [-4.88, 0.54]

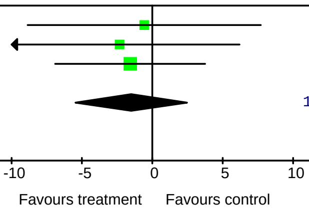
Test for heterogeneity: Chi² = 0.29, df = 1 (P = 0.59), I² = 0%
Test for overall effect: Z = 1.57 (P = 0.12)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 10 Weight change in kg at 36 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Pavlou 1989 2a	5	-3.83(7.10)	6	-3.25(6.83)	22.89	-0.58 [-8.86, 7.70]
Pavlou 1989 2b	5	-13.00(3.83)	5	-10.67(8.93)	21.65	-2.33 [-10.85, 6.19]
Wadden 1989	15	-5.11(8.28)	14	-3.54(6.26)	55.46	-1.57 [-6.89, 3.75]
Total (95% CI)	25		25		100.00	-1.51 [-5.47, 2.45]

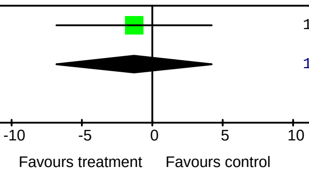
Test for heterogeneity: Chi² = 0.08, df = 2 (P = 0.96), I² = 0%
Test for overall effect: Z = 0.75 (P = 0.46)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 11 Weight change in kg at 48 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 1997	29	-7.60(12.20)	26	-6.30(8.50)	100.00	-1.30 [-6.81, 4.21]
Total (95% CI)	29		26		100.00	-1.30 [-6.81, 4.21]

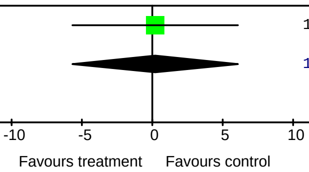
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.46 (P = 0.64)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 12 Weight change in kg at 60 months

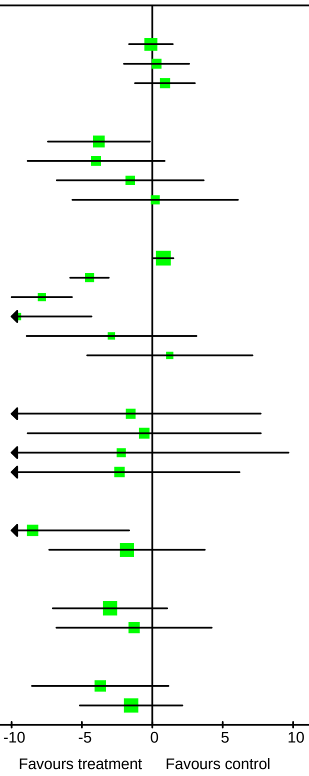
Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wadden 1989	22	2.90(11.26)	15	2.70(6.97)	100.00	0.20 [-5.68, 6.08]
Total (95% CI)	22		15		100.00	0.20 [-5.68, 6.08]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.07 (P = 0.95)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 13 Weight change in kg over time

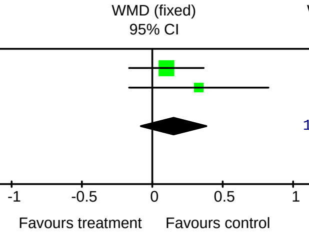
Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Dansinger 2005						
Dansinger 2 months	40	-3.60(3.30)	40	-3.50(3.80)	50.10	-0.10 [-1.66, 1.46]
Dansinger 6 months	40	-3.20(4.90)	40	-3.50(5.60)	22.92	0.30 [-2.01, 2.61]
Dansinger 12 months	40	-2.10(4.80)	40	-3.00(4.90)	26.97	0.90 [-1.23, 3.03]
02 Wadden 1989						
Wadden 6 months	31	-16.80(6.68)	22	-13.00(6.57)	41.50	-3.80 [-7.41, -0.19]
Wadden 12 months	25	-10.60(8.00)	22	-6.60(8.91)	22.89	-4.00 [-8.87, 0.87]
Wadden 36 months	16	-5.11(8.28)	14	-3.54(6.26)	19.93	-1.57 [-6.79, 3.65]
Wadden 60 months	22	2.90(11.26)	15	2.70(6.97)	15.68	0.20 [-5.68, 6.08]
03 Wadden 1994						
Wadden 1 week	28	-0.67(1.54)	21	-1.45(1.05)	69.32	0.78 [0.05, 1.51]
Wadden 5 weeks	28	-8.51(2.37)	21	-4.05(2.47)	19.36	-4.46 [-5.83, -3.09]
Wadden 9 weeks	28	-13.29(4.02)	21	-5.44(3.61)	7.94	-7.85 [-10.00, -5.71]
Wadden 6months	26	-21.45(9.63)	17	-11.86(7.89)	1.32	-9.59 [-14.86, -4.32]
Wadden 12months	23	-17.33(9.86)	17	-14.43(9.46)	1.00	-2.90 [-8.94, 3.14]
Wadden 18months	21	-10.94(9.97)	16	-12.18(8.23)	1.06	1.24 [-4.63, 7.11]
04 Pavlou 1989 2						
Pavlou 2a 18 months	5	-7.29(7.98)	6	-5.75(7.54)	24.84	-1.54 [-10.78, 7.70]
Pavlou 2a 36 months	5	-3.83(7.10)	6	-3.25(6.83)	30.90	-0.58 [-8.86, 7.70]
Pavlou 2b 18 months	5	-14.04(9.89)	5	-11.83(9.26)	15.03	-2.21 [-14.09, 9.67]
Pavlou 2b 36 months	5	-13.00(3.83)	5	-10.67(8.93)	29.22	-2.33 [-10.85, 6.19]
05 Wing 1991						
Wing 5 months	17	-18.60(11.18)	16	-10.10(8.77)	39.55	-8.50 [-15.33, -1.67]
Wing 18 months	17	-8.60(9.20)	16	-6.80(6.90)	60.45	-1.80 [-7.33, 3.73]
06 Torgerson 1997						
Torgerson 24 months	58	-9.20(13.00)	55	-6.20(8.70)	64.84	-3.00 [-7.06, 1.06]
Torgerson 48 months	29	-7.60(12.20)	26	-6.30(8.50)	35.16	-1.30 [-6.81, 4.21]
07 Wing 1994						
Wing 12 months	41	-14.20(10.30)	38	-10.50(11.60)	36.11	-3.70 [-8.55, 1.15]
Wing 24 months	36	-7.20(8.00)	37	-5.70(7.90)	63.89	-1.50 [-5.15, 2.15]



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 14 Change in TC mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.11(0.59)	40	-0.21(0.62)	77.73	0.10 [-0.17, 0.37]
Wing 1994	36	0.02(1.08)	37	-0.31(1.08)	22.27	0.33 [-0.17, 0.83]
Total (95% CI)	76		77		100.00	0.15 [-0.08, 0.39]

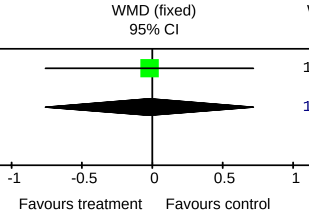
Test for heterogeneity: Chi² = 0.64, df = 1 (P = 0.42), I² = 0%
Test for overall effect: Z = 1.27 (P = 0.21)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 15 Change in TC mmol/l at 18 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1991	17	0.29(1.08)	16	0.31(1.08)	100.00	-0.02 [-0.76, 0.72]
Total (95% CI)	17		16		100.00	-0.02 [-0.76, 0.72]

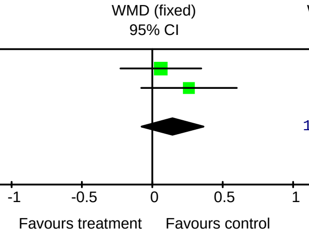
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.05 (P = 0.96)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 16 Change in LDLC mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.18(0.62)	40	-0.24(0.69)	58.25	0.06 [-0.23, 0.35]
Wing 1994	36	0.13(0.74)	37	-0.13(0.74)	41.75	0.26 [-0.08, 0.60]
Total (95% CI)	76		77		100.00	0.14 [-0.08, 0.36]

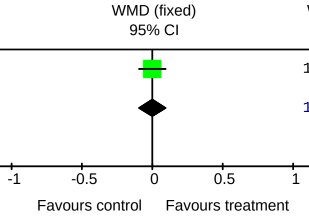
Test for heterogeneity: Chi² = 0.78, df = 1 (P = 0.38), I² = 0%
Test for overall effect: Z = 1.28 (P = 0.20)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 17 Change in HDLC mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.09(0.18)	40	0.09(0.25)	100.00	0.00 [-0.10, 0.10]
Total (95% CI)	40		40		100.00	0.00 [-0.10, 0.10]

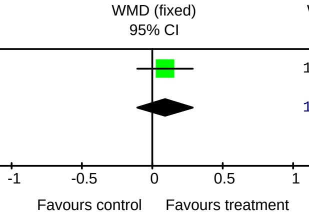
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 18 Change in HDLC mmol/l at 18 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1991	17	0.22(0.29)	16	0.13(0.29)	100.00	0.09 [-0.11, 0.29]
Total (95% CI)	17		16		100.00	0.09 [-0.11, 0.29]

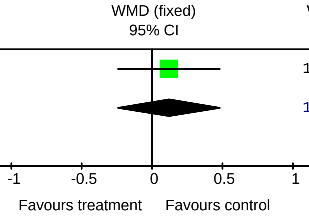
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.89 (P = 0.37)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 19 Change in TG mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.02(0.94)	40	-0.14(0.69)	100.00	0.12 [-0.24, 0.48]
Total (95% CI)	40		40		100.00	0.12 [-0.24, 0.48]

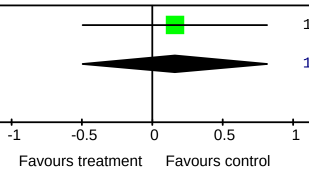
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.65 (P = 0.52)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 20 Change in TG mmol/l at 18 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1991	17	-0.13(0.96)	16	-0.29(0.96)	100.00	0.16 [-0.50, 0.82]
Total (95% CI)	17		16		100.00	0.16 [-0.50, 0.82]

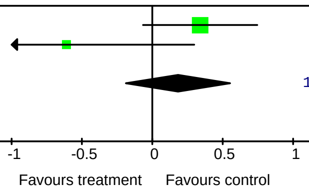
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.48 (P = 0.63)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 21 Change in FPG mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.08(0.77)	40	-0.26(1.06)	83.35	0.34 [-0.07, 0.75]
Wing 1994	36	-3.01(1.98)	37	-2.40(1.98)	16.65	-0.61 [-1.52, 0.30]
Total (95% CI)	76		77		100.00	0.18 [-0.19, 0.55]

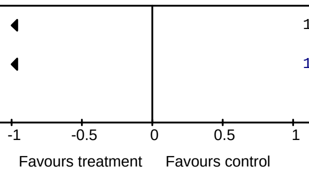
Test for heterogeneity: Chi² = 3.50, df = 1 (P = 0.06), I² = 71.4%
Test for overall effect: Z = 0.96 (P = 0.34)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 22 Change in FPG mmol/l at 18 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1991	17	-3.80(3.77)	16	0.70(3.77)	100.00	-4.50 [-7.07, -1.93]
Total (95% CI)	17		16		100.00	-4.50 [-7.07, -1.93]

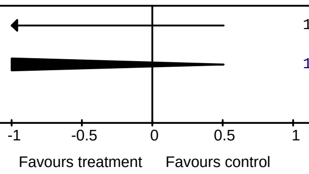
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.43 (P = 0.0006)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 23 Change in FPG mmol/l at 24 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1994	36	-1.22(4.56)	37	0.39(4.67)	100.00	-1.61 [-3.73, 0.51]
Total (95% CI)	36		37		100.00	-1.61 [-3.73, 0.51]

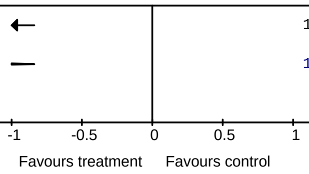
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.49 (P = 0.14)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 24 Change in %HbA1c at 18 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1991	17	-1.20(2.58)	16	1.40(2.58)	100.00	-2.60 [-4.36, -0.84]
Total (95% CI)	17		16		100.00	-2.60 [-4.36, -0.84]

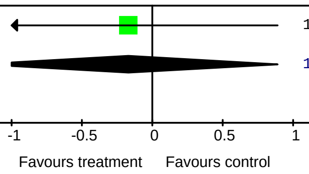
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.89 (P = 0.004)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 25 Change in %HbA1c at 24 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1994	36	0.07(2.22)	37	0.24(2.40)	100.00	-0.17 [-1.23, 0.89]
Total (95% CI)	36		37		100.00	-0.17 [-1.23, 0.89]

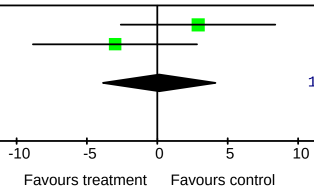
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.31 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 26 Change in SBP mmHg at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.20(12.00)	40	-2.70(13.00)		53.04	2.90 [-2.58, 8.38]
Wing 1994	36	-6.00(12.70)	37	-3.00(12.70)		46.96	-3.00 [-8.83, 2.83]
Total (95% CI)	76		77			100.00	0.13 [-3.86, 4.12]

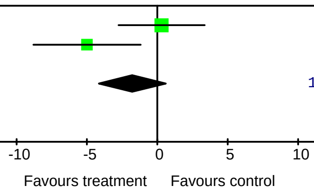
Test for heterogeneity: Chi² = 2.09, df = 1 (P = 0.15), I² = 52.1%
Test for overall effect: Z = 0.06 (P = 0.95)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 27 Change in DBP mmHg at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.40(7.50)	40	-1.70(6.40)		60.84	0.30 [-2.76, 3.36]
Wing 1994	36	-8.00(8.30)	37	-3.00(8.30)		39.16	-5.00 [-8.81, -1.19]
Total (95% CI)	76		77			100.00	-1.78 [-4.16, 0.61]

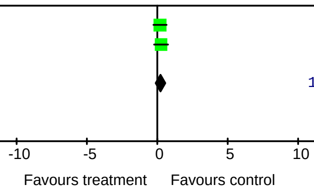
Test for heterogeneity: Chi² = 4.53, df = 1 (P = 0.03), I² = 77.9%
Test for overall effect: Z = 1.46 (P = 0.14)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 28 Change in TC mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.02(1.08)	40	-0.21(1.08)		52.29	0.19 [-0.28, 0.66]
Wing 1994	36	-0.31(1.08)	37	-0.57(1.08)		47.71	0.26 [-0.24, 0.76]
Total (95% CI)	76		77			100.00	0.22 [-0.12, 0.57]

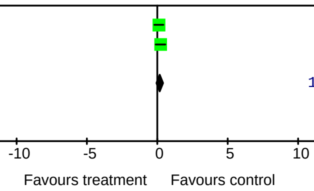
Test for heterogeneity: Chi² = 0.04, df = 1 (P = 0.84), I² = 0%
Test for overall effect: Z = 1.28 (P = 0.20)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 29 Change in LDLC mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.07(0.74)	40	-0.18(0.74)		52.29	0.11 [-0.21, 0.43]
Wing 1994	36	-0.08(0.74)	37	-0.31(0.74)		47.71	0.23 [-0.11, 0.57]
Total (95% CI)	76		77			100.00	0.17 [-0.07, 0.40]

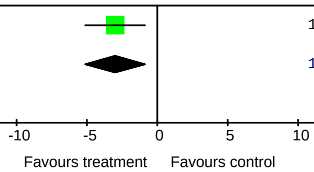
Test for heterogeneity: Chi² = 0.25, df = 1 (P = 0.62), I² = 0%
Test for overall effect: Z = 1.40 (P = 0.16)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 30 Change in FPG mmol/l at 5 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1991	17	-6.50(3.11)	16	-3.50(3.11)		100.00	-3.00 [-5.12, -0.88]
Total (95% CI)	17		16			100.00	-3.00 [-5.12, -0.88]

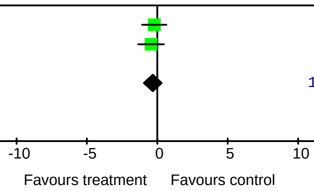
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.77 (P = 0.006)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 31 Change in FPG mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.43(1.98)	40	-0.21(1.98)		52.29	-0.22 [-1.09, 0.65]
Wing 1994	36	-3.62(1.98)	37	-3.17(1.98)		47.71	-0.45 [-1.36, 0.46]
Total (95% CI)	76		77			100.00	-0.33 [-0.96, 0.30]

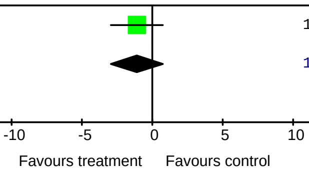
Test for heterogeneity: Chi² = 0.13, df = 1 (P = 0.72), I² = 0%
Test for overall effect: Z = 1.03 (P = 0.30)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 32 Change in %HbA1c at 5 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1991	17	-2.90(2.70)	16	-1.80(2.70)		100.00	-1.10 [-2.94, 0.74]
Total (95% CI)	17		16			100.00	-1.10 [-2.94, 0.74]

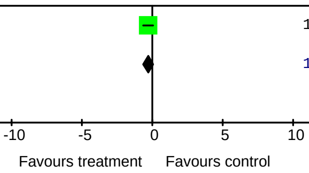
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.17 (P = 0.24)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 33 Change in %HbA1c at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1994	36	-2.00(0.76)	37	-1.70(0.76)		100.00	-0.30 [-0.65, 0.05]
Total (95% CI)	36		37			100.00	-0.30 [-0.65, 0.05]

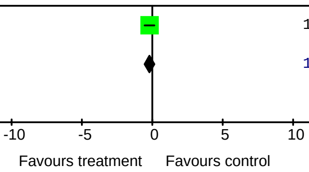
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.69 (P = 0.09)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 34 Change in %HbA1c at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1994	36	-1.50(0.76)	37	-1.30(0.76)		100.00	-0.20 [-0.55, 0.15]
Total (95% CI)	36		37			100.00	-0.20 [-0.55, 0.15]

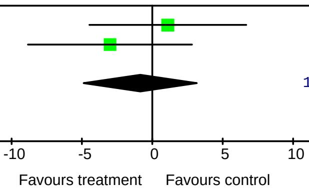
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.12 (P = 0.26)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 35 Change in SBP mmHg at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.70(12.70)	40	-4.80(12.70)		52.29	1.10 [-4.47, 6.67]
Wing 1994	36	-9.00(12.70)	37	-6.00(12.70)		47.71	-3.00 [-8.83, 2.83]
Total (95% CI)	76		77			100.00	-0.86 [-4.88, 3.17]

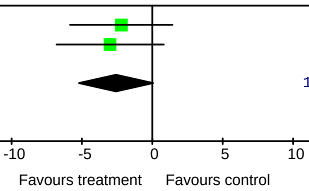
Test for heterogeneity: Chi² = 0.99, df = 1 (P = 0.32), I² = 0%
Test for overall effect: Z = 0.42 (P = 0.68)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 36 Change in DBP mmHg at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.00(8.30)	40	-1.80(8.30)		52.29	-2.20 [-5.84, 1.44]
Wing 1994	36	-6.00(8.30)	37	-3.00(8.30)		47.71	-3.00 [-6.81, 0.81]
Total (95% CI)	76		77			100.00	-2.58 [-5.21, 0.05]

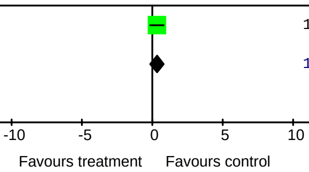
Test for heterogeneity: Chi² = 0.09, df = 1 (P = 0.77), I² = 0%
Test for overall effect: Z = 1.92 (P = 0.05)



Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 37 Change in TC mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.05(1.08)	40	-0.38(1.08)		100.00	0.33 [-0.14, 0.80]
Total (95% CI)	40		40			100.00	0.33 [-0.14, 0.80]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.37 (P = 0.17)

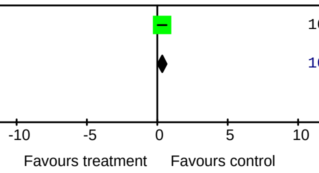


Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 38 Change in LDLC mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.03(0.74)	40	-0.31(0.74)	100.00	0.34 [0.02, 0.66]
Total (95% CI)	40		40		100.00	0.34 [0.02, 0.66]

Test for heterogeneity: not applicable
Test for overall effect: Z = 2.05 (P = 0.04)

WMD (fixed) 95% CI

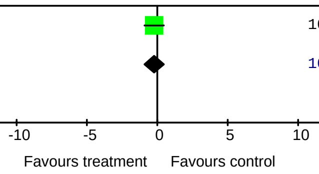


Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 39 Change in FPG mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.54(1.98)	40	-0.31(0.98)	100.00	-0.23 [-0.91, 0.45]
Total (95% CI)	40		40		100.00	-0.23 [-0.91, 0.45]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.66 (P = 0.51)

WMD (fixed) 95% CI

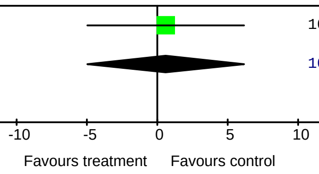


Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 40 Change in SBP mmHg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.20(12.70)	40	-4.80(12.70)	100.00	0.60 [-4.97, 6.17]
Total (95% CI)	40		40		100.00	0.60 [-4.97, 6.17]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.21 (P = 0.83)

WMD (fixed) 95% CI

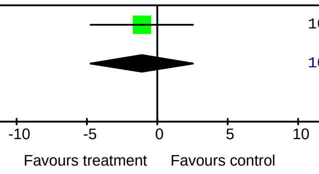


Review: DIET Analyses for adults
Comparison: 09 Protein sparing modified fast vs LCD
Outcome: 41 Change in DBP mmHg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	LCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.20(8.30)	40	-3.10(8.30)	100.00	-1.10 [-4.74, 2.54]
Total (95% CI)	40		40		100.00	-1.10 [-4.74, 2.54]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.59 (P = 0.55)

WMD (fixed) 95% CI

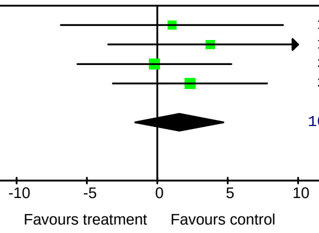


Review: DIET Analyses for adults
Comparison: 10 Protein sparing modified fast vs VLCD
Outcome: 01 Weight change in kg at 18 months

Study or sub-category	N	PSMF Mean (SD)	N	VLCD Mean (SD)	Weight %	WMD (fixed) 95% CI
Pavlou 1989 1ce	8	-8.64(8.36)	10	-9.68(8.65)	15.76	1.04 [-6.85, 8.93]
Pavlou 1989 1cg	8	-8.64(8.36)	18	-12.40(9.42)	18.71	3.76 [-3.49, 11.01]
Pavlou 1989 1df	8	-1.13(6.23)	13	-0.93(6.18)	32.82	-0.20 [-5.67, 5.27]
Pavlou 1989 1dh	8	-1.13(6.23)	16	-3.45(6.89)	32.70	2.32 [-3.16, 7.80]
Total (95% CI)	32		57		100.00	1.56 [-1.57, 4.69]

Test for heterogeneity: Chi² = 0.84, df = 3 (P = 0.84), I² = 0%
Test for overall effect: Z = 0.98 (P = 0.33)

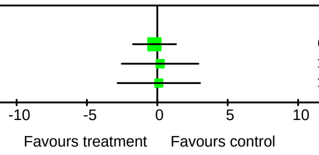
WMD (fixed) 95% CI



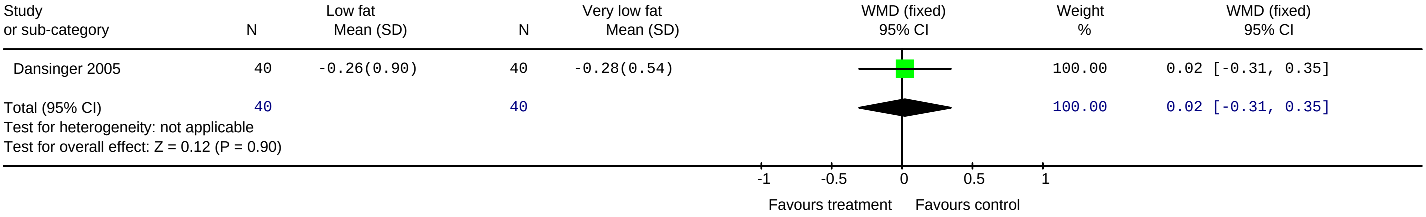
Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 01 Weight change in kg over time

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Dansinger 2005						
Dansinger 2 months	40	-3.80(3.60)	40	-3.60(3.40)	62.83	-0.20 [-1.73, 1.33]
Dansinger 6 months	40	-3.40(5.70)	40	-3.60(6.70)	19.91	0.20 [-2.53, 2.93]
Dansinger 12 months	40	-3.20(6.00)	40	-3.30(7.30)	17.25	0.10 [-2.83, 3.03]

WMD (fixed) 95% CI



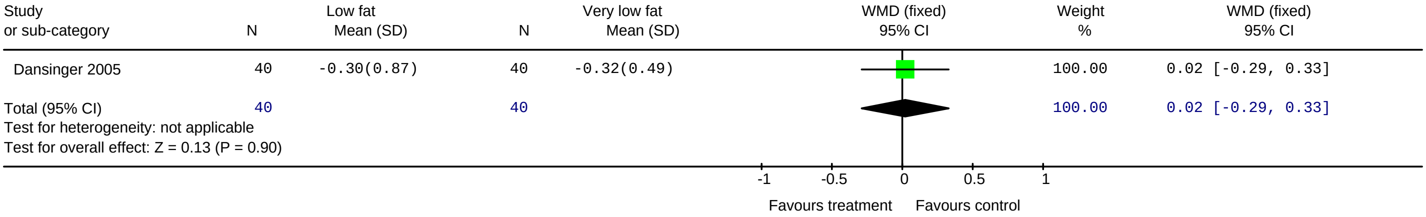
Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 02 Change in TC mmol/l at 12 months



Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.26(0.90)	40	-0.28(0.54)		100.00	0.02 [-0.31, 0.35]
Total (95% CI)	40		40			100.00	0.02 [-0.31, 0.35]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.12 (P = 0.90)

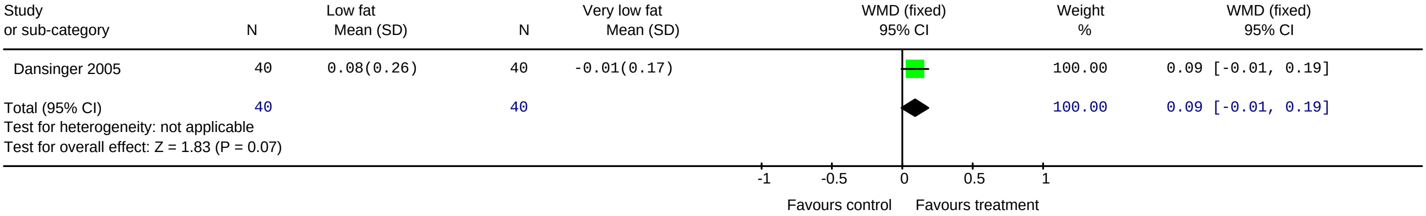
Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 03 Change in LDLC mmol/l at 12 months



Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.30(0.87)	40	-0.32(0.49)		100.00	0.02 [-0.29, 0.33]
Total (95% CI)	40		40			100.00	0.02 [-0.29, 0.33]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.13 (P = 0.90)

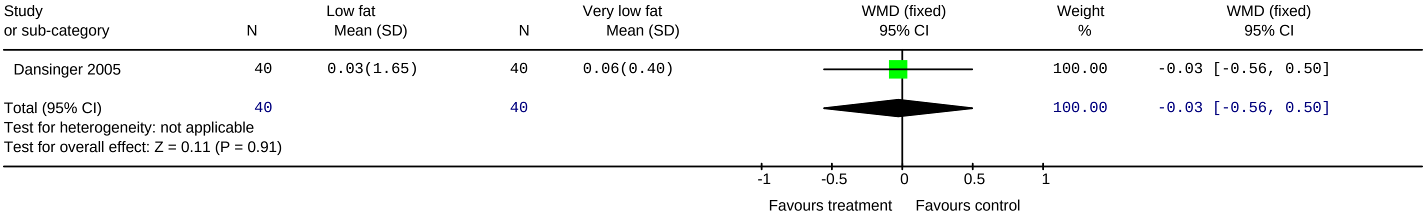
Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 04 Change in HDLC mmol/l at 12 months



Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.08(0.26)	40	-0.01(0.17)		100.00	0.09 [-0.01, 0.19]
Total (95% CI)	40		40			100.00	0.09 [-0.01, 0.19]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.83 (P = 0.07)

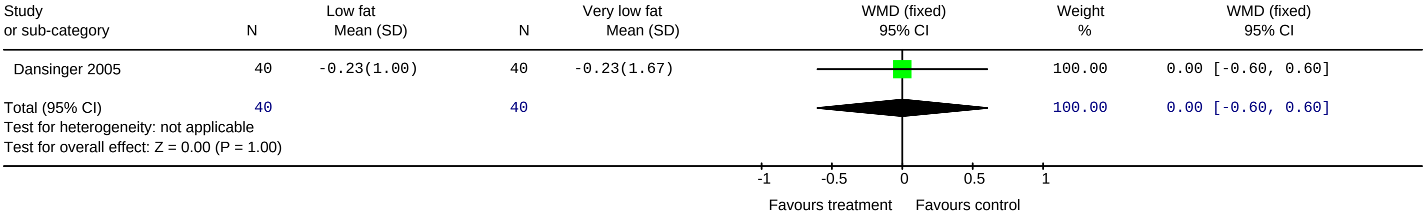
Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 05 Change in TG mmol/l at 12 months



Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.03(1.65)	40	0.06(0.40)		100.00	-0.03 [-0.56, 0.50]
Total (95% CI)	40		40			100.00	-0.03 [-0.56, 0.50]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.11 (P = 0.91)

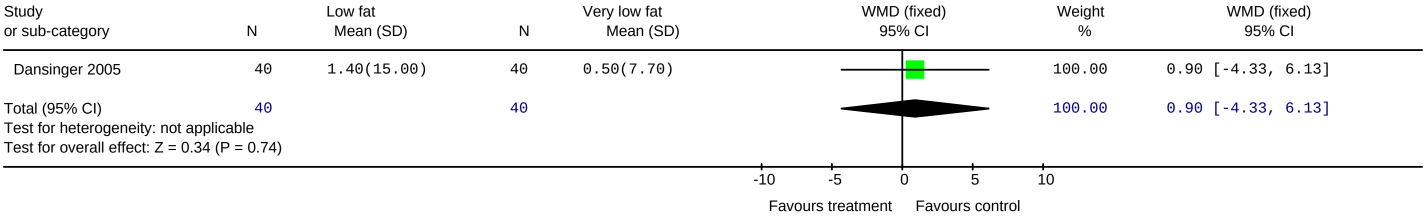
Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 06 Change in FPG mmol/l at 12 months



Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.23(1.00)	40	-0.23(1.67)		100.00	0.00 [-0.60, 0.60]
Total (95% CI)	40		40			100.00	0.00 [-0.60, 0.60]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)

Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 07 Change in SBP mmHg at 12 months



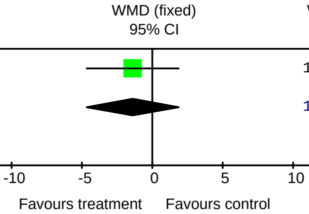
Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	1.40(15.00)	40	0.50(7.70)		100.00	0.90 [-4.33, 6.13]
Total (95% CI)	40		40			100.00	0.90 [-4.33, 6.13]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.34 (P = 0.74)

Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 08 Change in DBP mmHg at 12 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.20(9.50)	40	0.20(4.60)	100.00	-1.40 [-4.67, 1.87]
Total (95% CI)	40		40		100.00	-1.40 [-4.67, 1.87]

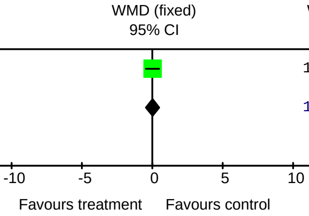
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.84 (P = 0.40)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 09 Change in TC mmol/l at 2 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.48(1.08)	40	-0.49(1.08)	100.00	0.01 [-0.46, 0.48]
Total (95% CI)	40		40		100.00	0.01 [-0.46, 0.48]

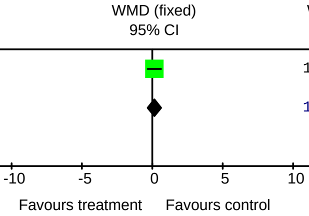
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.04 (P = 0.97)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 10 Change in TC mmol/l at 6 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.16(1.08)	40	-0.30(1.08)	100.00	0.14 [-0.33, 0.61]
Total (95% CI)	40		40		100.00	0.14 [-0.33, 0.61]

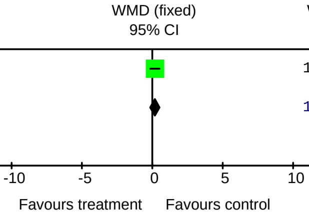
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.58 (P = 0.56)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 11 Change in LDLC mmol/l at 2 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.25(0.74)	40	-0.43(0.74)	100.00	0.18 [-0.14, 0.50]
Total (95% CI)	40		40		100.00	0.18 [-0.14, 0.50]

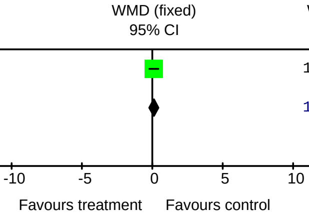
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.09 (P = 0.28)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 12 Change in LDLC mmol/l at 6 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.17(0.74)	40	-0.27(0.74)	100.00	0.10 [-0.22, 0.42]
Total (95% CI)	40		40		100.00	0.10 [-0.22, 0.42]

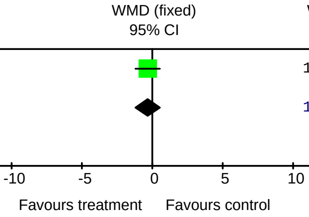
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.60 (P = 0.55)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 13 Change in FPG mmol/l at 2 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.50(1.98)	40	-0.17(1.98)	100.00	-0.33 [-1.20, 0.54]
Total (95% CI)	40		40		100.00	-0.33 [-1.20, 0.54]

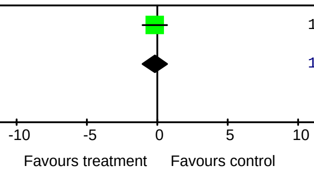
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.75 (P = 0.46)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 14 Change in FPG mmol/l at 6 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.46(1.98)	40	-0.28(1.98)	100.00	-0.18 [-1.05, 0.69]
Total (95% CI)	40		40		100.00	-0.18 [-1.05, 0.69]

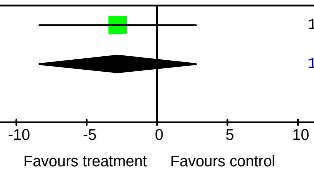
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.41 (P = 0.68)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 15 Change in SBP mmHg at 2 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.10(12.70)	40	-1.30(12.70)	100.00	-2.80 [-8.37, 2.77]
Total (95% CI)	40		40		100.00	-2.80 [-8.37, 2.77]

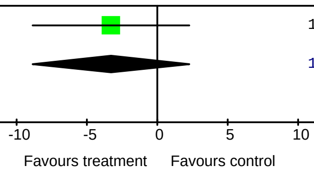
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.99 (P = 0.32)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 16 Change in SBP mmHg at 6 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.90(12.70)	40	-0.60(12.70)	100.00	-3.30 [-8.87, 2.27]
Total (95% CI)	40		40		100.00	-3.30 [-8.87, 2.27]

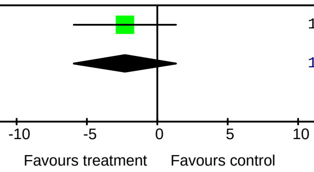
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.16 (P = 0.25)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 17 Change in DBP mmHg at 2 months

Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.80(8.30)	40	-2.50(8.30)	100.00	-2.30 [-5.94, 1.34]
Total (95% CI)	40		40		100.00	-2.30 [-5.94, 1.34]

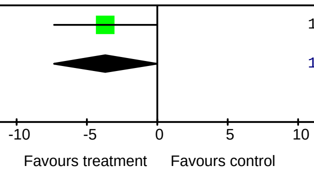
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.24 (P = 0.22)



Review: DIET Analyses for adults
Comparison: 11 Low fat diet vs very low fat diet
Outcome: 18 Change in DBP mmHg at 6 months

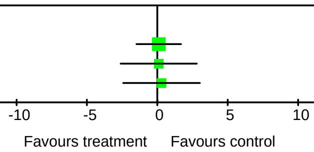
Study or sub-category	N	Low fat Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.00(8.30)	40	-0.30(8.30)	100.00	-3.70 [-7.34, -0.06]
Total (95% CI)	40		40		100.00	-3.70 [-7.34, -0.06]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.99 (P = 0.05)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 01 Weight change in kg over time

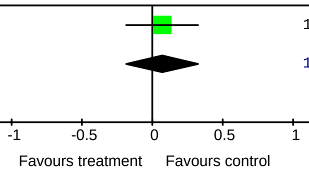
Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Dansinger 2005						
Dansinger 2 months	40	-3.50(3.80)	40	-3.60(3.40)	59.62	0.10 [-1.48, 1.68]
Dansinger 6 months	40	-3.50(5.60)	40	-3.60(6.70)	20.33	0.10 [-2.61, 2.81]
Dansinger 12 months	40	-3.00(4.90)	40	-3.30(7.30)	20.05	0.30 [-2.42, 3.02]



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 02 Change in TC mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.21(0.62)	40	-0.28(0.54)		100.00	0.07 [-0.18, 0.32]
Total (95% CI)	40		40			100.00	0.07 [-0.18, 0.32]

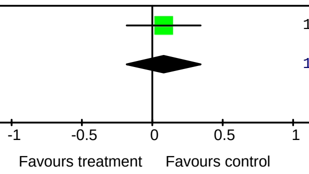
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.54 (P = 0.59)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 03 Change in LDLC mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.24(0.69)	40	-0.32(0.49)		100.00	0.08 [-0.18, 0.34]
Total (95% CI)	40		40			100.00	0.08 [-0.18, 0.34]

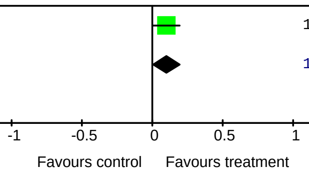
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.60 (P = 0.55)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 04 Change in HDLC mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.09(0.25)	40	-0.01(0.17)		100.00	0.10 [0.01, 0.19]
Total (95% CI)	40		40			100.00	0.10 [0.01, 0.19]

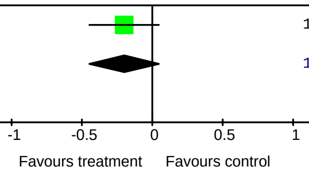
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.09 (P = 0.04)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 05 Change in TG mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.14(0.69)	40	0.06(0.40)		100.00	-0.20 [-0.45, 0.05]
Total (95% CI)	40		40			100.00	-0.20 [-0.45, 0.05]

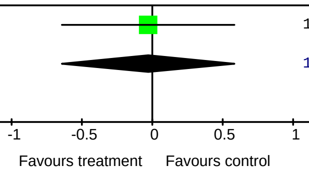
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.59 (P = 0.11)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 06 Change in FPG mmol/l at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.26(1.06)	40	-0.23(1.67)		100.00	-0.03 [-0.64, 0.58]
Total (95% CI)	40		40			100.00	-0.03 [-0.64, 0.58]

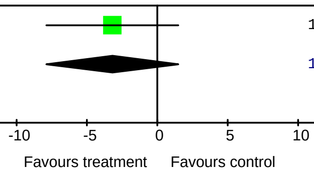
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.10 (P = 0.92)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 07 Change in SBP mmHg at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-2.70(13.00)	40	0.50(7.70)		100.00	-3.20 [-7.88, 1.48]
Total (95% CI)	40		40			100.00	-3.20 [-7.88, 1.48]

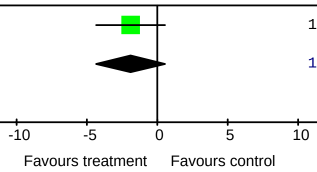
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.34 (P = 0.18)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 08 Change in DBP mmHg at 12 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.70(6.40)	40	0.20(4.60)		100.00	-1.90 [-4.34, 0.54]
Total (95% CI)	40		40			100.00	-1.90 [-4.34, 0.54]

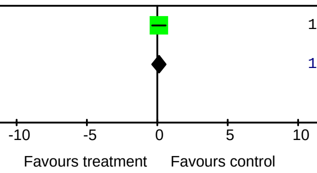
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.52 (P = 0.13)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 09 Change in TC mmol/l at 2 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.38(1.08)	40	-0.49(1.08)		100.00	0.11 [-0.36, 0.58]
Total (95% CI)	40		40			100.00	0.11 [-0.36, 0.58]

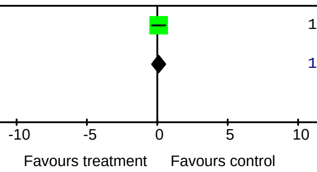
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.46 (P = 0.65)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 10 Change in TC mmol/l at 6 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.21(1.08)	40	-0.30(1.08)		100.00	0.09 [-0.38, 0.56]
Total (95% CI)	40		40			100.00	0.09 [-0.38, 0.56]

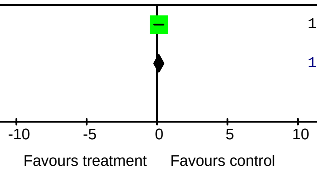
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.37 (P = 0.71)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 11 Change in LDLC mmol/l at 2 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.31(0.74)	40	-0.43(0.74)		100.00	0.12 [-0.20, 0.44]
Total (95% CI)	40		40			100.00	0.12 [-0.20, 0.44]

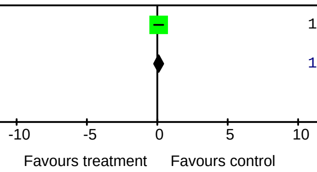
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.73 (P = 0.47)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 12 Change in LDLC mmol/l at 6 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.18(0.74)	40	-0.27(0.74)		100.00	0.09 [-0.23, 0.41]
Total (95% CI)	40		40			100.00	0.09 [-0.23, 0.41]

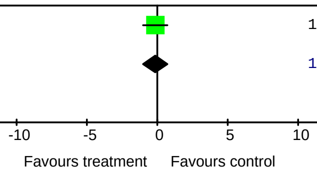
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.54 (P = 0.59)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 13 Change in FPG mmol/l at 2 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.31(1.98)	40	-0.17(1.98)		100.00	-0.14 [-1.01, 0.73]
Total (95% CI)	40		40			100.00	-0.14 [-1.01, 0.73]

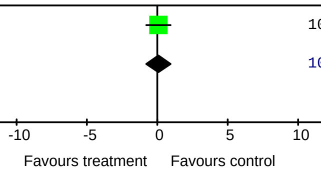
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.32 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 14 Change in FPG mmol/l at 6 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.21(1.98)	40	-0.28(1.98)	100.00	0.07 [-0.80, 0.94]
Total (95% CI)	40		40		100.00	0.07 [-0.80, 0.94]

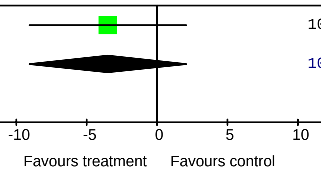
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.16 (P = 0.87)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 15 Change in SBP mmHg at 2 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.80(12.70)	40	-1.30(12.70)	100.00	-3.50 [-9.07, 2.07]
Total (95% CI)	40		40		100.00	-3.50 [-9.07, 2.07]

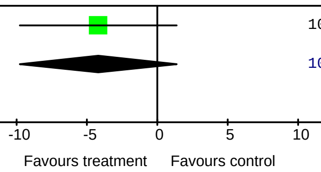
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.23 (P = 0.22)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 16 Change in SBP mmHg at 6 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.80(12.70)	40	-0.60(12.70)	100.00	-4.20 [-9.77, 1.37]
Total (95% CI)	40		40		100.00	-4.20 [-9.77, 1.37]

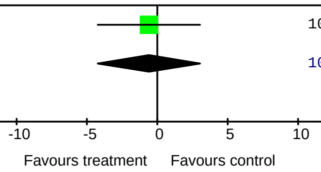
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.48 (P = 0.14)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 17 Change in DBP mmHg at 2 months

Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.10(8.30)	40	-2.50(8.30)	100.00	-0.60 [-4.24, 3.04]
Total (95% CI)	40		40		100.00	-0.60 [-4.24, 3.04]

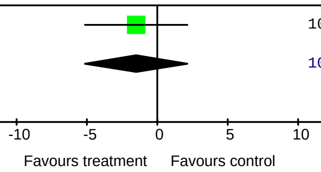
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.32 (P = 0.75)



Review: DIET Analyses for adults
Comparison: 12 LCD vs very low fat diet
Outcome: 18 Change in DBP mmHg at 6 months

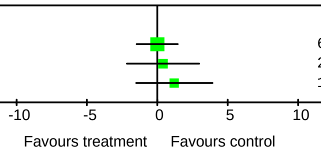
Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.80(8.30)	40	-0.30(8.30)	100.00	-1.50 [-5.14, 2.14]
Total (95% CI)	40		40		100.00	-1.50 [-5.14, 2.14]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.81 (P = 0.42)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 01 Weight change in kg over time

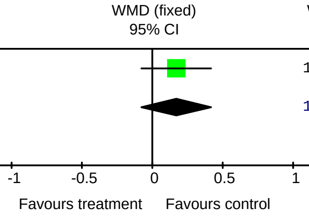
Study or sub-category	N	LCD Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Dansinger 2005						
Dansinger 2 months	40	-3.60(3.30)	40	-3.60(3.40)	61.73	0.00 [-1.47, 1.47]
Dansinger 6 months	40	-3.20(4.90)	40	-3.60(6.70)	20.11	0.40 [-2.17, 2.97]
Dansinger 12 months	40	-2.10(4.80)	40	-3.30(7.30)	18.16	1.20 [-1.51, 3.91]



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 02 Change in TC mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.11(0.59)	40	-0.28(0.54)	100.00	0.17 [-0.08, 0.42]
Total (95% CI)	40		40		100.00	0.17 [-0.08, 0.42]

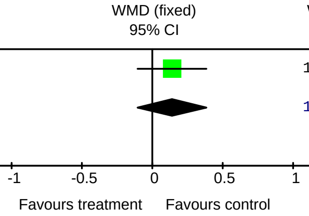
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.34 (P = 0.18)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 03 Change in LDLC mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.18(0.62)	40	-0.32(0.49)	100.00	0.14 [-0.10, 0.38]
Total (95% CI)	40		40		100.00	0.14 [-0.10, 0.38]

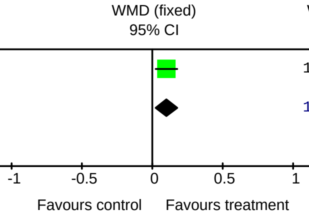
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.12 (P = 0.26)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 04 Change in HDLC mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.09(0.18)	40	-0.01(0.17)	100.00	0.10 [0.02, 0.18]
Total (95% CI)	40		40		100.00	0.10 [0.02, 0.18]

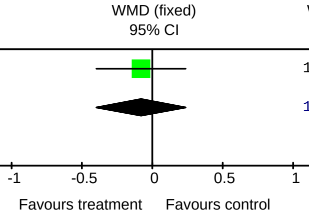
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.55 (P = 0.01)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 05 Change in TG mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.02(0.94)	40	0.06(0.40)	100.00	-0.08 [-0.40, 0.24]
Total (95% CI)	40		40		100.00	-0.08 [-0.40, 0.24]

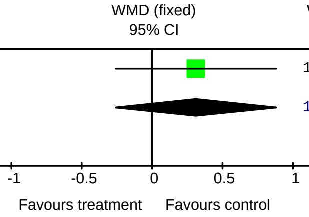
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.50 (P = 0.62)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 06 Change in FPG mmol/l at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.08(0.77)	40	-0.23(1.67)	100.00	0.31 [-0.26, 0.88]
Total (95% CI)	40		40		100.00	0.31 [-0.26, 0.88]

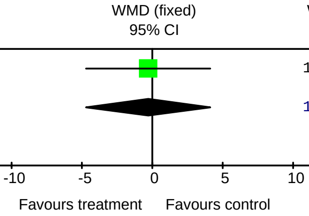
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.07 (P = 0.29)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 07 Change in SBP mmHg at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.20(12.00)	40	0.50(7.70)	100.00	-0.30 [-4.72, 4.12]
Total (95% CI)	40		40		100.00	-0.30 [-4.72, 4.12]

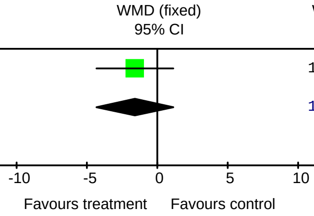
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.13 (P = 0.89)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 08 Change in DBP mmHg at 12 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-1.40(7.50)	40	0.20(4.60)	100.00	-1.60 [-4.33, 1.13]
Total (95% CI)	40		40		100.00	-1.60 [-4.33, 1.13]

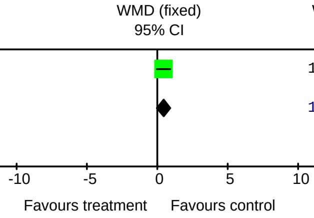
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.15 (P = 0.25)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 09 Change in TC mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.05(1.08)	40	-0.49(1.08)	100.00	0.44 [-0.03, 0.91]
Total (95% CI)	40		40		100.00	0.44 [-0.03, 0.91]

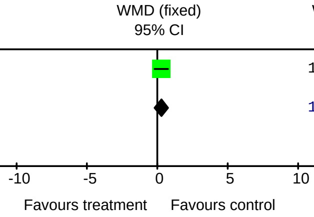
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.82 (P = 0.07)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 10 Change in TC mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.02(1.08)	40	-0.30(1.08)	100.00	0.28 [-0.19, 0.75]
Total (95% CI)	40		40		100.00	0.28 [-0.19, 0.75]

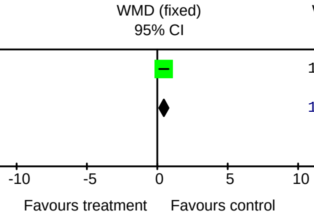
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.16 (P = 0.25)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 11 Change in LDLC mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	0.03(0.74)	40	-0.43(0.74)	100.00	0.46 [0.14, 0.78]
Total (95% CI)	40		40		100.00	0.46 [0.14, 0.78]

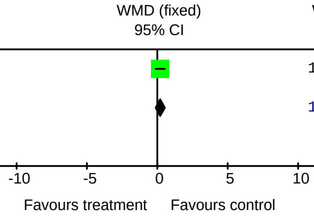
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.78 (P = 0.005)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 12 Change in LDLC mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.07(0.74)	40	-0.27(0.74)	100.00	0.20 [-0.12, 0.52]
Total (95% CI)	40		40		100.00	0.20 [-0.12, 0.52]

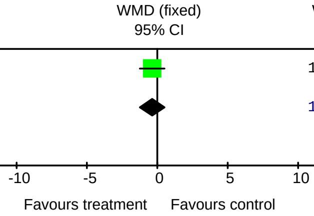
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.21 (P = 0.23)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 13 Change in FPG mmol/l at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.54(1.98)	40	-0.17(1.98)	100.00	-0.37 [-1.24, 0.50]
Total (95% CI)	40		40		100.00	-0.37 [-1.24, 0.50]

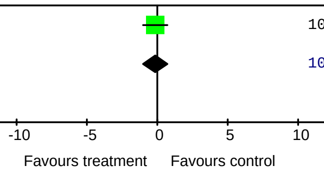
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.84 (P = 0.40)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 14 Change in FPG mmol/l at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-0.43(1.98)	40	-0.28(1.98)		100.00	-0.15 [-1.02, 0.72]
Total (95% CI)	40		40			100.00	-0.15 [-1.02, 0.72]

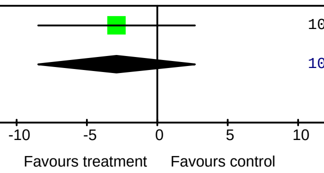
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.34 (P = 0.73)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 15 Change in SBP mmHg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.20(12.70)	40	-1.30(12.70)		100.00	-2.90 [-8.47, 2.67]
Total (95% CI)	40		40			100.00	-2.90 [-8.47, 2.67]

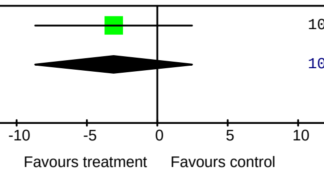
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.02 (P = 0.31)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 16 Change in SBP mmHg at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-3.70(12.70)	40	-0.60(12.70)		100.00	-3.10 [-8.67, 2.47]
Total (95% CI)	40		40			100.00	-3.10 [-8.67, 2.47]

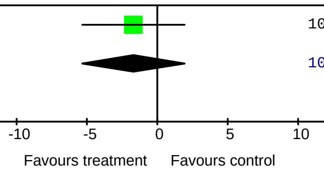
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.09 (P = 0.28)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 17 Change in DBP mmHg at 2 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.20(8.30)	40	-2.50(8.30)		100.00	-1.70 [-5.34, 1.94]
Total (95% CI)	40		40			100.00	-1.70 [-5.34, 1.94]

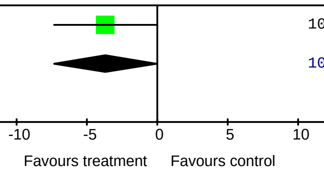
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.92 (P = 0.36)



Review: DIET Analyses for adults
Comparison: 13 PSMF vs very low fat diet
Outcome: 18 Change in DBP mmHg at 6 months

Study or sub-category	N	PSMF Mean (SD)	N	Very low fat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Dansinger 2005	40	-4.00(8.30)	40	-0.30(8.30)		100.00	-3.70 [-7.34, -0.06]
Total (95% CI)	40		40			100.00	-3.70 [-7.34, -0.06]

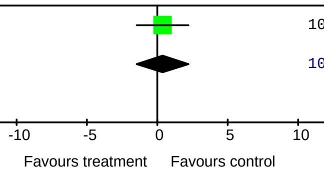
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.99 (P = 0.05)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 01 Weight change in kg at 16 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-8.18(3.02)	22	-8.55(3.10)		100.00	0.37 [-1.46, 2.20]
Total (95% CI)	21		22			100.00	0.37 [-1.46, 2.20]

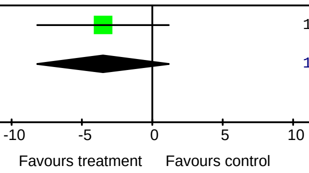
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.40 (P = 0.69)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 02 Weight change in kg at 6 months

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Due 2004	23	-9.40(8.58)	23	-5.90(7.58)		100.00	-3.50 [-8.18, 1.18]
Total (95% CI)	23		23			100.00	-3.50 [-8.18, 1.18]

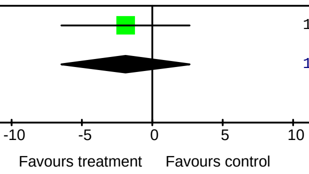
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.47 (P = 0.14)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Due 2004	23	-6.20(7.67)	18	-4.30(7.13)		100.00	-1.90 [-6.45, 2.65]
Total (95% CI)	23		18			100.00	-1.90 [-6.45, 2.65]

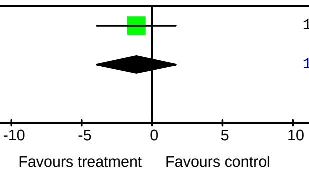
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.82 (P = 0.41)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 04 Weight change in kg at 68 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-3.85(5.60)	22	-2.73(3.53)		100.00	-1.12 [-3.93, 1.69]
Total (95% CI)	21		22			100.00	-1.12 [-3.93, 1.69]

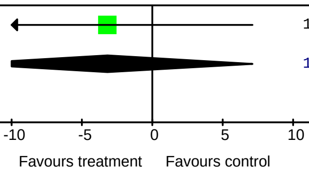
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.78 (P = 0.44)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 05 Weight change in kg at 24 months

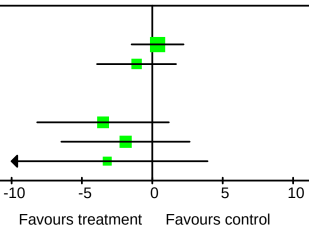
Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Due 2004	3	-6.40(7.73)	6	-3.20(6.82)		100.00	-3.20 [-13.51, 7.11]
Total (95% CI)	3		6			100.00	-3.20 [-13.51, 7.11]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.61 (P = 0.54)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 06 Weight change in kg over time

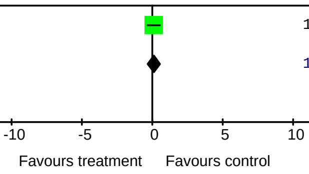
Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Brinkworth 2004							
Brinkworth 16 weeks	21	-8.18(3.02)	22	-8.55(3.10)		70.28	0.37 [-1.46, 2.20]
Brinkworth 68 weeks	21	-3.85(5.60)	22	-2.73(3.53)		29.72	-1.12 [-3.93, 1.69]
02 Due 2004							
Due 6 months	23	-9.40(8.58)	23	-5.90(7.58)		40.14	-3.50 [-8.18, 1.18]
Due 12 months	23	-6.20(7.67)	18	-4.30(7.13)		42.51	-1.90 [-6.45, 2.65]
Due 24 months	11	-6.40(7.73)	6	-3.20(6.82)		17.35	-3.20 [-10.32, 3.92]



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 07 Change in LDLC mmol/l at 16 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-0.20(0.74)	22	-0.30(0.74)		100.00	0.10 [-0.34, 0.54]
Total (95% CI)	21		22			100.00	0.10 [-0.34, 0.54]

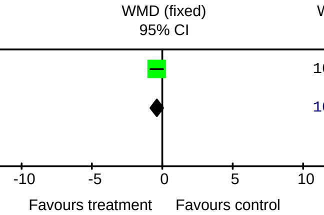
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.44 (P = 0.66)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 08 Change in LDLC mmol/l at 68 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	0.00(0.74)	22	0.40(0.74)	100.00	-0.40 [-0.84, 0.04]
Total (95% CI)	21		22		100.00	-0.40 [-0.84, 0.04]

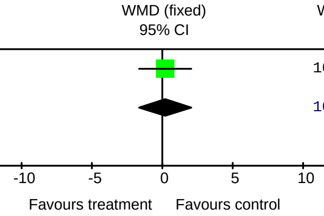
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.77 (P = 0.08)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 09 Change in FPG mmol/l at 16 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	0.10(3.11)	22	-0.10(3.11)	100.00	0.20 [-1.66, 2.06]
Total (95% CI)	21		22		100.00	0.20 [-1.66, 2.06]

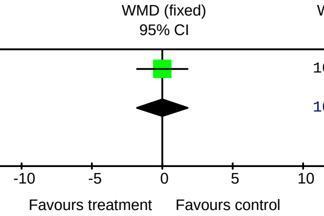
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.21 (P = 0.83)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 10 Change in FPG mmol/l at 6 months

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Due 2004	23	0.00(3.11)	23	0.00(3.11)	100.00	0.00 [-1.80, 1.80]
Total (95% CI)	23		23		100.00	0.00 [-1.80, 1.80]

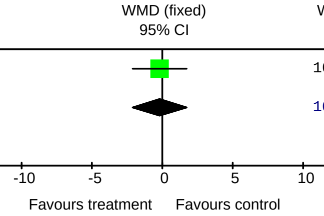
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 11 Change in FPG mmol/l at 12 months

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Due 2004	23	0.10(3.11)	18	0.30(3.11)	100.00	-0.20 [-2.12, 1.72]
Total (95% CI)	23		18		100.00	-0.20 [-2.12, 1.72]

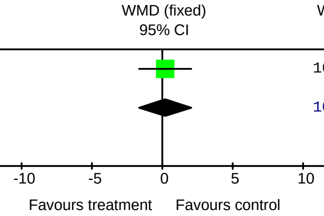
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.20 (P = 0.84)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 12 Change in FPG mmol/l at 68 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	0.30(3.11)	22	0.10(3.11)	100.00	0.20 [-1.66, 2.06]
Total (95% CI)	21		22		100.00	0.20 [-1.66, 2.06]

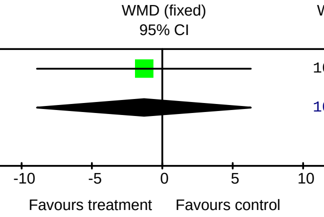
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.21 (P = 0.83)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 13 Change in SBP mmHg at 16 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-4.90(12.70)	22	-3.60(12.70)	100.00	-1.30 [-8.89, 6.29]
Total (95% CI)	21		22		100.00	-1.30 [-8.89, 6.29]

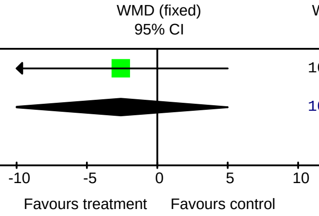
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.34 (P = 0.74)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 14 Change in SBP mmHg at 68 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-3.20(12.70)	22	-0.60(12.70)	100.00	-2.60 [-10.19, 4.99]
Total (95% CI)	21		22		100.00	-2.60 [-10.19, 4.99]

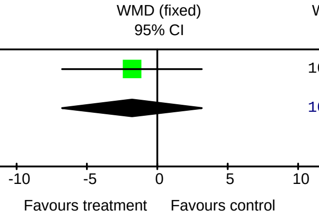
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.67 (P = 0.50)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 15 Change in DBP mmHg at 16 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-2.70(8.30)	22	-0.90(8.30)	100.00	-1.80 [-6.76, 3.16]
Total (95% CI)	21		22		100.00	-1.80 [-6.76, 3.16]

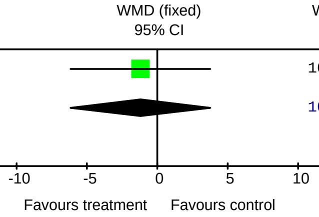
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.71 (P = 0.48)



Review: DIET Analyses for adults
Comparison: 14 High protein diet vs standard-medium protein diet
Outcome: 16 Change in DBP mmHg at 68 weeks

Study or sub-category	N	HP Mean (SD)	N	SP Mean (SD)	Weight %	WMD (fixed) 95% CI
Brinkworth 2004	21	-2.40(8.30)	22	-1.20(8.30)	100.00	-1.20 [-6.16, 3.76]
Total (95% CI)	21		22		100.00	-1.20 [-6.16, 3.76]

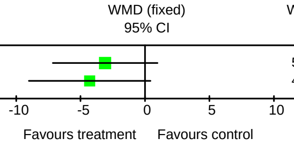
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.47 (P = 0.64)



3.2 *Behavioural interventions*

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 01 Diet and BT vs usual care
Outcome: 01 Weight change over time

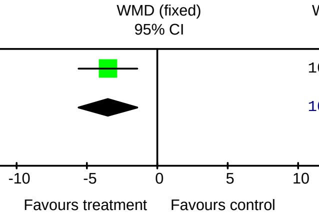
Study or sub-category	N	Diet and BT Mean (SD)	N	Usual care Mean (SD)	Weight %	WMD (fixed) 95% CI
Munsch 2003 16 weeks	41	-3.80(6.99)	12	-0.70(6.11)	57.40	-3.10 [-7.17, 0.97]
Munsch 2003 12months	41	-4.70(7.25)	8	-0.40(6.01)	42.60	-4.30 [-9.02, 0.42]



Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 02 Diet and BT vs information
Outcome: 01 Weight change in kg at 18 months

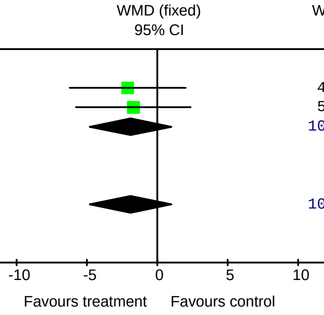
Study or sub-category	N	Diet and BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Messier 2004	82	-4.61(7.22)	78	-1.10(6.23)	100.00	-3.51 [-5.60, -1.42]
Total (95% CI)	82		78		100.00	-3.51 [-5.60, -1.42]

Test for heterogeneity: not applicable
Test for overall effect: Z = 3.30 (P = 0.0010)



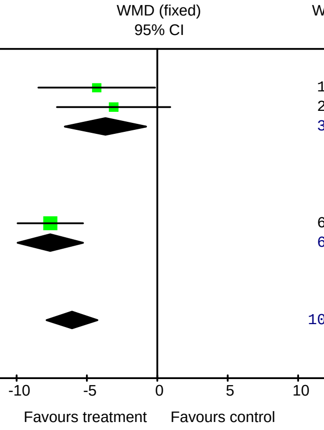
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 01 Weight change in kg at 3 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Cousin FAM	27	-3.00(6.76)	14	-0.90(6.17)	49.42	-2.10 [-6.22, 2.02]
Cousins IND	32	-2.60(6.65)	13	-0.90(6.17)	50.58	-1.70 [-5.77, 2.37]
Subtotal (95% CI)	59		27		100.00	-1.90 [-4.79, 1.00]
Test for heterogeneity: Chi² = 0.02, df = 1 (P = 0.89), I² = 0%						
Test for overall effect: Z = 1.29 (P = 0.20)						
Total (95% CI)	59		27		100.00	-1.90 [-4.79, 1.00]
Test for heterogeneity: Chi² = 0.02, df = 1 (P = 0.89), I² = 0%						
Test for overall effect: Z = 1.29 (P = 0.20)						



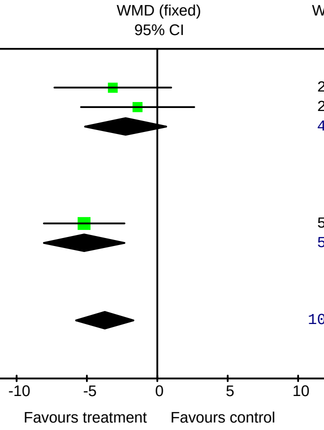
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 02 Weight change in kg at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Cousin FAM	27	-4.50(7.19)	14	-0.20(5.97)	19.05	-4.30 [-8.44, -0.16]
Cousins IND	32	-3.30(6.85)	13	-0.20(5.97)	20.19	-3.10 [-7.12, 0.92]
Subtotal (95% CI)	59		27		39.24	-3.68 [-6.57, -0.80]
Test for heterogeneity: Chi² = 0.17, df = 1 (P = 0.68), I² = 0%						
Test for overall effect: Z = 2.50 (P = 0.01)						
02 VLCD						
Wing 1998	35	-9.10(6.40)	32	-1.50(2.70)	60.76	-7.60 [-9.92, -5.28]
Subtotal (95% CI)	35		32		60.76	-7.60 [-9.92, -5.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 6.43 (P < 0.00001)						
Total (95% CI)	94		59		100.00	-6.06 [-7.87, -4.26]
Test for heterogeneity: Chi² = 4.47, df = 2 (P = 0.11), I² = 55.3%						
Test for overall effect: Z = 6.58 (P < 0.00001)						



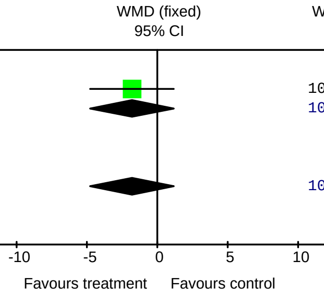
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Cousin FAM	27	-3.86(6.99)	14	-0.70(6.11)	24.05	-3.16 [-7.31, 0.99]
Cousins IND	32	-2.10(6.51)	13	-0.70(6.11)	25.66	-1.40 [-5.41, 2.61]
Subtotal (95% CI)	59		27		49.71	-2.25 [-5.14, 0.63]
Test for heterogeneity: Chi² = 0.36, df = 1 (P = 0.55), I² = 0%						
Test for overall effect: Z = 1.53 (P = 0.13)						
02 VLCD						
Wing 1998	33	-5.50(6.90)	29	-0.30(4.50)	50.29	-5.20 [-8.07, -2.33]
Subtotal (95% CI)	33		29		50.29	-5.20 [-8.07, -2.33]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.55 (P = 0.0004)						
Total (95% CI)	92		56		100.00	-3.73 [-5.77, -1.70]
Test for heterogeneity: Chi² = 2.38, df = 2 (P = 0.30), I² = 15.8%						
Test for overall effect: Z = 3.60 (P = 0.0003)						



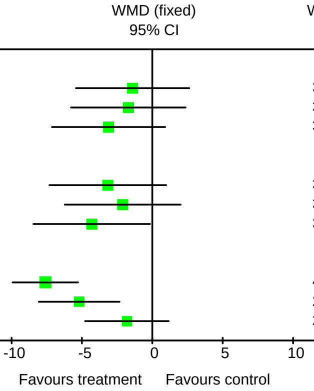
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 04 Weight change in kg at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-2.10(7.60)	31	-0.30(4.50)	100.00	-1.80 [-4.77, 1.17]
Subtotal (95% CI)	35		31		100.00	-1.80 [-4.77, 1.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.19 (P = 0.24)						
Total (95% CI)	35		31		100.00	-1.80 [-4.77, 1.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.19 (P = 0.24)						



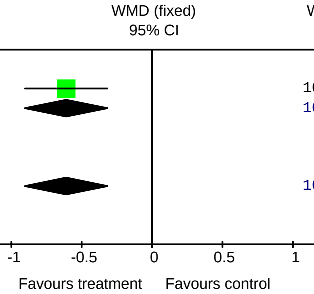
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 05 Weight change over time

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD Individual						
Cousins IND 12months	32	-2.10(6.51)	13	-0.70(6.11)	33.66	-1.40 [-5.41, 2.61]
Cousins IND 3 months	32	-2.60(6.65)	13	-0.90(6.17)	32.77	-1.70 [-5.77, 2.37]
Cousins IND 6 months	32	-3.30(6.85)	13	-0.20(5.97)	33.57	-3.10 [-7.12, 0.92]
02 LCD Family						
Cousins FAM 12months	27	-3.86(6.99)	14	-0.70(6.11)	33.13	-3.16 [-7.31, 0.99]
Cousins FAM 3 months	27	-3.00(6.76)	14	-0.90(6.17)	33.62	-2.10 [-6.22, 2.02]
Cousins FAM 6 months	27	-4.50(7.19)	14	-0.20(5.97)	33.25	-4.30 [-8.44, -0.16]
03 VLCD						
Wing 1998 6 months	35	-9.10(6.40)	32	-1.50(2.70)	44.25	-7.60 [-9.92, -5.28]
Wing 1998 12 months	33	-5.50(6.90)	29	-0.30(4.50)	28.89	-5.20 [-8.07, -2.33]
Wing 1998 24 months	35	-2.10(7.60)	31	-0.30(4.50)	26.86	-1.80 [-4.77, 1.17]



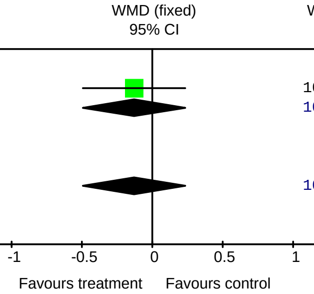
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 06 Change in TC mmol/l at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.49(0.71)	32	0.12(0.50)	100.00	-0.61 [-0.90, -0.32]
Subtotal (95% CI)	35		32		100.00	-0.61 [-0.90, -0.32]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.09 (P < 0.0001)						
Total (95% CI)	35		32		100.00	-0.61 [-0.90, -0.32]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.09 (P < 0.0001)						



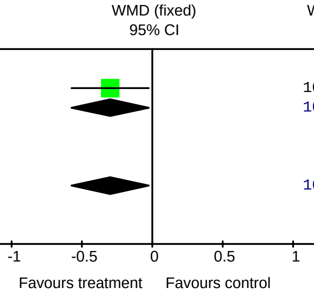
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 07 Change in TC mmol/l at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	33	0.26(0.76)	29	0.39(0.70)	100.00	-0.13 [-0.49, 0.23]
Subtotal (95% CI)	33		29		100.00	-0.13 [-0.49, 0.23]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						
Total (95% CI)	33		29		100.00	-0.13 [-0.49, 0.23]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						



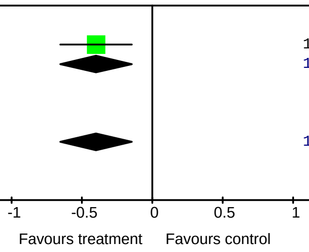
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 08 Change in TC mmol/l at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.12(0.61)	31	0.18(0.53)	100.00	-0.30 [-0.58, -0.02]
Subtotal (95% CI)	35		31		100.00	-0.30 [-0.58, -0.02]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.14 (P = 0.03)						
Total (95% CI)	35		31		100.00	-0.30 [-0.58, -0.02]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.14 (P = 0.03)						



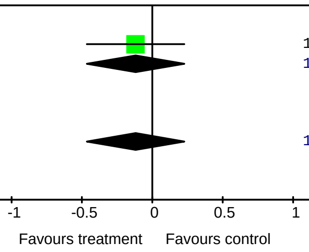
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 09 Change in LDLC mmol/l at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.32(0.60)	32	0.08(0.46)	100.00	-0.40 [-0.65, -0.15]
Subtotal (95% CI)	35		32		100.00	-0.40 [-0.65, -0.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.08 (P = 0.002)						
Total (95% CI)	35		32		100.00	-0.40 [-0.65, -0.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.08 (P = 0.002)						



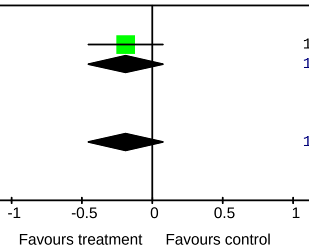
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 10 Change in LDLC mmol/l at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	33	0.12(0.73)	29	0.24(0.66)	100.00	-0.12 [-0.47, 0.23]
Subtotal (95% CI)	33		29		100.00	-0.12 [-0.47, 0.23]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.68 (P = 0.50)						
Total (95% CI)	33		29		100.00	-0.12 [-0.47, 0.23]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.68 (P = 0.50)						



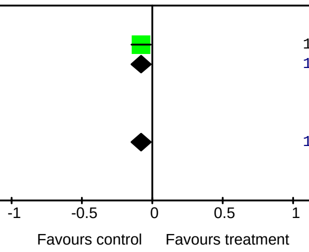
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 11 Change in LDLC mmol/l at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.16(0.63)	31	0.03(0.46)	100.00	-0.19 [-0.45, 0.07]
Subtotal (95% CI)	35		31		100.00	-0.19 [-0.45, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.41 (P = 0.16)						
Total (95% CI)	35		31		100.00	-0.19 [-0.45, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.41 (P = 0.16)						



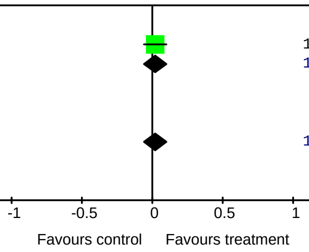
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 12 Change in HDLC mmol/l at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.10(0.17)	32	-0.02(0.11)	100.00	-0.08 [-0.15, -0.01]
Subtotal (95% CI)	35		32		100.00	-0.08 [-0.15, -0.01]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.31 (P = 0.02)						
Total (95% CI)	35		32		100.00	-0.08 [-0.15, -0.01]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.31 (P = 0.02)						



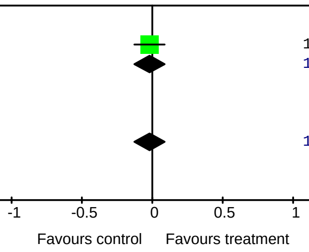
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 13 Change in HDLC mmol/l at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	33	0.10(0.16)	29	0.08(0.16)	100.00	0.02 [-0.06, 0.10]
Subtotal (95% CI)	33		29		100.00	0.02 [-0.06, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.49 (P = 0.62)						
Total (95% CI)	33		29		100.00	0.02 [-0.06, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.49 (P = 0.62)						



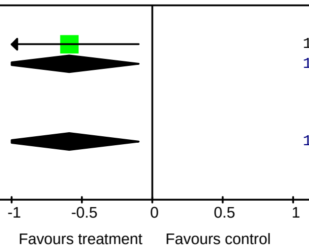
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 14 Change in HDLC mmol/l at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	35	0.02(0.20)	31	0.04(0.24)		100.00	-0.02 [-0.13, 0.09]
Subtotal (95% CI)	35		31			100.00	-0.02 [-0.13, 0.09]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.37 (P = 0.72)							
Total (95% CI)	35		31			100.00	-0.02 [-0.13, 0.09]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.37 (P = 0.72)							



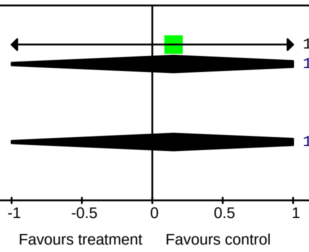
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 15 Change in TG mmol/l at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	35	-0.30(1.45)	32	0.29(0.32)		100.00	-0.59 [-1.08, -0.10]
Subtotal (95% CI)	35		32			100.00	-0.59 [-1.08, -0.10]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.35 (P = 0.02)							
Total (95% CI)	35		32			100.00	-0.59 [-1.08, -0.10]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.35 (P = 0.02)							



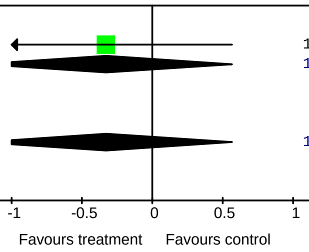
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 16 Change in TG mmol/l at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	33	0.55(3.77)	29	0.40(1.25)		100.00	0.15 [-1.21, 1.51]
Subtotal (95% CI)	33		29			100.00	0.15 [-1.21, 1.51]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.22 (P = 0.83)							
Total (95% CI)	33		29			100.00	0.15 [-1.21, 1.51]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.22 (P = 0.83)							



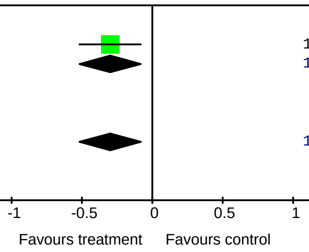
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 17 Change in TG mmol/l at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	35	0.19(2.42)	31	0.52(1.14)		100.00	-0.33 [-1.23, 0.57]
Subtotal (95% CI)	35		31			100.00	-0.33 [-1.23, 0.57]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.72 (P = 0.47)							
Total (95% CI)	35		31			100.00	-0.33 [-1.23, 0.57]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.72 (P = 0.47)							



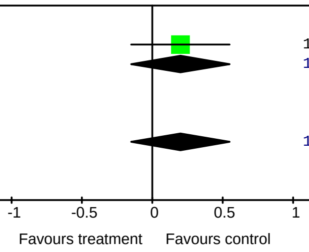
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 18 Change in FPG mmol/l at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	35	-0.20(0.40)	32	0.10(0.50)		100.00	-0.30 [-0.52, -0.08]
Subtotal (95% CI)	35		32			100.00	-0.30 [-0.52, -0.08]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.70 (P = 0.007)							
Total (95% CI)	35		32			100.00	-0.30 [-0.52, -0.08]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.70 (P = 0.007)							



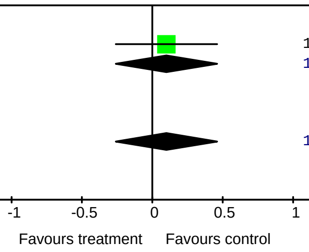
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 19 Change in FPG mmol/l at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	33	0.20(0.80)	29	0.00(0.60)	100.00	0.20 [-0.15, 0.55]
Subtotal (95% CI)	33		29		100.00	0.20 [-0.15, 0.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.12 (P = 0.26)						
Total (95% CI)	33		29		100.00	0.20 [-0.15, 0.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.12 (P = 0.26)						



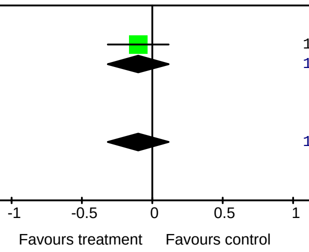
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 20 Change in FPG mmol/l at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	0.30(1.00)	31	0.20(0.40)	100.00	0.10 [-0.26, 0.46]
Subtotal (95% CI)	35		31		100.00	0.10 [-0.26, 0.46]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.54 (P = 0.59)						
Total (95% CI)	35		31		100.00	0.10 [-0.26, 0.46]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.54 (P = 0.59)						



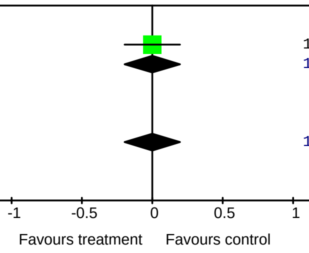
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 21 Change in %HbA1c at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	0.10(0.50)	32	0.20(0.40)	100.00	-0.10 [-0.32, 0.12]
Subtotal (95% CI)	35		32		100.00	-0.10 [-0.32, 0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.91 (P = 0.36)						
Total (95% CI)	35		32		100.00	-0.10 [-0.32, 0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.91 (P = 0.36)						



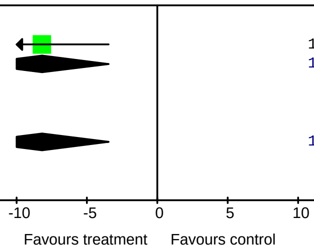
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 22 Change in %HbA1c at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.10(0.50)	31	-0.10(0.30)	100.00	0.00 [-0.20, 0.20]
Subtotal (95% CI)	35		31		100.00	0.00 [-0.20, 0.20]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	35		31		100.00	0.00 [-0.20, 0.20]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						



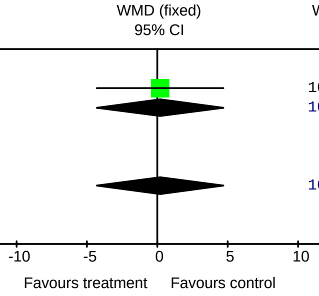
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 23 Change in SBP mmHg at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-10.20(9.20)	32	-2.00(10.50)	100.00	-8.20 [-12.95, -3.45]
Subtotal (95% CI)	35		32		100.00	-8.20 [-12.95, -3.45]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.39 (P = 0.0007)						
Total (95% CI)	35		32		100.00	-8.20 [-12.95, -3.45]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.39 (P = 0.0007)						



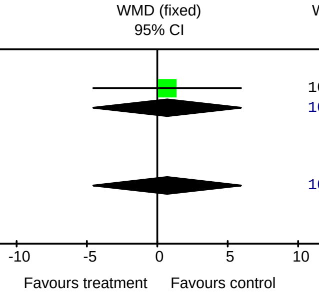
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 24 Change in SBP mmHg at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
02 VLCD						
Wing 1998	33	1.30(8.30)	29	1.10(9.60)	100.00	0.20 [-4.30, 4.70]
Subtotal (95% CI)	33		29		100.00	0.20 [-4.30, 4.70]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.09 (P = 0.93)						
Total (95% CI)	33		29		100.00	0.20 [-4.30, 4.70]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.09 (P = 0.93)						



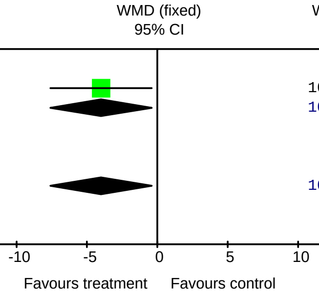
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 25 Change in SBP mmHg at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-0.80(9.40)	31	-1.50(12.00)	100.00	0.70 [-4.55, 5.95]
Subtotal (95% CI)	35		31		100.00	0.70 [-4.55, 5.95]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.26 (P = 0.79)						
Total (95% CI)	35		31		100.00	0.70 [-4.55, 5.95]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.26 (P = 0.79)						



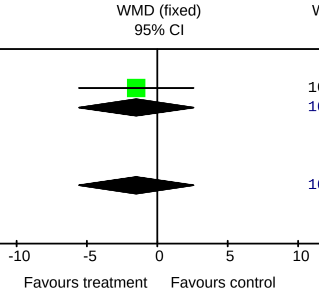
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 26 Change in DBP mmHg at 6 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	-6.20(6.90)	32	-2.20(8.00)	100.00	-4.00 [-7.59, -0.41]
Subtotal (95% CI)	35		32		100.00	-4.00 [-7.59, -0.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.18 (P = 0.03)						
Total (95% CI)	35		32		100.00	-4.00 [-7.59, -0.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.18 (P = 0.03)						



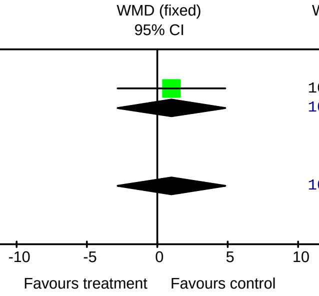
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 27 Change in DBP mmHg at 12 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	33	3.40(8.10)	29	4.90(8.20)	100.00	-1.50 [-5.57, 2.57]
Subtotal (95% CI)	33		29		100.00	-1.50 [-5.57, 2.57]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						
Total (95% CI)	33		29		100.00	-1.50 [-5.57, 2.57]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						

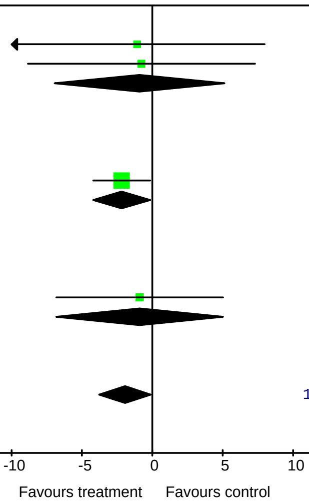


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 03 Active diet and BT vs passive (information only) diet and BT
Outcome: 28 Change in DBP mmHg at 24 months

Study or sub-category	N	Active diet and BT Mean (SD)	N	Passive diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	35	3.00(7.80)	31	2.00(8.00)	100.00	1.00 [-2.82, 4.82]
Subtotal (95% CI)	35		31		100.00	1.00 [-2.82, 4.82]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.51 (P = 0.61)						
Total (95% CI)	35		31		100.00	1.00 [-2.82, 4.82]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.51 (P = 0.61)						

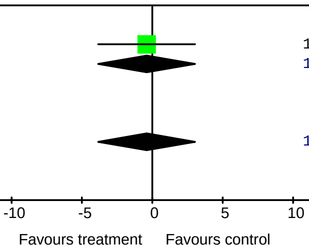


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 01 Weight change in kg at 10 weeks



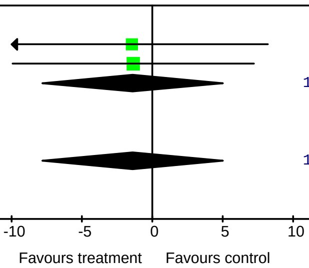
Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Murphy 1982 a	5	-8.16(8.23)	8	-7.08(7.92)	4.06	-1.08 [-10.14, 7.98]
Murphy 1982 b	8	-7.62(8.07)	7	-6.85(7.85)	5.12	-0.77 [-8.84, 7.30]
Subtotal (95% CI)	13		15		9.18	-0.91 [-6.93, 5.12]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.96), I² = 0%						
Test for overall effect: Z = 0.29 (P = 0.77)						
02 LCD, BT, and PA if no weight loss						
Pearce 1981	14	-6.50(2.91)	13	-4.32(2.45)	81.34	-2.18 [-4.20, -0.16]
Subtotal (95% CI)	14		13		81.34	-2.18 [-4.20, -0.16]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.11 (P = 0.03)						
03 Behavioural contracts						
Black 1984	11	-4.61(7.22)	11	-3.71(6.96)	9.49	-0.90 [-6.83, 5.03]
Subtotal (95% CI)	11		11		9.49	-0.90 [-6.83, 5.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.30 (P = 0.77)						
Total (95% CI)	38		39		100.00	-1.94 [-3.77, -0.12]
Test for heterogeneity: Chi² = 0.29, df = 3 (P = 0.96), I² = 0%						
Test for overall effect: Z = 2.08 (P = 0.04)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 02 Weight change in kg at 12 weeks (3 months)



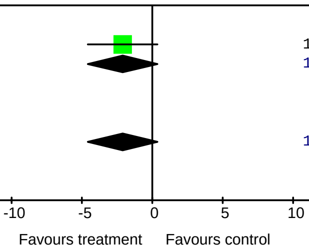
Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Cousins 1992	27	-3.00(6.76)	32	-2.60(6.65)	100.00	-0.40 [-3.84, 3.04]
Subtotal (95% CI)	27		32		100.00	-0.40 [-3.84, 3.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.23 (P = 0.82)						
Total (95% CI)	27		32		100.00	-0.40 [-3.84, 3.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.23 (P = 0.82)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 03 Weight change in kg at 15 weeks



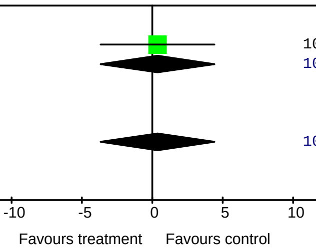
Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Murphy 1982 a	5	-9.43(8.59)	7	-7.98(8.17)	44.02	-1.45 [-11.11, 8.21]
Murphy 1982 b	8	-9.66(8.65)	7	-8.30(8.26)	55.98	-1.36 [-9.93, 7.21]
Subtotal (95% CI)	13		14		100.00	-1.40 [-7.81, 5.01]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.99), I² = 0%						
Test for overall effect: Z = 0.43 (P = 0.67)						
Total (95% CI)	13		14		100.00	-1.40 [-7.81, 5.01]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.99), I² = 0%						
Test for overall effect: Z = 0.43 (P = 0.67)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 04 Weight change in kg at 16 weeks (4 months)



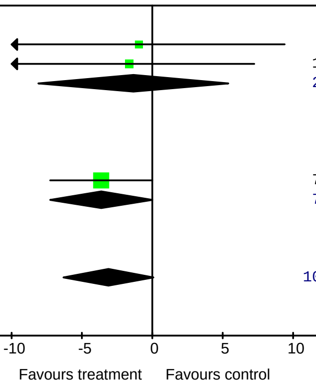
Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1999	80	-8.80(8.41)	86	-6.70(7.81)	100.00	-2.10 [-4.57, 0.37]
Subtotal (95% CI)	80		86		100.00	-2.10 [-4.57, 0.37]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.66 (P = 0.10)						
Total (95% CI)	80		86		100.00	-2.10 [-4.57, 0.37]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.66 (P = 0.10)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 05 Weight change in kg at 20 weeks



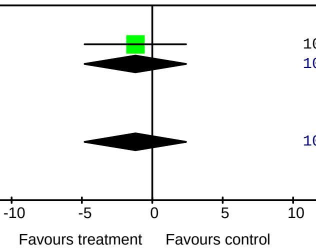
Study or sub-category	Family N	Family Mean (SD)	Individual N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1991 b	20	-8.66(5.08)	23	-9.03(8.26)	100.00	0.37 [-3.67, 4.41]
Subtotal (95% CI)	20		23		100.00	0.37 [-3.67, 4.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.18 (P = 0.86)						
Total (95% CI)	20		23		100.00	0.37 [-3.67, 4.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.18 (P = 0.86)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 06 Weight change in kg at 22 weeks



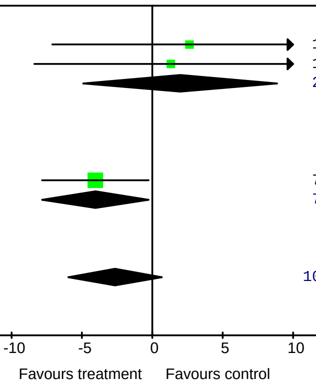
Study or sub-category	Family N	Family Mean (SD)	Individual N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Murphy 1982 a	5	-10.34(8.84)	6	-9.39(8.57)	9.52	-0.95 [-11.30, 9.40]
Murphy 1982 b	8	-10.89(9.00)	7	-9.25(8.53)	12.93	-1.64 [-10.52, 7.24]
Subtotal (95% CI)	13		13		22.45	-1.35 [-8.09, 5.39]
Test for heterogeneity: Chi² = 0.01, df = 1 (P = 0.92), I² = 0%						
Test for overall effect: Z = 0.39 (P = 0.70)						
02 LCD, BT, and PA if no weight loss						
Pearce 1981	12	-8.18(4.74)	12	-4.55(4.31)	77.55	-3.63 [-7.25, -0.01]
Subtotal (95% CI)	12		12		77.55	-3.63 [-7.25, -0.01]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.96 (P = 0.05)						
Total (95% CI)	25		25		100.00	-3.12 [-6.31, 0.07]
Test for heterogeneity: Chi² = 0.35, df = 2 (P = 0.84), I² = 0%						
Test for overall effect: Z = 1.91 (P = 0.06)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 07 Weight change in kg at 26 weeks (6 months)



Study or sub-category	Family N	Family Mean (SD)	Individual N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Cousins 1992	27	-4.50(7.19)	32	-3.30(6.85)	100.00	-1.20 [-4.80, 2.40]
Subtotal (95% CI)	27		32		100.00	-1.20 [-4.80, 2.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.65 (P = 0.51)						
Total (95% CI)	27		32		100.00	-1.20 [-4.80, 2.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.65 (P = 0.51)						

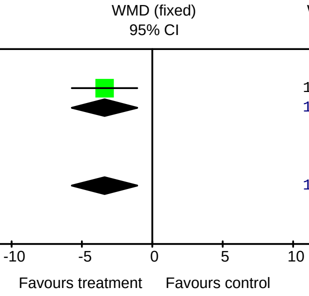
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 08 Weight change in kg at 36 weeks



Study or sub-category	Family N	Family Mean (SD)	Individual N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Murphy 1982 a	5	-6.89(7.87)	6	-9.53(8.61)	11.60	2.64 [-7.11, 12.39]
Murphy 1982 b	7	-8.21(8.24)	5	-9.53(8.61)	11.70	1.32 [-8.39, 11.03]
Subtotal (95% CI)	12		11		23.30	1.98 [-4.90, 8.86]
Test for heterogeneity: Chi² = 0.04, df = 1 (P = 0.85), I² = 0%						
Test for overall effect: Z = 0.56 (P = 0.57)						
02 LCD, BT, and PA if no weight loss						
Pearce 1981	12	-7.47(5.08)	12	-3.42(4.37)	76.70	-4.05 [-7.84, -0.26]
Subtotal (95% CI)	12		12		76.70	-4.05 [-7.84, -0.26]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.09 (P = 0.04)						
Total (95% CI)	24		23		100.00	-2.65 [-5.97, 0.67]
Test for heterogeneity: Chi² = 2.30, df = 2 (P = 0.32), I² = 12.9%						
Test for overall effect: Z = 1.56 (P = 0.12)						

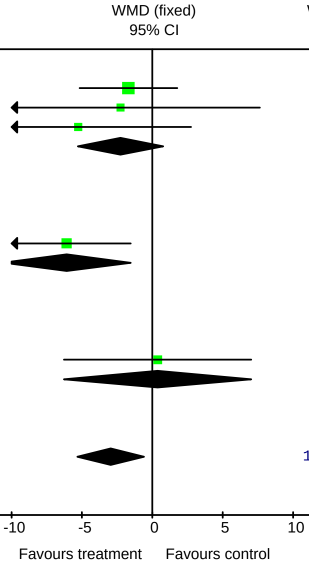
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 09 Weight change in kg at 40 weeks (10 months)

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1999	80	-7.70(8.09)	86	-4.30(7.13)	100.00	-3.40 [-5.73, -1.07]
Subtotal (95% CI)	80		86		100.00	-3.40 [-5.73, -1.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.86 (P = 0.004)						
Total (95% CI)	80		86		100.00	-3.40 [-5.73, -1.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.86 (P = 0.004)						



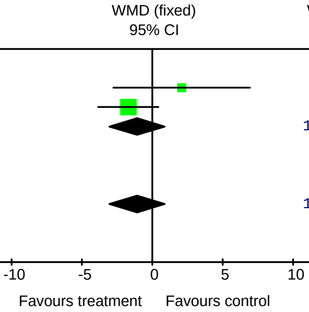
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 10 Weight change in kg at 52 weeks (12 months)

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Cousins 1992	27	-3.80(6.99)	32	-2.10(6.51)	46.20	-1.70 [-5.17, 1.77]
Murphy 1982 a	4	-5.44(7.46)	4	-3.18(6.81)	5.68	-2.26 [-12.16, 7.64]
Murphy 1982 b	8	-8.75(8.39)	6	-3.49(6.90)	8.65	-5.26 [-13.28, 2.76]
Subtotal (95% CI)	39		42		60.53	-2.26 [-5.29, 0.77]
Test for heterogeneity: Chi² = 0.64, df = 2 (P = 0.73), I² = 0%						
Test for overall effect: Z = 1.46 (P = 0.14)						
02 LCD, BT, and PA if no weight loss						
Pearce 1981	12	-8.25(5.38)	12	-2.16(5.97)	26.90	-6.09 [-10.64, -1.54]
Subtotal (95% CI)	12		12		26.90	-6.09 [-10.64, -1.54]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.63 (P = 0.009)						
03 Behavioural contracts						
Black 1984	11	-7.04(7.91)	11	-7.42(8.01)	12.57	0.38 [-6.27, 7.03]
Subtotal (95% CI)	11		11		12.57	0.38 [-6.27, 7.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.11 (P = 0.91)						
Total (95% CI)	62		65		100.00	-2.96 [-5.32, -0.60]
Test for heterogeneity: Chi² = 3.63, df = 4 (P = 0.46), I² = 0%						
Test for overall effect: Z = 2.46 (P = 0.01)						



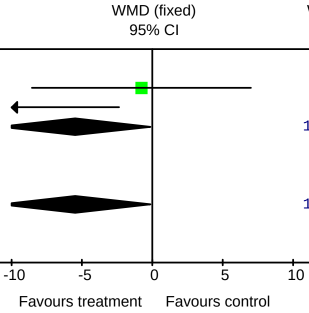
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 11 Weight change in kg at 18 months

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1991 b	20	-3.18(5.31)	23	-5.26(10.39)	16.30	2.08 [-2.76, 6.92]
Wing 1999	80	-4.70(7.25)	86	-3.00(6.76)	83.70	-1.70 [-3.84, 0.44]
Subtotal (95% CI)	100		109		100.00	-1.08 [-3.04, 0.87]
Test for heterogeneity: Chi² = 1.96, df = 1 (P = 0.16), I² = 49.0%						
Test for overall effect: Z = 1.09 (P = 0.28)						
Total (95% CI)	100		109		100.00	-1.08 [-3.04, 0.87]
Test for heterogeneity: Chi² = 1.96, df = 1 (P = 0.16), I² = 49.0%						
Test for overall effect: Z = 1.09 (P = 0.28)						



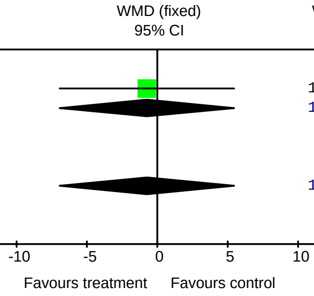
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 12 Weight change in kg at 24 months

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Murphy 1982 a	5	-3.36(6.86)	7	-2.59(6.65)	47.44	-0.77 [-8.54, 7.00]
Murphy 1982 b	8	-7.21(7.96)	7	2.54(6.63)	52.56	-9.75 [-17.14, -2.36]
Subtotal (95% CI)	13		14		100.00	-5.49 [-10.84, -0.14]
Test for heterogeneity: Chi² = 2.69, df = 1 (P = 0.10), I² = 62.9%						
Test for overall effect: Z = 2.01 (P = 0.04)						
Total (95% CI)	13		14		100.00	-5.49 [-10.84, -0.14]
Test for heterogeneity: Chi² = 2.69, df = 1 (P = 0.10), I² = 62.9%						
Test for overall effect: Z = 2.01 (P = 0.04)						



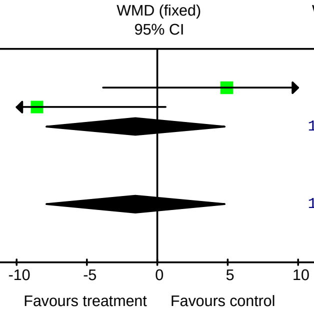
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 13 Weight change in kg at 43 months

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight loss programme and BT						
Rosenthal 1980	11	-4.37(7.15)	9	-3.62(6.94)	100.00	-0.75 [-6.95, 5.45]
Subtotal (95% CI)	11		9		100.00	-0.75 [-6.95, 5.45]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.24 (P = 0.81)						
Total (95% CI)	11		9		100.00	-0.75 [-6.95, 5.45]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.24 (P = 0.81)						



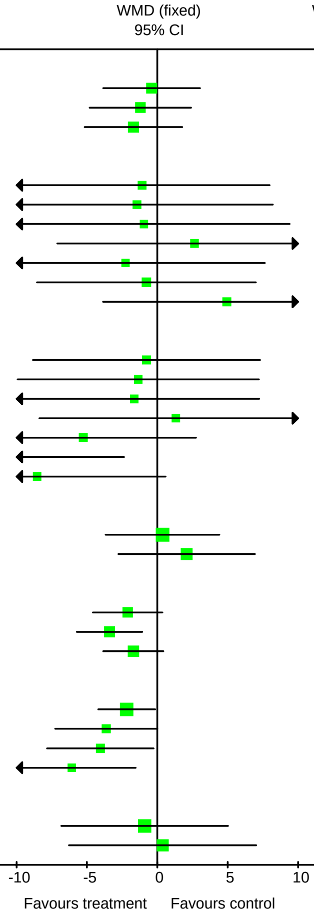
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 14 Weight change in kg at 48 months

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Murphy 1982 a	5	0.73(6.12)	4	-4.20(7.10)	51.91	4.93 [-3.86, 13.72]
Murphy 1982 b	6	-2.87(6.73)	4	5.67(7.52)	48.09	-8.54 [-17.67, 0.59]
Subtotal (95% CI)	11		8		100.00	-1.55 [-7.88, 4.78]
Test for heterogeneity: Chi² = 4.34, df = 1 (P = 0.04), I² = 77.0%						
Test for overall effect: Z = 0.48 (P = 0.63)						
Total (95% CI)	11		8		100.00	-1.55 [-7.88, 4.78]
Test for heterogeneity: Chi² = 4.34, df = 1 (P = 0.04), I² = 77.0%						
Test for overall effect: Z = 0.48 (P = 0.63)						



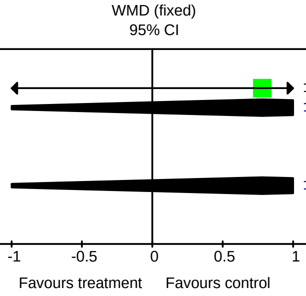
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 15 Weight change over time

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA Cousins						
Cousins 1992 12weeks	27	-3.00(6.76)	32	-2.60(6.65)	34.60	-0.40 [-3.84, 3.04]
Cousins 1992 26weeks	27	-4.50(7.19)	32	-3.30(6.85)	31.46	-1.20 [-4.80, 2.40]
Cousins 1992 12month	27	-3.80(6.99)	32	-2.10(6.51)	33.94	-1.70 [-5.17, 1.77]
02 LCD, BT, and PA Murphy 1991 a						
Murphy a 10 weeks	5	-8.16(8.23)	8	-7.08(7.92)	14.76	-1.08 [-10.14, 7.98]
Murphy a 15 weeks	5	-9.43(8.59)	7	-7.98(8.17)	13.00	-1.45 [-11.11, 8.21]
Murphy a 22 weeks	5	-10.34(8.84)	6	-9.39(8.57)	11.33	-0.95 [-11.30, 9.40]
Murphy a 36 weeks	5	-6.89(7.87)	6	-9.53(8.61)	12.76	2.64 [-7.11, 12.39]
Murphy a 12 months	4	-5.44(7.46)	4	-3.18(6.81)	12.38	-2.26 [-12.16, 7.64]
Murphy a 24 months	5	-3.36(6.86)	7	-2.59(6.65)	20.07	-0.77 [-8.54, 7.00]
Murphy a 48 months	5	0.73(6.12)	4	-4.20(7.10)	15.71	4.93 [-3.86, 13.72]
03 LCD, BT, and PA Murphy 1991 b						
Murphy b 10 weeks	8	-7.62(8.07)	7	-6.85(7.85)	15.65	-0.77 [-8.84, 7.30]
Murphy b 15 weeks	8	-9.66(8.65)	7	-8.30(8.26)	13.88	-1.36 [-9.93, 7.21]
Murphy b 22 weeks	8	-10.89(9.00)	7	-9.25(8.53)	12.92	-1.64 [-10.52, 7.24]
Murphy b 36 weeks	7	-8.21(8.24)	5	-9.53(8.61)	10.81	1.32 [-8.39, 11.03]
Murphy b 12 months	8	-8.75(8.39)	6	-3.49(6.90)	15.84	-5.26 [-13.28, 2.76]
Murphy b 24 months	8	-7.21(7.96)	7	2.54(6.63)	18.67	-9.75 [-17.14, -2.36]
Murphy b 48 months	6	-2.87(6.73)	4	5.67(7.52)	12.23	-8.54 [-17.67, 0.59]
04 LCD, BT, and PA Wing 1991 b						
Wing 1991 b 20 weeks	20	-8.66(5.08)	23	-9.03(8.26)	58.91	0.37 [-3.67, 4.41]
Wing 1991 b 18months	20	-3.18(5.31)	23	-5.26(10.39)	41.09	2.08 [-2.76, 6.92]
05 LCD, BT, and PA Wing 1999						
Wing 1999 16 weeks	80	-8.80(8.41)	86	-6.70(7.81)	28.81	-2.10 [-4.57, 0.37]
Wing 1999 40 weeks	80	-7.70(8.09)	86	-4.30(7.13)	32.57	-3.40 [-5.73, -1.07]
Wing 1999 18 months	80	-4.70(7.25)	86	-3.00(6.76)	38.62	-1.70 [-3.84, 0.44]
06 LCD, BT, and PA if no weight loss						
Pearce 1981 10 weeks	14	-6.50(2.91)	13	-4.32(2.45)	55.71	-2.18 [-4.20, -0.16]
Pearce 1981 22 weeks	12	-8.18(4.74)	12	-4.55(4.31)	17.37	-3.63 [-7.25, -0.01]
Pearce 1981 36 weeks	12	-7.47(5.08)	12	-3.42(4.37)	15.88	-4.05 [-7.84, -0.26]
Pearce 1981 12months	12	-8.25(5.38)	12	-2.16(5.97)	11.04	-6.09 [-10.64, -1.54]
07 Behavioural contracts						
Black 1984 10 weeks	11	-4.61(7.22)	11	-3.71(6.96)	55.75	-0.90 [-6.83, 5.03]
Black 1984 12 months	11	-7.04(7.91)	11	-7.42(8.01)	44.25	0.38 [-6.27, 7.03]



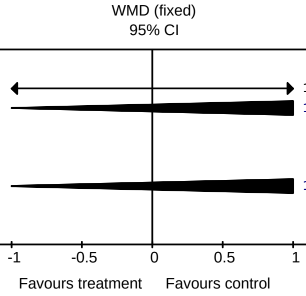
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 16 Change in FPG mmol/l at 20 weeks

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1991 b	20	-2.78(2.89)	23	-3.56(4.61)	100.00	0.78 [-1.49, 3.05]
Subtotal (95% CI)	20		23		100.00	0.78 [-1.49, 3.05]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.67 (P = 0.50)						
Total (95% CI)	20		23		100.00	0.78 [-1.49, 3.05]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.67 (P = 0.50)						



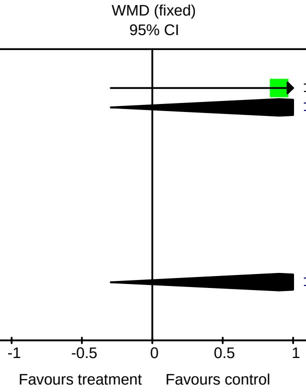
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 17 Change in FPG mmol/l at 72 weeks

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1991 b	20	-0.61(3.39)	23	-2.00(4.72)	100.00	1.39 [-1.04, 3.82]
Subtotal (95% CI)	20		23		100.00	1.39 [-1.04, 3.82]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.12 (P = 0.26)						
Total (95% CI)	20		23		100.00	1.39 [-1.04, 3.82]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.12 (P = 0.26)						



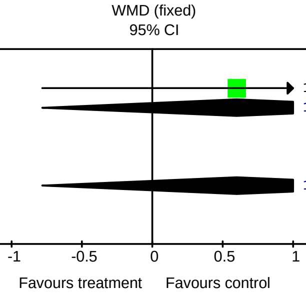
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 18 Change in %HbA1c at 20 weeks

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1991 b	20	-1.20(1.90)	23	-2.10(2.10)	100.00	0.90 [-0.30, 2.10]
Subtotal (95% CI)	20		23		100.00	0.90 [-0.30, 2.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.48 (P = 0.14)						
02 LCD, BT, and PA						
Subtotal (95% CI)	0		0			Not estimable
Test for heterogeneity: not applicable						
Test for overall effect: not applicable						
Total (95% CI)	20		23		100.00	0.90 [-0.30, 2.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.48 (P = 0.14)						



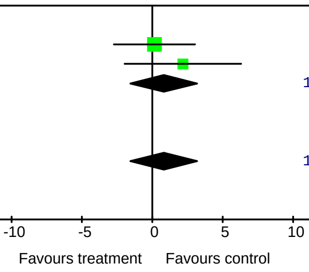
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 19 Change in %HbA1c at 72 weeks

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Wing 1991 b	20	-0.10(1.90)	23	-0.70(2.70)	100.00	0.60 [-0.78, 1.98]
Subtotal (95% CI)	20		23		100.00	0.60 [-0.78, 1.98]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.85 (P = 0.39)						
Total (95% CI)	20		23		100.00	0.60 [-0.78, 1.98]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.85 (P = 0.39)						



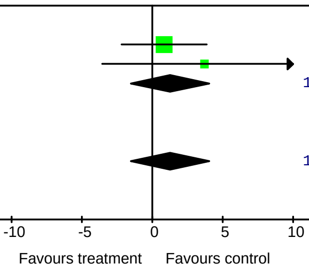
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 01 Weight change in kg at 10 weeks

Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Other						
Straw 1983 a	9	-3.68(2.90)	8	-3.83(3.14)	67.24	0.15 [-2.74, 3.04]
Straw 1983 b	5	-2.59(3.59)	6	-4.76(3.35)	32.76	2.17 [-1.96, 6.30]
Subtotal (95% CI)	14		14		100.00	0.81 [-1.55, 3.18]
Test for heterogeneity: Chi² = 0.62, df = 1 (P = 0.43), I² = 0%						
Test for overall effect: Z = 0.67 (P = 0.50)						
Total (95% CI)	14		14		100.00	0.81 [-1.55, 3.18]
Test for heterogeneity: Chi² = 0.62, df = 1 (P = 0.43), I² = 0%						
Test for overall effect: Z = 0.67 (P = 0.50)						



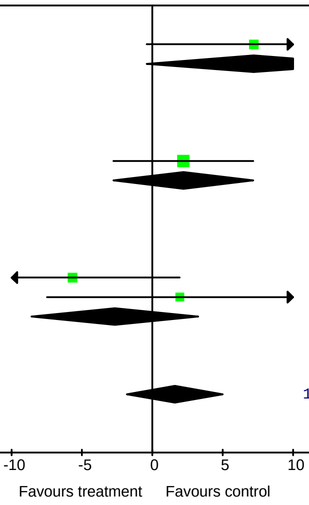
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 02 Weight change in kg at 16 weeks (4 months)

Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jones 1986	9	-3.95(3.67)	9	-4.79(2.81)	85.27	0.84 [-2.18, 3.86]
Long 1983	10	-4.60(7.22)	8	-8.30(8.26)	14.73	3.70 [-3.57, 10.97]
Subtotal (95% CI)	19		17		100.00	1.26 [-1.53, 4.05]
Test for heterogeneity: Chi² = 0.51, df = 1 (P = 0.48), I² = 0%						
Test for overall effect: Z = 0.89 (P = 0.38)						
Total (95% CI)	19		17		100.00	1.26 [-1.53, 4.05]
Test for heterogeneity: Chi² = 0.51, df = 1 (P = 0.48), I² = 0%						
Test for overall effect: Z = 0.89 (P = 0.38)						



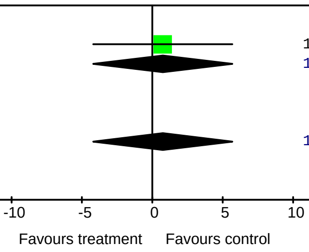
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Long 1983	7	-0.90(6.17)	7	-8.10(8.21)	20.02	7.20 [-0.41, 14.81]
Subtotal (95% CI)	7		7		20.02	7.20 [-0.41, 14.81]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.85 (P = 0.06)						
02 LCD, BT, and PA						
Hakala 1993	30	-14.80(8.90)	28	-17.00(10.30)	46.93	2.20 [-2.77, 7.17]
Subtotal (95% CI)	30		28		46.93	2.20 [-2.77, 7.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.87 (P = 0.39)						
03 Other						
Straw 1983 a	6	-3.98(7.04)	6	1.69(6.39)	20.03	-5.67 [-13.28, 1.94]
Straw 1983 b	5	-4.99(7.33)	5	-6.94(7.88)	13.02	1.95 [-7.48, 11.38]
Subtotal (95% CI)	11		11		33.05	-2.67 [-8.59, 3.25]
Test for heterogeneity: Chi² = 1.52, df = 1 (P = 0.22), I² = 34.2%						
Test for overall effect: Z = 0.88 (P = 0.38)						
Total (95% CI)	48		46		100.00	1.59 [-1.81, 5.00]
Test for heterogeneity: Chi² = 5.65, df = 3 (P = 0.13), I² = 46.9%						
Test for overall effect: Z = 0.92 (P = 0.36)						

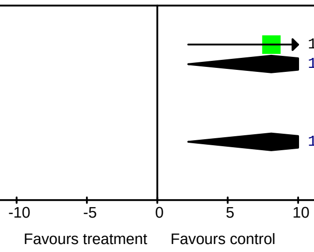


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 04 Weight change in kg at 18 months

Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jones 1986	8	-2.33(5.06)	9	-3.07(5.34)	100.00	0.74 [-4.21, 5.69]
Subtotal (95% CI)	8		9		100.00	0.74 [-4.21, 5.69]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.29 (P = 0.77)						
Total (95% CI)	8		9		100.00	0.74 [-4.21, 5.69]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.29 (P = 0.77)						

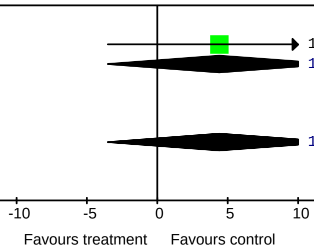


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 05 Weight change in kg at 24 months



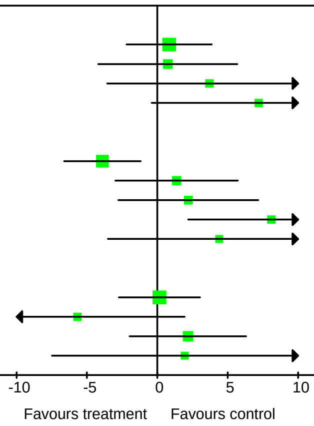
Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Hakala 1993	30	-4.20(9.70)	28	-12.30(12.90)	100.00	8.10 [2.19, 14.01]
Subtotal (95% CI)	30		28		100.00	8.10 [2.19, 14.01]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.69 (P = 0.007)						
Total (95% CI)	30		28		100.00	8.10 [2.19, 14.01]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.69 (P = 0.007)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 06 Weight change in kg at 60 months



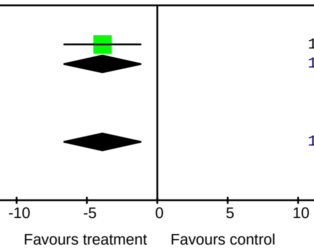
Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Hakala 1993	28	-2.40(12.00)	25	-6.80(16.70)	100.00	4.40 [-3.51, 12.31]
Subtotal (95% CI)	28		25		100.00	4.40 [-3.51, 12.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.09 (P = 0.28)						
Total (95% CI)	28		25		100.00	4.40 [-3.51, 12.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.09 (P = 0.28)						

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 07 Weight change over time



Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jones 1986 16 weeks	9	-3.95(3.67)	9	-4.79(2.81)	58.72	0.84 [-2.18, 3.86]
Jones 1986 18 months	8	-2.33(5.06)	9	-3.07(5.34)	21.89	0.74 [-4.21, 5.69]
Long 1983 16 weeks	10	-4.60(7.22)	8	-8.30(8.26)	10.14	3.70 [-3.57, 10.97]
Long 1983 12 months	7	-0.90(6.17)	7	-8.10(8.21)	9.25	7.20 [-0.41, 14.81]
02 LCD, BT, and PA						
Hakala 1993 3 months	30	-15.37(5.03)	28	-11.47(5.46)	49.72	-3.90 [-6.61, -1.19]
Hakala 1993 8 months	30	-14.80(8.30)	28	-16.17(8.58)	19.26	1.37 [-2.98, 5.72]
Hakala 1993 12months	30	-14.80(8.90)	28	-17.00(10.30)	14.75	2.20 [-2.77, 7.17]
Hakala 1993 24months	30	-4.20(9.70)	28	-12.30(12.90)	10.45	8.10 [2.19, 14.01]
Hakala 1993 60months	28	-2.40(12.00)	25	-6.80(16.70)	5.82	4.40 [-3.51, 12.31]
03 Other						
Straw 1983a 10 weeks	9	-3.68(2.90)	8	-3.83(3.14)	57.99	0.15 [-2.74, 3.04]
Straw 1983a 12months	6	-3.98(7.04)	6	1.69(6.39)	8.34	-5.67 [-13.28, 1.94]
Straw 1983b 10 weeks	5	-2.59(3.59)	6	-4.76(3.35)	28.25	2.17 [-1.96, 6.30]
Straw 1983b 12months	5	-4.99(7.33)	5	-6.94(7.88)	5.42	1.95 [-7.48, 11.38]

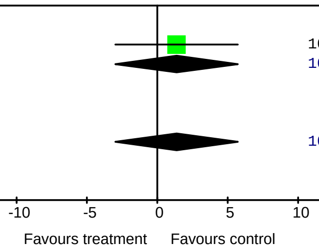
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 08 Weight change in kg at 3 months



Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Hakala 1993	30	-15.37(5.03)	28	-11.47(5.46)	100.00	-3.90 [-6.61, -1.19]
Subtotal (95% CI)	30		28		100.00	-3.90 [-6.61, -1.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.82 (P = 0.005)						
Total (95% CI)	30		28		100.00	-3.90 [-6.61, -1.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.82 (P = 0.005)						

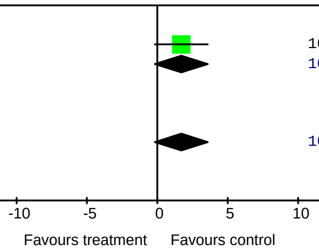
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 05 Group vs individual
Outcome: 09 Weight change in kg at 8 months

Study or sub-category	N	Group Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA						
Hakala 1993	30	-14.80(8.30)	28	-16.17(8.58)	100.00	1.37 [-2.98, 5.72]
Subtotal (95% CI)	30		28		100.00	1.37 [-2.98, 5.72]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.62 (P = 0.54)						
Total (95% CI)	30		28		100.00	1.37 [-2.98, 5.72]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.62 (P = 0.54)						



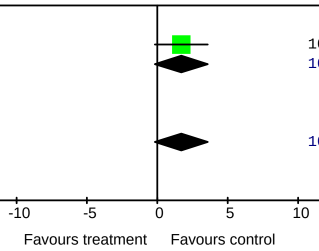
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 01 Weight change in kg at 3 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-8.30(2.64)	15	-10.00(2.75)	100.00	1.70 [-0.17, 3.57]
Subtotal (95% CI)	17		15		100.00	1.70 [-0.17, 3.57]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.78 (P = 0.08)						
Total (95% CI)	17		15		100.00	1.70 [-0.17, 3.57]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.78 (P = 0.08)						



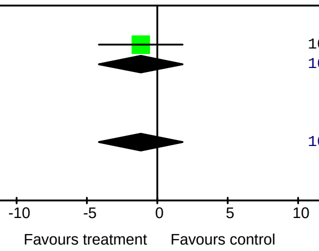
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 02 Weight change in kg at 6 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-10.60(2.64)	15	-12.30(2.75)	100.00	1.70 [-0.17, 3.57]
Subtotal (95% CI)	17		15		100.00	1.70 [-0.17, 3.57]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.78 (P = 0.08)						
Total (95% CI)	17		15		100.00	1.70 [-0.17, 3.57]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.78 (P = 0.08)						



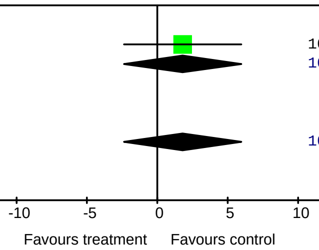
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-7.58(4.04)	15	-6.40(4.49)	100.00	-1.18 [-4.16, 1.80]
Subtotal (95% CI)	17		15		100.00	-1.18 [-4.16, 1.80]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.78 (P = 0.44)						
Total (95% CI)	17		15		100.00	-1.18 [-4.16, 1.80]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.78 (P = 0.44)						



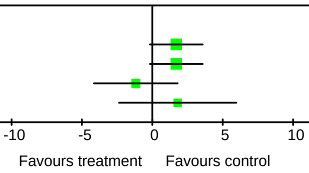
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 04 Weight change in kg at 24 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-6.80(5.77)	15	-8.60(6.20)	100.00	1.80 [-2.37, 5.97]
Subtotal (95% CI)	17		15		100.00	1.80 [-2.37, 5.97]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.85 (P = 0.40)						
Total (95% CI)	17		15		100.00	1.80 [-2.37, 5.97]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.85 (P = 0.40)						



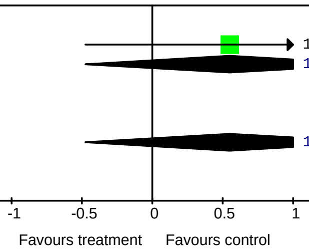
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 05 Weight change over time

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003 3 months	17	-8.30(2.64)	15	-10.00(2.75)	38.48	1.70 [-0.17, 3.57]
Melin 2003 6 months	17	-10.60(2.64)	15	-12.30(2.75)	38.48	1.70 [-0.17, 3.57]
Melin 2003 12 months	17	-7.58(4.04)	15	-6.40(4.49)	15.27	-1.18 [-4.16, 1.80]
Melin 2003 24 months	17	-6.80(5.77)	15	-8.60(6.20)	7.78	1.80 [-2.37, 5.97]



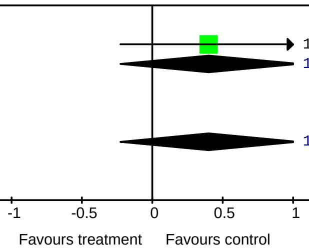
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 06 Change in FPG mmol/l at 3 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-0.35(1.44)	15	-0.90(1.51)	100.00	0.55 [-0.48, 1.58]
Subtotal (95% CI)	17		15		100.00	0.55 [-0.48, 1.58]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.05 (P = 0.29)						
Total (95% CI)	17		15		100.00	0.55 [-0.48, 1.58]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.05 (P = 0.29)						



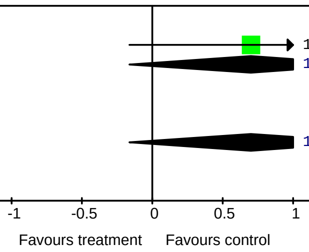
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 07 Change in FPG mmol/l at 6 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-0.20(0.87)	15	-0.60(0.93)	100.00	0.40 [-0.23, 1.03]
Subtotal (95% CI)	17		15		100.00	0.40 [-0.23, 1.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.25 (P = 0.21)						
Total (95% CI)	17		15		100.00	0.40 [-0.23, 1.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.25 (P = 0.21)						



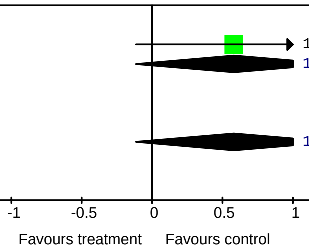
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 08 Change in FPG mmol/l at 12 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-0.20(1.15)	15	-0.90(1.32)	100.00	0.70 [-0.16, 1.56]
Subtotal (95% CI)	17		15		100.00	0.70 [-0.16, 1.56]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.59 (P = 0.11)						
Total (95% CI)	17		15		100.00	0.70 [-0.16, 1.56]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.59 (P = 0.11)						



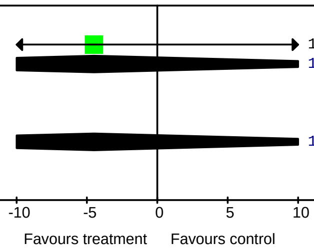
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 09 Change in FPG mmol/l at 24 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	0.08(0.99)	15	-0.50(1.01)	100.00	0.58 [-0.11, 1.27]
Subtotal (95% CI)	17		15		100.00	0.58 [-0.11, 1.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.64 (P = 0.10)						
Total (95% CI)	17		15		100.00	0.58 [-0.11, 1.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.64 (P = 0.10)						



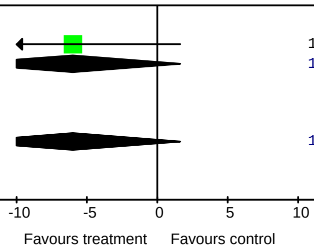
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 10 Change in SBP mmHg at 3 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Melin 2003	17	-6.90(27.42)	15	-2.40(37.88)		100.00	-4.50 [-27.68, 18.68]
Subtotal (95% CI)	17		15			100.00	-4.50 [-27.68, 18.68]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.38 (P = 0.70)							
Total (95% CI)	17		15			100.00	-4.50 [-27.68, 18.68]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.38 (P = 0.70)							



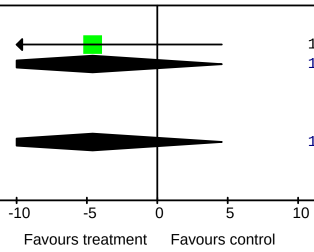
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 11 Change in SBP mmHg at 6 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Melin 2003	17	-8.10(10.72)	15	-2.10(11.23)		100.00	-6.00 [-13.63, 1.63]
Subtotal (95% CI)	17		15			100.00	-6.00 [-13.63, 1.63]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.54 (P = 0.12)							
Total (95% CI)	17		15			100.00	-6.00 [-13.63, 1.63]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.54 (P = 0.12)							



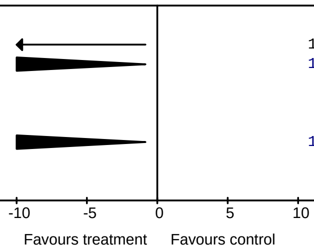
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 12 Change in SBP mmHg at 12 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Melin 2003	17	-5.00(12.37)	15	-0.40(13.94)		100.00	-4.60 [-13.78, 4.58]
Subtotal (95% CI)	17		15			100.00	-4.60 [-13.78, 4.58]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.98 (P = 0.33)							
Total (95% CI)	17		15			100.00	-4.60 [-13.78, 4.58]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.98 (P = 0.33)							



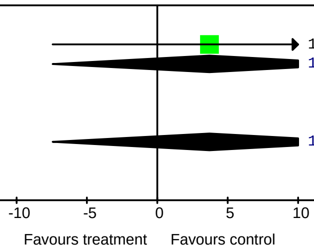
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 13 Change in SBP mmHg at 24 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Melin 2003	17	-9.80(17.11)	15	2.20(15.10)		100.00	-12.00 [-23.16, -0.84]
Subtotal (95% CI)	17		15			100.00	-12.00 [-23.16, -0.84]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.11 (P = 0.04)							
Total (95% CI)	17		15			100.00	-12.00 [-23.16, -0.84]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.11 (P = 0.04)							



Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 14 Change in DBP mmHg at 3 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Melin 2003	17	-3.50(13.19)	15	-7.20(18.20)		100.00	3.70 [-7.44, 14.84]
Subtotal (95% CI)	17		15			100.00	3.70 [-7.44, 14.84]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.65 (P = 0.52)							
Total (95% CI)	17		15			100.00	3.70 [-7.44, 14.84]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.65 (P = 0.52)							

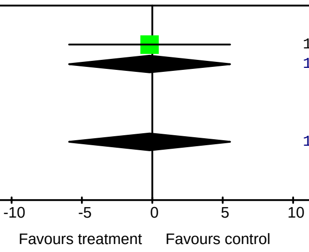


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 15 Change in DBP mmHg at 6 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-5.20(8.04)	15	-5.00(8.40)	100.00	-0.20 [-5.92, 5.52]
Subtotal (95% CI)	17		15		100.00	-0.20 [-5.92, 5.52]
Total (95% CI)	17		15		100.00	-0.20 [-5.92, 5.52]

Subtotal: Test for heterogeneity: not applicable
Test for overall effect: Z = 0.07 (P = 0.95)

Total: Test for heterogeneity: not applicable
Test for overall effect: Z = 0.07 (P = 0.95)

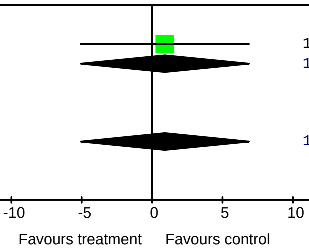


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 16 Change in DBP mmHg at 12 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-2.40(8.25)	15	-3.30(8.91)	100.00	0.90 [-5.08, 6.88]
Subtotal (95% CI)	17		15		100.00	0.90 [-5.08, 6.88]
Total (95% CI)	17		15		100.00	0.90 [-5.08, 6.88]

Subtotal: Test for heterogeneity: not applicable
Test for overall effect: Z = 0.30 (P = 0.77)

Total: Test for heterogeneity: not applicable
Test for overall effect: Z = 0.30 (P = 0.77)

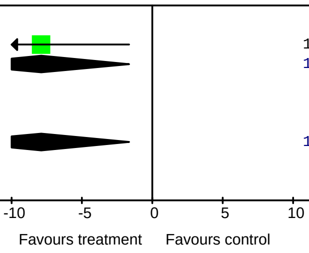


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 06 Intensive BT vs less intensive BT
Outcome: 17 Change in DBP mmHg at 24 months

Study or sub-category	N	INT BT and diet Mean (SD)	N	STD BT and diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Melin 2003	17	-6.60(9.57)	15	1.30(8.44)	100.00	-7.90 [-14.14, -1.66]
Subtotal (95% CI)	17		15		100.00	-7.90 [-14.14, -1.66]
Total (95% CI)	17		15		100.00	-7.90 [-14.14, -1.66]

Subtotal: Test for heterogeneity: not applicable
Test for overall effect: Z = 2.48 (P = 0.01)

Total: Test for heterogeneity: not applicable
Test for overall effect: Z = 2.48 (P = 0.01)

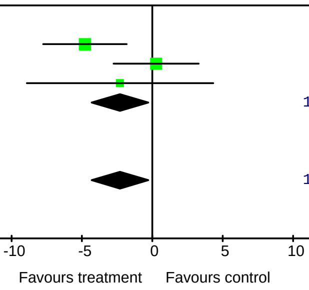


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 01 Weight change in kg at 16 weeks

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jones 1986 c	7	-8.74(2.35)	9	-3.95(3.67)	46.16	-4.79 [-7.75, -1.83]
Jones 1986 d	9	-4.52(3.66)	9	-4.79(2.81)	44.59	0.27 [-2.74, 3.28]
Long 1983	10	-6.90(7.87)	10	-4.60(7.22)	9.25	-2.30 [-8.92, 4.32]
Subtotal (95% CI)	26		28		100.00	-2.30 [-4.32, -0.29]
Total (95% CI)	26		28		100.00	-2.30 [-4.32, -0.29]

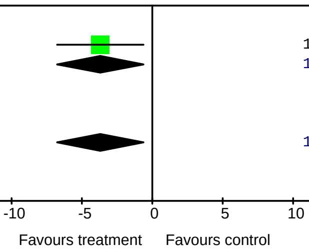
Subtotal: Test for heterogeneity: Chi² = 5.50, df = 2 (P = 0.06), I² = 63.7%
Test for overall effect: Z = 2.24 (P = 0.02)

Total: Test for heterogeneity: Chi² = 5.50, df = 2 (P = 0.06), I² = 63.7%
Test for overall effect: Z = 2.24 (P = 0.02)



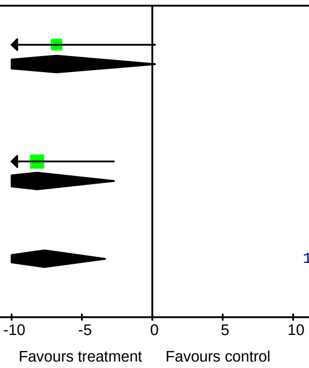
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 02 Weight change in kg at 6 months

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 PSMF						
Wadden 1989	31	-16.80(6.68)	23	-13.10(4.80)	100.00	-3.70 [-6.76, -0.64]
Subtotal (95% CI)	31		23		100.00	-3.70 [-6.76, -0.64]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.37 (P = 0.02)						
Total (95% CI)	31		23		100.00	-3.70 [-6.76, -0.64]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.37 (P = 0.02)						



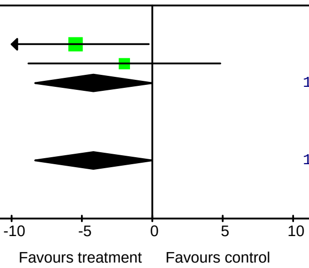
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Long 1983	9	-7.70(8.09)	7	-0.90(6.17)	37.85	-6.80 [-13.79, 0.19]
Subtotal (95% CI)	9		7		37.85	-6.80 [-13.79, 0.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.91 (P = 0.06)						
02 PSMF						
Wadden 1989	19	-12.89(8.91)	15	-4.70(7.31)	62.15	-8.19 [-13.64, -2.74]
Subtotal (95% CI)	19		15		62.15	-8.19 [-13.64, -2.74]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.94 (P = 0.003)						
Total (95% CI)	28		22		100.00	-7.66 [-11.96, -3.36]
Test for heterogeneity: Chi² = 0.09, df = 1 (P = 0.76), I² = 0%						
Test for overall effect: Z = 3.49 (P = 0.0005)						



Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 04 Weight change in kg at 18 months

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jones 1986 c	7	-7.79(5.21)	8	-2.33(5.06)	63.11	-5.46 [-10.67, -0.25]
Jones 1986 d	7	-5.06(7.91)	9	-3.07(5.34)	36.89	-1.99 [-8.81, 4.83]
Subtotal (95% CI)	14		17		100.00	-4.18 [-8.32, -0.04]
Test for heterogeneity: Chi² = 0.63, df = 1 (P = 0.43), I² = 0%						
Test for overall effect: Z = 1.98 (P = 0.05)						
Total (95% CI)	14		17		100.00	-4.18 [-8.32, -0.04]
Test for heterogeneity: Chi² = 0.63, df = 1 (P = 0.43), I² = 0%						
Test for overall effect: Z = 1.98 (P = 0.05)						

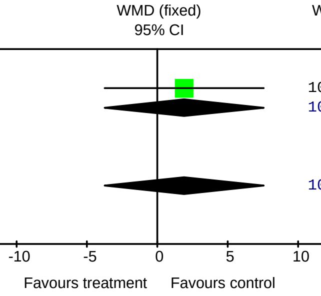


Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 05 Weight change in kg at 36 months

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 PSMF						
Wadden 1989	19	-5.11(8.28)	15	-2.20(8.50)	100.00	-2.91 [-8.60, 2.78]
Subtotal (95% CI)	19		15		100.00	-2.91 [-8.60, 2.78]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						
Total (95% CI)	19		15		100.00	-2.91 [-8.60, 2.78]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						

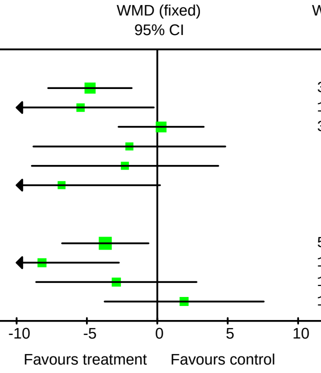
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 06 Weight change in kg at 60 months

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 PSMF						
Wadden 1989	22	2.90(11.26)	18	1.00(6.79)	100.00	1.90 [-3.75, 7.55]
Subtotal (95% CI)	22		18		100.00	1.90 [-3.75, 7.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.66 (P = 0.51)						
Total (95% CI)	22		18		100.00	1.90 [-3.75, 7.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.66 (P = 0.51)						



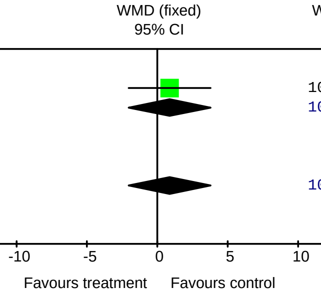
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 07 Diet and BT vs diet alone
Outcome: 07 Weight change over time

Study or sub-category	N	Diet and BT Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jones c 16 weeks	7	-8.74(2.35)	9	-3.95(3.67)	34.99	-4.79 [-7.75, -1.83]
Jones c 18 months	7	-7.79(5.21)	8	-2.33(5.06)	11.30	-5.46 [-10.67, -0.25]
Jones d 16 weeks	9	-4.52(3.66)	9	-4.79(2.81)	33.80	0.27 [-2.74, 3.28]
Jones d 18 months	7	-5.06(7.91)	9	-3.07(5.34)	6.61	-1.99 [-8.81, 4.83]
Long 1983 16 weeks	10	-6.90(7.87)	10	-4.60(7.22)	7.01	-2.30 [-8.92, 4.32]
Long 1983 12 months	9	-7.70(8.09)	7	-0.90(6.17)	6.29	-6.80 [-13.79, 0.19]
02 PSMF						
Wadden 1989 6 months	31	-16.80(6.68)	23	-13.10(4.80)	52.68	-3.70 [-6.76, -0.64]
Wadden 1989 12months	19	-12.89(8.91)	15	-4.70(7.31)	16.61	-8.19 [-13.64, -2.74]
Wadden 1989 36months	19	-5.11(8.28)	15	-2.20(8.50)	15.26	-2.91 [-8.60, 2.78]
Wadden 1989 60months	22	2.90(11.26)	18	1.00(6.79)	15.45	1.90 [-3.75, 7.55]



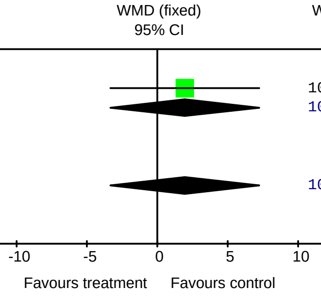
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 08 Comparison of different BT
Outcome: 01 Weight change in kg at 20 weeks

Study or sub-category	N	Treatment A Mean (SD)	N	Treatment B Mean (SD)	Weight %	WMD (fixed) 95% CI
01 BT and RP vs BT and PS						
Perri 2001	20	-8.41(4.55)	23	-9.28(5.21)	100.00	0.87 [-2.05, 3.79]
Subtotal (95% CI)	20		23		100.00	0.87 [-2.05, 3.79]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.58 (P = 0.56)						
Total (95% CI)	20		23		100.00	0.87 [-2.05, 3.79]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.58 (P = 0.56)						



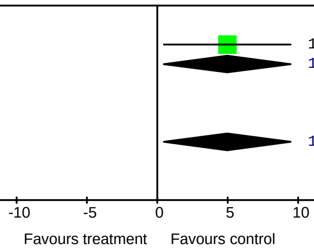
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 08 Comparison of different BT
Outcome: 02 Weight change in kg at 48 weeks

Study or sub-category	N	Treatment A Mean (SD)	N	Treatment B Mean (SD)	Weight %	WMD (fixed) 95% CI
01 BT and RP vs BT and PS						
Perri 2001	20	-9.38(8.57)	23	-11.33(9.12)	100.00	1.95 [-3.34, 7.24]
Subtotal (95% CI)	20		23		100.00	1.95 [-3.34, 7.24]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						
Total (95% CI)	20		23		100.00	1.95 [-3.34, 7.24]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						



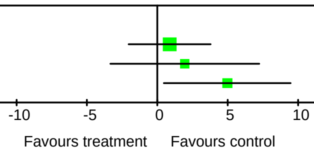
Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 08 Comparison of different BT
Outcome: 03 Weight change in kg at 68 weeks

Study or sub-category	N	Treatment A Mean (SD)	N	Treatment B Mean (SD)	Weight %	WMD (fixed) 95% CI
01 BT and RP vs BT and PS						
Perri 2001	20	-5.85(6.39)	23	-10.82(8.65)	100.00	4.97 [0.46, 9.48]
Subtotal (95% CI)	20		23		100.00	4.97 [0.46, 9.48]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.16 (P = 0.03)						
Total (95% CI)	20		23		100.00	4.97 [0.46, 9.48]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.16 (P = 0.03)						



Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 08 Comparison of different BT
Outcome: 04 Weight change over time

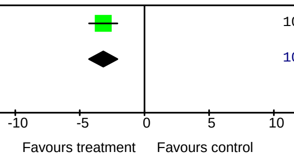
Study or sub-category	N	Treatment A Mean (SD)	N	Treatment B Mean (SD)	Weight %	WMD (fixed) 95% CI
01 BT and RP vs BT and PS						
Perri 2001 20 weeks	20	-8.41(4.55)	23	-9.28(5.21)	58.06	0.87 [-2.05, 3.79]
Perri 2001 48 weeks	20	-9.38(8.57)	23	-11.33(9.12)	17.65	1.95 [-3.34, 7.24]
Perri 2001 68 weeks	20	-5.85(6.39)	23	-10.82(8.65)	24.29	4.97 [0.46, 9.48]



3.3 Physical activity interventions

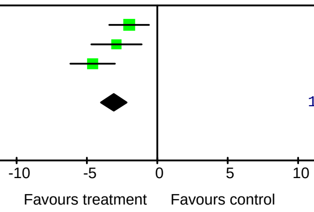
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 01 Weight change in kg at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	47	-3.00(2.80)	42	0.20(2.50)	100.00	-3.20 [-4.30, -2.10]
Total (95% CI)	47		42		100.00	-3.20 [-4.30, -2.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.70 (P < 0.00001)						



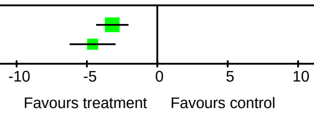
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-0.90(4.20)	43	1.10(2.62)	41.11	-2.00 [-3.41, -0.59]
Pritchard 1997	21	-2.60(3.30)	19	0.30(2.40)	26.00	-2.90 [-4.68, -1.12]
Wood 1988	47	-4.00(3.90)	42	0.60(3.70)	32.89	-4.60 [-6.18, -3.02]
Total (95% CI)	117		104		100.00	-3.09 [-4.00, -2.18]
Test for heterogeneity: Chi² = 5.84, df = 2 (P = 0.05), I² = 65.8%						
Test for overall effect: Z = 6.68 (P < 0.00001)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 03 Weight change over time

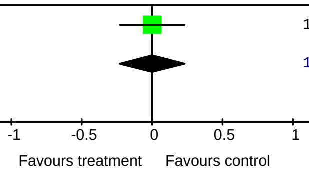
Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988 7 months	47	-3.00(2.80)	42	0.20(2.50)	67.30	-3.20 [-4.30, -2.10]
Wood 1988 12 months	47	-4.00(3.90)	42	0.60(3.70)	32.70	-4.60 [-6.18, -3.02]



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 04 Change in total cholesterol in mmol/l at 7 months

Study or sub-category	Activity N	Activity Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	47	-0.21(0.63)	42	-0.21(0.48)	100.00	0.00 [-0.23, 0.23]
Total (95% CI)	47		42		100.00	0.00 [-0.23, 0.23]

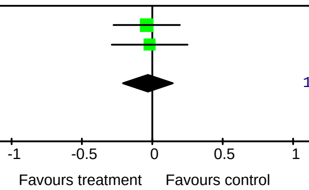
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	Activity N	Activity Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-0.20(0.56)	43	-0.16(0.59)	56.43	-0.04 [-0.28, 0.20]
Wood 1988	47	-0.25(0.64)	42	-0.23(0.65)	43.57	-0.02 [-0.29, 0.25]
Total (95% CI)	96		85		100.00	-0.03 [-0.21, 0.15]

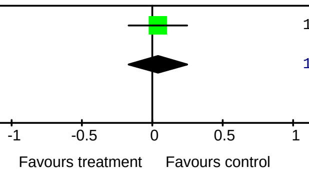
Test for heterogeneity: Chi² = 0.01, df = 1 (P = 0.91), I² = 0%
Test for overall effect: Z = 0.35 (P = 0.73)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 06 Change in LDL cholesterol in mmol/l at 7 months

Study or sub-category	Activity N	Activity Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	47	-0.11(0.54)	42	-0.15(0.46)	100.00	0.04 [-0.17, 0.25]
Total (95% CI)	47		42		100.00	0.04 [-0.17, 0.25]

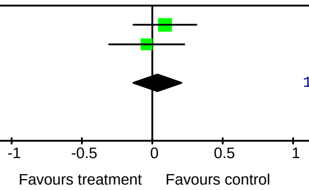
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.38 (P = 0.71)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 07 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	Activity N	Activity Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-0.13(0.49)	43	-0.22(0.59)	58.88	0.09 [-0.13, 0.31]
Wood 1988	47	-0.25(0.61)	42	-0.21(0.67)	41.12	-0.04 [-0.31, 0.23]
Total (95% CI)	96		85		100.00	0.04 [-0.13, 0.21]

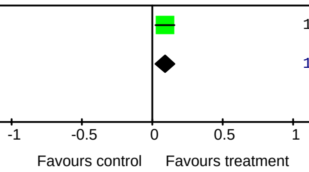
Test for heterogeneity: Chi² = 0.53, df = 1 (P = 0.46), I² = 0%
Test for overall effect: Z = 0.42 (P = 0.68)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 08 Change in HDL cholesterol in mmol/l at 7 months

Study or sub-category	Activity N	Activity Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	47	0.09(0.21)	41	0.00(0.10)	100.00	0.09 [0.02, 0.16]
Total (95% CI)	47		41		100.00	0.09 [0.02, 0.16]

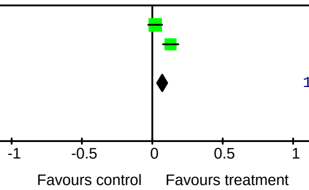
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.62 (P = 0.009)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 09 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	Activity N	Activity Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
ODES 1995	49	0.04(0.14)	43	0.02(0.10)	55.02	0.02 [-0.03, 0.07]
Wood 1988	47	0.11(0.15)	41	-0.02(0.11)	44.98	0.13 [0.08, 0.18]
Total (95% CI)	96		84		100.00	0.07 [0.03, 0.11]

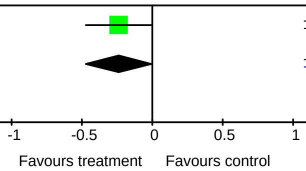
Test for heterogeneity: Chi² = 8.60, df = 1 (P = 0.003), I² = 88.4%
Test for overall effect: Z = 3.72 (P = 0.0002)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 10 Change in triglycerides in mmol/l at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	47	-0.25(0.61)	42	-0.01(0.51)		100.00	-0.24 [-0.47, -0.01]
Total (95% CI)	47		42			100.00	-0.24 [-0.47, -0.01]

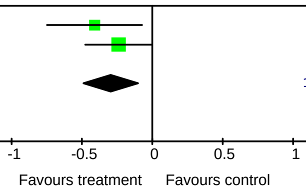
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.02 (P = 0.04)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 11 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-0.24(0.70)	43	0.17(0.92)		32.89	-0.41 [-0.75, -0.07]
Wood 1988	47	-0.16(0.53)	42	0.08(0.60)		67.11	-0.24 [-0.48, 0.00]
Total (95% CI)	96		85			100.00	-0.30 [-0.49, -0.10]

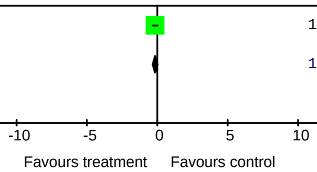
Test for heterogeneity: Chi² = 0.65, df = 1 (P = 0.42), I² = 0%
Test for overall effect: Z = 2.99 (P = 0.003)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 12 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-0.09(0.42)	43	0.07(0.46)		100.00	-0.16 [-0.34, 0.02]
Total (95% CI)	49		43			100.00	-0.16 [-0.34, 0.02]

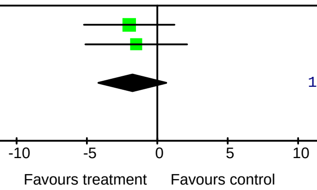
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.73 (P = 0.08)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 13 Change in DBP in mmHg at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-2.70(7.00)	43	-0.70(8.52)		55.83	-2.00 [-5.21, 1.21]
Wood 1988	42	-4.10(8.00)	35	-2.60(8.10)		44.17	-1.50 [-5.11, 2.11]
Total (95% CI)	91		78			100.00	-1.78 [-4.18, 0.62]

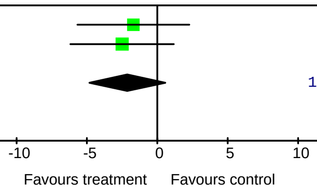
Test for heterogeneity: Chi² = 0.04, df = 1 (P = 0.84), I² = 0%
Test for overall effect: Z = 1.45 (P = 0.15)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 01 Physical activity vs control
Outcome: 14 Change in SBP in mmHg at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
ODES 1995	49	-2.20(7.70)	43	-0.50(11.15)		46.11	-1.70 [-5.67, 2.27]
Wood 1988	42	-6.60(8.40)	35	-4.10(8.00)		53.89	-2.50 [-6.17, 1.17]
Total (95% CI)	91		78			100.00	-2.13 [-4.83, 0.56]

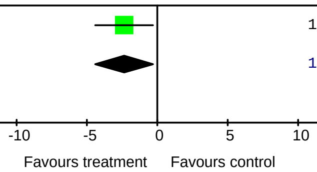
Test for heterogeneity: Chi² = 0.08, df = 1 (P = 0.77), I² = 0%
Test for overall effect: Z = 1.55 (P = 0.12)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 02 Physical activity vs information
Outcome: 01 Weight change in kg at 18 months

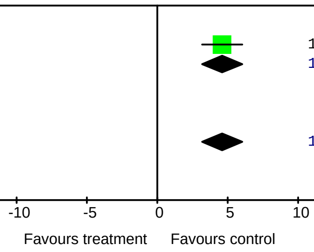
Study or sub-category	N	Activity Mean (SD)	N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Messier 2004	80	-3.46(6.89)	78	-1.10(6.23)		100.00	-2.36 [-4.41, -0.31]
Total (95% CI)	80		78			100.00	-2.36 [-4.41, -0.31]

Test for heterogeneity: not applicable
Test for overall effect: Z = 2.26 (P = 0.02)



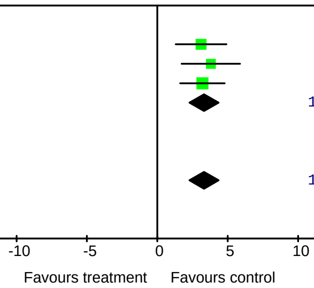
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 01 Weight change in kg at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wood 1988	47	-3.00(2.80)	42	-7.60(3.90)	100.00	4.60 [3.17, 6.03]
Subtotal (95% CI)	47		42		100.00	4.60 [3.17, 6.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 6.32 (P < 0.00001)						
Total (95% CI)	47		42		100.00	4.60 [3.17, 6.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 6.32 (P < 0.00001)						



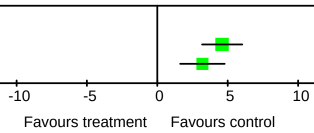
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	49	-0.90(4.20)	52	-4.00(5.05)	32.61	3.10 [1.29, 4.91]
Pritchard 1997	21	-2.60(3.30)	18	-6.40(3.30)	24.69	3.80 [1.72, 5.88]
Wood 1988	47	-4.00(3.90)	42	-7.20(3.70)	42.70	3.20 [1.62, 4.78]
Subtotal (95% CI)	117		112		100.00	3.32 [2.28, 4.35]
Test for heterogeneity: Chi² = 0.28, df = 2 (P = 0.87), I² = 0%						
Test for overall effect: Z = 6.30 (P < 0.00001)						
Total (95% CI)	117		112		100.00	3.32 [2.28, 4.35]
Test for heterogeneity: Chi² = 0.28, df = 2 (P = 0.87), I² = 0%						
Test for overall effect: Z = 6.30 (P < 0.00001)						



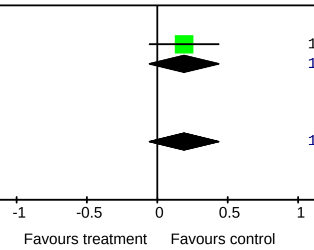
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 03 Weight change over time

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/deficit or low fat diet						
Wood 1988 7 months	47	-3.00(2.80)	42	-7.60(3.90)	55.12	4.60 [3.17, 6.03]
Wood 1988 12 months	47	-4.00(3.90)	42	-7.20(3.70)	44.88	3.20 [1.62, 4.78]



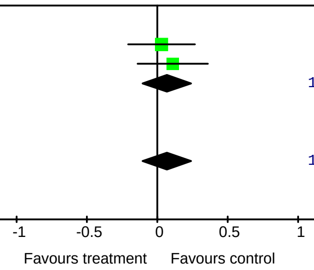
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 04 Change in total cholesterol in mmol/l at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wood 1988	47	-0.21(0.63)	42	-0.40(0.55)	100.00	0.19 [-0.06, 0.44]
Subtotal (95% CI)	47		42		100.00	0.19 [-0.06, 0.44]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						
Total (95% CI)	47		42		100.00	0.19 [-0.06, 0.44]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						



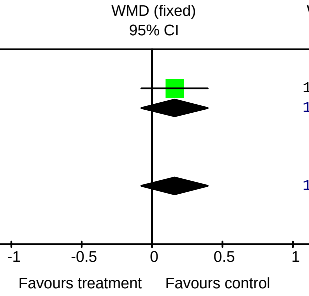
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	49	-0.20(0.56)	52	-0.23(0.65)	52.70	0.03 [-0.21, 0.27]
Wood 1988	47	-0.25(0.64)	42	-0.36(0.56)	47.30	0.11 [-0.14, 0.36]
Subtotal (95% CI)	96		94		100.00	0.07 [-0.10, 0.24]
Test for heterogeneity: Chi² = 0.21, df = 1 (P = 0.65), I² = 0%						
Test for overall effect: Z = 0.78 (P = 0.44)						
Total (95% CI)	96		94		100.00	0.07 [-0.10, 0.24]
Test for heterogeneity: Chi² = 0.21, df = 1 (P = 0.65), I² = 0%						
Test for overall effect: Z = 0.78 (P = 0.44)						



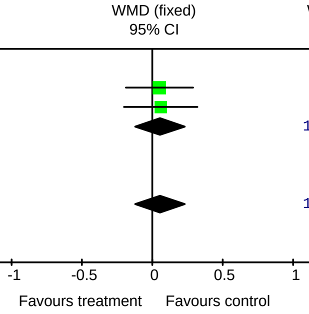
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 06 Change in LDL cholesterol in mmol/l at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wood 1988	47	-0.11(0.54)	42	-0.27(0.59)	100.00	0.16 [-0.08, 0.40]
Subtotal (95% CI)	47		42		100.00	0.16 [-0.08, 0.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.33 (P = 0.18)						
Total (95% CI)	47		42		100.00	0.16 [-0.08, 0.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.33 (P = 0.18)						



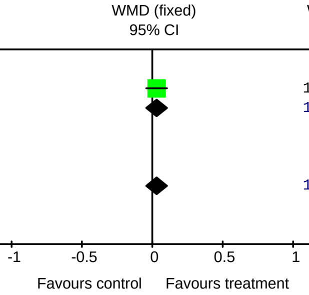
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 07 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	49	-0.13(0.49)	52	-0.18(0.72)	54.30	0.05 [-0.19, 0.29]
Wood 1988	47	-0.25(0.61)	42	-0.31(0.64)	45.70	0.06 [-0.20, 0.32]
Subtotal (95% CI)	96		94		100.00	0.05 [-0.12, 0.23]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.96), I² = 0%						
Test for overall effect: Z = 0.61 (P = 0.54)						
Total (95% CI)	96		94		100.00	0.05 [-0.12, 0.23]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.96), I² = 0%						
Test for overall effect: Z = 0.61 (P = 0.54)						



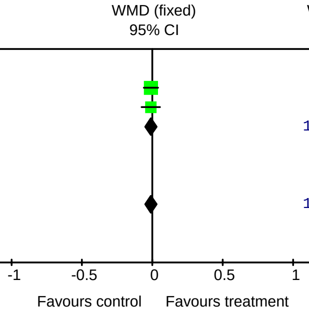
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 08 Change in HDL cholesterol in mmol/l at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wood 1988	47	0.09(0.21)	41	0.06(0.14)	100.00	0.03 [-0.04, 0.10]
Subtotal (95% CI)	47		41		100.00	0.03 [-0.04, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.80 (P = 0.43)						
Total (95% CI)	47		41		100.00	0.03 [-0.04, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.80 (P = 0.43)						



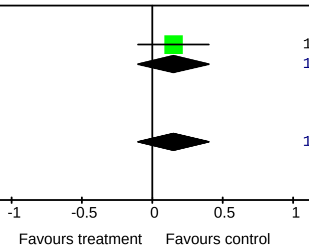
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 09 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	49	0.04(0.14)	52	0.05(0.12)	61.97	-0.01 [-0.06, 0.04]
Wood 1988	47	0.11(0.15)	41	0.12(0.16)	38.03	-0.01 [-0.08, 0.06]
Subtotal (95% CI)	96		93		100.00	-0.01 [-0.05, 0.03]
Test for heterogeneity: Chi² = 2.89E-32, df = 1 (P = 1.00), I² = 0%						
Test for overall effect: Z = 0.49 (P = 0.63)						
Total (95% CI)	96		93		100.00	-0.01 [-0.05, 0.03]
Test for heterogeneity: Chi² = 2.89E-32, df = 1 (P = 1.00), I² = 0%						
Test for overall effect: Z = 0.49 (P = 0.63)						



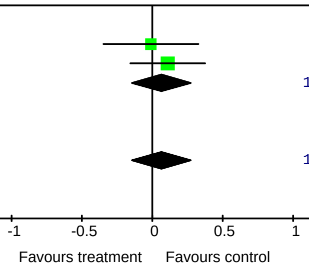
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 10 Change in triglycerides in mmol/l at 7 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Wood 1988	47	-0.25(0.61)	42	-0.40(0.60)		100.00	0.15 [-0.10, 0.40]
Subtotal (95% CI)	47		42			100.00	0.15 [-0.10, 0.40]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.17 (P = 0.24)							
Total (95% CI)	47		42			100.00	0.15 [-0.10, 0.40]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.17 (P = 0.24)							



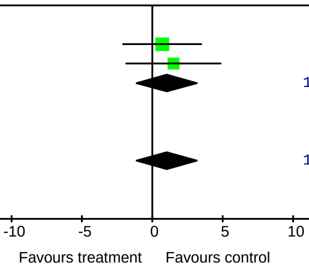
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 11 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
ODES 1995	49	-0.24(0.70)	52	-0.23(1.01)		38.22	-0.01 [-0.35, 0.33]
Wood 1988	47	-0.16(0.53)	42	-0.27(0.72)		61.78	0.11 [-0.16, 0.38]
Subtotal (95% CI)	96		94			100.00	0.06 [-0.14, 0.27]
Test for heterogeneity: Chi² = 0.30, df = 1 (P = 0.58), I² = 0%							
Test for overall effect: Z = 0.60 (P = 0.55)							
Total (95% CI)	96		94			100.00	0.06 [-0.14, 0.27]
Test for heterogeneity: Chi² = 0.30, df = 1 (P = 0.58), I² = 0%							
Test for overall effect: Z = 0.60 (P = 0.55)							



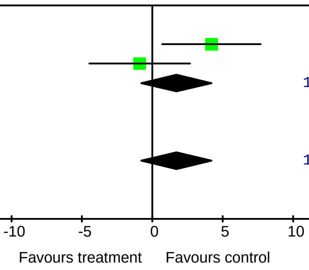
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 12 Change in DBP in mmHg at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
ODES 1995	49	-2.70(7.00)	52	-3.40(7.21)		59.40	0.70 [-2.07, 3.47]
Wood 1988	42	-4.10(8.00)	38	-5.60(7.30)		40.60	1.50 [-1.85, 4.85]
Subtotal (95% CI)	91		90			100.00	1.02 [-1.11, 3.16]
Test for heterogeneity: Chi² = 0.13, df = 1 (P = 0.72), I² = 0%							
Test for overall effect: Z = 0.94 (P = 0.35)							
Total (95% CI)	91		90			100.00	1.02 [-1.11, 3.16]
Test for heterogeneity: Chi² = 0.13, df = 1 (P = 0.72), I² = 0%							
Test for overall effect: Z = 0.94 (P = 0.35)							



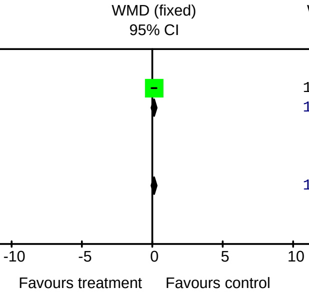
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 13 Change in SBP in mmHg at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
ODES 1995	49	-2.20(7.70)	52	-6.40(10.10)		51.16	4.20 [0.71, 7.69]
Wood 1988	42	-6.60(8.40)	38	-5.70(7.90)		48.84	-0.90 [-4.47, 2.67]
Subtotal (95% CI)	91		90			100.00	1.71 [-0.79, 4.21]
Test for heterogeneity: Chi² = 4.01, df = 1 (P = 0.05), I² = 75.0%							
Test for overall effect: Z = 1.34 (P = 0.18)							
Total (95% CI)	91		90			100.00	1.71 [-0.79, 4.21]
Test for heterogeneity: Chi² = 4.01, df = 1 (P = 0.05), I² = 75.0%							
Test for overall effect: Z = 1.34 (P = 0.18)							



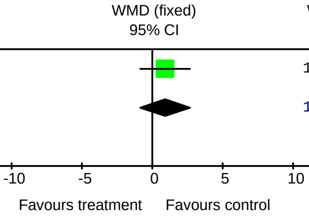
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 03 Physical activity vs diet
Outcome: 14 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	49	-0.09(0.42)	52	-0.21(0.50)	100.00	0.12 [-0.06, 0.30]
Subtotal (95% CI)	49		52		100.00	0.12 [-0.06, 0.30]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.31 (P = 0.19)						
Total (95% CI)	49		52		100.00	0.12 [-0.06, 0.30]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.31 (P = 0.19)						



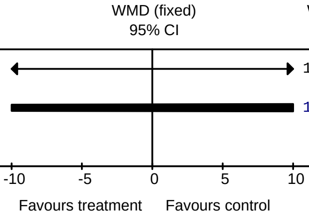
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 15 Change in body fat % at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-3.70(3.40)	38	-4.60(4.50)	100.00	0.90 [-0.86, 2.66]
Total (95% CI)	42		38		100.00	0.90 [-0.86, 2.66]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						



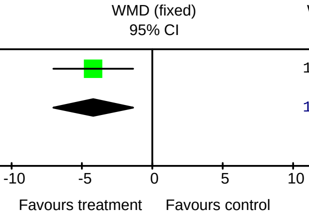
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 16 Change in calories/day at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-169.00(602.00)	38	-306.00(448.00)	100.00	137.00 [-94.16, 368.16]
Total (95% CI)	42		38		100.00	137.00 [-94.16, 368.16]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.16 (P = 0.25)						



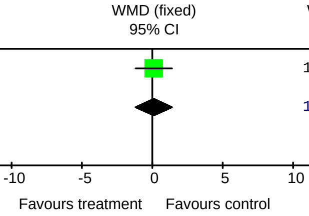
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 17 Change in fat in g/day at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-2.20(5.50)	38	2.00(7.20)	100.00	-4.20 [-7.03, -1.37]
Total (95% CI)	42		38		100.00	-4.20 [-7.03, -1.37]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.91 (P = 0.004)						



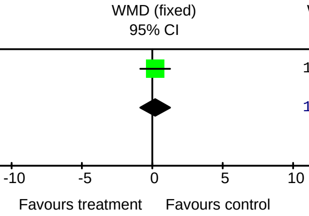
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 18 Change in saturated fat in g/day at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-0.90(2.90)	38	-1.00(3.00)	100.00	0.10 [-1.20, 1.40]
Total (95% CI)	42		38		100.00	0.10 [-1.20, 1.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.15 (P = 0.88)						



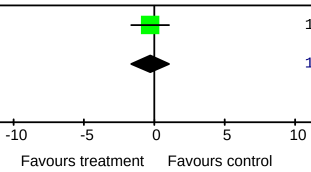
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 19 Change in polyunsaturated fat in g/day at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Wood 1988	42	0.00(2.50)	38	-0.20(2.30)	100.00	0.20 [-0.85, 1.25]
Total (95% CI)	42		38		100.00	0.20 [-0.85, 1.25]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.37 (P = 0.71)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 20 Change in monunsaturated fat in g/kcal at 12 months

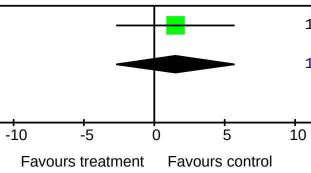
Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-1.10(2.60)	38	-0.80(3.40)		100.00	-0.30 [-1.64, 1.04]
Total (95% CI)	42		38			100.00	-0.30 [-1.64, 1.04]



Test for heterogeneity: not applicable
Test for overall effect: Z = 0.44 (P = 0.66)

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 21 Change in alcohol in g/day at 12 months

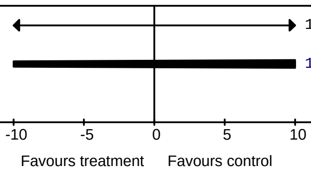
Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-3.30(1.60)	38	-4.80(13.00)		100.00	1.50 [-2.66, 5.66]
Total (95% CI)	42		38			100.00	1.50 [-2.66, 5.66]



Test for heterogeneity: not applicable
Test for overall effect: Z = 0.71 (P = 0.48)

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 22 Change in calcium in mg/day at 12 months

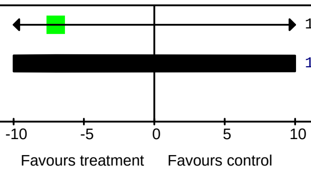
Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-25.00(316.00)	38	-111.00(333.00)		100.00	86.00 [-56.63, 228.63]
Total (95% CI)	42		38			100.00	86.00 [-56.63, 228.63]



Test for heterogeneity: not applicable
Test for overall effect: Z = 1.18 (P = 0.24)

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 23 Change in potassium in mg/day at 12 months

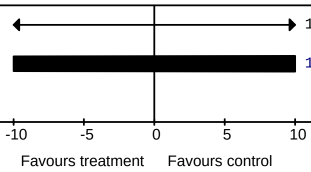
Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-215.00(758.00)	38	-208.00(823.00)		100.00	-7.00 [-354.88, 340.88]
Total (95% CI)	42		38			100.00	-7.00 [-354.88, 340.88]



Test for heterogeneity: not applicable
Test for overall effect: Z = 0.04 (P = 0.97)

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 24 Change in sodium in mg/day at 12 months

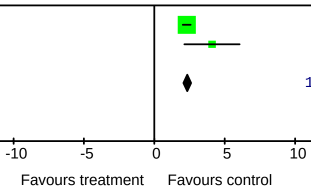
Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	42	-111.00(1083.00)	38	-148.00(856.00)		100.00	37.00 [-388.85, 462.85]
Total (95% CI)	42		38			100.00	37.00 [-388.85, 462.85]



Test for heterogeneity: not applicable
Test for overall effect: Z = 0.17 (P = 0.86)

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 25 Change in VO2 max in ml/kg/min at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
ODES 1995	49	4.00(0.70)	52	1.70(0.72)		98.05	2.30 [2.02, 2.58]
Wood 1988	46	4.10(5.90)	41	0.00(3.20)		1.95	4.10 [2.13, 6.07]
Total (95% CI)	95		93			100.00	2.34 [2.06, 2.61]

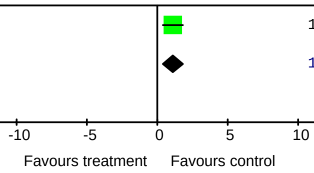


Test for heterogeneity: Chi² = 3.16, df = 1 (P = 0.08), I² = 68.3%
Test for overall effect: Z = 16.69 (P < 0.00001)

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 04 Physical activity vs diet (CALCULATIONS ONLY)
Outcome: 26 Change in treadmill test duration in min at 12 months

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wood 1988	46	0.30(2.00)	39	-0.80(1.30)		100.00	1.10 [0.39, 1.81]
Total (95% CI)	46		39			100.00	1.10 [0.39, 1.81]

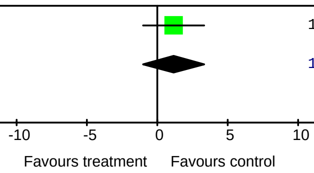
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.05 (P = 0.002)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 05 Physical activity vs diet and behaviour therapy
Outcome: 01 Weight change in kg at 18 months

Study or sub-category	N	Activity Mean (SD)	N	BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Messier 2004	80	-3.46(6.89)	82	-4.61(7.22)		100.00	1.15 [-1.02, 3.32]
Total (95% CI)	80		82			100.00	1.15 [-1.02, 3.32]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.04 (P = 0.30)



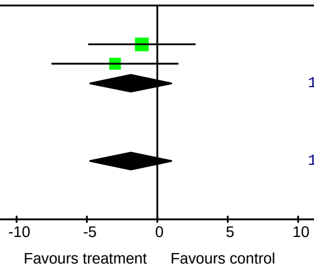
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 01 Weight change in kg at 4 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
MET 2003 a	25	0.40(6.03)	18	1.50(6.34)		58.47	-1.10 [-4.86, 2.66]
MET 2003 b	16	-2.90(6.74)	15	0.10(5.94)		41.53	-3.00 [-7.47, 1.47]
Subtotal (95% CI)	41		33			100.00	-1.89 [-4.77, 0.99]

Test for heterogeneity: Chi² = 0.41, df = 1 (P = 0.52), I² = 0%
Test for overall effect: Z = 1.29 (P = 0.20)

Total (95% CI)	41		33			100.00	-1.89 [-4.77, 0.99]

Test for heterogeneity: Chi² = 0.41, df = 1 (P = 0.52), I² = 0%
Test for overall effect: Z = 1.29 (P = 0.20)



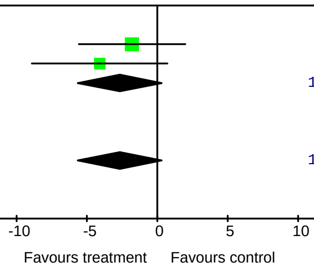
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 02 Weight change in kg at 9 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
MET 2003 a	25	0.10(5.94)	18	1.90(6.45)		61.85	-1.80 [-5.58, 1.98]
MET 2003 b	16	-5.30(7.41)	15	-1.20(6.25)		38.15	-4.10 [-8.92, 0.72]
Subtotal (95% CI)	41		33			100.00	-2.68 [-5.65, 0.30]

Test for heterogeneity: Chi² = 0.54, df = 1 (P = 0.46), I² = 0%
Test for overall effect: Z = 1.76 (P = 0.08)

Total (95% CI)	41		33			100.00	-2.68 [-5.65, 0.30]

Test for heterogeneity: Chi² = 0.54, df = 1 (P = 0.46), I² = 0%
Test for overall effect: Z = 1.76 (P = 0.08)



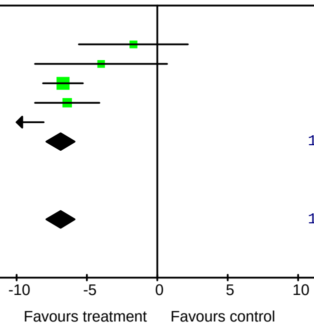
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
MET 2003 a	25	0.70(6.11)	18	2.40(6.59)		6.74	-1.70 [-5.57, 2.17]
MET 2003 b	16	-4.60(7.22)	15	-0.60(6.08)		4.60	-4.00 [-8.69, 0.69]
ODES 1995	65	-5.60(4.84)	43	1.10(2.62)		50.64	-6.70 [-8.11, -5.29]
Wood 1991a	42	-5.10(5.30)	39	1.30(5.20)		19.33	-6.40 [-8.69, -4.11]
Wood 1991b	39	-8.70(5.70)	40	1.70(4.80)		18.69	-10.40 [-12.73, -8.07]
Subtotal (95% CI)	187		155			100.00	-6.87 [-7.88, -5.87]

Test for heterogeneity: Chi² = 17.34, df = 4 (P = 0.002), I² = 76.9%
Test for overall effect: Z = 13.39 (P < 0.00001)

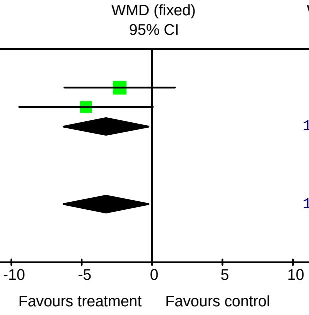
Total (95% CI)	187		155			100.00	-6.87 [-7.88, -5.87]

Test for heterogeneity: Chi² = 17.34, df = 4 (P = 0.002), I² = 76.9%
Test for overall effect: Z = 13.39 (P < 0.00001)



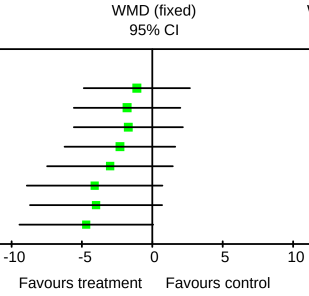
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 04 Weight change in kg at 16 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
MET 2003 a	25	0.60(6.08)	18	2.90(6.74)	59.42	-2.30 [-6.22, 1.62]
MET 2003 b	16	-5.20(7.39)	15	-0.50(6.06)	40.58	-4.70 [-9.45, 0.05]
Subtotal (95% CI)	41		33		100.00	-3.27 [-6.30, -0.25]
Test for heterogeneity: Chi² = 0.58, df = 1 (P = 0.44), I² = 0%						
Test for overall effect: Z = 2.12 (P = 0.03)						
Total (95% CI)	41		33		100.00	-3.27 [-6.30, -0.25]
Test for heterogeneity: Chi² = 0.58, df = 1 (P = 0.44), I² = 0%						
Test for overall effect: Z = 2.12 (P = 0.03)						



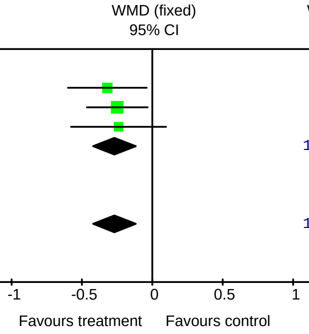
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 05 Weight change over time

Study or sub-category	N	Activity Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/deficit or low fat diet						
MET 2003 a 4 months	25	0.40(6.03)	18	1.50(6.34)	15.50	-1.10 [-4.86, 2.66]
MET 2003 a 9 months	25	0.10(5.94)	18	1.90(6.45)	15.36	-1.80 [-5.58, 1.98]
MET 2003 a 12 months	25	0.70(6.11)	18	2.40(6.59)	14.64	-1.70 [-5.57, 2.17]
MET 2003 a 16 months	25	0.60(6.08)	18	2.90(6.74)	14.28	-2.30 [-6.22, 1.62]
MET 2003 b 4 months	16	-2.90(6.74)	15	0.10(5.94)	11.01	-3.00 [-7.47, 1.47]
MET 2003 b 9 months	16	-5.30(7.41)	15	-1.20(6.25)	9.47	-4.10 [-8.92, 0.72]
MET 2003 b 12 months	16	-4.60(7.22)	15	-0.60(6.08)	9.99	-4.00 [-8.69, 0.69]
MET 2003 b 16 months	16	-5.20(7.39)	15	-0.50(6.06)	9.75	-4.70 [-9.45, 0.05]



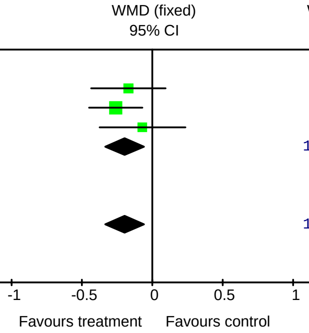
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 06 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.48(0.89)	43	-0.16(0.59)	29.76	-0.32 [-0.60, -0.04]
Wood 1991a	42	-0.28(0.52)	39	-0.03(0.47)	49.88	-0.25 [-0.47, -0.03]
Wood 1991b	39	-0.38(0.87)	40	-0.14(0.64)	20.36	-0.24 [-0.58, 0.10]
Subtotal (95% CI)	146		122		100.00	-0.27 [-0.42, -0.12]
Test for heterogeneity: Chi² = 0.19, df = 2 (P = 0.91), I² = 0%						
Test for overall effect: Z = 3.46 (P = 0.0005)						
Total (95% CI)	146		122		100.00	-0.27 [-0.42, -0.12]
Test for heterogeneity: Chi² = 0.19, df = 2 (P = 0.91), I² = 0%						
Test for overall effect: Z = 3.46 (P = 0.0005)						



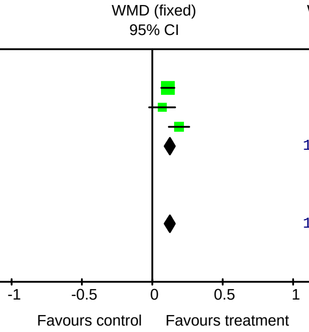
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 07 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.39(0.81)	43	-0.22(0.59)	27.07	-0.17 [-0.43, 0.09]
Wood 1991a	42	-0.29(0.46)	39	-0.03(0.41)	52.67	-0.26 [-0.45, -0.07]
Wood 1991b	39	-0.27(0.78)	40	-0.20(0.59)	20.26	-0.07 [-0.38, 0.24]
Subtotal (95% CI)	146		122		100.00	-0.20 [-0.33, -0.06]
Test for heterogeneity: Chi² = 1.13, df = 2 (P = 0.57), I² = 0%						
Test for overall effect: Z = 2.81 (P = 0.005)						
Total (95% CI)	146		122		100.00	-0.20 [-0.33, -0.06]
Test for heterogeneity: Chi² = 1.13, df = 2 (P = 0.57), I² = 0%						
Test for overall effect: Z = 2.81 (P = 0.005)						



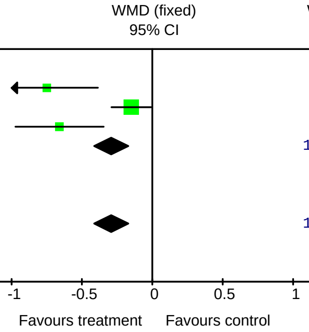
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 08 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	0.13(0.15)	43	0.02(0.10)	59.78	0.11 [0.06, 0.16]
Wood 1991a	42	0.02(0.18)	39	-0.05(0.24)	15.39	0.07 [-0.02, 0.16]
Wood 1991b	39	0.14(0.18)	40	-0.05(0.15)	24.83	0.19 [0.12, 0.26]
Subtotal (95% CI)	146		122		100.00	0.12 [0.09, 0.16]
Test for heterogeneity: Chi² = 4.76, df = 2 (P = 0.09), I² = 58.0%						
Test for overall effect: Z = 6.65 (P < 0.00001)						
Total (95% CI)	146		122		100.00	0.12 [0.09, 0.16]
Test for heterogeneity: Chi² = 4.76, df = 2 (P = 0.09), I² = 58.0%						
Test for overall effect: Z = 6.65 (P < 0.00001)						



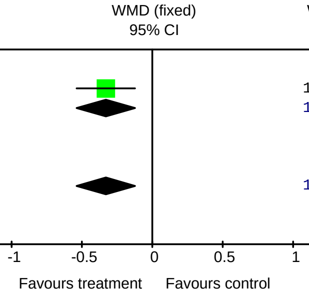
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 09 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.58(0.97)	43	0.17(0.92)	11.11	-0.75 [-1.11, -0.39]
Wood 1991a	42	-0.02(0.26)	39	0.13(0.37)	74.10	-0.15 [-0.29, -0.01]
Wood 1991b	39	-0.48(0.75)	40	0.18(0.67)	14.79	-0.66 [-0.97, -0.35]
Subtotal (95% CI)	146		122		100.00	-0.29 [-0.41, -0.17]
Test for heterogeneity: Chi² = 15.36, df = 2 (P = 0.0005), I² = 87.0%						
Test for overall effect: Z = 4.74 (P < 0.00001)						
Total (95% CI)	146		122		100.00	-0.29 [-0.41, -0.17]
Test for heterogeneity: Chi² = 15.36, df = 2 (P = 0.0005), I² = 87.0%						
Test for overall effect: Z = 4.74 (P < 0.00001)						



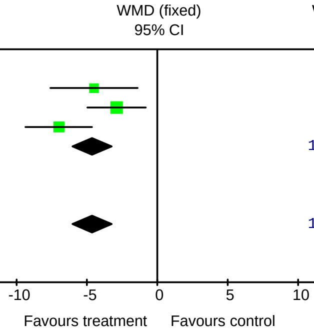
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 10 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.26(0.64)	43	0.07(0.46)	100.00	-0.33 [-0.54, -0.12]
Subtotal (95% CI)	65		43		100.00	-0.33 [-0.54, -0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.12 (P = 0.002)						
Total (95% CI)	65		43		100.00	-0.33 [-0.54, -0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.12 (P = 0.002)						



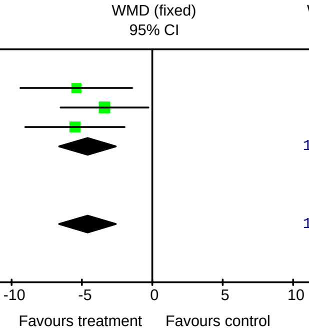
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 11 Change in DBP in mmHg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-5.20(7.26)	43	-0.70(8.52)	20.23	-4.50 [-7.60, -1.40]
Wood 1991a	42	-2.00(4.10)	39	0.90(5.30)	45.11	-2.90 [-4.97, -0.83]
Wood 1991b	39	-4.90(5.70)	40	2.10(5.00)	34.67	-7.00 [-9.37, -4.63]
Subtotal (95% CI)	146		122		100.00	-4.64 [-6.04, -3.25]
Test for heterogeneity: Chi² = 6.53, df = 2 (P = 0.04), I² = 69.4%						
Test for overall effect: Z = 6.53 (P < 0.00001)						
Total (95% CI)	146		122		100.00	-4.64 [-6.04, -3.25]
Test for heterogeneity: Chi² = 6.53, df = 2 (P = 0.04), I² = 69.4%						
Test for overall effect: Z = 6.53 (P < 0.00001)						



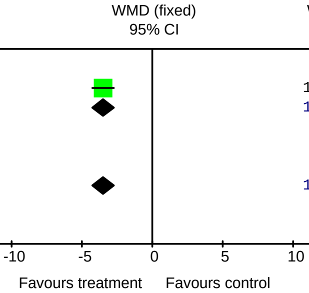
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 06 Physical activity and diet vs control (no treatment)
Outcome: 12 Change in SBP in mmHg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-5.90(8.87)	43	-0.50(11.15)	25.74	-5.40 [-9.37, -1.43]
Wood 1991a	42	-3.60(7.70)	39	-0.20(6.60)	41.76	-3.40 [-6.52, -0.28]
Wood 1991b	39	-5.40(8.30)	40	0.10(7.70)	32.50	-5.50 [-9.03, -1.97]
Subtotal (95% CI)	146		122		100.00	-4.60 [-6.61, -2.58]
Test for heterogeneity: Chi² = 0.97, df = 2 (P = 0.61), I² = 0%						
Test for overall effect: Z = 4.47 (P < 0.00001)						
Total (95% CI)	146		122		100.00	-4.60 [-6.61, -2.58]
Test for heterogeneity: Chi² = 0.97, df = 2 (P = 0.61), I² = 0%						
Test for overall effect: Z = 4.47 (P < 0.00001)						



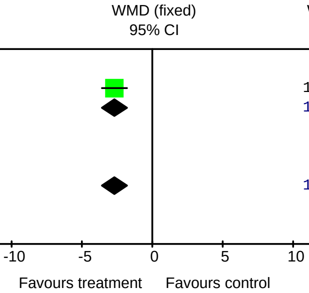
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	256	-4.50(5.00)	250	-1.00(3.70)	100.00	-3.50 [-4.27, -2.73]
Subtotal (95% CI)	256		250		100.00	-3.50 [-4.27, -2.73]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 8.97 (P < 0.00001)						
Total (95% CI)	256		250		100.00	-3.50 [-4.27, -2.73]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 8.97 (P < 0.00001)						



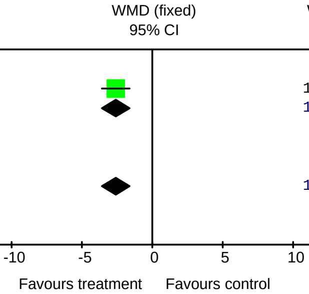
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 02 Weight change in kg at 24 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	244	-3.50(5.50)	226	-0.80(4.40)	100.00	-2.70 [-3.60, -1.80]
Subtotal (95% CI)	244		226		100.00	-2.70 [-3.60, -1.80]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.90 (P < 0.00001)						
Total (95% CI)	244		226		100.00	-2.70 [-3.60, -1.80]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.90 (P < 0.00001)						



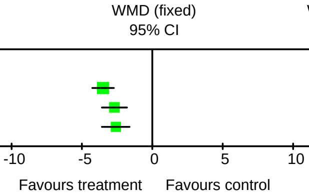
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 03 Weight change in kg at 36 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	231	-3.50(5.10)	203	-0.90(5.40)	100.00	-2.60 [-3.59, -1.61]
Subtotal (95% CI)	231		203		100.00	-2.60 [-3.59, -1.61]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.14 (P < 0.00001)						
Total (95% CI)	231		203		100.00	-2.60 [-3.59, -1.61]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.14 (P < 0.00001)						



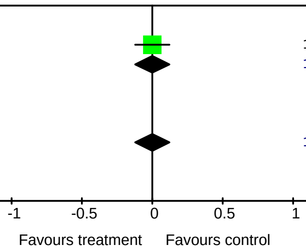
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 04 Weight change over time

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/deficit or low fat diet						
FDPS 12 months	256	-4.50(5.00)	250	-1.00(3.70)	43.07	-3.50 [-4.27, -2.73]
FDPS 24 months	244	-3.50(5.50)	226	-0.80(4.40)	31.31	-2.70 [-3.60, -1.80]
FDPS 36 months	231	-3.50(5.10)	203	-0.90(5.40)	25.62	-2.60 [-3.59, -1.61]



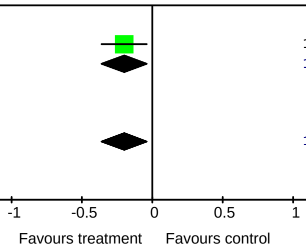
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	256	-0.10(0.70)	250	-0.10(0.70)	100.00	0.00 [-0.12, 0.12]
Subtotal (95% CI)	256		250		100.00	0.00 [-0.12, 0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	256		250		100.00	0.00 [-0.12, 0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						



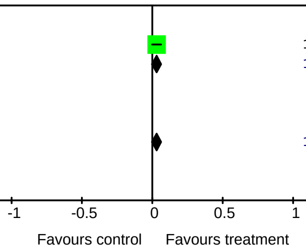
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 06 Change in total cholesterol in mmol/l at 36 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	231	-0.10(0.90)	203	0.10(0.80)	100.00	-0.20 [-0.36, -0.04]
Subtotal (95% CI)	231		203		100.00	-0.20 [-0.36, -0.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.45 (P = 0.01)						
Total (95% CI)	231		203		100.00	-0.20 [-0.36, -0.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.45 (P = 0.01)						



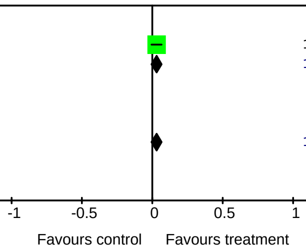
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 07 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	256	0.05(0.19)	250	0.02(0.17)	100.00	0.03 [0.00, 0.06]
Subtotal (95% CI)	256		250		100.00	0.03 [0.00, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.87 (P = 0.06)						
Total (95% CI)	256		250		100.00	0.03 [0.00, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.87 (P = 0.06)						



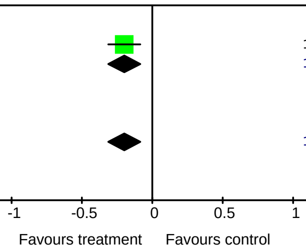
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 08 Change in HDL cholesterol in mmol/l at 36 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	231	0.14(0.20)	203	0.11(0.19)	100.00	0.03 [-0.01, 0.07]
Subtotal (95% CI)	231		203		100.00	0.03 [-0.01, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.60 (P = 0.11)						
Total (95% CI)	231		203		100.00	0.03 [-0.01, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.60 (P = 0.11)						



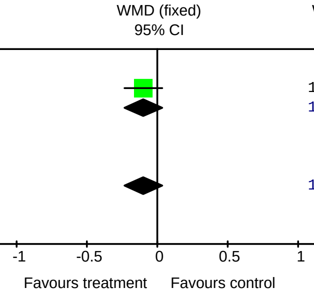
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 09 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	256	-0.20(0.60)	250	0.00(0.70)	100.00	-0.20 [-0.31, -0.09]
Subtotal (95% CI)	256		250		100.00	-0.20 [-0.31, -0.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.45 (P = 0.0006)						
Total (95% CI)	256		250		100.00	-0.20 [-0.31, -0.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.45 (P = 0.0006)						



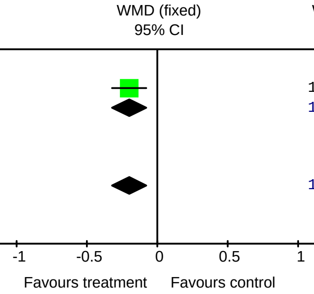
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 10 Change in triglycerides in mmol/l at 36 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	231	-0.10(0.60)	203	0.00(0.80)	100.00	-0.10 [-0.23, 0.03]
Subtotal (95% CI)	231		203		100.00	-0.10 [-0.23, 0.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.46 (P = 0.15)						
Total (95% CI)	231		203		100.00	-0.10 [-0.23, 0.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.46 (P = 0.15)						



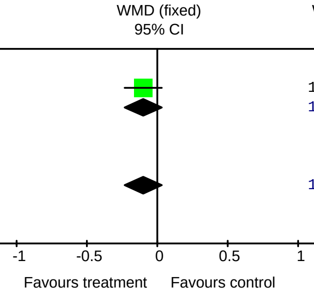
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 11 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	256	-0.20(0.70)	250	0.00(0.70)	100.00	-0.20 [-0.32, -0.08]
Subtotal (95% CI)	256		250		100.00	-0.20 [-0.32, -0.08]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.21 (P = 0.001)						
Total (95% CI)	256		250		100.00	-0.20 [-0.32, -0.08]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.21 (P = 0.001)						



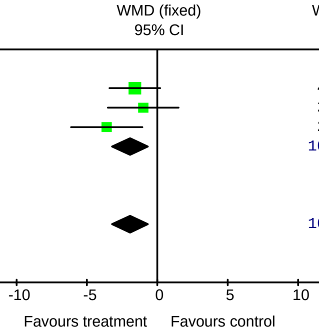
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 07 Physical activity and diet vs information
Outcome: 12 Change in fasting plasma glucose in mmol/l at 36 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
FDPS 2003	231	0.00(0.70)	203	0.10(0.70)	100.00	-0.10 [-0.23, 0.03]
Subtotal (95% CI)	231		203		100.00	-0.10 [-0.23, 0.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.48 (P = 0.14)						
Total (95% CI)	231		203		100.00	-0.10 [-0.23, 0.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.48 (P = 0.14)						

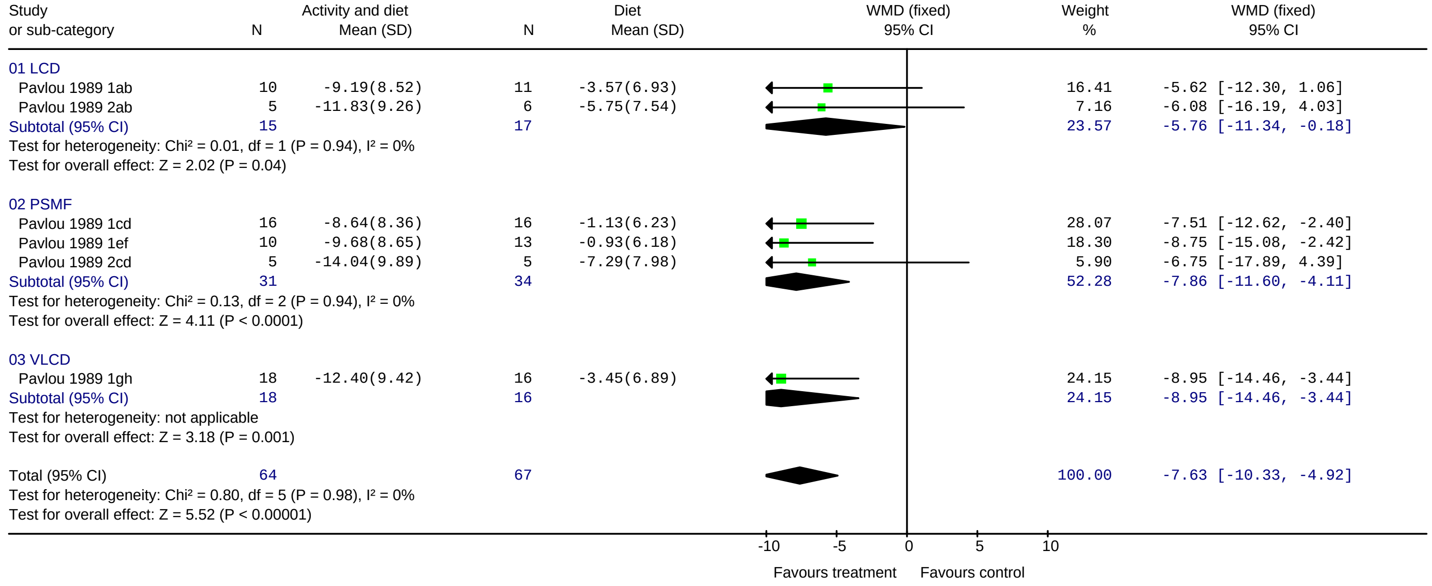


Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-5.60(4.84)	52	-4.00(5.05)	49.37	-1.60 [-3.41, 0.21]
Wood 1991a	42	-5.10(5.30)	31	-4.10(5.50)	25.54	-1.00 [-3.51, 1.51]
Wood 1991b	39	-8.70(5.70)	40	-5.10(5.80)	25.09	-3.60 [-6.14, -1.06]
Subtotal (95% CI)	146		123		100.00	-1.95 [-3.22, -0.68]
Test for heterogeneity: Chi² = 2.32, df = 2 (P = 0.31), I² = 13.8%						
Test for overall effect: Z = 3.01 (P = 0.003)						
Total (95% CI)	146		123		100.00	-1.95 [-3.22, -0.68]
Test for heterogeneity: Chi² = 2.32, df = 2 (P = 0.31), I² = 13.8%						
Test for overall effect: Z = 3.01 (P = 0.003)						

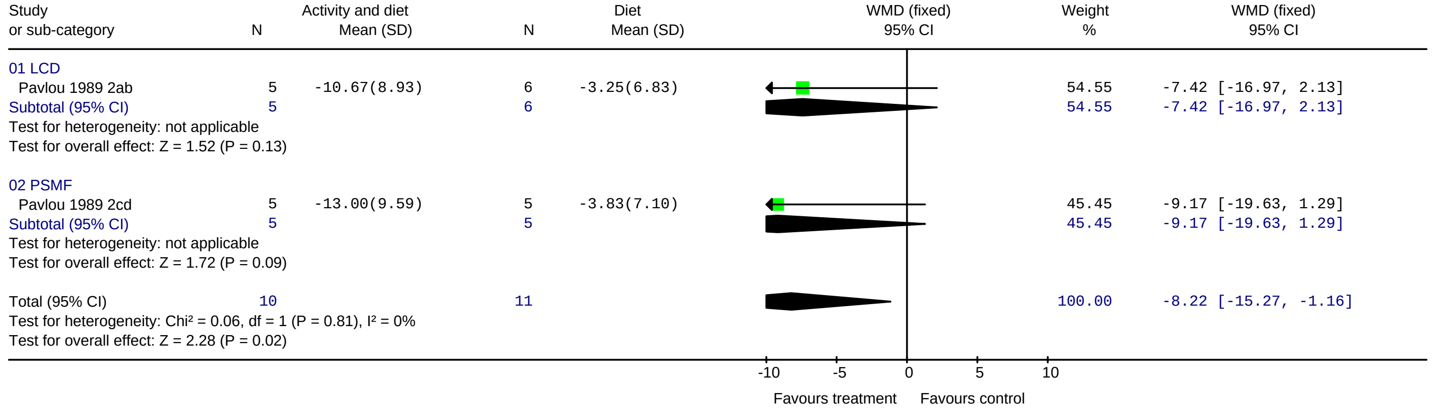


Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 02 Weight change in kg at 18 months



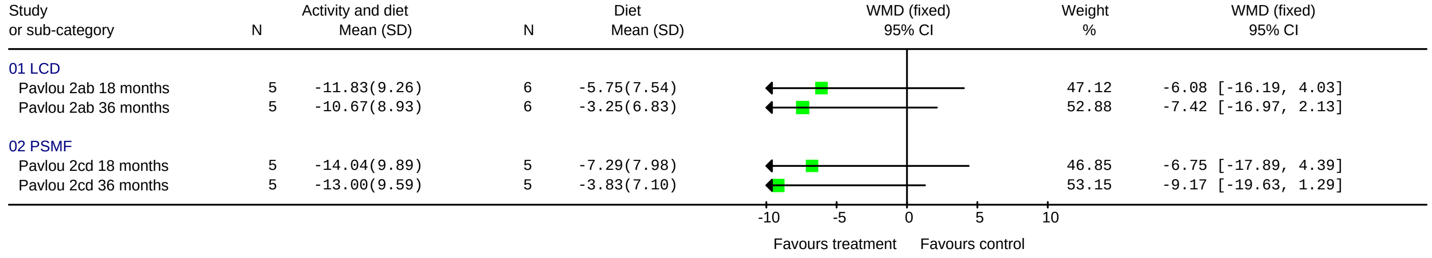
Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Pavlou 1989 1ab	10	-9.19(8.52)	11	-3.57(6.93)	16.41	-5.62 [-12.30, 1.06]
Pavlou 1989 2ab	5	-11.83(9.26)	6	-5.75(7.54)	7.16	-6.08 [-16.19, 4.03]
Subtotal (95% CI)	15		17		23.57	-5.76 [-11.34, -0.18]
Test for heterogeneity: Chi² = 0.01, df = 1 (P = 0.94), I² = 0%						
Test for overall effect: Z = 2.02 (P = 0.04)						
02 PSMF						
Pavlou 1989 1cd	16	-8.64(8.36)	16	-1.13(6.23)	28.07	-7.51 [-12.62, -2.40]
Pavlou 1989 1ef	10	-9.68(8.65)	13	-0.93(6.18)	18.30	-8.75 [-15.08, -2.42]
Pavlou 1989 2cd	5	-14.04(9.89)	5	-7.29(7.98)	5.90	-6.75 [-17.89, 4.39]
Subtotal (95% CI)	31		34		52.28	-7.86 [-11.60, -4.11]
Test for heterogeneity: Chi² = 0.13, df = 2 (P = 0.94), I² = 0%						
Test for overall effect: Z = 4.11 (P < 0.0001)						
03 VLCD						
Pavlou 1989 1gh	18	-12.40(9.42)	16	-3.45(6.89)	24.15	-8.95 [-14.46, -3.44]
Subtotal (95% CI)	18		16		24.15	-8.95 [-14.46, -3.44]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.18 (P = 0.001)						
Total (95% CI)	64		67		100.00	-7.63 [-10.33, -4.92]
Test for heterogeneity: Chi² = 0.80, df = 5 (P = 0.98), I² = 0%						
Test for overall effect: Z = 5.52 (P < 0.00001)						

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 03 Weight change in kg at 36 months

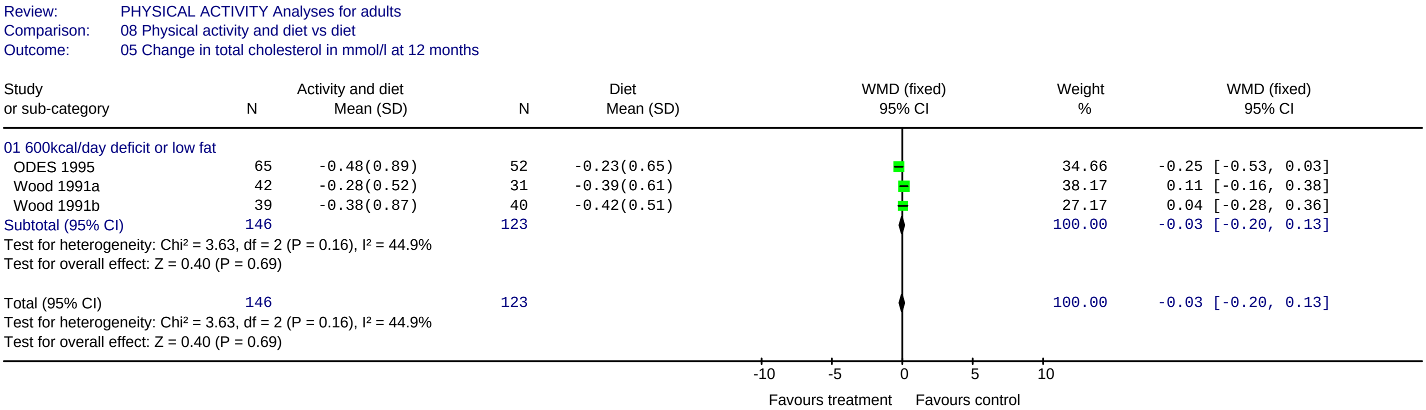


Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Pavlou 1989 2ab	5	-10.67(8.93)	6	-3.25(6.83)	54.55	-7.42 [-16.97, 2.13]
Subtotal (95% CI)	5		6		54.55	-7.42 [-16.97, 2.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						
02 PSMF						
Pavlou 1989 2cd	5	-13.00(9.59)	5	-3.83(7.10)	45.45	-9.17 [-19.63, 1.29]
Subtotal (95% CI)	5		5		45.45	-9.17 [-19.63, 1.29]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.72 (P = 0.09)						
Total (95% CI)	10		11		100.00	-8.22 [-15.27, -1.16]
Test for heterogeneity: Chi² = 0.06, df = 1 (P = 0.81), I² = 0%						
Test for overall effect: Z = 2.28 (P = 0.02)						

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 04 Weight change over time

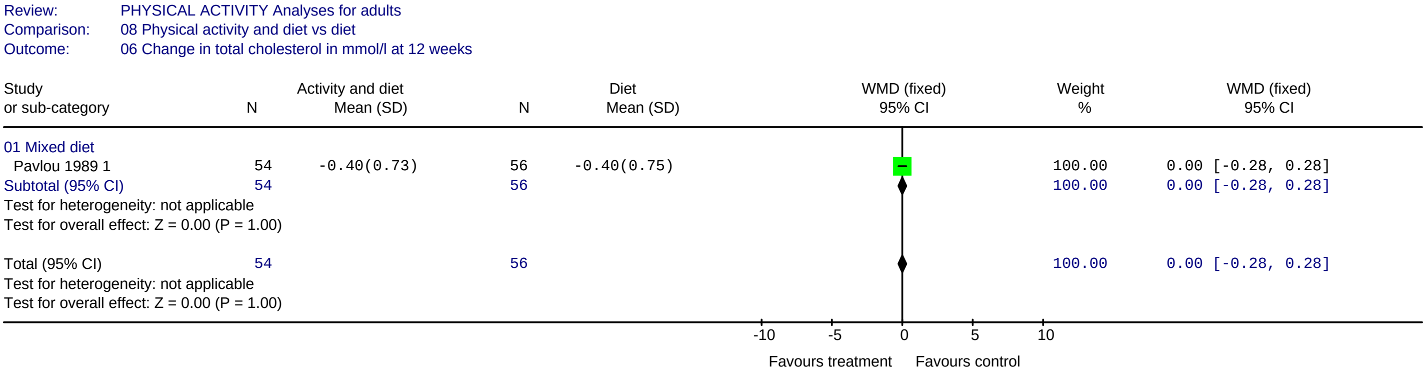


Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Pavlou 2ab 18 months	5	-11.83(9.26)	6	-5.75(7.54)	47.12	-6.08 [-16.19, 4.03]
Pavlou 2ab 36 months	5	-10.67(8.93)	6	-3.25(6.83)	52.88	-7.42 [-16.97, 2.13]
02 PSMF						
Pavlou 2cd 18 months	5	-14.04(9.89)	5	-7.29(7.98)	46.85	-6.75 [-17.89, 4.39]
Pavlou 2cd 36 months	5	-13.00(9.59)	5	-3.83(7.10)	53.15	-9.17 [-19.63, 1.29]



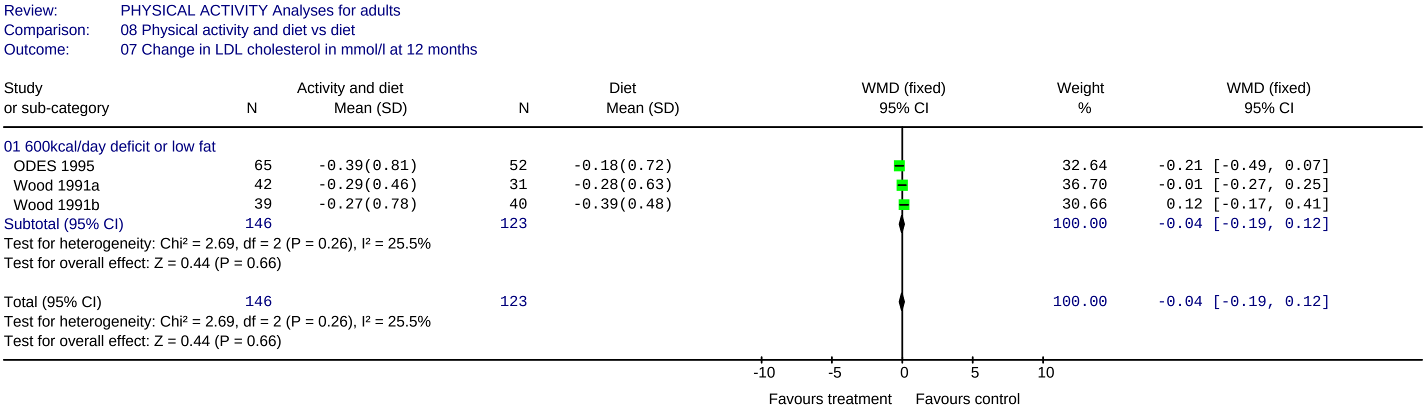
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.48(0.89)	52	-0.23(0.65)	34.66	-0.25 [-0.53, 0.03]
Wood 1991a	42	-0.28(0.52)	31	-0.39(0.61)	38.17	0.11 [-0.16, 0.38]
Wood 1991b	39	-0.38(0.87)	40	-0.42(0.51)	27.17	0.04 [-0.28, 0.36]
Subtotal (95% CI)	146		123		100.00	-0.03 [-0.20, 0.13]
Test for heterogeneity: Chi² = 3.63, df = 2 (P = 0.16), I² = 44.9%						
Test for overall effect: Z = 0.40 (P = 0.69)						
Total (95% CI)	146		123		100.00	-0.03 [-0.20, 0.13]
Test for heterogeneity: Chi² = 3.63, df = 2 (P = 0.16), I² = 44.9%						
Test for overall effect: Z = 0.40 (P = 0.69)						



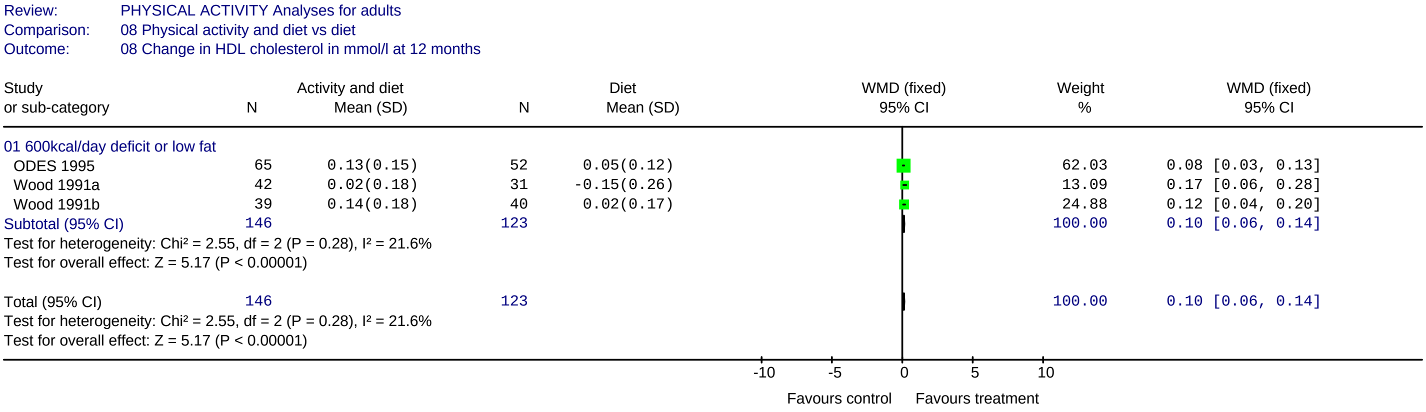
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 06 Change in total cholesterol in mmol/l at 12 weeks

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Mixed diet						
Pavlou 1989 1	54	-0.40(0.73)	56	-0.40(0.75)	100.00	0.00 [-0.28, 0.28]
Subtotal (95% CI)	54		56		100.00	0.00 [-0.28, 0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	54		56		100.00	0.00 [-0.28, 0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 07 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.39(0.81)	52	-0.18(0.72)	32.64	-0.21 [-0.49, 0.07]
Wood 1991a	42	-0.29(0.46)	31	-0.28(0.63)	36.70	-0.01 [-0.27, 0.25]
Wood 1991b	39	-0.27(0.78)	40	-0.39(0.48)	30.66	0.12 [-0.17, 0.41]
Subtotal (95% CI)	146		123		100.00	-0.04 [-0.19, 0.12]
Test for heterogeneity: Chi² = 2.69, df = 2 (P = 0.26), I² = 25.5%						
Test for overall effect: Z = 0.44 (P = 0.66)						
Total (95% CI)	146		123		100.00	-0.04 [-0.19, 0.12]
Test for heterogeneity: Chi² = 2.69, df = 2 (P = 0.26), I² = 25.5%						
Test for overall effect: Z = 0.44 (P = 0.66)						

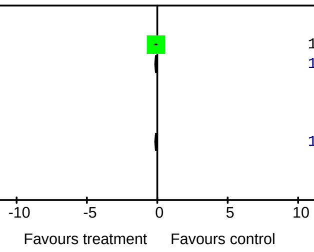


Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 08 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	0.13(0.15)	52	0.05(0.12)	62.03	0.08 [0.03, 0.13]
Wood 1991a	42	0.02(0.18)	31	-0.15(0.26)	13.09	0.17 [0.06, 0.28]
Wood 1991b	39	0.14(0.18)	40	0.02(0.17)	24.88	0.12 [0.04, 0.20]
Subtotal (95% CI)	146		123		100.00	0.10 [0.06, 0.14]
Test for heterogeneity: Chi² = 2.55, df = 2 (P = 0.28), I² = 21.6%						
Test for overall effect: Z = 5.17 (P < 0.00001)						
Total (95% CI)	146		123		100.00	0.10 [0.06, 0.14]
Test for heterogeneity: Chi² = 2.55, df = 2 (P = 0.28), I² = 21.6%						
Test for overall effect: Z = 5.17 (P < 0.00001)						

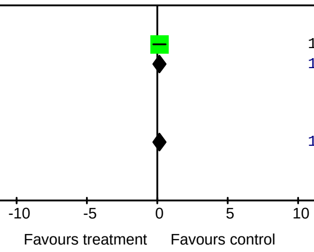
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 09 Change in HDL cholesterol in mmol/l at 12 weeks

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Mixed diet							
Pavlou 1989 1	54	-0.20(0.15)	56	-0.10(0.15)		100.00	-0.10 [-0.16, -0.04]
Subtotal (95% CI)	54		56			100.00	-0.10 [-0.16, -0.04]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.50 (P = 0.0005)							
Total (95% CI)	54		56			100.00	-0.10 [-0.16, -0.04]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.50 (P = 0.0005)							



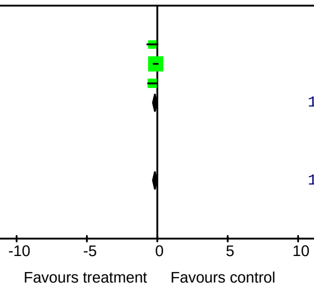
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 10 Change in triglycerides in mmol/l at 12 weeks

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Mixed diet							
Pavlou 1989 1	54	-0.33(0.73)	56	-0.48(1.50)		100.00	0.15 [-0.29, 0.59]
Subtotal (95% CI)	54		56			100.00	0.15 [-0.29, 0.59]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.67 (P = 0.50)							
Total (95% CI)	54		56			100.00	0.15 [-0.29, 0.59]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.67 (P = 0.50)							



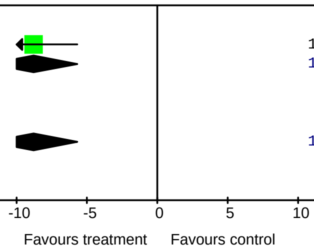
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 11 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
ODES 1995	65	-0.58(0.97)	52	-0.23(1.01)		11.96	-0.35 [-0.71, 0.01]
Wood 1991a	42	-0.02(0.26)	31	0.09(0.36)		70.41	-0.11 [-0.26, 0.04]
Wood 1991b	39	-0.48(0.75)	40	-0.12(0.59)		17.63	-0.36 [-0.66, -0.06]
Subtotal (95% CI)	146		123			100.00	-0.18 [-0.31, -0.06]
Test for heterogeneity: Chi² = 3.09, df = 2 (P = 0.21), I² = 35.3%							
Test for overall effect: Z = 2.86 (P = 0.004)							
Total (95% CI)	146		123			100.00	-0.18 [-0.31, -0.06]
Test for heterogeneity: Chi² = 3.09, df = 2 (P = 0.21), I² = 35.3%							
Test for overall effect: Z = 2.86 (P = 0.004)							



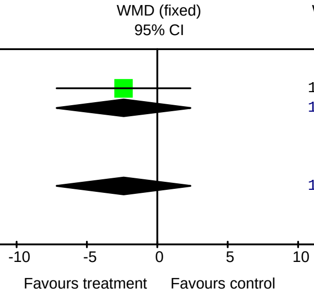
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 12 Change in DBP in mmHg at 6 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Mixed diet							
Pavlou 1989 1	54	-11.50(8.30)	56	-2.70(8.30)		100.00	-8.80 [-11.90, -5.70]
Subtotal (95% CI)	54		56			100.00	-8.80 [-11.90, -5.70]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 5.56 (P < 0.00001)							
Total (95% CI)	54		56			100.00	-8.80 [-11.90, -5.70]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 5.56 (P < 0.00001)							



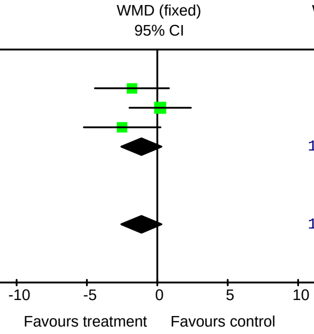
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 13 Change in SBP in mmHd at 6 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Mixed diet						
Pavlou 1989 1	54	-6.30(12.70)	56	-3.90(12.70)	100.00	-2.40 [-7.15, 2.35]
Subtotal (95% CI)	54		56		100.00	-2.40 [-7.15, 2.35]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.99 (P = 0.32)						
Total (95% CI)	54		56		100.00	-2.40 [-7.15, 2.35]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.99 (P = 0.32)						



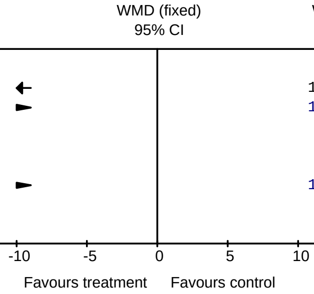
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 14 Change in DBP in mmHg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-5.20(7.26)	52	-3.40(7.21)	29.39	-1.80 [-4.44, 0.84]
Wood 1991a	42	-2.00(4.10)	31	-2.20(5.10)	42.93	0.20 [-1.98, 2.38]
Wood 1991b	39	-4.90(5.70)	40	-2.40(6.60)	27.68	-2.50 [-5.22, 0.22]
Subtotal (95% CI)	146		123		100.00	-1.14 [-2.56, 0.29]
Test for heterogeneity: Chi² = 2.65, df = 2 (P = 0.27), I² = 24.6%						
Test for overall effect: Z = 1.56 (P = 0.12)						
Total (95% CI)	146		123		100.00	-1.14 [-2.56, 0.29]
Test for heterogeneity: Chi² = 2.65, df = 2 (P = 0.27), I² = 24.6%						
Test for overall effect: Z = 1.56 (P = 0.12)						



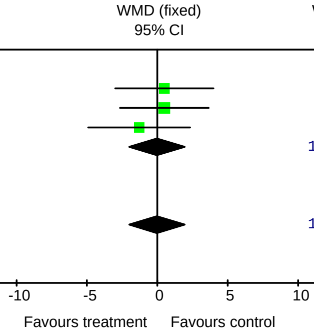
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 15 Change in DBP in mmHg at 18 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Mixed diet						
Pavlou 1989 1	54	-10.40(8.30)	56	1.70(8.30)	100.00	-12.10 [-15.20, -9.00]
Subtotal (95% CI)	54		56		100.00	-12.10 [-15.20, -9.00]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 7.64 (P < 0.00001)						
Total (95% CI)	54		56		100.00	-12.10 [-15.20, -9.00]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 7.64 (P < 0.00001)						



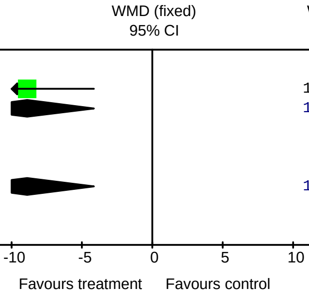
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 16 Change in SBP in mmHg at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-5.90(8.87)	52	-6.40(10.10)	31.61	0.50 [-2.99, 3.99]
Wood 1991a	42	-3.60(7.70)	31	-4.10(6.00)	38.97	0.50 [-2.64, 3.64]
Wood 1991b	39	-5.40(8.30)	40	-4.10(8.10)	29.43	-1.30 [-4.92, 2.32]
Subtotal (95% CI)	146		123		100.00	-0.03 [-1.99, 1.93]
Test for heterogeneity: Chi² = 0.67, df = 2 (P = 0.71), I² = 0%						
Test for overall effect: Z = 0.03 (P = 0.98)						
Total (95% CI)	146		123		100.00	-0.03 [-1.99, 1.93]
Test for heterogeneity: Chi² = 0.67, df = 2 (P = 0.71), I² = 0%						
Test for overall effect: Z = 0.03 (P = 0.98)						



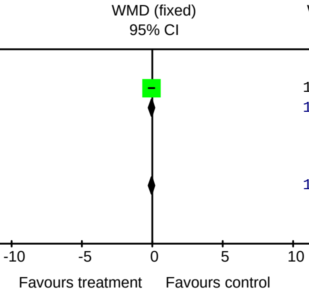
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 17 Change in SBP in mmHg at 18 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Mixed diet						
Pavlou 1989 1	54	-7.70(12.70)	56	1.20(12.70)	100.00	-8.90 [-13.65, -4.15]
Subtotal (95% CI)	54		56		100.00	-8.90 [-13.65, -4.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.67 (P = 0.0002)						
Total (95% CI)	54		56		100.00	-8.90 [-13.65, -4.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.67 (P = 0.0002)						



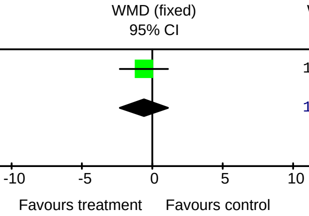
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 08 Physical activity and diet vs diet
Outcome: 18 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Activity and diet Mean (SD)	N	Diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
ODES 1995	65	-0.26(0.64)	52	-0.21(0.50)	100.00	-0.05 [-0.26, 0.16]
Subtotal (95% CI)	65		52		100.00	-0.05 [-0.26, 0.16]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.47 (P = 0.64)						
Total (95% CI)	65		52		100.00	-0.05 [-0.26, 0.16]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.47 (P = 0.64)						



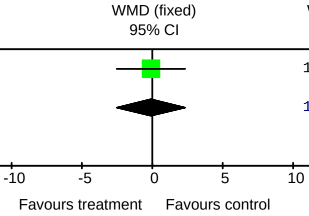
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	-2.10(4.20)	32	-1.50(2.70)	100.00	-0.60 [-2.31, 1.11]
Total (95% CI)	33		32		100.00	-0.60 [-2.31, 1.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.69 (P = 0.49)						



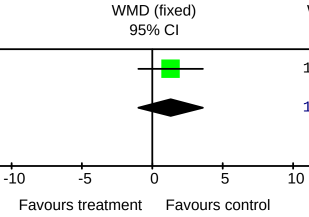
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	28	-0.40(4.80)	29	-0.30(4.50)	100.00	-0.10 [-2.52, 2.32]
Total (95% CI)	28		29		100.00	-0.10 [-2.52, 2.32]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.08 (P = 0.94)						



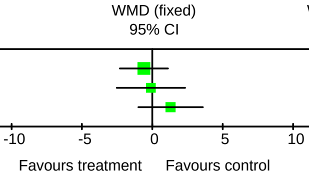
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 03 Weight change in kg at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	1.00(4.70)	31	-0.30(4.50)	100.00	1.30 [-0.99, 3.59]
Total (95% CI)	31		31		100.00	1.30 [-0.99, 3.59]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.11 (P = 0.27)						



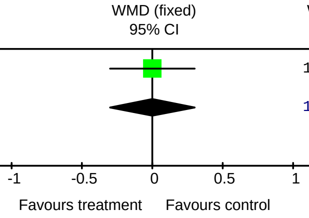
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 04 Weight change over time

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998 6 months	33	-2.10(4.20)	32	-1.50(2.70)	48.56	-0.60 [-2.31, 1.11]
Wing 1998 12 months	28	-0.40(4.80)	29	-0.30(4.50)	24.34	-0.10 [-2.52, 2.32]
Wing 1998 24 months	31	1.00(4.70)	31	-0.30(4.50)	27.10	1.30 [-0.99, 3.59]



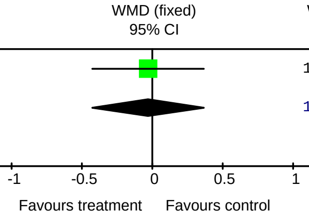
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 05 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	0.12(0.72)	32	0.12(0.50)	100.00	0.00 [-0.30, 0.30]
Total (95% CI)	33		32		100.00	0.00 [-0.30, 0.30]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						



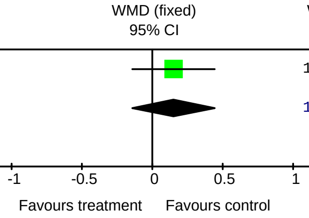
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 06 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	28	0.36(0.82)	29	0.39(0.70)	100.00	-0.03 [-0.43, 0.37]
Total (95% CI)	28		29		100.00	-0.03 [-0.43, 0.37]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.15 (P = 0.88)						



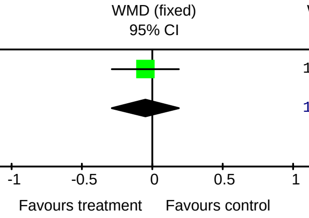
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 07 Change in total cholesterol in mmol/l at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	0.33(0.64)	31	0.18(0.53)	100.00	0.15 [-0.14, 0.44]
Total (95% CI)	31		31		100.00	0.15 [-0.14, 0.44]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.01 (P = 0.31)						



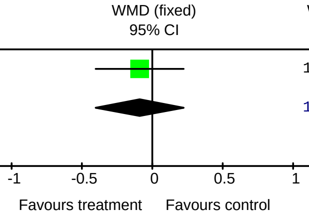
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 08 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	0.03(0.52)	32	0.08(0.46)	100.00	-0.05 [-0.29, 0.19]
Total (95% CI)	33		32		100.00	-0.05 [-0.29, 0.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.41 (P = 0.68)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 09 Change in LDL cholesterol in mmol/l at 12 months

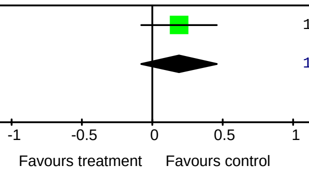
Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	28	0.15(0.54)	29	0.24(0.66)	100.00	-0.09 [-0.40, 0.22]
Total (95% CI)	28		29		100.00	-0.09 [-0.40, 0.22]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.56 (P = 0.57)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 10 Change in LDL cholesterol on mmol/l at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	0.22(0.61)	31	0.03(0.46)	100.00	0.19 [-0.08, 0.46]
Total (95% CI)	31		31		100.00	0.19 [-0.08, 0.46]

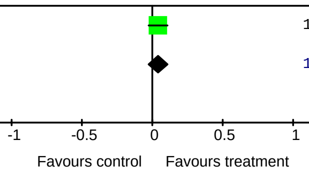
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.38 (P = 0.17)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 11 Change in HDL cholesterol in mmol/l at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	0.02(0.16)	32	-0.02(0.11)	100.00	0.04 [-0.03, 0.11]
Total (95% CI)	33		32		100.00	0.04 [-0.03, 0.11]

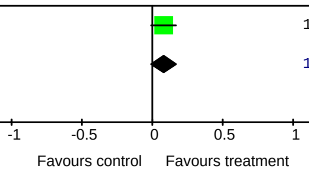
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.18 (P = 0.24)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 12 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	28	0.16(0.18)	29	0.08(0.16)	100.00	0.08 [-0.01, 0.17]
Total (95% CI)	28		29		100.00	0.08 [-0.01, 0.17]

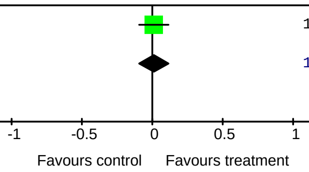
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.77 (P = 0.08)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 13 Change in HDL cholesterol in mmol/l at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	0.05(0.17)	31	0.04(0.24)	100.00	0.01 [-0.09, 0.11]
Total (95% CI)	31		31		100.00	0.01 [-0.09, 0.11]

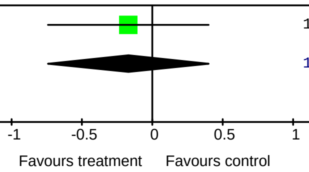
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.19 (P = 0.85)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 14 Change in triglycerides in mmol/l at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	0.12(1.64)	32	0.29(0.32)	100.00	-0.17 [-0.74, 0.40]
Total (95% CI)	33		32		100.00	-0.17 [-0.74, 0.40]

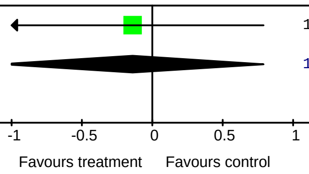
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.58 (P = 0.56)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 15 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	28	0.26(2.19)	29	0.40(1.25)	100.00	-0.14 [-1.07, 0.79]
Total (95% CI)	28		29		100.00	-0.14 [-1.07, 0.79]

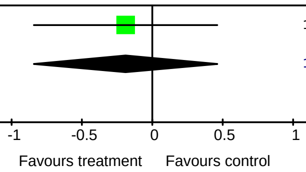
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.30 (P = 0.77)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 16 Change in triglycerides in mmol/l at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	0.33(1.46)	31	0.52(1.14)	100.00	-0.19 [-0.84, 0.46]
Total (95% CI)	31		31		100.00	-0.19 [-0.84, 0.46]

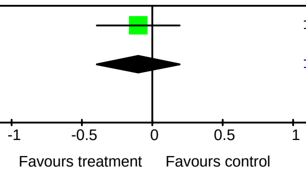
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.57 (P = 0.57)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 17 Change in fasting plasma glucose in mmol/l at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	0.00(0.70)	32	0.10(0.50)	100.00	-0.10 [-0.40, 0.20]
Total (95% CI)	33		32		100.00	-0.10 [-0.40, 0.20]

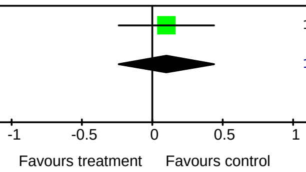
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.66 (P = 0.51)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 18 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	28	0.10(0.70)	29	0.00(0.60)	100.00	0.10 [-0.24, 0.44]
Total (95% CI)	28		29		100.00	0.10 [-0.24, 0.44]

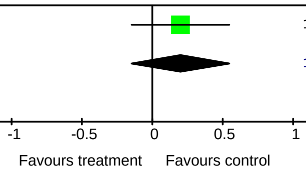
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.58 (P = 0.56)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 19 Change in fasting plasma glucose in mmol/l at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	0.40(0.90)	31	0.20(0.40)	100.00	0.20 [-0.15, 0.55]
Total (95% CI)	31		31		100.00	0.20 [-0.15, 0.55]

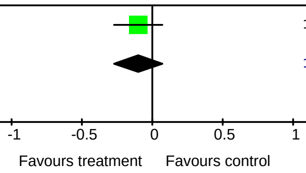
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.13 (P = 0.26)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 20 Change in %HbA1c at 6 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	33	0.10(0.30)	32	0.20(0.40)	100.00	-0.10 [-0.27, 0.07]
Total (95% CI)	33		32		100.00	-0.10 [-0.27, 0.07]

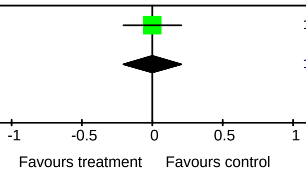
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.14 (P = 0.26)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 21 Change in %HbA1c at 24 months

Study or sub-category	N	PA+BT Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
Wing 1998	31	-0.10(0.50)	31	-0.10(0.30)	100.00	0.00 [-0.21, 0.21]
Total (95% CI)	31		31		100.00	0.00 [-0.21, 0.21]

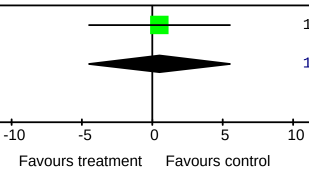
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 22 Change in DBP in mmHg at 6 months

Study or sub-category	PA+BT N	PA+BT Mean (SD)	Information N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1998	33	-1.70(12.20)	32	-2.20(8.00)		100.00	0.50 [-4.50, 5.50]
Total (95% CI)	33		32			100.00	0.50 [-4.50, 5.50]

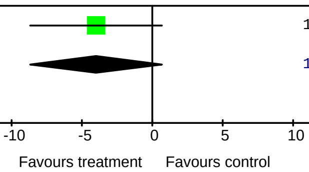
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.20 (P = 0.84)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 23 Change in DBP in mmHg at 12 months

Study or sub-category	PA+BT N	PA+BT Mean (SD)	Information N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1998	28	0.90(9.70)	29	4.90(8.20)		100.00	-4.00 [-8.67, 0.67]
Total (95% CI)	28		29			100.00	-4.00 [-8.67, 0.67]

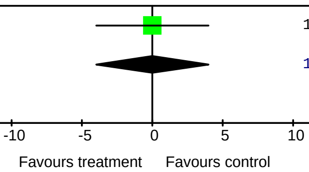
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.68 (P = 0.09)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 24 Change in DBP in mmHg at 24 months

Study or sub-category	PA+BT N	PA+BT Mean (SD)	Information N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1998	31	2.00(8.00)	31	2.00(8.00)		100.00	0.00 [-3.98, 3.98]
Total (95% CI)	31		31			100.00	0.00 [-3.98, 3.98]

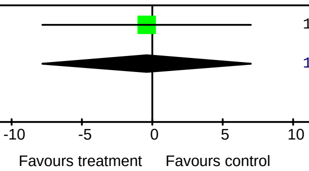
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 25 Change in SBP in mmHg at 6 months

Study or sub-category	PA+BT N	PA+BT Mean (SD)	Information N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1998	33	-2.40(18.90)	32	-2.00(10.50)		100.00	-0.40 [-7.80, 7.00]
Total (95% CI)	33		32			100.00	-0.40 [-7.80, 7.00]

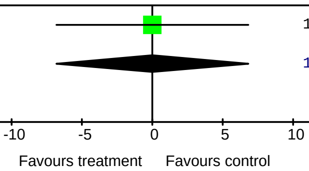
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.11 (P = 0.92)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 26 Change in SBP in mmHg at 12 months

Study or sub-category	PA+BT N	PA+BT Mean (SD)	Information N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1998	28	1.10(15.80)	29	1.10(9.60)		100.00	0.00 [-6.82, 6.82]
Total (95% CI)	28		29			100.00	0.00 [-6.82, 6.82]

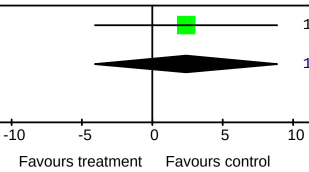
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 09 Physical activity and BT vs information (passive BT)
Outcome: 27 Change in SBP in mmHg at 24 months

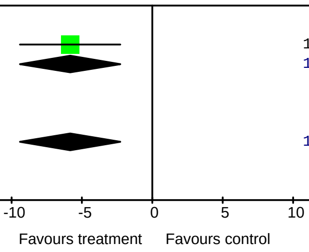
Study or sub-category	PA+BT N	PA+BT Mean (SD)	Information N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Wing 1998	31	0.90(13.90)	31	-1.50(12.00)		100.00	2.40 [-4.06, 8.86]
Total (95% CI)	31		31			100.00	2.40 [-4.06, 8.86]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.73 (P = 0.47)



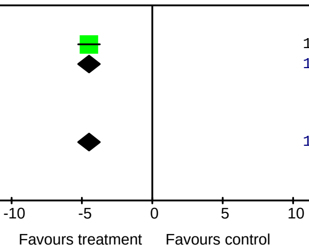
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 01 Weight change in kg at 16 weeks

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Ost 1976	11	-9.35(4.47)	11	-3.51(4.04)		100.00	-5.84 [-9.40, -2.28]
Subtotal (95% CI)	11		11			100.00	-5.84 [-9.40, -2.28]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.21 (P = 0.001)							
Total (95% CI)	11		11			100.00	-5.84 [-9.40, -2.28]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.21 (P = 0.001)							



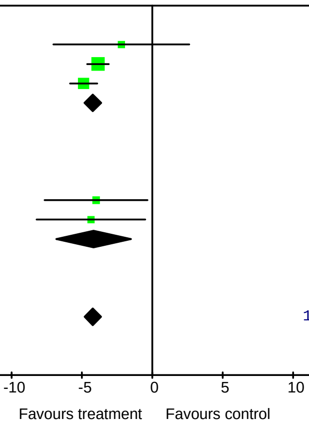
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 02 Weight change in kg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
TOHP II 2001	565	-4.40(7.16)	561	0.10(5.94)		100.00	-4.50 [-5.27, -3.73]
Subtotal (95% CI)	565		561			100.00	-4.50 [-5.27, -3.73]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 11.48 (P < 0.00001)							
Total (95% CI)	565		561			100.00	-4.50 [-5.27, -3.73]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 11.48 (P < 0.00001)							



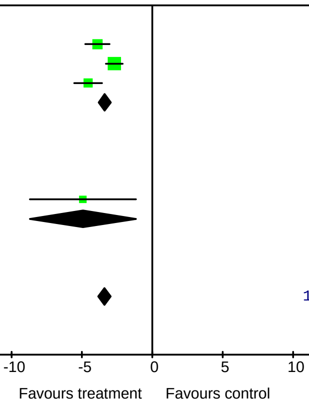
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 03 Weight change in kg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Ost 1976	11	-4.60(6.20)	11	-2.40(5.30)		1.45	-2.20 [-7.02, 2.62]
TOHP II 2001	545	-3.33(6.86)	551	0.53(6.06)		57.29	-3.86 [-4.63, -3.09]
TONE 1998	133	-5.36(4.56)	125	-0.48(3.24)		36.47	-4.88 [-5.84, -3.92]
Subtotal (95% CI)	689		687			95.22	-4.23 [-4.82, -3.63]
Test for heterogeneity: Chi² = 3.33, df = 2 (P = 0.19), I² = 40.0%							
Test for overall effect: Z = 13.93 (P < 0.00001)							
02 LCD							
Jalkanen 1991	24	-4.00(7.05)	25	0.00(5.92)		2.52	-4.00 [-7.65, -0.35]
Jeffery 1993	24	-5.87(7.58)	27	-1.51(6.34)		2.26	-4.36 [-8.22, -0.50]
Subtotal (95% CI)	48		52			4.78	-4.17 [-6.82, -1.52]
Test for heterogeneity: Chi² = 0.02, df = 1 (P = 0.89), I² = 0%							
Test for overall effect: Z = 3.08 (P = 0.002)							
Total (95% CI)	737		739			100.00	-4.22 [-4.80, -3.64]
Test for heterogeneity: Chi² = 3.35, df = 4 (P = 0.50), I² = 0%							
Test for overall effect: Z = 14.26 (P < 0.00001)							



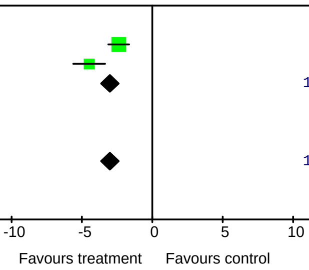
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 04 Weight change in kg at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
TOHP I 1992	293	-3.83(6.12)	235	0.07(4.01)		25.49	-3.90 [-4.77, -3.03]
TOHP II 2001	545	-2.00(5.80)	551	0.70(4.20)		53.38	-2.70 [-3.30, -2.10]
TONE 1998	131	-4.77(4.52)	122	-0.21(3.44)		19.78	-4.56 [-5.55, -3.57]
Subtotal (95% CI)	969		908			98.65	-3.38 [-3.82, -2.94]
Test for heterogeneity: Chi² = 11.81, df = 2 (P = 0.003), I² = 83.1%							
Test for overall effect: Z = 15.02 (P < 0.00001)							
02 LCD							
Jeffery 1993	24	-5.55(7.49)	27	-0.62(6.09)		1.35	-4.93 [-8.71, -1.15]
Subtotal (95% CI)	24		27			1.35	-4.93 [-8.71, -1.15]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.56 (P = 0.01)							
Total (95% CI)	993		935			100.00	-3.40 [-3.84, -2.97]
Test for heterogeneity: Chi² = 12.45, df = 3 (P = 0.006), I² = 75.9%							
Test for overall effect: Z = 15.22 (P < 0.00001)							



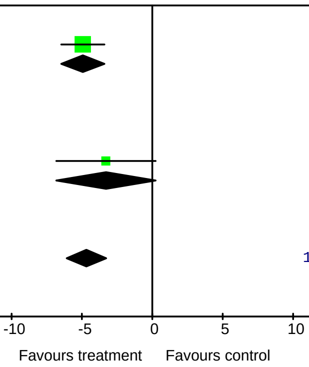
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 05 Weight change in kg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
TOHP II 2001	545	-1.22(6.26)	551	1.17(6.25)		69.81	-2.39 [-3.13, -1.65]
TONE 1998	104	-4.58(4.55)	95	-0.09(3.53)		30.19	-4.49 [-5.62, -3.36]
Subtotal (95% CI)	649		646			100.00	-3.02 [-3.64, -2.41]
Test for heterogeneity: Chi² = 9.32, df = 1 (P = 0.002), I² = 89.3%							
Test for overall effect: Z = 9.58 (P < 0.00001)							
Total (95% CI)	649		646			100.00	-3.02 [-3.64, -2.41]
Test for heterogeneity: Chi² = 9.32, df = 1 (P = 0.002), I² = 89.3%							
Test for overall effect: Z = 9.58 (P < 0.00001)							



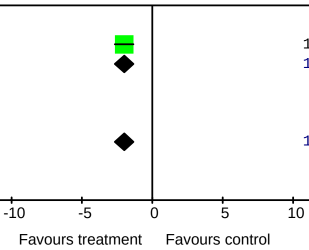
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 06 Weight change in kg at 30 months

Study or sub-category	N	Activity Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
TONE 1998	60	-4.99(4.11)	53	-0.05(4.17)		84.18	-4.94 [-6.47, -3.41]
Subtotal (95% CI)	60		53			84.18	-4.94 [-6.47, -3.41]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 6.33 (P < 0.00001)							
02 LCD							
Jeffery 1993	24	-3.05(6.78)	27	0.25(5.99)		15.82	-3.30 [-6.83, 0.23]
Subtotal (95% CI)	24		27			15.82	-3.30 [-6.83, 0.23]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.83 (P = 0.07)							
Total (95% CI)	84		80			100.00	-4.68 [-6.08, -3.28]
Test for heterogeneity: Chi² = 0.70, df = 1 (P = 0.40), I² = 0%							
Test for overall effect: Z = 6.53 (P < 0.00001)							



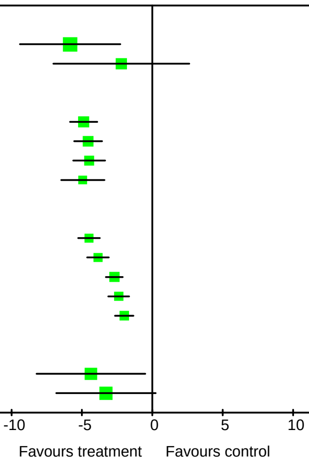
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 07 Weight change in kg at 36 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
TOHP II 2001	547	-0.20(5.90)	554	1.80(5.30)		100.00	-2.00 [-2.66, -1.34]
Subtotal (95% CI)	547		554			100.00	-2.00 [-2.66, -1.34]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 5.91 (P < 0.00001)							
Total (95% CI)	547		554			100.00	-2.00 [-2.66, -1.34]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 5.91 (P < 0.00001)							



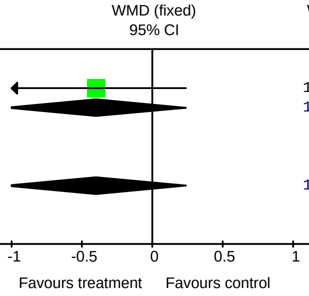
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 08 Weight change over time

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Ost 1976 - 600kcal/deficit or low fat							
Ost 1976 4 months	11	-9.35(4.47)	11	-3.51(4.04)		64.70	-5.84 [-9.40, -2.28]
Ost 1976 12 months	11	-4.60(6.20)	11	-2.40(5.30)		35.30	-2.20 [-7.02, 2.62]
02 TONE 1998 - 600kcal/deficit or low fat							
TONE 12 months	133	-5.36(4.56)	125	-0.48(3.24)		32.55	-4.88 [-5.84, -3.92]
TONE 18 months	131	-4.77(4.52)	122	-0.21(3.44)		30.93	-4.56 [-5.55, -3.57]
TONE 24 months	104	-4.58(4.55)	95	-0.09(3.53)		23.69	-4.49 [-5.62, -3.36]
TONE 30 months	60	-4.99(4.11)	53	-0.05(4.17)		12.83	-4.94 [-6.47, -3.41]
03 TOHP II 2001 - 600kcal/deficit or low fat							
TOHP II 6 months	565	-4.40(7.16)	561	0.10(5.94)		16.46	-4.50 [-5.27, -3.73]
TOHP II 12 months	545	-3.33(6.86)	551	0.53(6.06)		16.53	-3.86 [-4.63, -3.09]
TOHP II 18 months	545	-2.00(5.80)	551	0.70(4.20)		26.97	-2.70 [-3.30, -2.10]
TOHP II 24 months	545	-1.22(6.26)	551	1.17(6.25)		17.71	-2.39 [-3.13, -1.65]
TOHP II 36 months	557	-0.20(5.90)	554	1.80(5.30)		22.34	-2.00 [-2.66, -1.34]
04 Jeffery 1993 - LCD							
Jeffery 1993 12month	24	-5.87(7.58)	27	-1.51(6.34)		45.52	-4.36 [-8.22, -0.50]
Jeffery 1993 30month	24	-3.05(6.78)	27	0.25(5.99)		54.48	-3.30 [-6.83, 0.23]



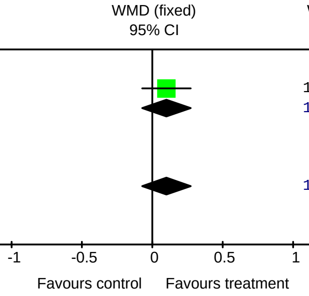
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 09 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jalkanen 1991	22	-0.20(1.08)	22	0.20(1.08)	100.00	-0.40 [-1.04, 0.24]
Subtotal (95% CI)	22		22		100.00	-0.40 [-1.04, 0.24]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.23 (P = 0.22)						
Total (95% CI)	22		22		100.00	-0.40 [-1.04, 0.24]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.23 (P = 0.22)						



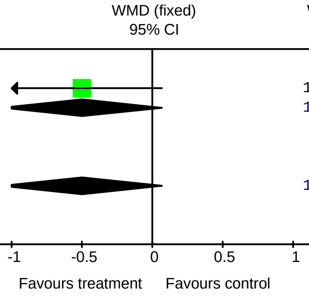
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 10 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jalkanen 1991	22	0.10(0.29)	22	0.00(0.29)	100.00	0.10 [-0.07, 0.27]
Subtotal (95% CI)	22		22		100.00	0.10 [-0.07, 0.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.14 (P = 0.25)						
Total (95% CI)	22		22		100.00	0.10 [-0.07, 0.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.14 (P = 0.25)						



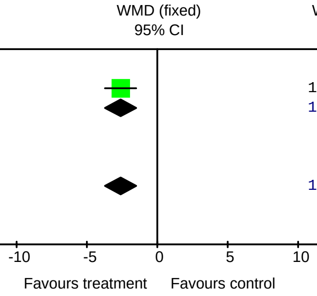
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 12 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD						
Jalkanen 1991	22	-0.50(0.96)	22	0.00(0.96)	100.00	-0.50 [-1.07, 0.07]
Subtotal (95% CI)	22		22		100.00	-0.50 [-1.07, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.73 (P = 0.08)						
Total (95% CI)	22		22		100.00	-0.50 [-1.07, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.73 (P = 0.08)						



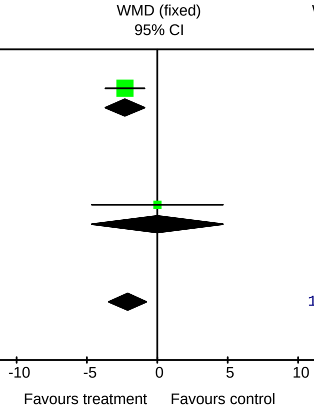
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 13 Change in DBP in mmHg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP I 1992	299	-6.30(6.92)	239	-3.70(6.18)	100.00	-2.60 [-3.71, -1.49]
Subtotal (95% CI)	299		239		100.00	-2.60 [-3.71, -1.49]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.60 (P < 0.00001)						
Total (95% CI)	299		239		100.00	-2.60 [-3.71, -1.49]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.60 (P < 0.00001)						



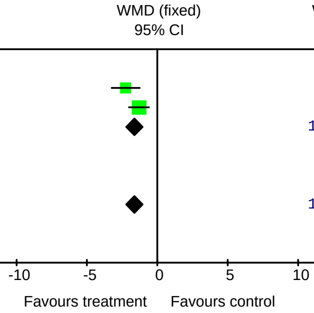
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 14 Change in DBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP I 1992	287	-5.40(8.47)	237	-3.10(7.70)	91.84	-2.30 [-3.69, -0.91]
Subtotal (95% CI)	287		237		91.84	-2.30 [-3.69, -0.91]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.25 (P = 0.001)						
02 LCD						
Jalkanen 1991	24	-11.00(8.30)	25	-11.00(8.30)	8.16	0.00 [-4.65, 4.65]
Subtotal (95% CI)	24		25		8.16	0.00 [-4.65, 4.65]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	311		262		100.00	-2.11 [-3.44, -0.78]
Test for heterogeneity: Chi² = 0.86, df = 1 (P = 0.35), I² = 0%						
Test for overall effect: Z = 3.12 (P = 0.002)						



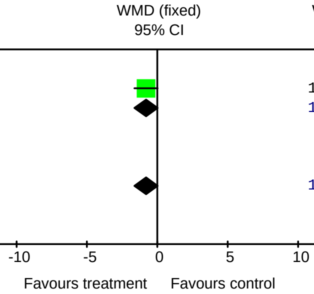
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 15 Change in DBP in mmHg at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP I 1992	308	-6.16(5.88)	256	-3.91(6.12)	34.12	-2.25 [-3.25, -1.25]
TOHP II 2001	533	-4.50(6.10)	525	-3.20(5.80)	65.88	-1.30 [-2.02, -0.58]
Subtotal (95% CI)	841		781		100.00	-1.62 [-2.21, -1.04]
Test for heterogeneity: Chi² = 2.30, df = 1 (P = 0.13), I² = 56.5%						
Test for overall effect: Z = 5.47 (P < 0.00001)						
Total (95% CI)	841		781		100.00	-1.62 [-2.21, -1.04]
Test for heterogeneity: Chi² = 2.30, df = 1 (P = 0.13), I² = 56.5%						
Test for overall effect: Z = 5.47 (P < 0.00001)						



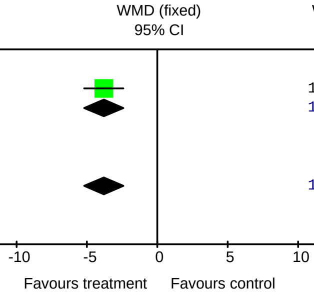
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 16 Change in DBP in mmHg at 36 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP II 2001	527	-3.20(6.50)	514	-2.40(7.00)	100.00	-0.80 [-1.62, 0.02]
Subtotal (95% CI)	527		514		100.00	-0.80 [-1.62, 0.02]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.91 (P = 0.06)						
Total (95% CI)	527		514		100.00	-0.80 [-1.62, 0.02]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.91 (P = 0.06)						



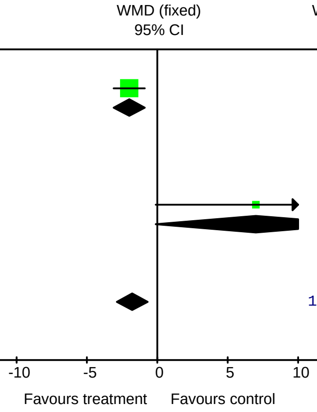
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 17 Change in SBP in mmHg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP I 1992	299	-6.50(8.65)	239	-2.70(7.73)	100.00	-3.80 [-5.19, -2.41]
Subtotal (95% CI)	299		239		100.00	-3.80 [-5.19, -2.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.37 (P < 0.00001)						
Total (95% CI)	299		239		100.00	-3.80 [-5.19, -2.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 5.37 (P < 0.00001)						



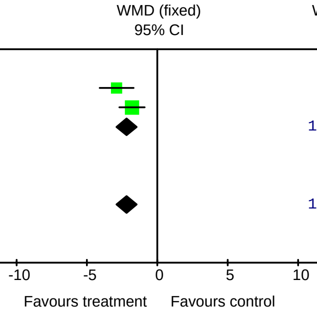
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 18 Change in SBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP I 1992	287	-5.80(6.78)	237	-3.80(6.16)	97.63	-2.00 [-3.11, -0.89]
Subtotal (95% CI)	287		237		97.63	-2.00 [-3.11, -0.89]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.53 (P = 0.0004)						
02 LCD						
Jalkanen 1991	24	-8.00(12.70)	25	-15.00(12.70)	2.37	7.00 [-0.11, 14.11]
Subtotal (95% CI)	24		25		2.37	7.00 [-0.11, 14.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.93 (P = 0.05)						
Total (95% CI)	311		262		100.00	-1.79 [-2.88, -0.69]
Test for heterogeneity: Chi² = 6.00, df = 1 (P = 0.01), I² = 83.3%						
Test for overall effect: Z = 3.19 (P = 0.001)						



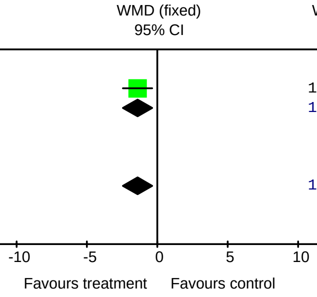
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 19 Change in SBP in mmHg at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP I 1992	308	-5.35(7.19)	256	-2.45(7.37)	35.64	-2.90 [-4.11, -1.69]
TOHP II 2001	533	-3.60(7.90)	525	-1.80(7.00)	64.36	-1.80 [-2.70, -0.90]
Subtotal (95% CI)	841		781		100.00	-2.19 [-2.91, -1.47]
Test for heterogeneity: Chi² = 2.05, df = 1 (P = 0.15), I² = 51.2%						
Test for overall effect: Z = 5.96 (P < 0.00001)						
Total (95% CI)	841		781		100.00	-2.19 [-2.91, -1.47]
Test for heterogeneity: Chi² = 2.05, df = 1 (P = 0.15), I² = 51.2%						
Test for overall effect: Z = 5.96 (P < 0.00001)						



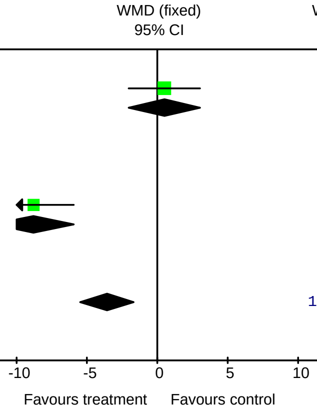
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 20 Change in SBP in mmHg at 36 months

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
TOHP II 2001	527	-0.80(8.70)	514	0.60(8.50)	100.00	-1.40 [-2.44, -0.36]
Subtotal (95% CI)	527		514		100.00	-1.40 [-2.44, -0.36]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.63 (P = 0.009)						
Total (95% CI)	527		514		100.00	-1.40 [-2.44, -0.36]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.63 (P = 0.009)						



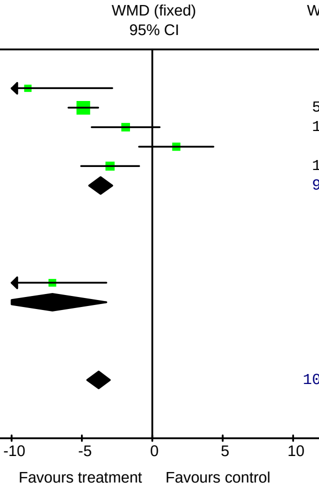
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Narayan 1998	45	1.00(6.20)	45	0.50(6.06)	56.17	0.50 [-2.03, 3.03]
Subtotal (95% CI)	45		45		56.17	0.50 [-2.03, 3.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.39 (P = 0.70)						
02 VLCD						
Wing 1998	31	-10.30(7.70)	32	-1.50(2.70)	43.83	-8.80 [-11.67, -5.93]
Subtotal (95% CI)	31		32		43.83	-8.80 [-11.67, -5.93]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 6.02 (P < 0.00001)						
Total (95% CI)	76		77		100.00	-3.58 [-5.47, -1.68]
Test for heterogeneity: Chi² = 22.70, df = 1 (P < 0.00001), I² = 95.6%						
Test for overall effect: Z = 3.69 (P = 0.0002)						



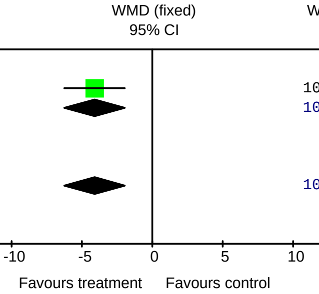
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Djuric 2002a	9	-8.00(5.50)	6	0.85(6.00)	1.82	-8.85 [-14.85, -2.85]
Lindahl 1999	93	-5.40(4.44)	93	-0.50(2.75)	57.93	-4.90 [-5.96, -3.84]
Mayer-Davis 2004	49	-2.20(6.54)	56	-0.30(6.00)	11.21	-1.90 [-4.31, 0.51]
Narayan 1998	45	2.50(6.62)	45	0.80(6.14)	9.38	1.70 [-0.94, 4.34]
Wolf 2004	73	-2.40(6.59)	71	0.60(6.08)	15.23	-3.00 [-5.07, -0.93]
Subtotal (95% CI)	269		271		95.57	-3.67 [-4.50, -2.85]
Test for heterogeneity: Chi² = 26.41, df = 4 (P < 0.0001), I² = 84.9%						
Test for overall effect: Z = 8.71 (P < 0.00001)						
02 VLCD						
Wing 1998	30	-7.40(9.70)	29	-0.30(4.50)	4.43	-7.10 [-10.94, -3.26]
Subtotal (95% CI)	30		29		4.43	-7.10 [-10.94, -3.26]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.63 (P = 0.0003)						
Total (95% CI)	299		300		100.00	-3.82 [-4.63, -3.02]
Test for heterogeneity: Chi² = 29.34, df = 5 (P < 0.0001), I² = 83.0%						
Test for overall effect: Z = 9.28 (P < 0.00001)						



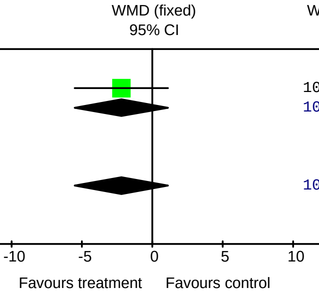
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 03 Weight change in kg at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Messier 2004	76	-5.20(7.37)	78	-1.10(6.23)	100.00	-4.10 [-6.26, -1.94]
Subtotal (95% CI)	76		78		100.00	-4.10 [-6.26, -1.94]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.72 (P = 0.0002)						
Total (95% CI)	76		78		100.00	-4.10 [-6.26, -1.94]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.72 (P = 0.0002)						



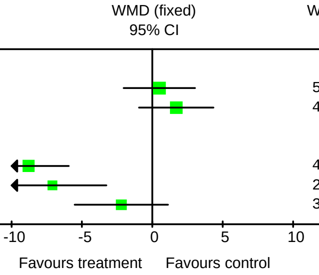
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 04 Weight change in kg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-2.50(8.40)	31	-0.30(4.50)	100.00	-2.20 [-5.51, 1.11]
Subtotal (95% CI)	32		31		100.00	-2.20 [-5.51, 1.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.30 (P = 0.19)						
Total (95% CI)	32		31		100.00	-2.20 [-5.51, 1.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.30 (P = 0.19)						



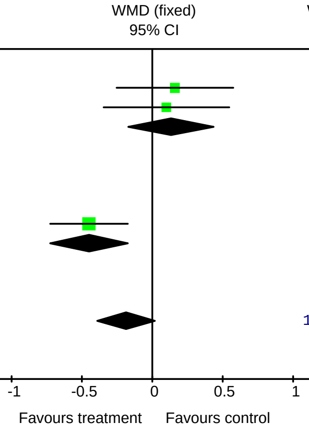
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 05 Weight change over time

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Narayan 1998 - 600kcal/deficit or low fat						
Narayan 6 months	45	1.00(6.20)	45	0.50(6.06)	52.03	0.50 [-2.03, 3.03]
Narayan 12 months	45	2.50(6.62)	45	0.80(6.14)	47.97	1.70 [-0.94, 4.34]
02 Wing 1998 - VLCD						
Wing 1998 6 months	31	-10.30(7.70)	32	-1.50(2.70)	43.35	-8.80 [-11.67, -5.93]
Wing 1998 12 months	30	-7.40(9.70)	29	-0.30(4.50)	24.19	-7.10 [-10.94, -3.26]
Wing 1998 24 months	32	-2.50(8.40)	31	-0.30(4.50)	32.46	-2.20 [-5.51, 1.11]



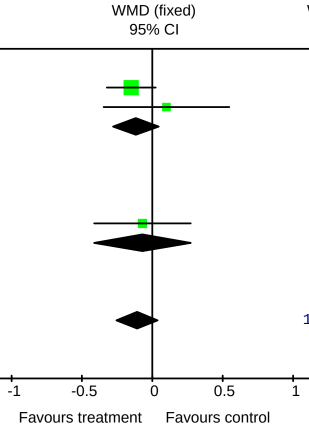
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 06 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Mayer-Davis 2004	49	0.00(1.08)	56	-0.16(1.08)	24.31	0.16 [-0.25, 0.57]
Narayan 1998	45	0.00(1.08)	45	-0.10(1.08)	20.93	0.10 [-0.35, 0.55]
Subtotal (95% CI)	94		101		45.24	0.13 [-0.17, 0.44]
Test for heterogeneity: Chi² = 0.04, df = 1 (P = 0.85), I² = 0%						
Test for overall effect: Z = 0.85 (P = 0.39)						
02 VLCD						
Wing 1998	31	-0.33(0.61)	32	0.12(0.50)	54.76	-0.45 [-0.73, -0.17]
Subtotal (95% CI)	31		32		54.76	-0.45 [-0.73, -0.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.20 (P = 0.001)						
Total (95% CI)	125		133		100.00	-0.19 [-0.39, 0.02]
Test for heterogeneity: Chi² = 7.78, df = 2 (P = 0.02), I² = 74.3%						
Test for overall effect: Z = 1.79 (P = 0.07)						



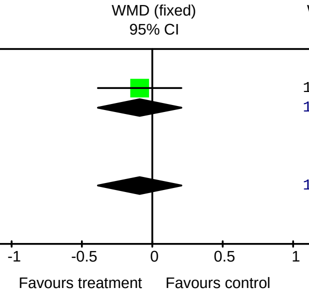
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 07 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Lindahl 1999	93	-0.21(0.70)	93	-0.06(0.49)	71.00	-0.15 [-0.32, 0.02]
Narayan 1998	45	0.20(1.08)	45	0.10(1.08)	10.75	0.10 [-0.35, 0.55]
Subtotal (95% CI)	138		138		81.75	-0.12 [-0.28, 0.04]
Test for heterogeneity: Chi² = 1.05, df = 1 (P = 0.31), I² = 4.5%						
Test for overall effect: Z = 1.42 (P = 0.16)						
02 VLCD						
Wing 1998	30	0.32(0.64)	29	0.39(0.70)	18.25	-0.07 [-0.41, 0.27]
Subtotal (95% CI)	30		29		18.25	-0.07 [-0.41, 0.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.40 (P = 0.69)						
Total (95% CI)	168		167		100.00	-0.11 [-0.25, 0.04]
Test for heterogeneity: Chi² = 1.11, df = 2 (P = 0.58), I² = 0%						
Test for overall effect: Z = 1.45 (P = 0.15)						



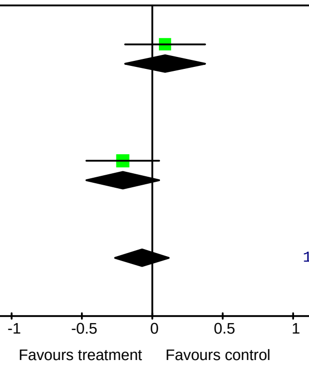
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 08 Change in total cholesterol in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.09(0.67)	31	0.18(0.53)	100.00	-0.09 [-0.39, 0.21]
Subtotal (95% CI)	32		31		100.00	-0.09 [-0.39, 0.21]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.59 (P = 0.55)						
Total (95% CI)	32		31		100.00	-0.09 [-0.39, 0.21]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.59 (P = 0.55)						



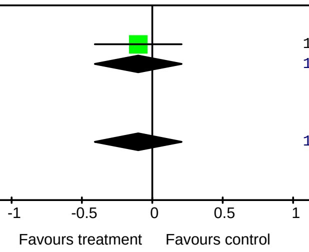
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 09 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat							
Mayer-Davis 2004	49	-0.09(0.74)	56	-0.18(0.74)		45.46	0.09 [-0.19, 0.37]
Subtotal (95% CI)	49		56			45.46	0.09 [-0.19, 0.37]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.62 (P = 0.53)							
02 VLCD							
Wing 1998	31	-0.13(0.58)	32	0.08(0.46)		54.54	-0.21 [-0.47, 0.05]
Subtotal (95% CI)	31		32			54.54	-0.21 [-0.47, 0.05]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.59 (P = 0.11)							
Total (95% CI)	80		88			100.00	-0.07 [-0.26, 0.12]
Test for heterogeneity: Chi² = 2.34, df = 1 (P = 0.13), I² = 57.3%							
Test for overall effect: Z = 0.75 (P = 0.45)							



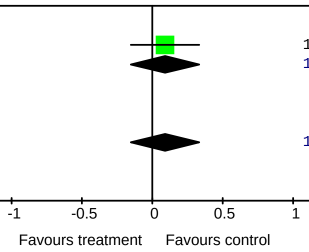
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 10 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	30	0.14(0.54)	29	0.24(0.66)		100.00	-0.10 [-0.41, 0.21]
Subtotal (95% CI)	30		29			100.00	-0.10 [-0.41, 0.21]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.64 (P = 0.52)							
Total (95% CI)	30		29			100.00	-0.10 [-0.41, 0.21]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.64 (P = 0.52)							



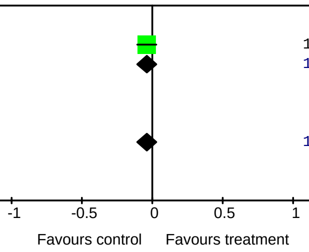
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 11 Change in LDL cholesterol on mmol/l at 24 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	32	0.12(0.52)	31	0.03(0.46)		100.00	0.09 [-0.15, 0.33]
Subtotal (95% CI)	32		31			100.00	0.09 [-0.15, 0.33]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.73 (P = 0.47)							
Total (95% CI)	32		31			100.00	0.09 [-0.15, 0.33]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.73 (P = 0.47)							



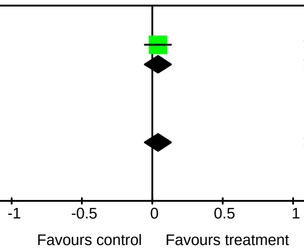
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 12 Change in HDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
02 VLCD							
Wing 1998	31	-0.06(0.16)	32	-0.02(0.11)		100.00	-0.04 [-0.11, 0.03]
Subtotal (95% CI)	31		32			100.00	-0.04 [-0.11, 0.03]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.15 (P = 0.25)							
Total (95% CI)	31		32			100.00	-0.04 [-0.11, 0.03]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.15 (P = 0.25)							



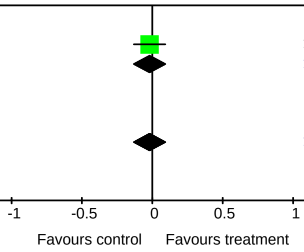
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 13 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	0.12(0.20)	29	0.08(0.16)	100.00	0.04 [-0.05, 0.13]
Subtotal (95% CI)	30		29		100.00	0.04 [-0.05, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.85 (P = 0.40)						
Total (95% CI)	30		29		100.00	0.04 [-0.05, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.85 (P = 0.40)						



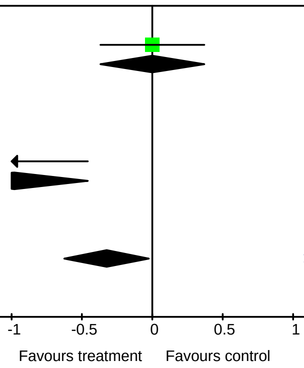
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 14 Change in HDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.02(0.21)	31	0.04(0.24)	100.00	-0.02 [-0.13, 0.09]
Subtotal (95% CI)	32		31		100.00	-0.02 [-0.13, 0.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.35 (P = 0.73)						
Total (95% CI)	32		31		100.00	-0.02 [-0.13, 0.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.35 (P = 0.73)						



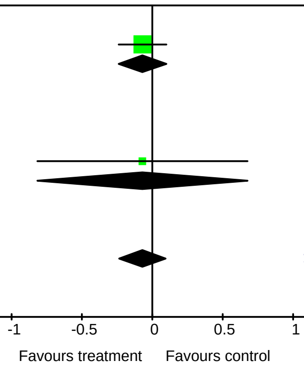
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 15 Change in triglycerides in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Mayer-Davis 2004	49	0.01(0.96)	56	0.01(0.96)	66.82	0.00 [-0.37, 0.37]
Subtotal (95% CI)	49		56		66.82	0.00 [-0.37, 0.37]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
02 VLCD						
Wing 1998	31	-0.69(1.45)	32	0.29(0.32)	33.18	-0.98 [-1.50, -0.46]
Subtotal (95% CI)	31		32		33.18	-0.98 [-1.50, -0.46]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.68 (P = 0.0002)						
Total (95% CI)	80		88		100.00	-0.33 [-0.63, -0.02]
Test for heterogeneity: Chi² = 9.04, df = 1 (P = 0.003), I² = 88.9%						
Test for overall effect: Z = 2.12 (P = 0.03)						



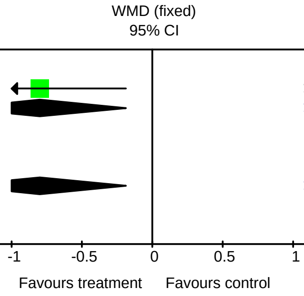
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 16 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Lindahl 1999	93	-0.16(0.59)	93	-0.09(0.59)	95.08	-0.07 [-0.24, 0.10]
Subtotal (95% CI)	93		93		95.08	-0.07 [-0.24, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.81 (P = 0.42)						
02 VLCD						
Wing 1998	30	0.33(1.65)	29	0.40(1.25)	4.92	-0.07 [-0.82, 0.68]
Subtotal (95% CI)	30		29		4.92	-0.07 [-0.82, 0.68]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.18 (P = 0.85)						
Total (95% CI)	123		122		100.00	-0.07 [-0.24, 0.10]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 1.00), I² = 0%						
Test for overall effect: Z = 0.83 (P = 0.41)						



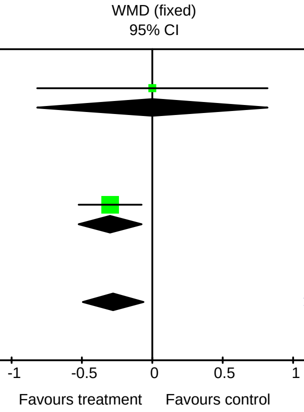
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 17 Change in triglycerides in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-0.28(1.33)	31	0.52(1.14)	100.00	-0.80 [-1.41, -0.19]
Subtotal (95% CI)	32		31		100.00	-0.80 [-1.41, -0.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.57 (P = 0.01)						
Total (95% CI)	32		31		100.00	-0.80 [-1.41, -0.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.57 (P = 0.01)						



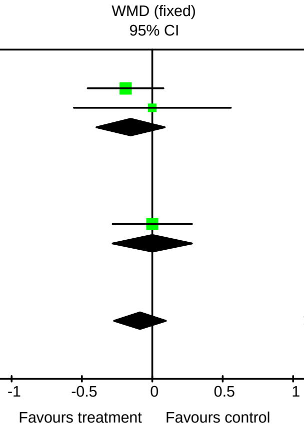
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 18 Change in fasting plasma glucose in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Narayan 1998	45	0.10(1.98)	45	0.10(1.98)	6.93	0.00 [-0.82, 0.82]
Subtotal (95% CI)	45		45		6.93	0.00 [-0.82, 0.82]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
02 VLCD						
Wing 1998	31	-0.20(0.40)	32	0.10(0.50)	93.07	-0.30 [-0.52, -0.08]
Subtotal (95% CI)	31		32		93.07	-0.30 [-0.52, -0.08]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.63 (P = 0.008)						
Total (95% CI)	76		77		100.00	-0.28 [-0.49, -0.06]
Test for heterogeneity: Chi² = 0.48, df = 1 (P = 0.49), I² = 0%						
Test for overall effect: Z = 2.54 (P = 0.01)						



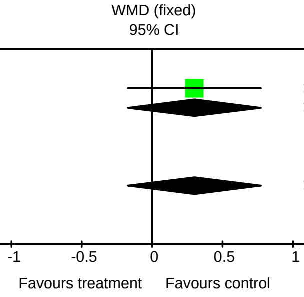
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 19 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Lindahl 1999	93	-0.50(0.68)	93	-0.31(1.14)	46.57	-0.19 [-0.46, 0.08]
Narayan 1998	45	0.10(1.35)	45	0.10(1.35)	10.89	0.00 [-0.56, 0.56]
Subtotal (95% CI)	138		138		57.47	-0.15 [-0.40, 0.09]
Test for heterogeneity: Chi² = 0.36, df = 1 (P = 0.55), I² = 0%						
Test for overall effect: Z = 1.24 (P = 0.21)						
02 VLCD						
Wing 1998	30	0.00(0.50)	29	0.00(0.60)	42.53	0.00 [-0.28, 0.28]
Subtotal (95% CI)	30		29		42.53	0.00 [-0.28, 0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	168		167		100.00	-0.09 [-0.27, 0.10]
Test for heterogeneity: Chi² = 1.02, df = 2 (P = 0.60), I² = 0%						
Test for overall effect: Z = 0.94 (P = 0.35)						



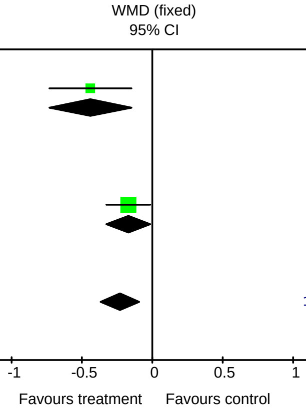
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 20 Change in fasting plasma glucose in mmol/l at 24 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.50(1.30)	31	0.20(0.40)	100.00	0.30 [-0.17, 0.77]
Subtotal (95% CI)	32		31		100.00	0.30 [-0.17, 0.77]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.25 (P = 0.21)						
Total (95% CI)	32		31		100.00	0.30 [-0.17, 0.77]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.25 (P = 0.21)						



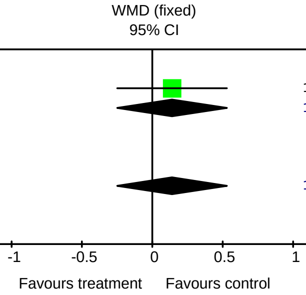
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 22 Change in %HbA1c at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Mayer-Davis 2004	49	-1.56(0.76)	56	-1.12(0.76)	22.15	-0.44 [-0.73, -0.15]
Subtotal (95% CI)	49		56		22.15	-0.44 [-0.73, -0.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.96 (P = 0.003)						
02 VLCD						
Wing 1998	31	0.03(0.20)	32	0.20(0.40)	77.85	-0.17 [-0.33, -0.01]
Subtotal (95% CI)	31		32		77.85	-0.17 [-0.33, -0.01]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.14 (P = 0.03)						
Total (95% CI)	80		88		100.00	-0.23 [-0.37, -0.09]
Test for heterogeneity: Chi² = 2.57, df = 1 (P = 0.11), I² = 61.1%						
Test for overall effect: Z = 3.28 (P = 0.001)						



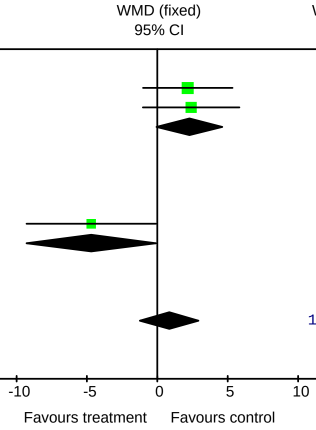
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 23 Change in %HbA1c at 24 months

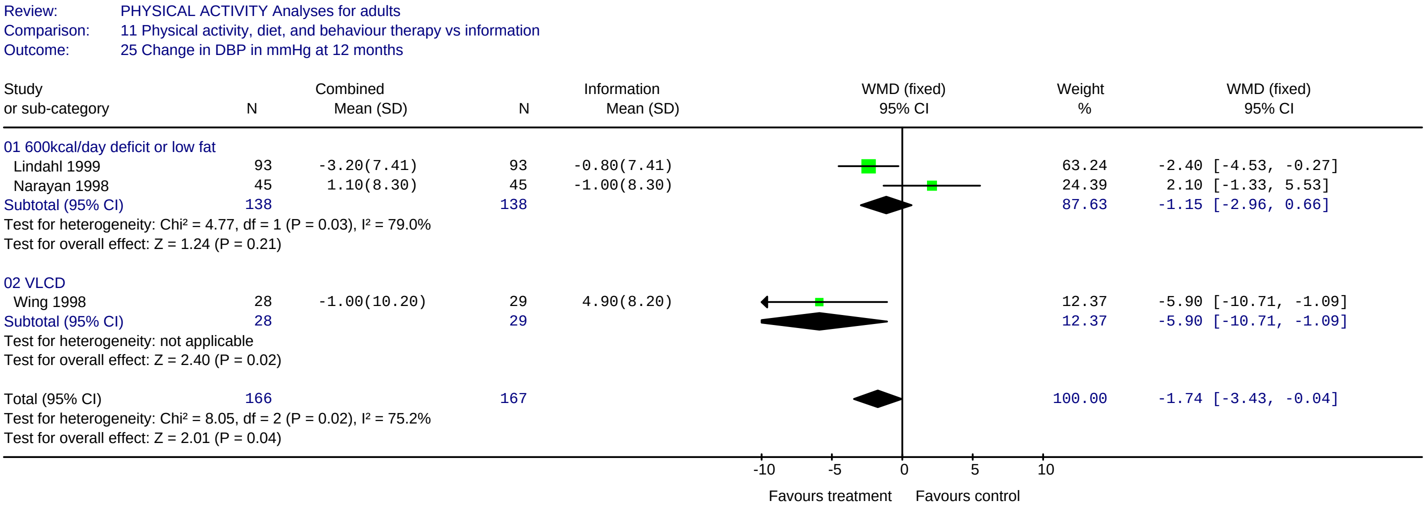
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.04(1.08)	31	-0.10(0.30)	100.00	0.14 [-0.25, 0.53]
Subtotal (95% CI)	32		31		100.00	0.14 [-0.25, 0.53]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.71 (P = 0.48)						
Total (95% CI)	32		31		100.00	0.14 [-0.25, 0.53]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.71 (P = 0.48)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 24 Change in DBP in mmHg at 6 months

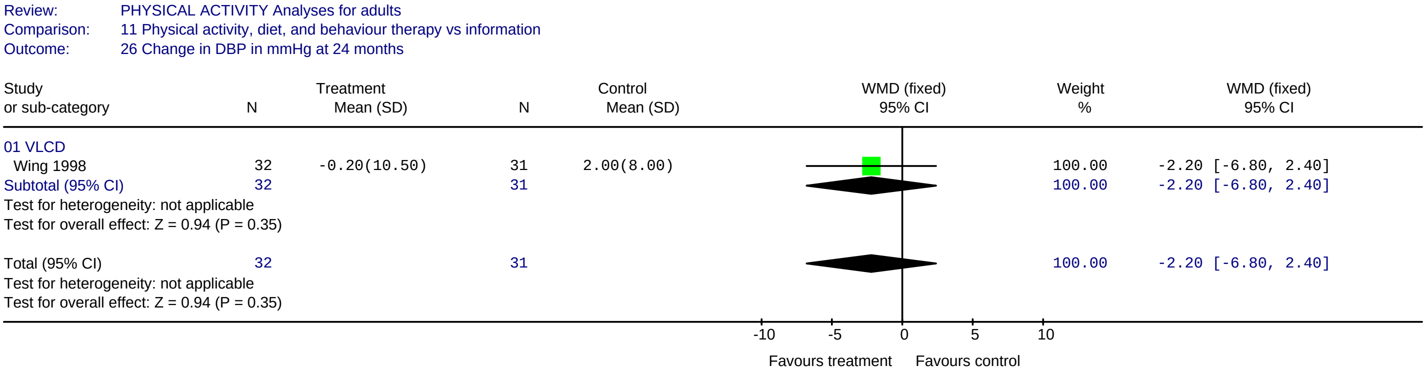
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Mayer-Davis 2004	49	-0.49(8.30)	56	-2.65(8.30)	42.71	2.16 [-1.02, 5.34]
Narayan 1998	45	2.50(8.30)	45	0.10(8.30)	36.77	2.40 [-1.03, 5.83]
Subtotal (95% CI)	94		101		79.49	2.27 [-0.06, 4.60]
Test for heterogeneity: Chi² = 0.01, df = 1 (P = 0.92), I² = 0%						
Test for overall effect: Z = 1.91 (P = 0.06)						
02 VLCD						
Wing 1998	31	-6.90(10.40)	32	-2.20(8.00)	20.51	-4.70 [-9.29, -0.11]
Subtotal (95% CI)	31		32		20.51	-4.70 [-9.29, -0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.01 (P = 0.04)						
Total (95% CI)	125		133		100.00	0.84 [-1.24, 2.92]
Test for heterogeneity: Chi² = 7.05, df = 2 (P = 0.03), I² = 71.6%						
Test for overall effect: Z = 0.79 (P = 0.43)						





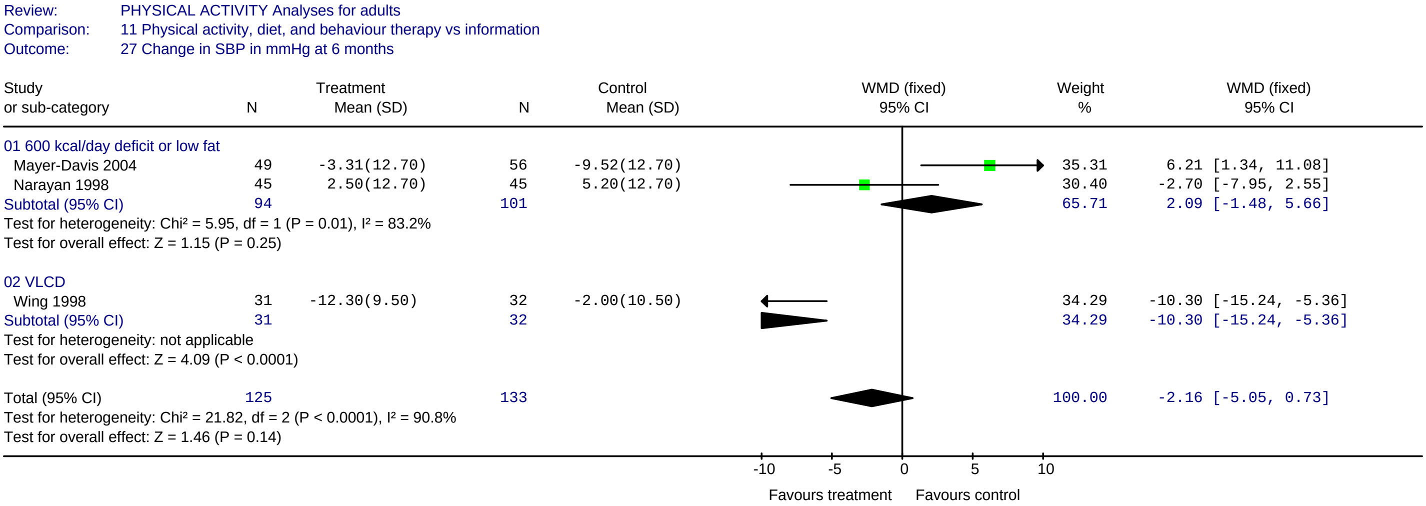
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 25 Change in DBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Lindahl 1999	93	-3.20(7.41)	93	-0.80(7.41)	63.24	-2.40 [-4.53, -0.27]
Narayan 1998	45	1.10(8.30)	45	-1.00(8.30)	24.39	2.10 [-1.33, 5.53]
Subtotal (95% CI)	138		138		87.63	-1.15 [-2.96, 0.66]
Test for heterogeneity: Chi² = 4.77, df = 1 (P = 0.03), I² = 79.0%						
Test for overall effect: Z = 1.24 (P = 0.21)						
02 VLCD						
Wing 1998	28	-1.00(10.20)	29	4.90(8.20)	12.37	-5.90 [-10.71, -1.09]
Subtotal (95% CI)	28		29		12.37	-5.90 [-10.71, -1.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.40 (P = 0.02)						
Total (95% CI)	166		167		100.00	-1.74 [-3.43, -0.04]
Test for heterogeneity: Chi² = 8.05, df = 2 (P = 0.02), I² = 75.2%						
Test for overall effect: Z = 2.01 (P = 0.04)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 26 Change in DBP in mmHg at 24 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-0.20(10.50)	31	2.00(8.00)	100.00	-2.20 [-6.80, 2.40]
Subtotal (95% CI)	32		31		100.00	-2.20 [-6.80, 2.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.94 (P = 0.35)						
Total (95% CI)	32		31		100.00	-2.20 [-6.80, 2.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.94 (P = 0.35)						

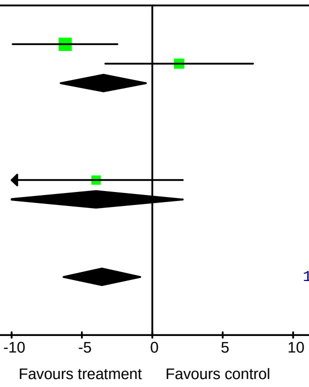


Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 27 Change in SBP in mmHg at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Mayer-Davis 2004	49	-3.31(12.70)	56	-9.52(12.70)	35.31	6.21 [1.34, 11.08]
Narayan 1998	45	2.50(12.70)	45	5.20(12.70)	30.40	-2.70 [-7.95, 2.55]
Subtotal (95% CI)	94		101		65.71	2.09 [-1.48, 5.66]
Test for heterogeneity: Chi² = 5.95, df = 1 (P = 0.01), I² = 83.2%						
Test for overall effect: Z = 1.15 (P = 0.25)						
02 VLCD						
Wing 1998	31	-12.30(9.50)	32	-2.00(10.50)	34.29	-10.30 [-15.24, -5.36]
Subtotal (95% CI)	31		32		34.29	-10.30 [-15.24, -5.36]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.09 (P < 0.0001)						
Total (95% CI)	125		133		100.00	-2.16 [-5.05, 0.73]
Test for heterogeneity: Chi² = 21.82, df = 2 (P < 0.0001), I² = 90.8%						
Test for overall effect: Z = 1.46 (P = 0.14)						

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 28 Change in SBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Information Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Lindahl 1999	93	-4.90(14.81)	93	1.30(10.79)		53.52	-6.20 [-9.92, -2.48]
Narayan 1998	45	6.00(12.70)	45	4.10(12.70)		26.96	1.90 [-3.35, 7.15]
Subtotal (95% CI)	138		138			80.48	-3.49 [-6.52, -0.45]
Test for heterogeneity: Chi² = 6.09, df = 1 (P = 0.01), I² = 83.6%							
Test for overall effect: Z = 2.25 (P = 0.02)							
02 VLCD							
Wing 1998	30	-2.90(14.20)	29	1.10(9.60)		19.52	-4.00 [-10.17, 2.17]
Subtotal (95% CI)	30		29			19.52	-4.00 [-10.17, 2.17]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.27 (P = 0.20)							
Total (95% CI)	168		167			100.00	-3.59 [-6.31, -0.86]
Test for heterogeneity: Chi² = 6.11, df = 2 (P = 0.05), I² = 67.3%							
Test for overall effect: Z = 2.58 (P = 0.010)							

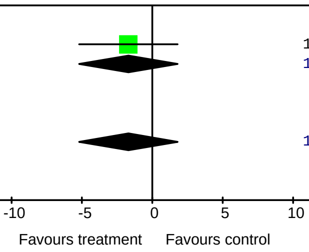


Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 11 Physical activity, diet, and behaviour therapy vs information
Outcome: 29 Change in SBP in mmHg at 24 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	32	-4.80(15.00)	31	-1.50(12.00)		100.00	-3.30 [-10.00, 3.40]
Subtotal (95% CI)	32		31			100.00	-3.30 [-10.00, 3.40]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.97 (P = 0.33)							
Total (95% CI)	32		31			100.00	-3.30 [-10.00, 3.40]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.97 (P = 0.33)							

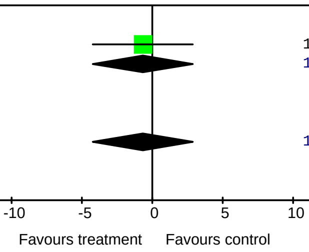
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-2.90(6.74)	26	-1.20(6.25)		100.00	-1.70 [-5.20, 1.80]
Subtotal (95% CI)	27		26			100.00	-1.70 [-5.20, 1.80]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.95 (P = 0.34)							
Total (95% CI)	27		26			100.00	-1.70 [-5.20, 1.80]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.95 (P = 0.34)							



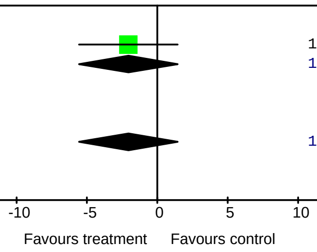
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-2.74(6.69)	26	-2.07(6.50)		100.00	-0.67 [-4.22, 2.88]
Subtotal (95% CI)	27		26			100.00	-0.67 [-4.22, 2.88]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.37 (P = 0.71)							
Total (95% CI)	27		26			100.00	-0.67 [-4.22, 2.88]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.37 (P = 0.71)							



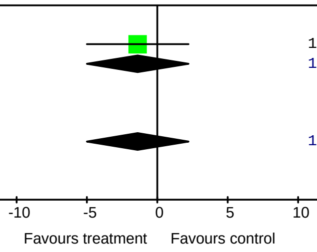
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 03 Weight change in kg at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-3.14(6.80)	26	-1.08(6.22)		100.00	-2.06 [-5.57, 1.45]
Subtotal (95% CI)	27		26			100.00	-2.06 [-5.57, 1.45]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.15 (P = 0.25)							
Total (95% CI)	27		26			100.00	-2.06 [-5.57, 1.45]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.15 (P = 0.25)							



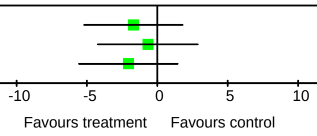
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 04 Weight change in kg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-3.50(6.91)	26	-2.10(6.51)		100.00	-1.40 [-5.01, 2.21]
Subtotal (95% CI)	27		26			100.00	-1.40 [-5.01, 2.21]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.76 (P = 0.45)							
Total (95% CI)	27		26			100.00	-1.40 [-5.01, 2.21]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.76 (P = 0.45)							



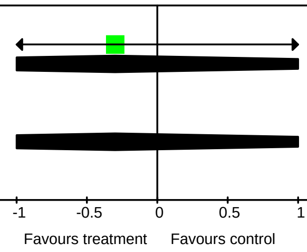
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 05 Weight change over time

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Blonk 1994 6 months	27	-2.90(6.74)	26	-1.20(6.25)		33.72	-1.70 [-5.20, 1.80]
Blonk 1994 12 months	27	-2.74(6.69)	26	-2.07(6.50)		32.72	-0.67 [-4.22, 2.88]
Blonk 1994 18 months	27	-3.14(6.80)	26	-1.08(6.22)		33.56	-2.06 [-5.57, 1.45]



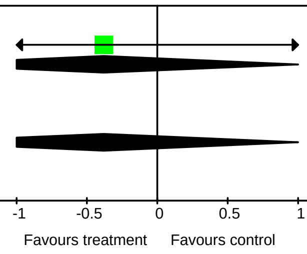
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 06 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-0.20(5.97)	26	0.10(5.94)		100.00	-0.30 [-3.51, 2.91]
Subtotal (95% CI)	27		26			100.00	-0.30 [-3.51, 2.91]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.18 (P = 0.85)							
Total (95% CI)	27		26			100.00	-0.30 [-3.51, 2.91]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.18 (P = 0.85)							



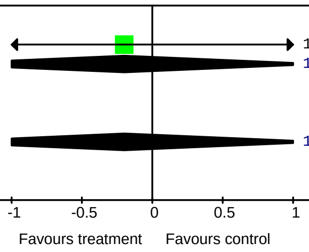
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 07 Change in %HbA1c at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-0.39(2.58)	26	-0.01(2.58)		100.00	-0.38 [-1.77, 1.01]
Subtotal (95% CI)	27		26			100.00	-0.38 [-1.77, 1.01]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.54 (P = 0.59)							
Total (95% CI)	27		26			100.00	-0.38 [-1.77, 1.01]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.54 (P = 0.59)							



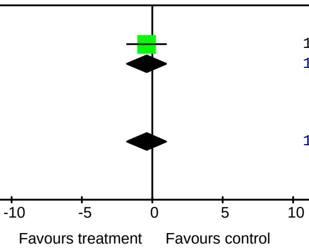
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 08 Change in %HbA1c at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-0.30(2.58)	26	-0.10(2.58)		100.00	-0.20 [-1.59, 1.19]
Subtotal (95% CI)	27		26			100.00	-0.20 [-1.59, 1.19]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.28 (P = 0.78)							
Total (95% CI)	27		26			100.00	-0.20 [-1.59, 1.19]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.28 (P = 0.78)							



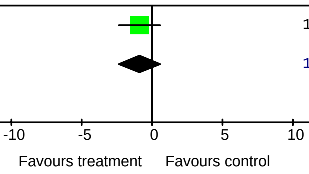
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 09 Change in %HbA1c at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Blonk 1994	27	-0.01(2.58)	26	0.40(2.58)		100.00	-0.41 [-1.80, 0.98]
Subtotal (95% CI)	27		26			100.00	-0.41 [-1.80, 0.98]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.58 (P = 0.56)							
Total (95% CI)	27		26			100.00	-0.41 [-1.80, 0.98]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.58 (P = 0.56)							



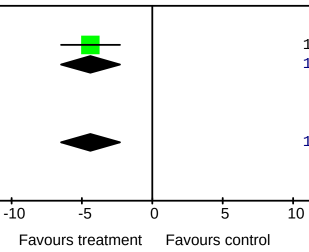
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 12 Physical activity, diet, and behaviour therapy vs diet
Outcome: 10 Change in %HbA1c at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Blonk 1994	27	-1.00(2.70)	26	-0.10(2.70)		100.00	-0.90 [-2.35, 0.55]
Total (95% CI)	27		26			100.00	-0.90 [-2.35, 0.55]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.21 (P = 0.23)							



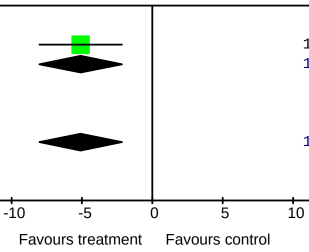
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 01 Weight change in kg at 12 weeks

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Bacon 2002	23	-3.70(4.70)	29	0.70(2.30)		100.00	-4.40 [-6.50, -2.30]
Subtotal (95% CI)	23		29			100.00	-4.40 [-6.50, -2.30]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 4.12 (P < 0.0001)							
Total (95% CI)	23		29			100.00	-4.40 [-6.50, -2.30]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 4.12 (P < 0.0001)							



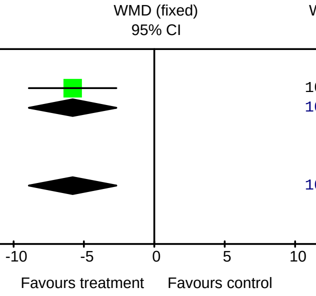
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 02 Weight change in kg at 24 weeks

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Bacon 2002	23	-4.60(6.50)	29	0.50(3.40)		100.00	-5.10 [-8.03, -2.17]
Subtotal (95% CI)	23		29			100.00	-5.10 [-8.03, -2.17]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.41 (P = 0.0006)							
Total (95% CI)	23		29			100.00	-5.10 [-8.03, -2.17]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.41 (P = 0.0006)							



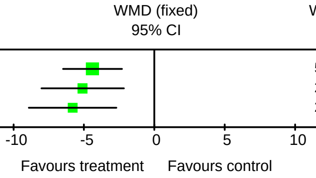
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 03 Weight change in kg at 12 months

Study		Combined		BT alone	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 600kcal/day deficit or low fat						
Bacon 2002	23	-5.90(6.30)	29	-0.10(4.80)	100.00	-5.80 [-8.91, -2.69]
Subtotal (95% CI)	23		29		100.00	-5.80 [-8.91, -2.69]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.65 (P = 0.0003)						
Total (95% CI)	23		29		100.00	-5.80 [-8.91, -2.69]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.65 (P = 0.0003)						



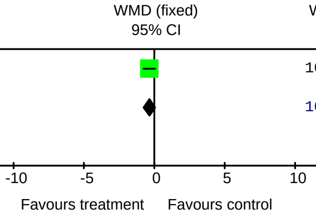
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 04 Weight change over time

Study		Combined		BT	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Bacon 12 weeks	23	-3.70(4.70)	29	0.70(2.30)	50.90	-4.40 [-6.50, -2.30]
Bacon 24 weeks	23	-4.60(6.50)	29	0.50(3.40)	26.02	-5.10 [-8.03, -2.17]
Bacon 12 months	23	-5.90(6.30)	29	-0.10(4.80)	23.08	-5.80 [-8.91, -2.69]



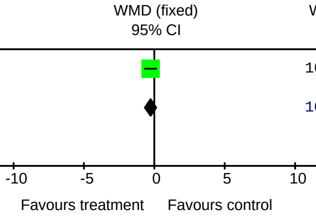
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 05 Change in LDL cholesterol in mmol/l at 12 weeks

Study		Combined		BT alone	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Bacon 2002	23	-0.29(0.74)	29	0.07(0.74)	100.00	-0.36 [-0.76, 0.04]
Total (95% CI)	23		29		100.00	-0.36 [-0.76, 0.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.74 (P = 0.08)						



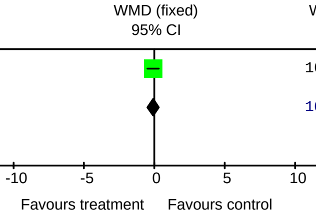
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 06 Change in LDL cholesterol in mmol/l at 24 weeks

Study		Combined		BT alone	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Bacon 2002	23	-0.10(0.74)	29	0.17(0.74)	100.00	-0.27 [-0.67, 0.13]
Total (95% CI)	23		29		100.00	-0.27 [-0.67, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.31 (P = 0.19)						



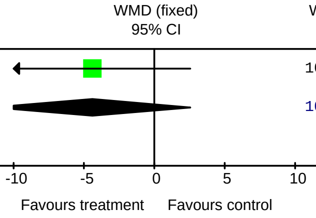
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 07 Change in LDL cholesterol in mmol/l at 12 months

Study		Combined		BT alone	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Bacon 2002	23	-0.31(0.74)	29	-0.23(0.74)	100.00	-0.08 [-0.48, 0.32]
Total (95% CI)	23		29		100.00	-0.08 [-0.48, 0.32]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.39 (P = 0.70)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 08 Change in SBP in mmHg at 12 weeks

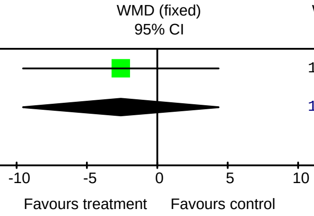
Study		Combined		BT alone	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
Bacon 2002	23	-1.70(12.70)	29	2.70(12.70)	100.00	-4.40 [-11.35, 2.55]
Total (95% CI)	23		29		100.00	-4.40 [-11.35, 2.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.24 (P = 0.21)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 09 Change in SBP in mmHg at 24 weeks

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	Weight %	WMD (fixed) 95% CI
Bacon 2002	23	-7.80(12.70)	29	-5.20(12.70)	100.00	-2.60 [-9.55, 4.35]
Total (95% CI)	23		29		100.00	-2.60 [-9.55, 4.35]

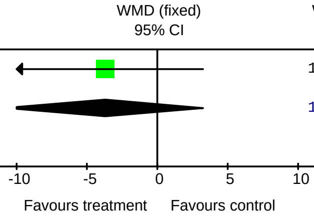
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.73 (P = 0.46)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 10 Change in SBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	Weight %	WMD (fixed) 95% CI
Bacon 2002	23	-8.20(12.70)	29	-4.50(12.70)	100.00	-3.70 [-10.65, 3.25]
Total (95% CI)	23		29		100.00	-3.70 [-10.65, 3.25]

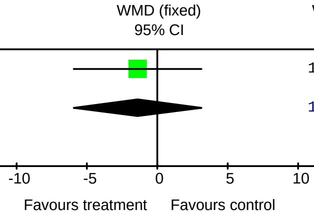
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.04 (P = 0.30)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 11 Change in DBP in mmHg at 12 weeks

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	Weight %	WMD (fixed) 95% CI
Bacon 2002	23	0.00(8.30)	29	1.40(8.30)	100.00	-1.40 [-5.94, 3.14]
Total (95% CI)	23		29		100.00	-1.40 [-5.94, 3.14]

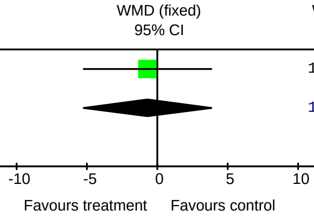
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.60 (P = 0.55)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 12 Change in DBP in mmHg at 24 weeks

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	Weight %	WMD (fixed) 95% CI
Bacon 2002	23	-2.20(8.30)	29	-1.50(8.30)	100.00	-0.70 [-5.24, 3.84]
Total (95% CI)	23		29		100.00	-0.70 [-5.24, 3.84]

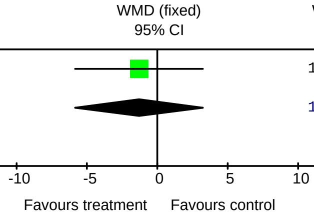
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.30 (P = 0.76)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 13 Physical activity, diet, and behaviour therapy vs behaviour therapy
Outcome: 13 Change in DBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	BT alone Mean (SD)	Weight %	WMD (fixed) 95% CI
Bacon 2002	23	-1.80(8.30)	29	-0.50(8.30)	100.00	-1.30 [-5.84, 3.24]
Total (95% CI)	23		29		100.00	-1.30 [-5.84, 3.24]

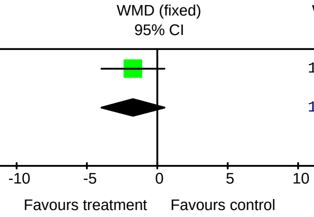
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.56 (P = 0.57)



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 14 Physical activity, diet and behaviour therapy vs physical activity
Outcome: 01 Weight change in kg at 18 months

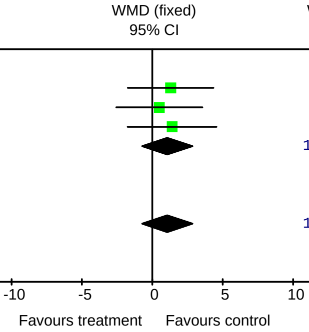
Study or sub-category	N	Activity and BT Mean (SD)	N	Activity Mean (SD)	Weight %	WMD (fixed) 95% CI
Messier 2004	76	-5.20(7.37)	80	-3.46(6.89)	100.00	-1.74 [-3.98, 0.50]
Total (95% CI)	76		80		100.00	-1.74 [-3.98, 0.50]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.52 (P = 0.13)



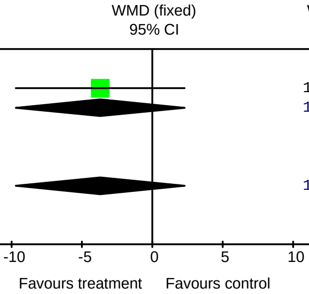
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 01 Weight change in kg at 2 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wadden 1998 aerobic	21	-10.10(3.70)	7	-11.40(3.50)	34.32	1.30 [-1.74, 4.34]
Wadden 1998 mixed	17	-10.90(3.40)	7	-11.40(3.50)	33.92	0.50 [-2.56, 3.56]
Wadden 1998 strength	18	-10.00(3.90)	7	-11.40(3.50)	31.76	1.40 [-1.76, 4.56]
Subtotal (95% CI)	56		21		100.00	1.06 [-0.72, 2.84]
Test for heterogeneity: Chi² = 0.20, df = 2 (P = 0.91), I² = 0%						
Test for overall effect: Z = 1.17 (P = 0.24)						
Total (95% CI)	56		21		100.00	1.06 [-0.72, 2.84]
Test for heterogeneity: Chi² = 0.20, df = 2 (P = 0.91), I² = 0%						
Test for overall effect: Z = 1.17 (P = 0.24)						



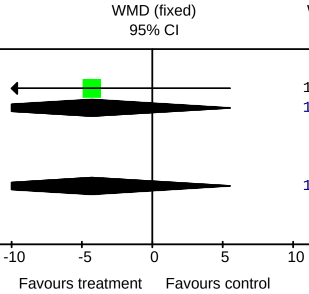
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 02 Weight change in kg at 10 weeks

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wing 1988	13	-9.30(8.55)	15	-5.60(7.50)	100.00	-3.70 [-9.70, 2.30]
Subtotal (95% CI)	13		15		100.00	-3.70 [-9.70, 2.30]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.21 (P = 0.23)						
Total (95% CI)	13		15		100.00	-3.70 [-9.70, 2.30]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.21 (P = 0.23)						



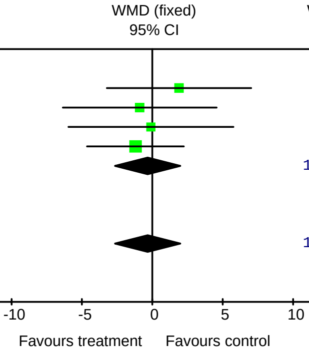
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 03 Weight change in kg at 4 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Sikand 1988	11	-21.80(12.08)	10	-17.50(10.87)	100.00	-4.30 [-14.12, 5.52]
Subtotal (95% CI)	11		10		100.00	-4.30 [-14.12, 5.52]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.86 (P = 0.39)						
Total (95% CI)	11		10		100.00	-4.30 [-14.12, 5.52]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.86 (P = 0.39)						



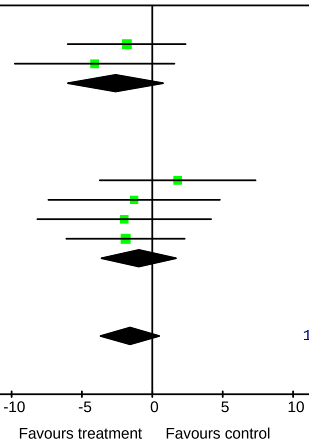
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 04 Weight change in kg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wadden 1998 aerobic	21	-15.80(6.80)	7	-17.70(5.70)	20.55	1.90 [-3.23, 7.03]
Wadden 1998 mixed	17	-18.60(7.30)	7	-17.70(5.70)	18.09	-0.90 [-6.37, 4.57]
Wadden 1998 strength	18	-17.80(8.80)	7	-17.70(5.70)	15.73	-0.10 [-5.96, 5.76]
Wing 1998	31	-10.30(7.70)	35	-9.10(6.40)	45.63	-1.20 [-4.64, 2.24]
Subtotal (95% CI)	87		56		100.00	-0.34 [-2.66, 1.99]
Test for heterogeneity: Chi² = 1.02, df = 3 (P = 0.80), I² = 0%						
Test for overall effect: Z = 0.28 (P = 0.78)						
Total (95% CI)	87		56		100.00	-0.34 [-2.66, 1.99]
Test for heterogeneity: Chi² = 1.02, df = 3 (P = 0.80), I² = 0%						
Test for overall effect: Z = 0.28 (P = 0.78)						



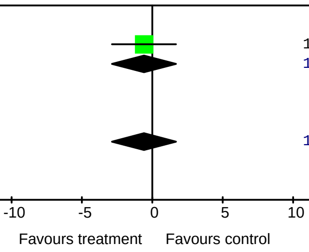
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 05 Weight change in kg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Foreyt 1993	27	-8.13(8.24)	29	-6.32(7.70)		24.72	-1.81 [-5.99, 2.37]
Wing 1988	13	-7.90(8.15)	15	-3.80(6.99)		13.47	-4.10 [-9.77, 1.57]
Subtotal (95% CI)	40		44			38.19	-2.62 [-5.98, 0.75]
Test for heterogeneity: Chi² = 0.41, df = 1 (P = 0.52), I² = 0%							
Test for overall effect: Z = 1.52 (P = 0.13)							
02 VLCD							
Wadden 1998 aerobic	21	-13.50(9.10)	7	-15.30(5.30)		14.16	1.80 [-3.73, 7.33]
Wadden 1998 mixed	17	-16.60(9.80)	7	-15.30(5.30)		11.66	-1.30 [-7.39, 4.79]
Wadden 1998 strength	18	-17.30(10.30)	7	-15.30(5.30)		11.38	-2.00 [-8.17, 4.17]
Wing 1998	30	-7.40(9.70)	33	-5.50(6.90)		24.61	-1.90 [-6.09, 2.29]
Subtotal (95% CI)	86		54			61.81	-0.96 [-3.60, 1.69]
Test for heterogeneity: Chi² = 1.27, df = 3 (P = 0.74), I² = 0%							
Test for overall effect: Z = 0.71 (P = 0.48)							
Total (95% CI)	126		98			100.00	-1.59 [-3.67, 0.49]
Test for heterogeneity: Chi² = 2.25, df = 5 (P = 0.81), I² = 0%							
Test for overall effect: Z = 1.50 (P = 0.13)							



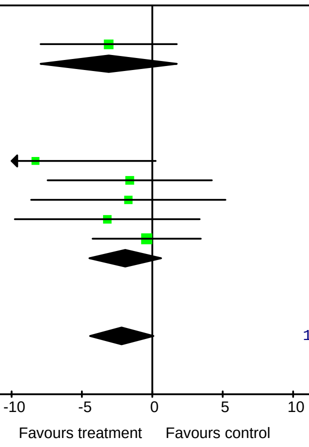
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 06 Weight change in kg at 18 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Messier 2004	76	-5.20(7.37)	82	-4.61(7.22)		100.00	-0.59 [-2.87, 1.69]
Subtotal (95% CI)	76		82			100.00	-0.59 [-2.87, 1.69]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.51 (P = 0.61)							
Total (95% CI)	76		82			100.00	-0.59 [-2.87, 1.69]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.51 (P = 0.61)							



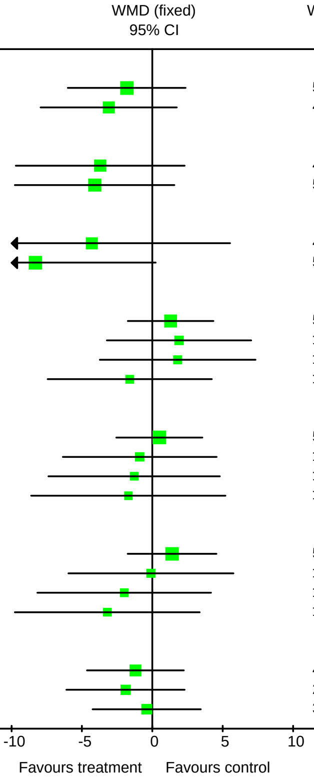
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 07 Weight change in kg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat							
Foreyt 1993	21	-2.20(6.70)	15	0.90(7.70)		21.64	-3.10 [-7.94, 1.74]
Subtotal (95% CI)	21		15			21.64	-3.10 [-7.94, 1.74]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.26 (P = 0.21)							
02 VLCD							
Sikand 1988	7	-9.10(9.20)	8	-0.80(7.40)		6.96	-8.30 [-16.83, 0.23]
Wadden 1998 aerobic	21	-8.50(8.20)	7	-6.90(6.30)		14.85	-1.60 [-7.44, 4.24]
Wadden 1998 mixed	17	-8.60(10.70)	7	-6.90(6.30)		10.62	-1.70 [-8.60, 5.20]
Wadden 1998 strength	18	-10.10(10.00)	7	-6.90(6.30)		11.74	-3.20 [-9.77, 3.37]
Wing 1998	32	-2.50(8.40)	35	-2.10(7.60)		34.18	-0.40 [-4.25, 3.45]
Subtotal (95% CI)	95		64			78.36	-1.92 [-4.47, 0.62]
Test for heterogeneity: Chi² = 2.91, df = 4 (P = 0.57), I² = 0%							
Test for overall effect: Z = 1.48 (P = 0.14)							
Total (95% CI)	116		79			100.00	-2.18 [-4.43, 0.07]
Test for heterogeneity: Chi² = 3.09, df = 5 (P = 0.69), I² = 0%							
Test for overall effect: Z = 1.90 (P = 0.06)							



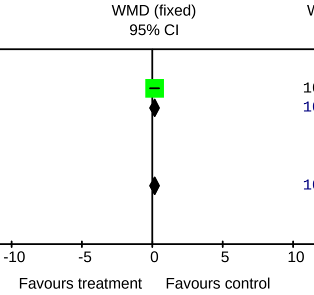
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 08 Weight change over time

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Foreyt - 600kcal deficit or low fat						
Foreyt 1993 12months	27	-8.13(8.24)	29	-6.32(7.70)	57.19	-1.81 [-5.99, 2.37]
Foreyt 1993 24months	21	-2.20(6.70)	15	0.90(7.70)	42.81	-3.10 [-7.94, 1.74]
02 Wing 1988 - 600kcal deficit or low fat						
Wing 1988 10 weeks	13	-9.30(8.55)	15	-5.60(7.50)	47.16	-3.70 [-9.70, 2.30]
Wing 1988 12 months	13	-7.90(8.15)	15	-3.80(6.99)	52.84	-4.10 [-9.77, 1.57]
03 Sikand - VLCD						
Sikand 1988 4 months	11	-21.80(12.08)	10	-17.50(10.87)	43.02	-4.30 [-14.12, 5.52]
Sikand 1988 24months	7	-9.10(9.20)	8	-0.80(7.40)	56.98	-8.30 [-16.83, 0.23]
04 Wadden aerobic - VLCD						
Wadden aer 2 months	21	-10.10(3.70)	7	-11.40(3.50)	51.99	1.30 [-1.74, 4.34]
Wadden aer 6 months	21	-15.80(6.80)	7	-17.70(5.70)	18.25	1.90 [-3.23, 7.03]
Wadden aer 12 months	21	-13.50(9.10)	7	-15.30(5.30)	15.69	1.80 [-3.73, 7.33]
Wadden aer 24 months	21	-8.50(8.20)	7	-6.90(6.30)	14.07	-1.60 [-7.44, 4.24]
05 Wadden mixed - VLCD						
Wadden mix 2 months	17	-10.90(3.40)	7	-11.40(3.50)	56.82	0.50 [-2.56, 3.56]
Wadden mix 6 months	17	-18.60(7.30)	7	-17.70(5.70)	17.76	-0.90 [-6.37, 4.57]
Wadden mix 12 months	17	-16.60(9.80)	7	-15.30(5.30)	14.29	-1.30 [-7.39, 4.79]
Wadden mix 24 months	17	-8.60(10.70)	7	-6.90(6.30)	11.13	-1.70 [-8.60, 5.20]
06 Wadden strength - VLCD						
Wadden str 2 months	18	-10.00(3.90)	7	-11.40(3.50)	56.08	1.40 [-1.76, 4.56]
Wadden str 6 months	18	-17.80(8.80)	7	-17.70(5.70)	16.27	-0.10 [-5.96, 5.76]
Wadden str 12 months	18	-17.30(10.30)	7	-15.30(5.30)	14.69	-2.00 [-8.17, 4.17]
Wadden str 24 months	18	-10.10(10.00)	7	-6.90(6.30)	12.96	-3.20 [-9.77, 3.37]
07 Wing 1998 - VLCD						
Wing 1998 6 months	31	-10.30(7.70)	35	-9.10(6.40)	40.44	-1.20 [-4.64, 2.24]
Wing 1998 12 months	30	-7.40(9.70)	33	-5.50(6.90)	27.23	-1.90 [-6.09, 2.29]
Wing 1998 24 months	32	-2.50(8.40)	35	-2.10(7.60)	32.34	-0.40 [-4.25, 3.45]



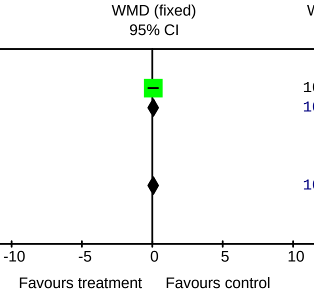
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 09 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
02 VLCD						
Wing 1998	31	-0.33(0.61)	35	-0.49(0.71)	100.00	0.16 [-0.16, 0.48]
Subtotal (95% CI)	31		35		100.00	0.16 [-0.16, 0.48]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.98 (P = 0.32)						
Total (95% CI)	31		35		100.00	0.16 [-0.16, 0.48]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.98 (P = 0.32)						



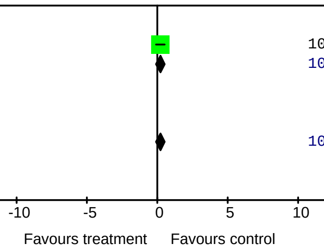
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 10 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	0.32(0.64)	33	0.26(0.76)	100.00	0.06 [-0.29, 0.41]
Subtotal (95% CI)	30		33		100.00	0.06 [-0.29, 0.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.34 (P = 0.73)						
Total (95% CI)	30		33		100.00	0.06 [-0.29, 0.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.34 (P = 0.73)						



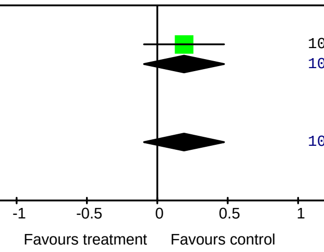
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 11 Change in total cholesterol in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	32	0.09(0.67)	35	-0.12(0.61)		100.00	0.21 [-0.10, 0.52]
Subtotal (95% CI)	32		35			100.00	0.21 [-0.10, 0.52]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.34 (P = 0.18)							
Total (95% CI)	32		35			100.00	0.21 [-0.10, 0.52]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.34 (P = 0.18)							



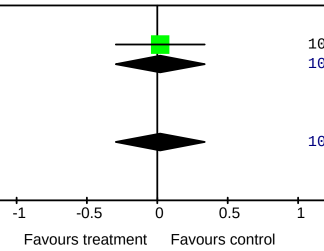
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 12 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	31	-0.13(0.58)	35	-0.32(0.60)		100.00	0.19 [-0.09, 0.47]
Subtotal (95% CI)	31		35			100.00	0.19 [-0.09, 0.47]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.31 (P = 0.19)							
Total (95% CI)	31		35			100.00	0.19 [-0.09, 0.47]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.31 (P = 0.19)							



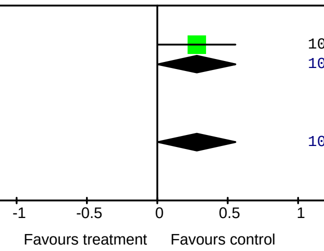
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 13 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	30	0.14(0.54)	33	0.12(0.73)		100.00	0.02 [-0.30, 0.34]
Subtotal (95% CI)	30		33			100.00	0.02 [-0.30, 0.34]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.12 (P = 0.90)							
Total (95% CI)	30		33			100.00	0.02 [-0.30, 0.34]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.12 (P = 0.90)							



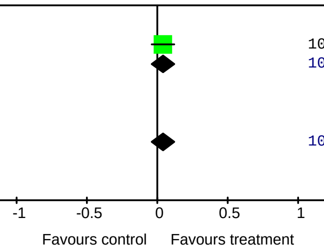
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 14 Change in LDL cholesterol on mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	32	0.12(0.52)	35	-0.16(0.63)		100.00	0.28 [0.00, 0.56]
Subtotal (95% CI)	32		35			100.00	0.28 [0.00, 0.56]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.99 (P = 0.05)							
Total (95% CI)	32		35			100.00	0.28 [0.00, 0.56]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.99 (P = 0.05)							



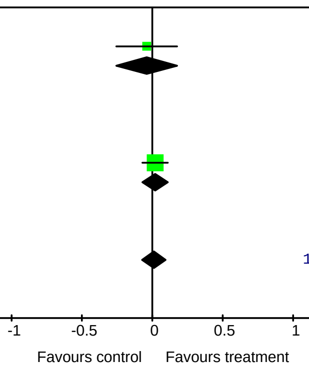
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 15 Change in HDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	31	-0.06(0.16)	35	-0.10(0.17)		100.00	0.04 [-0.04, 0.12]
Subtotal (95% CI)	31		35			100.00	0.04 [-0.04, 0.12]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.98 (P = 0.32)							
Total (95% CI)	31		35			100.00	0.04 [-0.04, 0.12]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.98 (P = 0.32)							



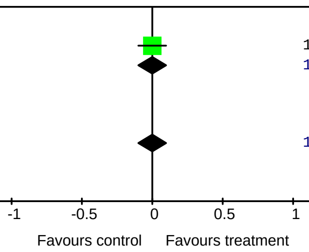
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 16 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wing 1988	13	0.06(0.29)	15	0.10(0.29)	14.87	-0.04 [-0.26, 0.18]
Subtotal (95% CI)	13		15		14.87	-0.04 [-0.26, 0.18]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.36 (P = 0.72)						
02 VLCD						
Wing 1998	30	0.12(0.20)	33	0.10(0.16)	85.13	0.02 [-0.07, 0.11]
Subtotal (95% CI)	30		33		85.13	0.02 [-0.07, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.44 (P = 0.66)						
Total (95% CI)	43		48		100.00	0.01 [-0.07, 0.09]
Test for heterogeneity: Chi² = 0.25, df = 1 (P = 0.61), I² = 0%						
Test for overall effect: Z = 0.26 (P = 0.79)						



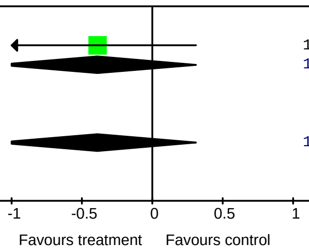
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 17 Change in HDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.02(0.21)	35	0.02(0.20)	100.00	0.00 [-0.10, 0.10]
Subtotal (95% CI)	32		35		100.00	0.00 [-0.10, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	32		35		100.00	0.00 [-0.10, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						



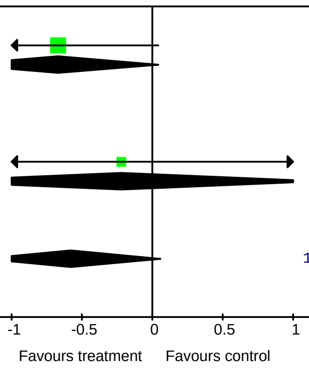
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 18 Change in triglycerides in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-0.69(1.45)	35	-0.30(1.45)	100.00	-0.39 [-1.09, 0.31]
Subtotal (95% CI)	31		35		100.00	-0.39 [-1.09, 0.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.09 (P = 0.28)						
Total (95% CI)	31		35		100.00	-0.39 [-1.09, 0.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.09 (P = 0.28)						



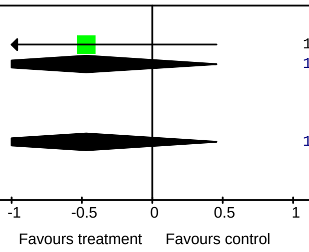
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 19 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wing 1988	13	-0.64(0.96)	15	0.03(0.96)	79.76	-0.67 [-1.38, 0.04]
Subtotal (95% CI)	13		15		79.76	-0.67 [-1.38, 0.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						
02 VLCD						
Wing 1998	30	0.33(1.65)	33	0.55(3.77)	20.24	-0.22 [-1.64, 1.20]
Subtotal (95% CI)	30		33		20.24	-0.22 [-1.64, 1.20]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.30 (P = 0.76)						
Total (95% CI)	43		48		100.00	-0.58 [-1.22, 0.06]
Test for heterogeneity: Chi² = 0.31, df = 1 (P = 0.58), I² = 0%						
Test for overall effect: Z = 1.78 (P = 0.07)						



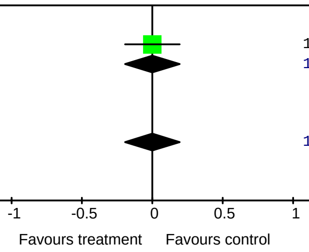
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 20 Change in triglycerides in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-0.28(1.33)	35	0.19(2.42)	100.00	-0.47 [-1.39, 0.45]
Subtotal (95% CI)	32		35		100.00	-0.47 [-1.39, 0.45]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						
Total (95% CI)	32		35		100.00	-0.47 [-1.39, 0.45]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						



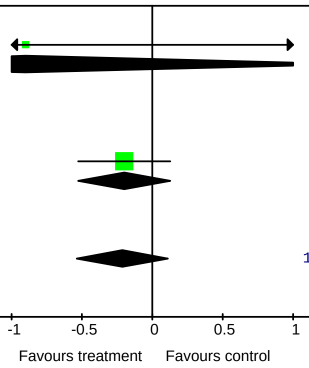
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 21 Change in fasting plasma glucose in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-0.20(0.40)	35	-0.20(0.40)	100.00	0.00 [-0.19, 0.19]
Subtotal (95% CI)	31		35		100.00	0.00 [-0.19, 0.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)	31		35		100.00	0.00 [-0.19, 0.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						



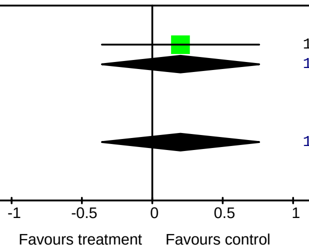
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 22 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Wood 1988	13	-1.70(3.11)	15	-0.80(3.11)	1.96	-0.90 [-3.21, 1.41]
Subtotal (95% CI)	13		15		1.96	-0.90 [-3.21, 1.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.76 (P = 0.45)						
02 VLCD						
Wing 1998	30	0.00(0.50)	33	0.20(0.80)	98.04	-0.20 [-0.53, 0.13]
Subtotal (95% CI)	30		33		98.04	-0.20 [-0.53, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.20 (P = 0.23)						
Total (95% CI)	43		48		100.00	-0.21 [-0.54, 0.11]
Test for heterogeneity: Chi² = 0.35, df = 1 (P = 0.56), I² = 0%						
Test for overall effect: Z = 1.30 (P = 0.19)						



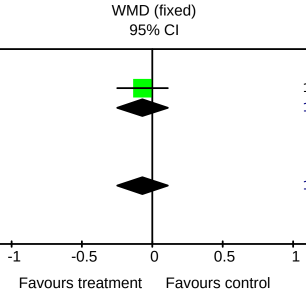
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 23 Change in fasting plasma glucose in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.50(1.30)	35	0.30(1.00)	100.00	0.20 [-0.36, 0.76]
Subtotal (95% CI)	32		35		100.00	0.20 [-0.36, 0.76]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						
Total (95% CI)	32		35		100.00	0.20 [-0.36, 0.76]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						



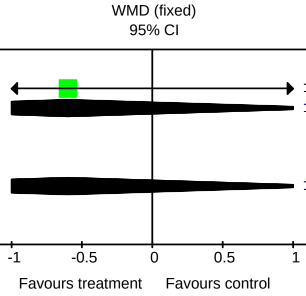
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 24 Change in %HbA1c at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	0.03(0.20)	35	0.10(0.50)	100.00	-0.07 [-0.25, 0.11]
Subtotal (95% CI)	31		35		100.00	-0.07 [-0.25, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.76 (P = 0.45)						
Total (95% CI)	31		35		100.00	-0.07 [-0.25, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.76 (P = 0.45)						



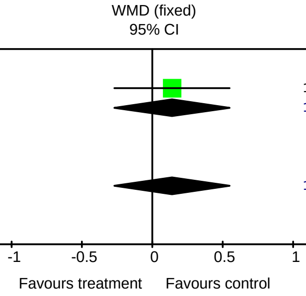
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 25 Change in %HbA1c at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600kcal/day deficit or low fat						
Wing 1988	13	-1.40(2.58)	15	-0.80(2.58)	100.00	-0.60 [-2.52, 1.32]
Subtotal (95% CI)	13		15		100.00	-0.60 [-2.52, 1.32]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.61 (P = 0.54)						
Total (95% CI)	13		15		100.00	-0.60 [-2.52, 1.32]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.61 (P = 0.54)						



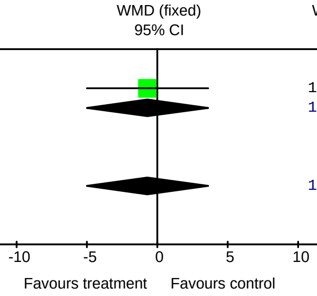
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 26 Change in %HbA1c at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.04(1.08)	35	-0.10(0.50)	100.00	0.14 [-0.27, 0.55]
Subtotal (95% CI)	32		35		100.00	0.14 [-0.27, 0.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.67 (P = 0.50)						
Total (95% CI)	32		35		100.00	0.14 [-0.27, 0.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.67 (P = 0.50)						



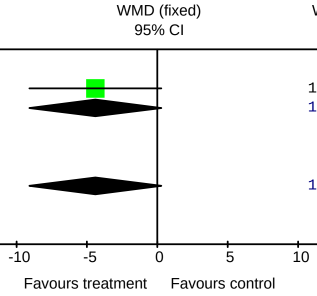
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 27 Change in DBP in mmHg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-6.90(10.40)	35	-6.20(6.90)	100.00	-0.70 [-5.02, 3.62]
Subtotal (95% CI)	31		35		100.00	-0.70 [-5.02, 3.62]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.32 (P = 0.75)						
Total (95% CI)	31		35		100.00	-0.70 [-5.02, 3.62]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.32 (P = 0.75)						



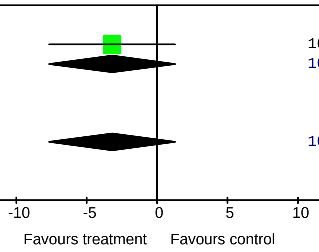
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 28 Change in DBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	28	-1.00(10.20)	33	3.40(8.10)	100.00	-4.40 [-9.08, 0.28]
Subtotal (95% CI)	28		33		100.00	-4.40 [-9.08, 0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						
Total (95% CI)	28		33		100.00	-4.40 [-9.08, 0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						



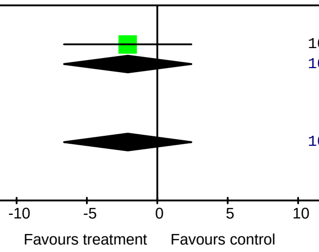
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 29 Change in DBP in mmHg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-0.20(10.50)	35	3.00(7.80)	100.00	-3.20 [-7.66, 1.26]
Subtotal (95% CI)	32		35		100.00	-3.20 [-7.66, 1.26]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.41 (P = 0.16)						
Total (95% CI)	32		35		100.00	-3.20 [-7.66, 1.26]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.41 (P = 0.16)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 30 Change in SBP in mmHg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-12.30(9.50)	35	-10.20(9.20)	100.00	-2.10 [-6.62, 2.42]
Subtotal (95% CI)	31		35		100.00	-2.10 [-6.62, 2.42]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.91 (P = 0.36)						
Total (95% CI)	31		35		100.00	-2.10 [-6.62, 2.42]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.91 (P = 0.36)						

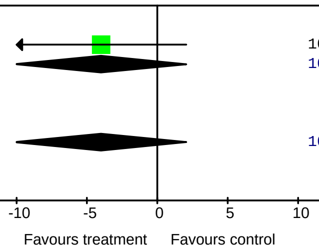


Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 31 Change in SBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	-2.90(14.20)	33	1.30(8.30)	100.00	-4.20 [-10.02, 1.62]
Subtotal (95% CI)	30		33		100.00	-4.20 [-10.02, 1.62]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.42 (P = 0.16)						
Total (95% CI)	30		33		100.00	-4.20 [-10.02, 1.62]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.42 (P = 0.16)						

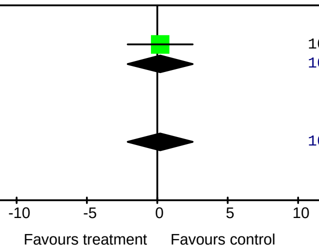
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 32 Change in SBP in mmHg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-4.80(15.00)	35	-0.80(9.40)	100.00	-4.00 [-10.06, 2.06]
Subtotal (95% CI)	32		35		100.00	-4.00 [-10.06, 2.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.29 (P = 0.20)						
Total (95% CI)	32		35		100.00	-4.00 [-10.06, 2.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.29 (P = 0.20)						



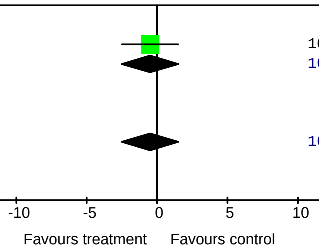
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 33 Change in fasting plasma glucose in mmol/l at 10 weeks

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat						
Wing 1988	13	-3.20(3.11)	15	-3.40(3.11)	100.00	0.20 [-2.11, 2.51]
Subtotal (95% CI)	13		15		100.00	0.20 [-2.11, 2.51]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.17 (P = 0.87)						
Total (95% CI)	13		15		100.00	0.20 [-2.11, 2.51]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.17 (P = 0.87)						



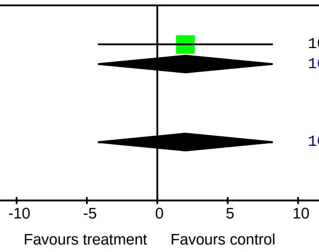
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 34 Change in %HbA1c at 10 weeks

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat							
Wing 1988	13	-2.40(2.70)	15	-1.90(2.70)		100.00	-0.50 [-2.51, 1.51]
Subtotal (95% CI)	13		15			100.00	-0.50 [-2.51, 1.51]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.49 (P = 0.63)							
Total (95% CI)	13		15			100.00	-0.50 [-2.51, 1.51]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.49 (P = 0.63)							



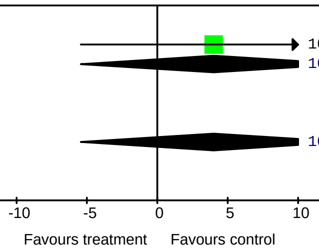
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 35 Change in DBP in mmHg at 10 weeks

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat							
Wing 1988	13	3.00(8.30)	15	1.00(8.30)		100.00	2.00 [-4.16, 8.16]
Subtotal (95% CI)	13		15			100.00	2.00 [-4.16, 8.16]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.64 (P = 0.52)							
Total (95% CI)	13		15			100.00	2.00 [-4.16, 8.16]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.64 (P = 0.52)							



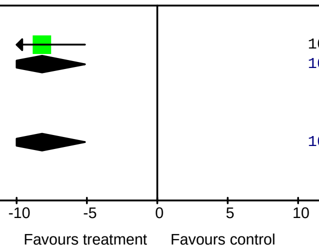
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 15 Physical activity, diet, and behaviour therapy vs diet and BT
Outcome: 36 Change in SBP in mmHg at 10 weeks

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 600 kcal/day deficit or low fat							
Wing 1988	13	-2.00(12.70)	15	-6.00(12.70)		100.00	4.00 [-5.43, 13.43]
Subtotal (95% CI)	13		15			100.00	4.00 [-5.43, 13.43]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.83 (P = 0.41)							
Total (95% CI)	13		15			100.00	4.00 [-5.43, 13.43]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.83 (P = 0.41)							



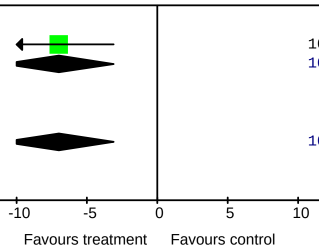
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	31	-10.30(7.70)	33	-2.10(4.20)		100.00	-8.20 [-11.27, -5.13]
Subtotal (95% CI)	31		33			100.00	-8.20 [-11.27, -5.13]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 5.24 (P < 0.00001)							
Total (95% CI)	31		33			100.00	-8.20 [-11.27, -5.13]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 5.24 (P < 0.00001)							



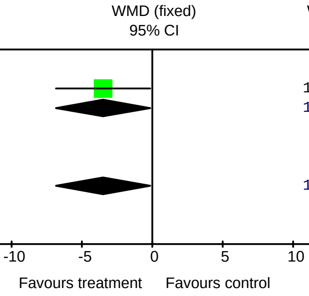
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	30	-7.40(9.70)	28	-0.40(4.80)		100.00	-7.00 [-10.90, -3.10]
Subtotal (95% CI)	30		28			100.00	-7.00 [-10.90, -3.10]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.52 (P = 0.0004)							
Total (95% CI)	30		28			100.00	-7.00 [-10.90, -3.10]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.52 (P = 0.0004)							



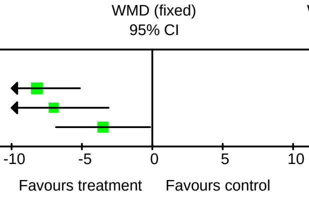
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 03 Weight change in kg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-2.50(8.40)	31	1.00(4.70)	100.00	-3.50 [-6.85, -0.15]
Subtotal (95% CI)	32		31		100.00	-3.50 [-6.85, -0.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.05 (P = 0.04)						
Total (95% CI)	32		31		100.00	-3.50 [-6.85, -0.15]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.05 (P = 0.04)						



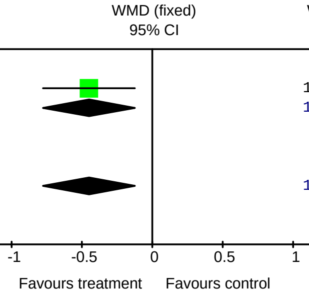
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 04 Weight change over time

Study or sub-category	N	Combined Mean (SD)	N	Diet and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Wing 1998 - VLCD						
Wing 1998 6 months	31	-10.30(7.70)	33	-2.10(4.20)	40.70	-8.20 [-11.27, -5.13]
Wing 1998 12 months	30	-7.40(9.70)	28	-0.40(4.80)	25.16	-7.00 [-10.90, -3.10]
Wing 1998 24 months	32	-2.50(8.40)	31	1.00(4.70)	34.14	-3.50 [-6.85, -0.15]



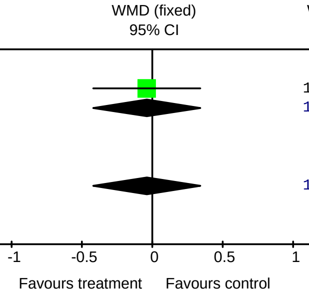
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 05 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-0.33(0.61)	33	0.12(0.72)	100.00	-0.45 [-0.78, -0.12]
Subtotal (95% CI)	31		33		100.00	-0.45 [-0.78, -0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.70 (P = 0.007)						
Total (95% CI)	31		33		100.00	-0.45 [-0.78, -0.12]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.70 (P = 0.007)						



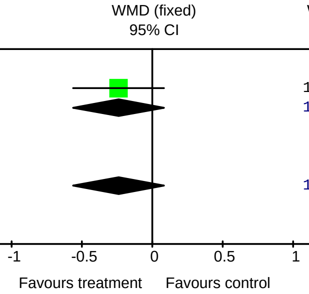
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 06 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	0.32(0.64)	28	0.36(0.82)	100.00	-0.04 [-0.42, 0.34]
Subtotal (95% CI)	30		28		100.00	-0.04 [-0.42, 0.34]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.21 (P = 0.84)						
Total (95% CI)	30		28		100.00	-0.04 [-0.42, 0.34]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.21 (P = 0.84)						



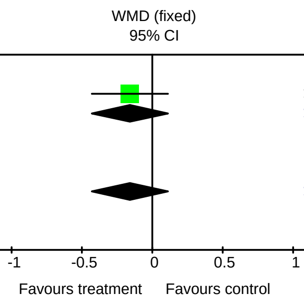
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 07 Change in total cholesterol in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.09(0.67)	31	0.33(0.64)	100.00	-0.24 [-0.56, 0.08]
Subtotal (95% CI)	32		31		100.00	-0.24 [-0.56, 0.08]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.45 (P = 0.15)						
Total (95% CI)	32		31		100.00	-0.24 [-0.56, 0.08]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.45 (P = 0.15)						



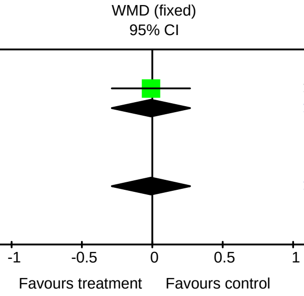
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 08 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-0.13(0.58)	33	0.03(0.52)	100.00	-0.16 [-0.43, 0.11]
Subtotal (95% CI)	31		33		100.00	-0.16 [-0.43, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.16 (P = 0.25)						
Total (95% CI)	31		33		100.00	-0.16 [-0.43, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.16 (P = 0.25)						



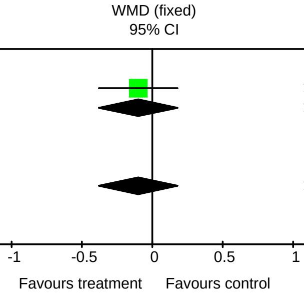
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 09 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	0.14(0.54)	28	0.15(0.54)	100.00	-0.01 [-0.29, 0.27]
Subtotal (95% CI)	30		28		100.00	-0.01 [-0.29, 0.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.07 (P = 0.94)						
Total (95% CI)	30		28		100.00	-0.01 [-0.29, 0.27]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.07 (P = 0.94)						



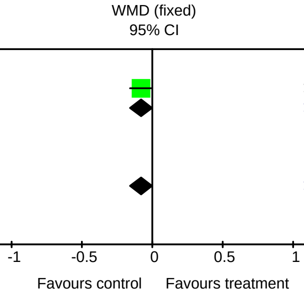
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 10 Change in LDL cholesterol on mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.12(0.52)	31	0.22(0.61)	100.00	-0.10 [-0.38, 0.18]
Subtotal (95% CI)	32		31		100.00	-0.10 [-0.38, 0.18]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						
Total (95% CI)	32		31		100.00	-0.10 [-0.38, 0.18]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						



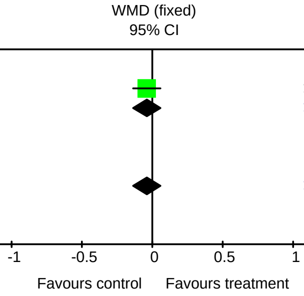
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 11 Change in HDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-0.06(0.16)	33	0.02(0.16)	100.00	-0.08 [-0.16, 0.00]
Subtotal (95% CI)	31		33		100.00	-0.08 [-0.16, 0.00]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.00 (P = 0.05)						
Total (95% CI)	31		33		100.00	-0.08 [-0.16, 0.00]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.00 (P = 0.05)						



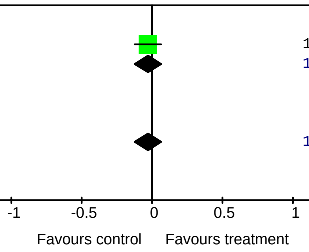
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 12 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	0.12(0.20)	28	0.16(0.18)	100.00	-0.04 [-0.14, 0.06]
Subtotal (95% CI)	30		28		100.00	-0.04 [-0.14, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.80 (P = 0.42)						
Total (95% CI)	30		28		100.00	-0.04 [-0.14, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.80 (P = 0.42)						



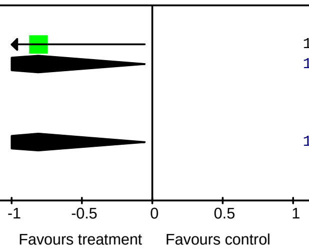
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 13 Change in HDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	32	0.02(0.21)	31	0.05(0.17)		100.00	-0.03 [-0.12, 0.06]
Subtotal (95% CI)	32		31			100.00	-0.03 [-0.12, 0.06]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.62 (P = 0.53)							
Total (95% CI)	32		31			100.00	-0.03 [-0.12, 0.06]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.62 (P = 0.53)							



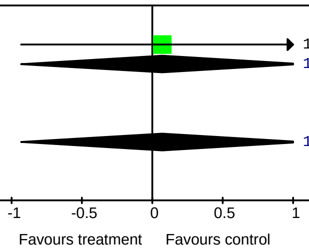
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 14 Change in triglycerides in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	31	-0.69(1.45)	33	0.12(1.64)		100.00	-0.81 [-1.57, -0.05]
Subtotal (95% CI)	31		33			100.00	-0.81 [-1.57, -0.05]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.10 (P = 0.04)							
Total (95% CI)	31		33			100.00	-0.81 [-1.57, -0.05]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.10 (P = 0.04)							



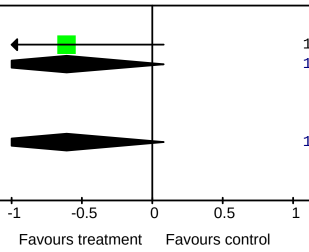
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 15 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	30	0.33(1.65)	28	0.26(2.19)		100.00	0.07 [-0.93, 1.07]
Subtotal (95% CI)	30		28			100.00	0.07 [-0.93, 1.07]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.14 (P = 0.89)							
Total (95% CI)	30		28			100.00	0.07 [-0.93, 1.07]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.14 (P = 0.89)							



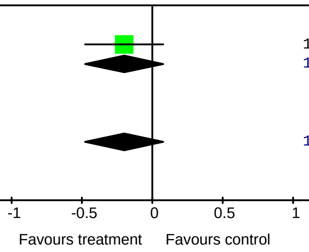
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 16 Change in triglycerides in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	32	-0.28(1.33)	31	0.33(1.46)		100.00	-0.61 [-1.30, 0.08]
Subtotal (95% CI)	32		31			100.00	-0.61 [-1.30, 0.08]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.73 (P = 0.08)							
Total (95% CI)	32		31			100.00	-0.61 [-1.30, 0.08]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.73 (P = 0.08)							



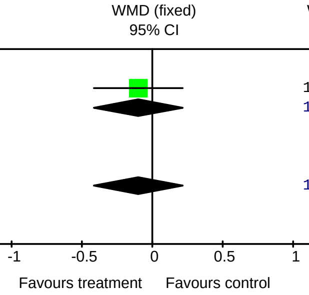
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 17 Change in fasting plasma glucose in mmol/l at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 VLCD							
Wing 1998	31	-0.20(0.40)	33	0.00(0.70)		100.00	-0.20 [-0.48, 0.08]
Subtotal (95% CI)	31		33			100.00	-0.20 [-0.48, 0.08]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.41 (P = 0.16)							
Total (95% CI)	31		33			100.00	-0.20 [-0.48, 0.08]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.41 (P = 0.16)							



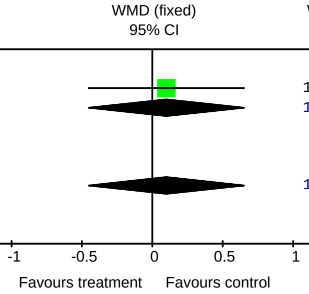
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 18 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	0.00(0.50)	28	0.10(0.70)	100.00	-0.10 [-0.42, 0.22]
Subtotal (95% CI)	30		28		100.00	-0.10 [-0.42, 0.22]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.62 (P = 0.53)						
Total (95% CI)	30		28		100.00	-0.10 [-0.42, 0.22]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.62 (P = 0.53)						



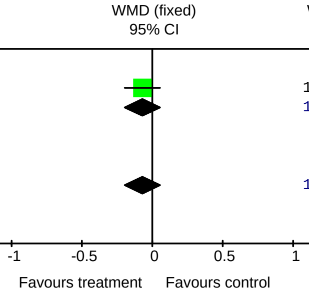
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 19 Change in fasting plasma glucose in mmol/l at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.50(1.30)	31	0.40(0.90)	100.00	0.10 [-0.45, 0.65]
Subtotal (95% CI)	32		31		100.00	0.10 [-0.45, 0.65]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.36 (P = 0.72)						
Total (95% CI)	32		31		100.00	0.10 [-0.45, 0.65]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.36 (P = 0.72)						



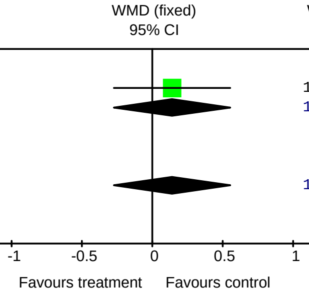
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 20 Change in %HbA1c at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	0.03(0.20)	33	0.10(0.30)	100.00	-0.07 [-0.19, 0.05]
Subtotal (95% CI)	31		33		100.00	-0.07 [-0.19, 0.05]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.10 (P = 0.27)						
Total (95% CI)	31		33		100.00	-0.07 [-0.19, 0.05]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.10 (P = 0.27)						



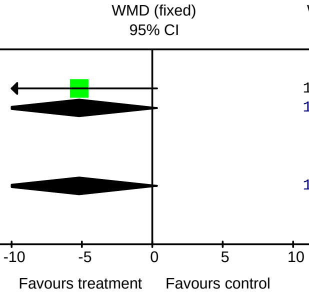
Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 21 Change in %HbA1c at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	0.04(1.08)	31	-0.10(0.50)	100.00	0.14 [-0.27, 0.55]
Subtotal (95% CI)	32		31		100.00	0.14 [-0.27, 0.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.66 (P = 0.51)						
Total (95% CI)	32		31		100.00	0.14 [-0.27, 0.55]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.66 (P = 0.51)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 22 Change in DBP in mmHg at 6 months

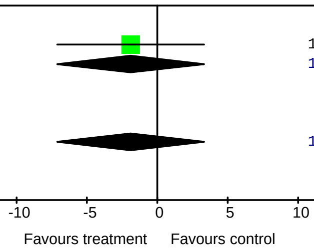
Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-6.90(10.40)	33	-1.70(12.20)	100.00	-5.20 [-10.74, 0.34]
Subtotal (95% CI)	31		33		100.00	-5.20 [-10.74, 0.34]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						
Total (95% CI)	31		33		100.00	-5.20 [-10.74, 0.34]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 23 Change in DBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	28	-1.00(10.20)	28	0.90(9.70)	100.00	-1.90 [-7.11, 3.31]
Subtotal (95% CI)	28		28		100.00	-1.90 [-7.11, 3.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.71 (P = 0.48)						
Total (95% CI)	28		28		100.00	-1.90 [-7.11, 3.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.71 (P = 0.48)						

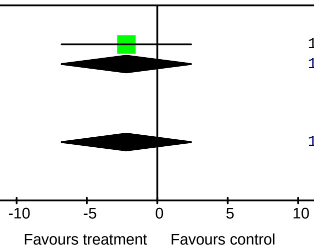
WMD (fixed) 95% CI



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 24 Change in DBP in mmHg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-0.20(10.50)	31	2.00(8.00)	100.00	-2.20 [-6.80, 2.40]
Subtotal (95% CI)	32		31		100.00	-2.20 [-6.80, 2.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.94 (P = 0.35)						
Total (95% CI)	32		31		100.00	-2.20 [-6.80, 2.40]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.94 (P = 0.35)						

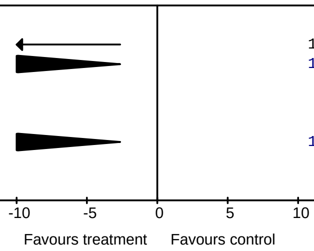
WMD (fixed) 95% CI



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 25 Change in SBP in mmHg at 6 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	31	-12.30(9.50)	33	-2.40(18.90)	100.00	-9.90 [-17.16, -2.64]
Subtotal (95% CI)	31		33		100.00	-9.90 [-17.16, -2.64]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.67 (P = 0.008)						
Total (95% CI)	31		33		100.00	-9.90 [-17.16, -2.64]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.67 (P = 0.008)						

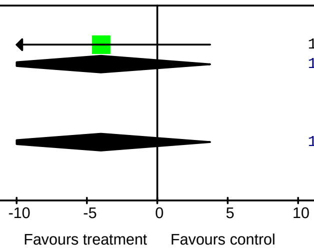
WMD (fixed) 95% CI



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 26 Change in SBP in mmHg at 12 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	30	-2.90(14.20)	28	1.10(15.80)	100.00	-4.00 [-11.75, 3.75]
Subtotal (95% CI)	30		28		100.00	-4.00 [-11.75, 3.75]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.01 (P = 0.31)						
Total (95% CI)	30		28		100.00	-4.00 [-11.75, 3.75]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.01 (P = 0.31)						

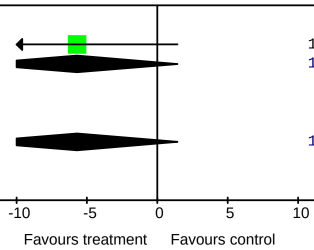
WMD (fixed) 95% CI



Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 16 Physical activity, diet, and behaviour therapy vs activity and BT
Outcome: 27 Change in SBP in mmHg at 24 months

Study or sub-category	N	Combined Mean (SD)	N	Activity and BT Mean (SD)	Weight %	WMD (fixed) 95% CI
01 VLCD						
Wing 1998	32	-4.80(15.00)	31	0.90(13.90)	100.00	-5.70 [-12.84, 1.44]
Subtotal (95% CI)	32		31		100.00	-5.70 [-12.84, 1.44]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.57 (P = 0.12)						
Total (95% CI)	32		31		100.00	-5.70 [-12.84, 1.44]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.57 (P = 0.12)						

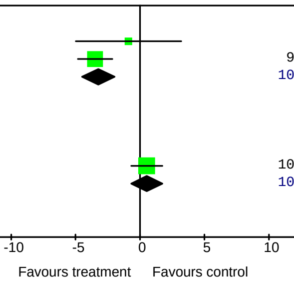
WMD (fixed) 95% CI



3.4 *Orlistat*

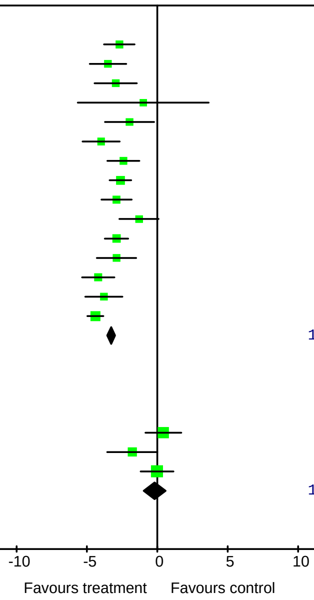
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Derosa 2003	25	-5.10(7.36)	23	-4.20(7.10)	9.59	-0.90 [-4.99, 3.19]
Hauptman 2000	210	-5.46(7.46)	212	-1.97(6.47)	90.41	-3.49 [-4.82, -2.16]
Subtotal (95% CI)	235		235		100.00	-3.24 [-4.51, -1.97]
Test for heterogeneity: Chi² = 1.39, df = 1 (P = 0.24), I² = 28.1%						
Test for overall effect: Z = 5.01 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	1.72(6.40)	212	1.21(6.26)	100.00	0.51 [-0.70, 1.72]
Subtotal (95% CI)	210		212		100.00	0.51 [-0.70, 1.72]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.83 (P = 0.41)						



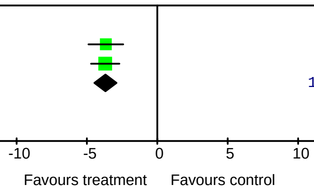
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Bakris 2002	267	-5.40(6.40)	265	-2.70(6.40)	6.44	-2.70 [-3.79, -1.61]
Broom 2002a	259	-5.80(8.50)	263	-2.30(6.40)	4.56	-3.50 [-4.79, -2.21]
Davidson 1999	657	-8.76(9.48)	223	-5.81(10.01)	3.38	-2.95 [-4.45, -1.45]
Derosa 2003	25	-8.60(8.35)	23	-7.60(8.07)	0.35	-1.00 [-5.65, 3.65]
Finer 2000	110	-3.29(6.85)	108	-1.31(6.29)	2.50	-1.98 [-3.73, -0.23]
Hauptman 2000	210	-5.40(7.44)	212	-1.41(6.31)	4.39	-3.99 [-5.31, -2.67]
Hollander 1998	156	-3.84(5.00)	151	-1.43(5.10)	5.97	-2.41 [-3.54, -1.28]
Kelley 2002	266	-3.89(4.40)	269	-1.27(4.59)	13.13	-2.62 [-3.38, -1.86]
Krempf 2003	346	-5.95(7.60)	350	-3.05(6.78)	6.65	-2.90 [-3.97, -1.83]
Lindgarde 2000	190	-4.20(7.03)	186	-2.90(6.74)	3.93	-1.30 [-2.69, 0.09]
Miles 2002	250	-4.70(4.74)	254	-1.80(4.78)	11.03	-2.90 [-3.73, -2.07]
Rossner 2000	241	-8.13(8.22)	236	-5.23(7.40)	3.87	-2.90 [-4.30, -1.50]
Sjostrom 1998	343	-8.10(8.21)	340	-3.90(7.02)	5.81	-4.20 [-5.35, -3.05]
Swinburn 2005	170	-4.70(7.70)	169	-0.90(4.20)	4.38	-3.80 [-5.12, -2.48]
Torgerson 2004	1650	-10.60(8.91)	1637	-6.20(7.67)	23.60	-4.40 [-4.97, -3.83]
Subtotal (95% CI)	5140		4686		100.00	-3.27 [-3.55, -3.00]
Test for heterogeneity: Chi² = 38.06, df = 14 (P = 0.0005), I² = 63.2%						
Test for overall effect: Z = 23.25 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	2.92(6.74)	212	2.49(6.62)	37.00	0.43 [-0.84, 1.70]
Hill 1999	113	2.62(6.66)	121	4.40(7.16)	19.17	-1.78 [-3.55, -0.01]
Rossner 2000	241	2.15(6.52)	236	2.17(6.53)	43.83	-0.02 [-1.19, 1.15]
Subtotal (95% CI)	564		569		100.00	-0.19 [-0.97, 0.58]
Test for heterogeneity: Chi² = 4.09, df = 2 (P = 0.13), I² = 51.1%						
Test for overall effect: Z = 0.48 (P = 0.63)						



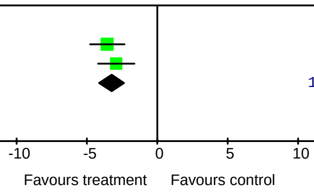
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 03 Weight change in kg at 18 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	-3.68(6.96)	212	-0.02(5.97)	40.29	-3.66 [-4.90, -2.42]
Krempf 2003	346	-5.05(7.34)	350	-1.35(6.30)	59.71	-3.70 [-4.72, -2.68]
Subtotal (95% CI)	556		562		100.00	-3.68 [-4.47, -2.90]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.96), I² = 0%						
Test for overall effect: Z = 9.19 (P < 0.00001)						



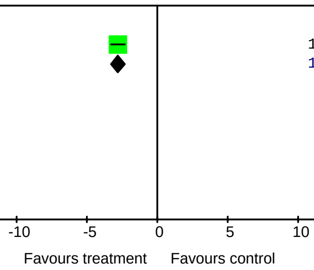
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 04 Weight change at 24 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	-2.48(6.62)	212	1.08(6.22)	52.66	-3.56 [-4.79, -2.33]
Rossner 2000	241	-5.98(7.61)	236	-3.06(6.78)	47.34	-2.92 [-4.21, -1.63]
Subtotal (95% CI)	451		448		100.00	-3.26 [-4.15, -2.37]
Test for heterogeneity: Chi² = 0.50, df = 1 (P = 0.48), I² = 0%						
Test for overall effect: Z = 7.18 (P < 0.00001)						



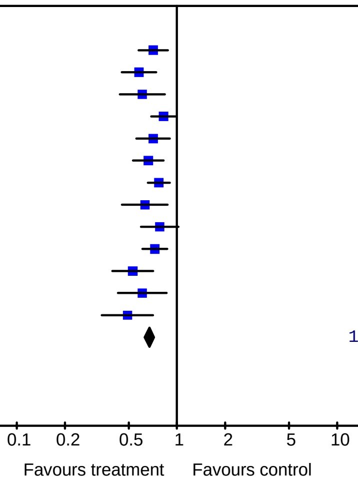
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 05 Weight change in kg at 48 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Torgerson 2004	1650	-5.80(7.56)	1637	-3.00(6.76)		100.00	-2.80 [-3.29, -2.31]
Subtotal (95% CI)	1650		1637			100.00	-2.80 [-3.29, -2.31]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 11.20 (P < 0.00001)							
02 Weight maintenance							
Subtotal (95% CI)	0		0				Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							



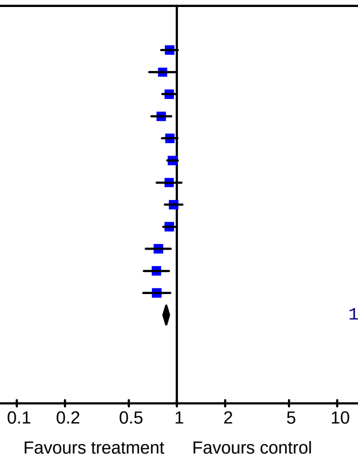
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 06 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Bakris 2002	54/100	76/100		8.53	0.71 [0.57, 0.88]
Broom 2002a	44/100	76/100		8.53	0.58 [0.45, 0.74]
Davidson 1999	34/100	56/100		6.29	0.61 [0.44, 0.84]
Finer 2000	65/100	79/100		8.87	0.82 [0.69, 0.98]
Hauptman 2000	49/100	69/100		7.74	0.71 [0.56, 0.90]
Hollander 1998	51/100	77/100		8.64	0.66 [0.53, 0.83]
Kelley 2002	67/100	87/100		9.76	0.77 [0.66, 0.90]
Krempf 2003	34/100	54/100		6.06	0.63 [0.45, 0.87]
Lindgarde 2000	46/100	59/100		6.62	0.78 [0.60, 1.02]
Miles 2002	61/100	84/100		9.43	0.73 [0.61, 0.87]
Rossner 2000	36/100	68/100		7.63	0.53 [0.39, 0.71]
Sjostrom 1998	31/100	51/100		5.72	0.61 [0.43, 0.86]
Torgerson 2004	27/100	55/100		6.17	0.49 [0.34, 0.71]
Subtotal (95% CI)	1300	1300		100.00	0.67 [0.63, 0.72]
Total events: 599 (Orlistat + diet), 891 (Placebo + diet)					
Test for heterogeneity: Chi² = 17.93, df = 12 (P = 0.12), I² = 33.1%					
Test for overall effect: Z = 11.52 (P < 0.00001)					



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 07 Failure to achieve at least 10% loss of initial body weight at 12 months

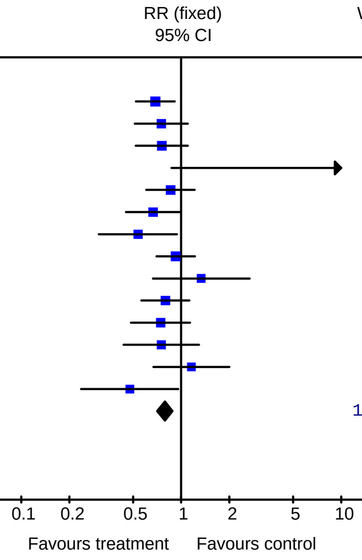
Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Broom 2002a	80/100	89/100		8.62	0.90 [0.80, 1.01]
Davidson 1999	61/100	75/100		7.27	0.81 [0.67, 0.99]
Finer 2000	84/100	94/100		9.11	0.89 [0.81, 0.99]
Hauptman 2000	71/100	89/100		8.62	0.80 [0.69, 0.92]
Hollander 1998	82/100	91/100		8.82	0.90 [0.81, 1.01]
Kelley 2002	90/100	96/100		9.30	0.94 [0.87, 1.01]
Krempf 2003	67/100	75/100		7.27	0.89 [0.75, 1.07]
Lindgarde 2000	81/100	85/100		8.24	0.95 [0.84, 1.08]
Miles 2002	86/100	96/100		9.30	0.90 [0.82, 0.98]
Rossner 2000	62/100	81/100		7.85	0.77 [0.64, 0.92]
Sjostrom 1998	61/100	82/100		7.95	0.74 [0.62, 0.89]
Torgerson 2004	59/100	79/100		7.66	0.75 [0.62, 0.91]
Subtotal (95% CI)	1200	1200		100.00	0.86 [0.82, 0.89]
Total events: 884 (Orlistat + diet), 1032 (Placebo + diet)					
Test for heterogeneity: Chi² = 18.42, df = 11 (P = 0.07), I² = 40.3%					
Test for overall effect: Z = 7.60 (P < 0.00001)					



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 08 Failure to complete at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Bakris 2002	42/100	61/100	13.22	0.69 [0.52, 0.91]
Broom 2002a	30/100	40/100	8.67	0.75 [0.51, 1.10]
Davidson 1999	31/100	41/100	8.88	0.76 [0.52, 1.10]
Derosa 2003	7/100	0/100	0.11	15.00 [0.87, 259.16]
Finer 2000	36/100	42/100	9.10	0.86 [0.61, 1.21]
Hauptman 2000	28/100	42/100	9.10	0.67 [0.45, 0.98]
Hollander 1998	15/100	28/100	6.07	0.54 [0.31, 0.94]
Kelley 2002	48/100	52/100	11.27	0.92 [0.70, 1.22]
Lindgarde 2000	16/100	12/100	2.60	1.33 [0.67, 2.67]
Miles 2002	35/100	44/100	9.53	0.80 [0.56, 1.13]
Rossner 2000	26/100	35/100	7.58	0.74 [0.49, 1.14]
Sjostrom 1998	18/100	24/100	5.20	0.75 [0.44, 1.29]
Swinburn 2005	22/100	19/100	4.12	1.16 [0.67, 2.00]
Torgerson 2004	10/100	21/100	4.55	0.48 [0.24, 0.96]
Subtotal (95% CI)	1400	1400	100.00	0.79 [0.71, 0.88]

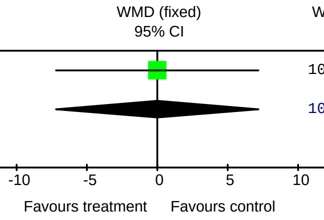
Total events: 364 (Orlistat + diet), 461 (Placebo + diet)
Test for heterogeneity: Chi² = 15.31, df = 13 (P = 0.29), I² = 15.1%
Test for overall effect: Z = 4.17 (P < 0.0001)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 09 Change in SBP in mmHg at 6 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Derosa 2003	25	-2.00(12.70)	23	-2.00(12.70)	100.00	0.00 [-7.19, 7.19]
Total (95% CI)	25		23		100.00	0.00 [-7.19, 7.19]

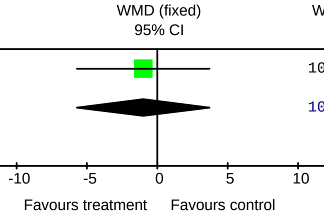
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 10 Change in DBP in mmHg at 6 months

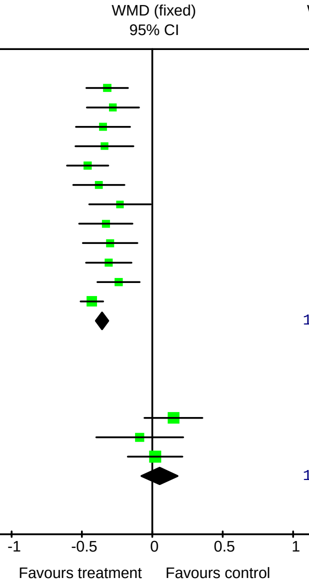
Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Derosa 2003	25	-1.00(8.30)	23	0.00(8.30)	100.00	-1.00 [-5.70, 3.70]
Total (95% CI)	25		23		100.00	-1.00 [-5.70, 3.70]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.42 (P = 0.68)



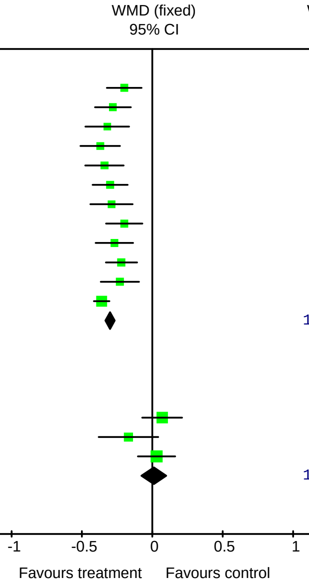
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 11 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Bakris 2002	267	-0.36(0.94)	265	-0.04(0.79)	8.91	-0.32 [-0.47, -0.17]
Broom 2002a	259	-0.12(1.08)	263	0.16(1.08)	5.65	-0.28 [-0.47, -0.09]
Finer 2000	110	-0.05(0.76)	108	0.30(0.68)	5.30	-0.35 [-0.54, -0.16]
Hauptman 2000	210	-0.04(1.08)	212	0.30(1.08)	4.57	-0.34 [-0.55, -0.13]
Hollander 1998	156	-0.05(0.60)	151	0.41(0.70)	9.09	-0.46 [-0.61, -0.31]
Kelley 2002	266	-0.30(1.08)	276	0.08(1.08)	5.86	-0.38 [-0.56, -0.20]
Lindgarde 2000	190	0.03(1.08)	186	0.26(1.08)	4.07	-0.23 [-0.45, -0.01]
Miles 2002	250	-0.27(1.08)	254	0.06(1.08)	5.45	-0.33 [-0.52, -0.14]
Rossner 2000	241	-0.35(1.08)	236	-0.05(1.08)	5.16	-0.30 [-0.49, -0.11]
Sjostrom 1998	343	-0.08(1.08)	340	0.23(1.08)	7.39	-0.31 [-0.47, -0.15]
Swinburn 2005	170	-0.08(0.73)	169	0.16(0.68)	8.60	-0.24 [-0.39, -0.09]
Torgerson 2004	1487	-0.51(1.08)	1295	-0.08(1.08)	29.96	-0.43 [-0.51, -0.35]
Subtotal (95% CI)	3949		3755		100.00	-0.36 [-0.40, -0.31]
Test for heterogeneity: Chi² = 10.44, df = 11 (P = 0.49), I² = 0%						
Test for overall effect: Z = 15.92 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.29(1.08)	212	0.14(1.08)	38.83	0.15 [-0.06, 0.36]
Hill 1999	87	0.08(1.08)	102	0.17(1.08)	17.28	-0.09 [-0.40, 0.22]
Rossner 2000	241	0.38(1.08)	236	0.36(1.08)	43.89	0.02 [-0.17, 0.21]
Subtotal (95% CI)	538		550		100.00	0.05 [-0.08, 0.18]
Test for heterogeneity: Chi² = 1.78, df = 2 (P = 0.41), I² = 0%						
Test for overall effect: Z = 0.79 (P = 0.43)						



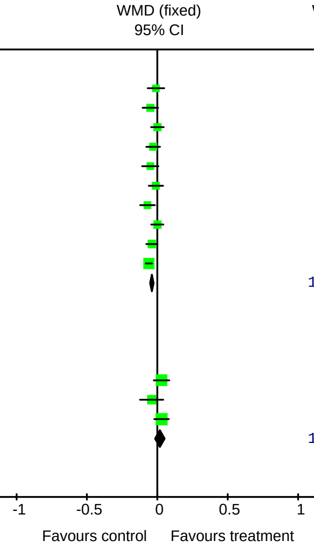
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 12 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Bakris 2002	267	-0.31(0.76)	265	-0.11(0.70)	6.74	-0.20 [-0.32, -0.08]
Broom 2002a	259	-0.30(0.74)	263	-0.02(0.74)	6.44	-0.28 [-0.41, -0.15]
Finer 2000	110	-0.11(0.63)	108	0.21(0.53)	4.35	-0.32 [-0.47, -0.17]
Hauptman 2000	210	-0.12(0.74)	212	0.25(0.74)	5.21	-0.37 [-0.51, -0.23]
Hollander 1998	156	-0.12(0.50)	151	0.22(0.70)	5.57	-0.34 [-0.48, -0.20]
Kelley 2002	266	-0.38(0.74)	276	-0.08(0.74)	6.68	-0.30 [-0.42, -0.18]
Lindgarde 2000	190	-0.22(0.74)	186	0.07(0.74)	4.64	-0.29 [-0.44, -0.14]
Miles 2002	250	-0.25(0.74)	254	-0.05(0.74)	6.22	-0.20 [-0.33, -0.07]
Rossner 2000	241	-0.33(0.74)	236	-0.06(0.74)	5.88	-0.27 [-0.40, -0.14]
Sjostrom 1998	343	-0.09(0.74)	340	0.13(0.74)	8.43	-0.22 [-0.33, -0.11]
Swinburn 2005	170	-0.12(0.65)	169	0.11(0.62)	5.68	-0.23 [-0.37, -0.09]
Torgerson 2004	1487	-0.42(0.74)	1295	-0.06(0.74)	34.16	-0.36 [-0.42, -0.30]
Subtotal (95% CI)	3949		3755		100.00	-0.30 [-0.33, -0.27]
Test for heterogeneity: Chi² = 14.02, df = 11 (P = 0.23), I² = 21.5%						
Test for overall effect: Z = 18.25 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.18(0.74)	212	0.11(0.74)	38.83	0.07 [-0.07, 0.21]
Hill 1999	87	-0.05(0.74)	102	0.12(0.74)	17.28	-0.17 [-0.38, 0.04]
Rossner 2000	241	0.37(0.74)	236	0.34(0.74)	43.89	0.03 [-0.10, 0.16]
Subtotal (95% CI)	538		550		100.00	0.01 [-0.08, 0.10]
Test for heterogeneity: Chi² = 3.56, df = 2 (P = 0.17), I² = 43.8%						
Test for overall effect: Z = 0.24 (P = 0.81)						



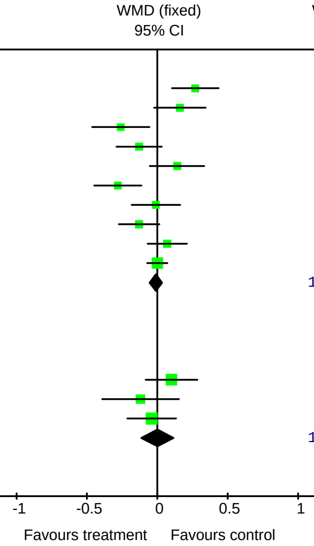
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 13 Change in HDL cholesterol in mmol/l at 12 months

Study		Orlistat + diet		Placebo + diet	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Finer 2000	110	0.15(0.23)	108	0.16(0.21)	4.96	-0.01 [-0.07, 0.05]
Hauptman 2000	210	0.06(0.29)	212	0.11(0.29)	5.53	-0.05 [-0.11, 0.01]
Hollander 1998	156	0.06(0.20)	151	0.06(0.20)	8.46	0.00 [-0.04, 0.04]
Kelley 2002	266	0.02(0.29)	276	0.05(0.29)	7.10	-0.03 [-0.08, 0.02]
Lindgarde 2000	190	0.03(0.29)	186	0.08(0.29)	4.93	-0.05 [-0.11, 0.01]
Miles 2002	250	0.09(0.29)	254	0.10(0.29)	6.61	-0.01 [-0.06, 0.04]
Rossner 2000	241	0.08(0.29)	236	0.15(0.29)	6.25	-0.07 [-0.12, -0.02]
Sjostrom 1998	343	0.10(0.29)	340	0.10(0.29)	8.95	0.00 [-0.04, 0.04]
Swinburn 2005	170	0.04(0.18)	169	0.08(0.19)	10.91	-0.04 [-0.08, 0.00]
Torgerson 2004	1487	0.04(0.29)	1295	0.10(0.29)	36.30	-0.06 [-0.08, -0.04]
Subtotal (95% CI)	3423		3227		100.00	-0.04 [-0.05, -0.03]
Test for heterogeneity: Chi² = 13.62, df = 9 (P = 0.14), I² = 33.9%						
Test for overall effect: Z = 5.88 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.01(0.29)	212	-0.02(0.29)	38.72	0.03 [-0.03, 0.09]
Hill 1999	89	-0.04(0.29)	103	0.00(0.29)	17.52	-0.04 [-0.12, 0.04]
Rossner 2000	241	0.04(0.29)	236	0.01(0.29)	43.76	0.03 [-0.02, 0.08]
Subtotal (95% CI)	540		551		100.00	0.02 [-0.02, 0.05]
Test for heterogeneity: Chi² = 2.29, df = 2 (P = 0.32), I² = 12.8%						
Test for overall effect: Z = 1.01 (P = 0.31)						



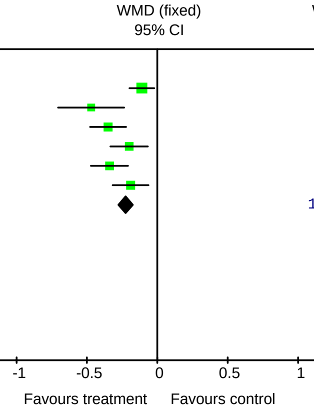
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 14 Change in triglycerides in mmol/l at 12 months

Study		Orlistat + diet		Placebo + diet	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Broom 2002a	259	0.44(0.96)	263	0.17(0.96)	7.09	0.27 [0.11, 0.43]
Hauptman 2000	210	0.06(0.96)	212	-0.10(0.96)	5.73	0.16 [-0.02, 0.34]
Hollander 1998	156	0.02(0.80)	151	0.28(1.00)	4.67	-0.26 [-0.46, -0.06]
Kelley 2002	266	0.18(0.96)	276	0.31(0.96)	7.35	-0.13 [-0.29, 0.03]
Lindgarde 2000	190	0.18(0.96)	186	0.04(0.96)	5.10	0.14 [-0.05, 0.33]
Miles 2002	250	-0.25(0.96)	254	0.03(0.96)	6.84	-0.28 [-0.45, -0.11]
Rossner 2000	241	-0.09(0.96)	236	-0.08(0.96)	6.47	-0.01 [-0.18, 0.16]
Sjostrom 1998	343	-0.07(0.96)	340	0.06(0.96)	9.27	-0.13 [-0.27, 0.01]
Swinburn 2005	170	0.01(0.73)	169	-0.06(0.57)	9.89	0.07 [-0.07, 0.21]
Torgerson 2004	1487	-0.12(0.96)	1295	-0.12(0.96)	37.58	0.00 [-0.07, 0.07]
Subtotal (95% CI)	3572		3382		100.00	-0.01 [-0.06, 0.03]
Test for heterogeneity: Chi² = 38.62, df = 9 (P < 0.0001), I² = 76.7%						
Test for overall effect: Z = 0.50 (P = 0.62)						
02 Weight maintenance						
Hauptman 2000	210	0.15(0.96)	212	0.05(0.96)	38.72	0.10 [-0.08, 0.28]
Hill 1999	89	0.02(0.96)	103	0.14(0.96)	17.52	-0.12 [-0.39, 0.15]
Rossner 2000	241	-0.01(0.96)	236	0.03(0.96)	43.76	-0.04 [-0.21, 0.13]
Subtotal (95% CI)	540		551		100.00	0.00 [-0.11, 0.11]
Test for heterogeneity: Chi² = 2.10, df = 2 (P = 0.35), I² = 4.7%						
Test for overall effect: Z = 0.00 (P = 1.00)						



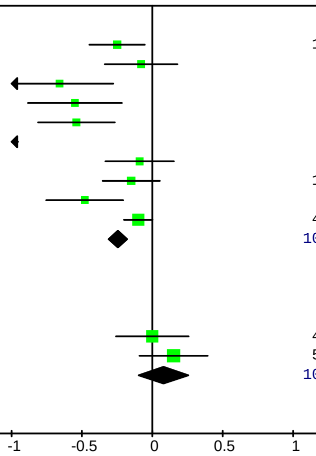
Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 15 Change in HbA1c% at 12 months

Study		Orlistat + diet		Placebo + diet	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Broom 2002a	259	0.08(0.43)	263	0.19(0.58)	33.98	-0.11 [-0.20, -0.02]
Hollander 1998	156	-0.15(1.00)	151	0.32(1.10)	4.70	-0.47 [-0.71, -0.23]
Kelley 2002	266	-0.62(0.76)	276	-0.27(0.76)	15.88	-0.35 [-0.48, -0.22]
Lindgarde 2000	190	-0.25(0.78)	186	-0.05(0.51)	14.72	-0.20 [-0.33, -0.07]
Miles 2002	250	-0.75(0.76)	254	-0.41(0.76)	14.77	-0.34 [-0.47, -0.21]
Swinburn 2005	170	-0.04(0.60)	169	0.15(0.60)	15.94	-0.19 [-0.32, -0.06]
Subtotal (95% CI)	1291		1299		100.00	-0.23 [-0.28, -0.17]
Test for heterogeneity: Chi² = 17.77, df = 5 (P = 0.003), I² = 71.9%						
Test for overall effect: Z = 8.65 (P < 0.00001)						
02 Weight maintenance						
Subtotal (95% CI)	0		0			Not estimable
Test for heterogeneity: not applicable						
Test for overall effect: not applicable						



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 16 Change in fasting plasma glucose in mmol/l at 12 months

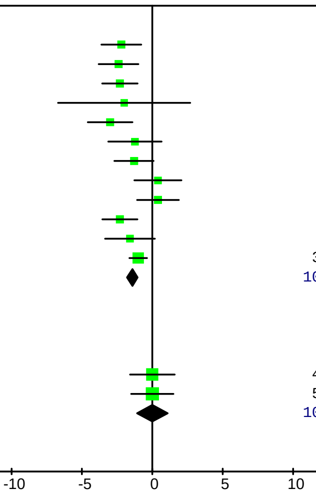
Study	Orlistat + diet		Placebo + diet		WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Broom 2002a	259	-0.19(1.26)	263	0.06(1.02)		11.11	-0.25 [-0.45, -0.05]
Hauptman 2000	210	0.03(1.35)	212	0.11(1.35)		6.49	-0.08 [-0.34, 0.18]
Hollander 1998	156	0.04(1.60)	151	0.70(1.80)		2.96	-0.66 [-1.04, -0.28]
Kelley 2002	266	-1.63(1.98)	276	-1.08(1.98)		3.87	-0.55 [-0.88, -0.22]
Lindgarde 2000	190	-0.46(1.35)	186	0.08(1.35)		5.78	-0.54 [-0.81, -0.27]
Miles 2002	250	-2.00(1.98)	254	-0.70(1.98)		3.60	-1.30 [-1.65, -0.95]
Rossner 2000	241	0.01(1.35)	236	0.10(1.35)		7.33	-0.09 [-0.33, 0.15]
Sjostrom 1998	343	-0.21(1.35)	340	-0.06(1.35)		10.50	-0.15 [-0.35, 0.05]
Swinburn 2005	170	-0.19(1.13)	169	0.29(1.42)		5.77	-0.48 [-0.75, -0.21]
Torgerson 2004	1487	0.10(1.35)	1295	0.20(1.35)		42.58	-0.10 [-0.20, 0.00]
Subtotal (95% CI)	3572		3382			100.00	-0.24 [-0.31, -0.18]
Test for heterogeneity: Chi² = 62.84, df = 9 (P < 0.00001), I² = 85.7%							
Test for overall effect: Z = 7.30 (P < 0.00001)							
02 Weight maintenance							
Hauptman 2000	210	0.13(1.35)	212	0.13(1.35)		46.94	0.00 [-0.26, 0.26]
Rossner 2000	241	0.03(1.35)	236	-0.12(1.35)		53.06	0.15 [-0.09, 0.39]
Subtotal (95% CI)	451		448			100.00	0.08 [-0.10, 0.26]
Test for heterogeneity: Chi² = 0.69, df = 1 (P = 0.41), I² = 0%							
Test for overall effect: Z = 0.88 (P = 0.38)							



Favours treatment Favours control

Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 17 Change in DBP in mmHg at 12 months

Study	Orlistat + diet		Placebo + diet		WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Bakris 2002	267	-11.40(8.30)	265	-9.20(8.40)		6.86	-2.20 [-3.62, -0.78]
Broom 2002a	259	-5.50(8.30)	263	-3.10(8.30)		6.81	-2.40 [-3.82, -0.98]
Davidson 1999	657	-1.00(8.30)	223	1.30(8.30)		8.69	-2.30 [-3.56, -1.04]
Derosa 2003	25	-4.00(8.30)	23	-2.00(8.30)		0.63	-2.00 [-6.70, 2.70]
Hauptman 2000	210	-1.00(8.30)	212	2.00(8.30)		5.51	-3.00 [-4.58, -1.42]
Hollander 1998	156	-1.01(8.00)	151	0.23(8.90)		3.85	-1.24 [-3.14, 0.66]
Kelley 2002	266	-2.30(8.30)	276	-1.00(8.30)		7.07	-1.30 [-2.70, 0.10]
Lindgarde 2000	190	-0.90(8.30)	186	-1.30(8.30)		4.91	0.40 [-1.28, 2.08]
Rossner 2000	241	-0.90(8.30)	236	-1.30(8.30)		6.22	0.40 [-1.09, 1.89]
Sjostrom 1998	343	-2.10(8.30)	340	0.20(8.30)		8.91	-2.30 [-3.54, -1.06]
Swinburn 2005	170	-2.96(8.01)	169	-1.37(8.59)		4.42	-1.59 [-3.36, 0.18]
Torgerson 2004	1487	-3.60(8.30)	1295	-2.60(8.30)		36.13	-1.00 [-1.62, -0.38]
Subtotal (95% CI)	4271		3639			100.00	-1.42 [-1.80, -1.05]
Test for heterogeneity: Chi² = 22.78, df = 11 (P = 0.02), I² = 51.7%							
Test for overall effect: Z = 7.51 (P < 0.00001)							
02 Weight maintenance							
Hauptman 2000	210	2.00(8.30)	212	2.00(8.30)		46.94	0.00 [-1.58, 1.58]
Rossner 2000	241	1.30(8.30)	236	1.30(8.30)		53.06	0.00 [-1.49, 1.49]
Subtotal (95% CI)	451		448			100.00	0.00 [-1.09, 1.09]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 1.00), I² = 0%							
Test for overall effect: Z = 0.00 (P = 1.00)							



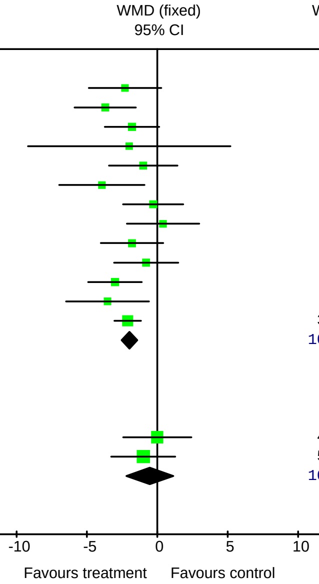
Favours treatment Favours control

Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 18 Change in SBP in mmHg at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Bakris 2002	267	-13.30(15.20)	265	-11.00(15.00)	4.74	-2.30 [-4.87, 0.27]
Broom 2002a	259	-6.00(12.70)	263	-2.30(12.70)	6.57	-3.70 [-5.88, -1.52]
Davidson 1999	657	-0.80(12.70)	223	1.00(12.70)	8.39	-1.80 [-3.73, 0.13]
Derosa 2003	25	-6.00(12.70)	23	-4.00(12.70)	0.60	-2.00 [-9.19, 5.19]
Hauptman 2000	210	2.00(12.70)	212	3.00(12.70)	5.32	-1.00 [-3.42, 1.42]
Hollander 1998	156	0.21(12.80)	151	4.15(14.20)	3.41	-3.94 [-6.97, -0.91]
Kelley 2002	266	-1.20(12.70)	276	-0.90(12.70)	6.82	-0.30 [-2.44, 1.84]
Lindgarde 2000	190	-0.50(12.70)	186	-0.90(12.70)	4.74	0.40 [-2.17, 2.97]
Miles 2002	250	-2.10(12.70)	254	-0.30(12.70)	6.35	-1.80 [-4.02, 0.42]
Rossner 2000	241	-2.70(12.70)	236	-1.90(12.70)	6.01	-0.80 [-3.08, 1.48]
Sjostrom 1998	343	-2.00(12.70)	340	1.00(12.70)	8.60	-3.00 [-4.90, -1.10]
Swinburn 2005	170	-4.05(13.00)	169	-0.51(14.70)	3.58	-3.54 [-6.49, -0.59]
Torgerson 2004	1487	-7.30(12.70)	1295	-5.20(12.70)	34.88	-2.10 [-3.05, -1.15]
Subtotal (95% CI)	4521		3893		100.00	-1.98 [-2.54, -1.42]
02 Weight maintenance						
Hauptman 2000	210	2.00(12.70)	212	2.00(12.70)	46.94	0.00 [-2.42, 2.42]
Rossner 2000	241	2.10(12.70)	236	3.10(12.70)	53.06	-1.00 [-3.28, 1.28]
Subtotal (95% CI)	451		448		100.00	-0.53 [-2.19, 1.13]

01 Weight reduction: Test for heterogeneity: Chi² = 13.68, df = 12 (P = 0.32), I² = 12.3%
Test for overall effect: Z = 6.96 (P < 0.00001)

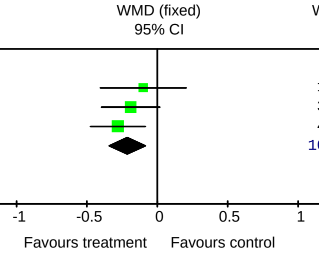
02 Weight maintenance: Test for heterogeneity: Chi² = 0.35, df = 1 (P = 0.56), I² = 0%
Test for overall effect: Z = 0.63 (P = 0.53)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 19 Change in total cholesterol in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	0.11(1.08)	89	0.21(1.08)	17.71	-0.10 [-0.40, 0.20]
Hauptman 2000	210	0.25(1.08)	212	0.44(1.08)	38.63	-0.19 [-0.40, 0.02]
Rossner 2000	241	0.03(1.08)	236	0.31(1.08)	43.66	-0.28 [-0.47, -0.09]
Subtotal (95% CI)	557		537		100.00	-0.21 [-0.34, -0.09]

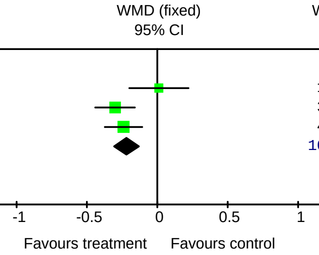
Test for heterogeneity: Chi² = 1.04, df = 2 (P = 0.60), I² = 0%
Test for overall effect: Z = 3.26 (P = 0.001)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 20 Change in LDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	104	0.05(0.74)	88	0.04(0.74)	17.50	0.01 [-0.20, 0.22]
Hauptman 2000	210	0.06(0.74)	212	0.36(0.74)	38.73	-0.30 [-0.44, -0.16]
Rossner 2000	241	0.04(0.74)	236	0.28(0.74)	43.77	-0.24 [-0.37, -0.11]
Subtotal (95% CI)	555		536		100.00	-0.22 [-0.31, -0.13]

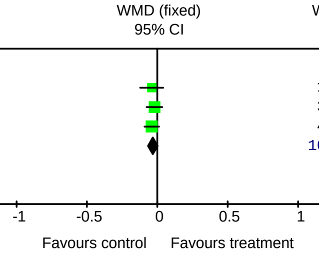
Test for heterogeneity: Chi² = 5.92, df = 2 (P = 0.05), I² = 66.2%
Test for overall effect: Z = 4.90 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 21 Change in HDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	0.11(0.29)	89	0.15(0.29)	17.71	-0.04 [-0.12, 0.04]
Hauptman 2000	210	0.07(0.29)	212	0.09(0.29)	38.63	-0.02 [-0.08, 0.04]
Rossner 2000	241	0.12(0.29)	236	0.16(0.29)	43.66	-0.04 [-0.09, 0.01]
Subtotal (95% CI)	557		537		100.00	-0.03 [-0.07, 0.00]

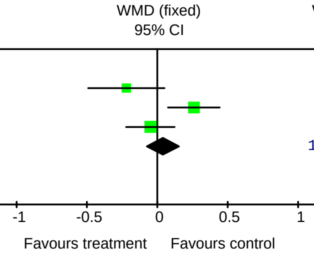
Test for heterogeneity: Chi² = 0.31, df = 2 (P = 0.86), I² = 0%
Test for overall effect: Z = 1.84 (P = 0.07)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 22 Change in triglycerides in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	-0.07(0.96)	89	0.15(0.96)	17.71	-0.22 [-0.49, 0.05]
Hauptman 2000	210	0.21(0.96)	212	-0.05(0.96)	38.63	0.26 [0.08, 0.44]
Rossner 2000	241	-0.10(0.96)	236	-0.05(0.96)	43.66	-0.05 [-0.22, 0.12]
Subtotal (95% CI)	557		537		100.00	0.04 [-0.07, 0.15]

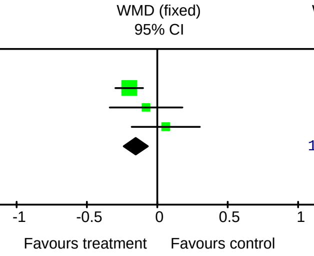
Test for heterogeneity: Chi² = 10.14, df = 2 (P = 0.006), I² = 80.3%
Test for overall effect: Z = 0.68 (P = 0.50)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 23 Change in fasting plasma glucose in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	0.06(0.31)	89	0.26(0.38)	76.23	-0.20 [-0.30, -0.10]
Hauptman 2000	210	0.16(1.35)	212	0.24(1.35)	11.16	-0.08 [-0.34, 0.18]
Rossner 2000	241	0.04(1.35)	236	-0.02(1.35)	12.61	0.06 [-0.18, 0.30]
Subtotal (95% CI)	557		537		100.00	-0.15 [-0.24, -0.07]

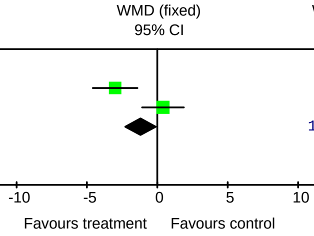
Test for heterogeneity: Chi² = 4.15, df = 2 (P = 0.13), I² = 51.8%
Test for overall effect: Z = 3.50 (P = 0.0005)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 24 Change in DBP mmHg at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	1.00(8.30)	212	4.00(8.30)	46.94	-3.00 [-4.58, -1.42]
Rossner 2000	241	0.40(8.30)	236	0.00(8.30)	53.06	0.40 [-1.09, 1.89]
Subtotal (95% CI)	451		448		100.00	-1.20 [-2.28, -0.11]

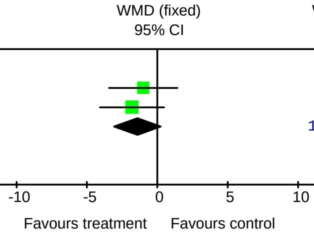
Test for heterogeneity: Chi² = 9.39, df = 1 (P = 0.002), I² = 89.4%
Test for overall effect: Z = 2.16 (P = 0.03)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 25 Change in SBP mmHg at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	4.00(12.70)	212	5.00(12.70)	46.94	-1.00 [-3.42, 1.42]
Rossner 2000	241	-0.60(12.70)	236	1.20(12.70)	53.06	-1.80 [-4.08, 0.48]
Subtotal (95% CI)	451		448		100.00	-1.42 [-3.08, 0.24]

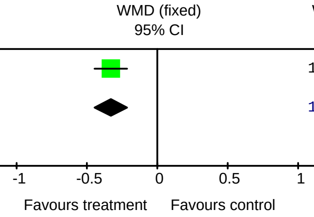
Test for heterogeneity: Chi² = 0.22, df = 1 (P = 0.64), I² = 0%
Test for overall effect: Z = 1.68 (P = 0.09)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 26 Change in total cholesterol in mmol/l at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-0.46(1.08)	567	-0.13(1.08)	100.00	-0.33 [-0.44, -0.22]
Total (95% CI)	851		567		100.00	-0.33 [-0.44, -0.22]

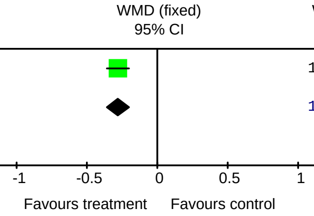
Test for heterogeneity: not applicable
Test for overall effect: Z = 5.64 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 27 Change in LDL cholesterol in mmol/l at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-0.47(0.74)	567	-0.19(0.74)	100.00	-0.28 [-0.36, -0.20]
Total (95% CI)	851		567		100.00	-0.28 [-0.36, -0.20]

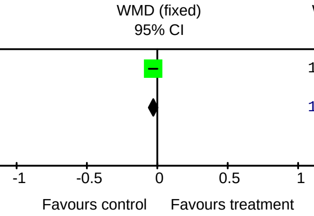
Test for heterogeneity: not applicable
Test for overall effect: Z = 6.98 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 28 Change in HDL cholesterol in mmol/l at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	0.08(0.29)	567	0.11(0.29)	100.00	-0.03 [-0.06, 0.00]
Total (95% CI)	851		567		100.00	-0.03 [-0.06, 0.00]

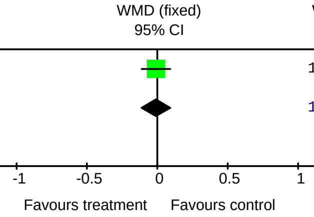
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.91 (P = 0.06)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 29 Change in triglycerides in mmol/l at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	0.05(0.96)	567	0.06(0.96)	100.00	-0.01 [-0.11, 0.09]
Total (95% CI)	851		567		100.00	-0.01 [-0.11, 0.09]

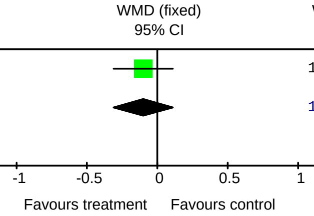
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.19 (P = 0.85)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 30 Change in fasting plasma glucose in mmol/l at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	0.10(1.98)	567	0.20(1.98)	100.00	-0.10 [-0.31, 0.11]
Total (95% CI)	851		567		100.00	-0.10 [-0.31, 0.11]

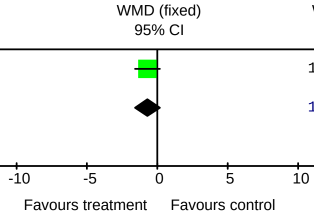
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.93 (P = 0.35)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 31 Change in DBP in mmHg at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-2.60(8.30)	567	-1.90(8.30)	100.00	-0.70 [-1.58, 0.18]
Total (95% CI)	851		567		100.00	-0.70 [-1.58, 0.18]

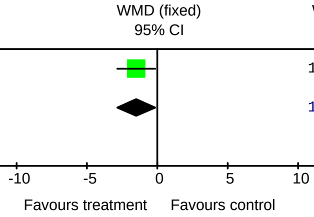
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.56 (P = 0.12)



Review: Orlistat UPDATE adults only
Comparison: 01 Orlistat 360mg/day + diet vs placebo + diet (all studies)
Outcome: 32 Change in SBP in mmHg at 48 months

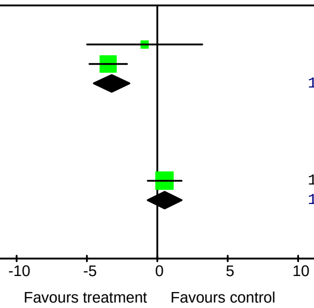
Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-4.90(12.70)	567	-3.40(12.70)	100.00	-1.50 [-2.85, -0.15]
Total (95% CI)	851		567		100.00	-1.50 [-2.85, -0.15]

Test for heterogeneity: not applicable
Test for overall effect: Z = 2.18 (P = 0.03)



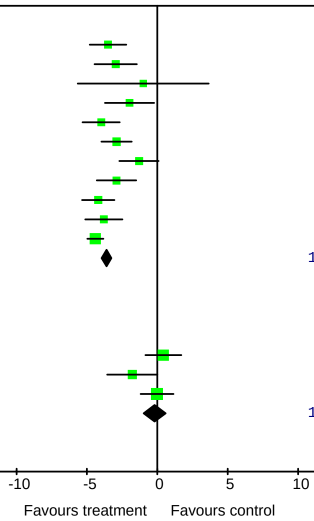
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Derosa 2003	25	-5.10(7.36)	23	-4.20(7.10)	9.59	-0.90 [-4.99, 3.19]
Hauptman 2000	210	-5.46(7.46)	212	-1.97(6.47)	90.41	-3.49 [-4.82, -2.16]
Subtotal (95% CI)	235		235		100.00	-3.24 [-4.51, -1.97]
Test for heterogeneity: Chi² = 1.39, df = 1 (P = 0.24), I² = 28.1%						
Test for overall effect: Z = 5.01 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	1.72(6.40)	212	1.21(6.26)	100.00	0.51 [-0.70, 1.72]
Subtotal (95% CI)	210		212		100.00	0.51 [-0.70, 1.72]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.83 (P = 0.41)						



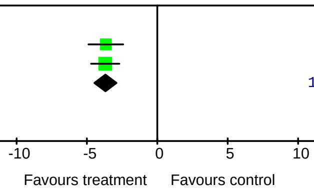
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002a	259	-5.80(8.50)	263	-2.30(6.40)	7.19	-3.50 [-4.79, -2.21]
Davidson 1999	657	-8.76(9.48)	223	-5.81(10.01)	5.33	-2.95 [-4.45, -1.45]
Derosa 2003	25	-8.60(8.35)	23	-7.60(8.07)	0.56	-1.00 [-5.65, 3.65]
Finer 2000	110	-3.29(6.85)	108	-1.31(6.29)	3.94	-1.98 [-3.73, -0.23]
Hauptman 2000	210	-5.40(7.44)	212	-1.41(6.31)	6.93	-3.99 [-5.31, -2.67]
Krempf 2003	346	-5.95(7.60)	350	-3.05(6.78)	10.48	-2.90 [-3.97, -1.83]
Lindgarde 2000	190	-4.20(7.03)	186	-2.90(6.74)	6.20	-1.30 [-2.69, 0.09]
Rossner 2000	241	-8.13(8.22)	236	-5.23(7.40)	6.10	-2.90 [-4.30, -1.50]
Sjostrom 1998	343	-8.10(8.21)	340	-3.90(7.02)	9.16	-4.20 [-5.35, -3.05]
Swinburn 2005	170	-4.70(7.70)	169	-0.90(4.20)	6.90	-3.80 [-5.12, -2.48]
Torgerson 2004	1650	-10.60(8.91)	1637	-6.20(7.67)	37.20	-4.40 [-4.97, -3.83]
Subtotal (95% CI)	4201		3747		100.00	-3.61 [-3.96, -3.27]
Test for heterogeneity: Chi² = 27.43, df = 10 (P = 0.002), I² = 63.5%						
Test for overall effect: Z = 20.44 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	2.92(6.74)	212	2.49(6.62)	37.00	0.43 [-0.84, 1.70]
Hill 1999	113	2.62(6.66)	121	4.40(7.16)	19.17	-1.78 [-3.55, -0.01]
Rossner 2000	241	2.15(6.52)	236	2.17(6.53)	43.83	-0.02 [-1.19, 1.15]
Subtotal (95% CI)	564		569		100.00	-0.19 [-0.97, 0.58]
Test for heterogeneity: Chi² = 4.09, df = 2 (P = 0.13), I² = 51.1%						
Test for overall effect: Z = 0.48 (P = 0.63)						



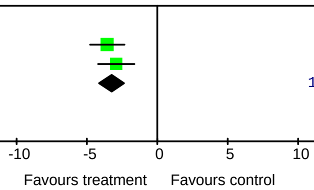
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 03 Weight change in kg at 18 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	-3.68(6.96)	212	-0.02(5.97)	40.29	-3.66 [-4.90, -2.42]
Krempf 2003	346	-5.05(7.34)	350	-1.35(6.30)	59.71	-3.70 [-4.72, -2.68]
Subtotal (95% CI)	556		562		100.00	-3.68 [-4.47, -2.90]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.96), I² = 0%						
Test for overall effect: Z = 9.19 (P < 0.00001)						



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 04 Weight change at 24 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	-2.48(6.62)	212	1.08(6.22)	52.66	-3.56 [-4.79, -2.33]
Rossner 2000	241	-5.98(7.61)	236	-3.06(6.78)	47.34	-2.92 [-4.21, -1.63]
Subtotal (95% CI)	451		448		100.00	-3.26 [-4.15, -2.37]
Test for heterogeneity: Chi² = 0.50, df = 1 (P = 0.48), I² = 0%						
Test for overall effect: Z = 7.18 (P < 0.00001)						



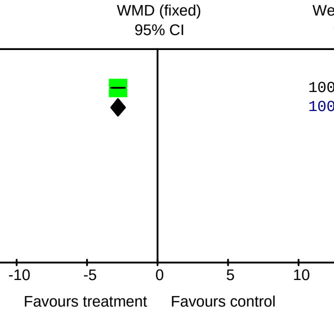
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 05 Weight change in kg at 48 months

Study	Orlistat + diet		Placebo + diet		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Torgerson 2004	1650	-5.80(7.56)	1637	-3.00(6.76)	100.00	-2.80 [-3.29, -2.31]
Subtotal (95% CI)	1650		1637		100.00	-2.80 [-3.29, -2.31]

Test for heterogeneity: not applicable
Test for overall effect: Z = 11.20 (P < 0.00001)

Study	Orlistat + diet		Placebo + diet		Weight	WMD (fixed)
02 Weight maintenance						
Subtotal (95% CI)	0		0			Not estimable

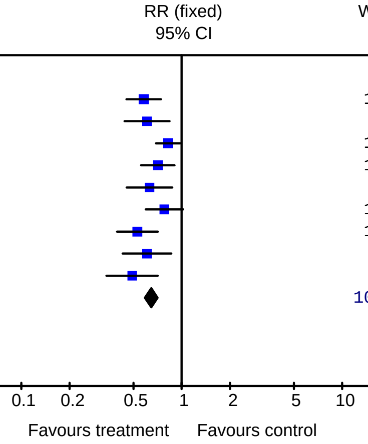
Test for heterogeneity: not applicable
Test for overall effect: not applicable



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 06 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Broom 2002a	44/100	76/100	13.40	0.58 [0.45, 0.74]
Davidson 1999	34/100	56/100	9.88	0.61 [0.44, 0.84]
Finer 2000	65/100	79/100	13.93	0.82 [0.69, 0.98]
Hauptman 2000	49/100	69/100	12.17	0.71 [0.56, 0.90]
Krempf 2003	34/100	54/100	9.52	0.63 [0.45, 0.87]
Lindgarde 2000	46/100	59/100	10.41	0.78 [0.60, 1.02]
Rossner 2000	36/100	68/100	11.99	0.53 [0.39, 0.71]
Sjostrom 1998	31/100	51/100	8.99	0.61 [0.43, 0.86]
Torgerson 2004	27/100	55/100	9.70	0.49 [0.34, 0.71]
Subtotal (95% CI)	900	900	100.00	0.65 [0.59, 0.71]

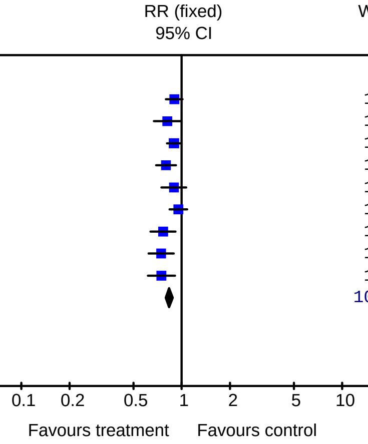
Total events: 366 (Orlistat + diet), 567 (Placebo + diet)
Test for heterogeneity: Chi² = 14.74, df = 8 (P = 0.06), I² = 45.7%
Test for overall effect: Z = 9.33 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 07 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Broom 2002a	80/100	89/100	11.88	0.90 [0.80, 1.01]
Davidson 1999	61/100	75/100	10.01	0.81 [0.67, 0.99]
Finer 2000	84/100	94/100	12.55	0.89 [0.81, 0.99]
Hauptman 2000	71/100	89/100	11.88	0.80 [0.69, 0.92]
Krempf 2003	67/100	75/100	10.01	0.89 [0.75, 1.07]
Lindgarde 2000	81/100	85/100	11.35	0.95 [0.84, 1.08]
Rossner 2000	62/100	81/100	10.81	0.77 [0.64, 0.92]
Sjostrom 1998	61/100	82/100	10.95	0.74 [0.62, 0.89]
Torgerson 2004	59/100	79/100	10.55	0.75 [0.62, 0.91]
Subtotal (95% CI)	900	900	100.00	0.84 [0.79, 0.88]

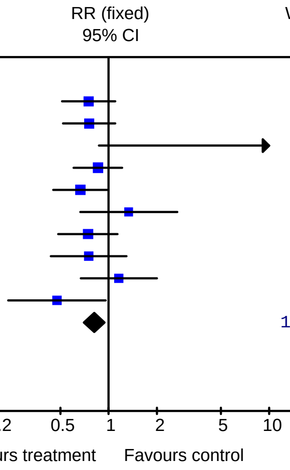
Total events: 626 (Orlistat + diet), 749 (Placebo + diet)
Test for heterogeneity: Chi² = 12.20, df = 8 (P = 0.14), I² = 34.4%
Test for overall effect: Z = 6.81 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 08 Failure to complete at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Broom 2002a	30/100	40/100	14.47	0.75 [0.51, 1.10]
Davidson 1999	31/100	41/100	14.83	0.76 [0.52, 1.10]
Derosa 2003	7/100	0/100	0.18	15.00 [0.87, 259.16]
Finer 2000	36/100	42/100	15.19	0.86 [0.61, 1.21]
Hauptman 2000	28/100	42/100	15.19	0.67 [0.45, 0.98]
Lindgarde 2000	16/100	12/100	4.34	1.33 [0.67, 2.67]
Rossner 2000	26/100	35/100	12.66	0.74 [0.49, 1.14]
Sjostrom 1998	18/100	24/100	8.68	0.75 [0.44, 1.29]
Swinburn 2005	22/100	19/100	6.87	1.16 [0.67, 2.00]
Torgerson 2004	10/100	21/100	7.59	0.48 [0.24, 0.96]
Subtotal (95% CI)	1000	1000	100.00	0.81 [0.70, 0.94]

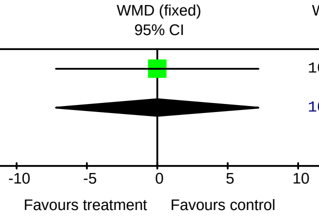
Total events: 224 (Orlistat + diet), 276 (Placebo + diet)
Test for heterogeneity: Chi² = 11.45, df = 9 (P = 0.25), I² = 21.4%
Test for overall effect: Z = 2.76 (P = 0.006)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 09 Change in SBP mmHg at 6 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Derosa 2003	25	-2.00(12.70)	23	-2.00(12.70)	100.00	0.00 [-7.19, 7.19]
Total (95% CI)	25		23		100.00	0.00 [-7.19, 7.19]

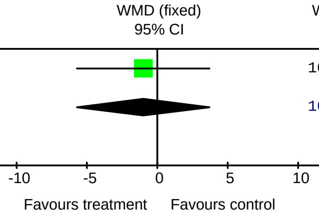
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 10 Change in DBP mmHg at 6 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Derosa 2003	25	-1.00(8.30)	23	0.00(8.30)	100.00	-1.00 [-5.70, 3.70]
Total (95% CI)	25		23		100.00	-1.00 [-5.70, 3.70]

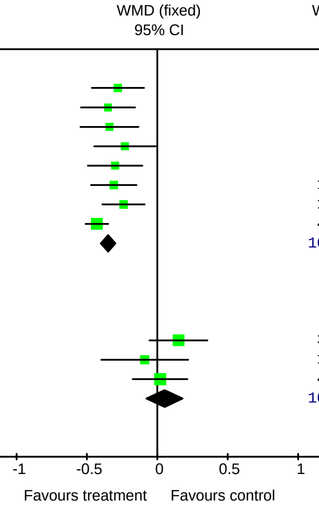
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.42 (P = 0.68)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 11 Change in total cholesterol in mmol/l at 12 months

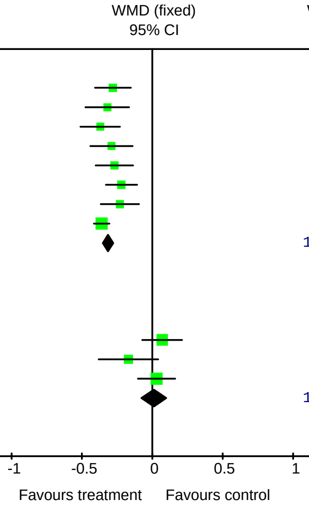
Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002a	259	-0.12(1.08)	263	0.16(1.08)	7.99	-0.28 [-0.47, -0.09]
Finer 2000	110	-0.05(0.76)	108	0.30(0.68)	7.49	-0.35 [-0.54, -0.16]
Hauptman 2000	210	-0.04(1.08)	212	0.30(1.08)	6.46	-0.34 [-0.55, -0.13]
Lindgarde 2000	190	0.03(1.08)	186	0.26(1.08)	5.75	-0.23 [-0.45, -0.01]
Rossner 2000	241	-0.35(1.08)	236	-0.05(1.08)	7.30	-0.30 [-0.49, -0.11]
Sjostrom 1998	343	-0.08(1.08)	340	0.23(1.08)	10.45	-0.31 [-0.47, -0.15]
Swinburn 2005	170	-0.08(0.73)	169	0.16(0.68)	12.17	-0.24 [-0.39, -0.09]
Torgerson 2004	1487	-0.51(1.08)	1295	-0.08(1.08)	42.38	-0.43 [-0.51, -0.35]
Subtotal (95% CI)	3010		2809		100.00	-0.35 [-0.40, -0.30]
Test for heterogeneity: Chi² = 8.07, df = 7 (P = 0.33), I² = 13.2%						
Test for overall effect: Z = 13.08 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.29(1.08)	212	0.14(1.08)	38.83	0.15 [-0.06, 0.36]
Hill 1999	87	0.08(1.08)	102	0.17(1.08)	17.28	-0.09 [-0.40, 0.22]
Rossner 2000	241	0.38(1.08)	236	0.36(1.08)	43.89	0.02 [-0.17, 0.21]
Subtotal (95% CI)	538		550		100.00	0.05 [-0.08, 0.18]

Test for heterogeneity: Chi² = 1.78, df = 2 (P = 0.41), I² = 0%
Test for overall effect: Z = 0.79 (P = 0.43)



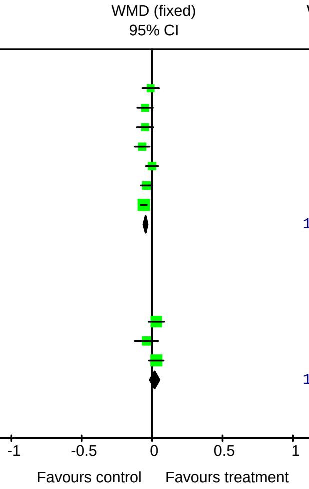
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 12 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002a	259	-0.30(0.74)	263	-0.02(0.74)	8.61	-0.28 [-0.41, -0.15]
Finer 2000	110	-0.11(0.63)	108	0.21(0.53)	5.82	-0.32 [-0.47, -0.17]
Hauptman 2000	210	-0.12(0.74)	212	0.25(0.74)	6.96	-0.37 [-0.51, -0.23]
Lindgarde 2000	190	-0.22(0.74)	186	0.07(0.74)	6.20	-0.29 [-0.44, -0.14]
Rossner 2000	241	-0.33(0.74)	236	-0.06(0.74)	7.87	-0.27 [-0.40, -0.14]
Sjostrom 1998	343	-0.09(0.74)	340	0.13(0.74)	11.27	-0.22 [-0.33, -0.11]
Swinburn 2005	170	-0.12(0.65)	169	0.11(0.62)	7.59	-0.23 [-0.37, -0.09]
Torgerson 2004	1487	-0.42(0.74)	1295	-0.06(0.74)	45.68	-0.36 [-0.42, -0.30]
Subtotal (95% CI)	3010		2809		100.00	-0.31 [-0.35, -0.28]
Test for heterogeneity: Chi² = 8.32, df = 7 (P = 0.31), I² = 15.8%						
Test for overall effect: Z = 16.54 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.18(0.74)	212	0.11(0.74)	38.83	0.07 [-0.07, 0.21]
Hill 1999	87	-0.05(0.74)	102	0.12(0.74)	17.28	-0.17 [-0.38, 0.04]
Rossner 2000	241	0.37(0.74)	236	0.34(0.74)	43.89	0.03 [-0.10, 0.16]
Subtotal (95% CI)	538		550		100.00	0.01 [-0.08, 0.10]
Test for heterogeneity: Chi² = 3.56, df = 2 (P = 0.17), I² = 43.8%						
Test for overall effect: Z = 0.24 (P = 0.81)						



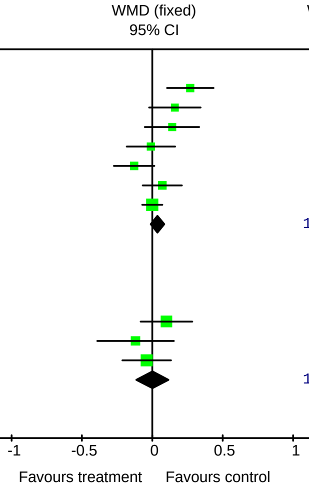
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 13 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Finer 2000	110	0.15(0.23)	108	0.16(0.21)	6.37	-0.01 [-0.07, 0.05]
Hauptman 2000	210	0.06(0.29)	212	0.11(0.29)	7.11	-0.05 [-0.11, 0.01]
Lindgarde 2000	190	0.03(0.29)	186	0.08(0.29)	6.33	-0.05 [-0.11, 0.01]
Rossner 2000	241	0.08(0.29)	236	0.15(0.29)	8.03	-0.07 [-0.12, -0.02]
Sjostrom 1998	343	0.10(0.29)	340	0.10(0.29)	11.50	0.00 [-0.04, 0.04]
Swinburn 2005	170	0.04(0.18)	169	0.08(0.19)	14.02	-0.04 [-0.08, 0.00]
Torgerson 2004	1487	0.04(0.29)	1295	0.10(0.29)	46.63	-0.06 [-0.08, -0.04]
Subtotal (95% CI)	2751		2546		100.00	-0.05 [-0.06, -0.03]
Test for heterogeneity: Chi² = 8.30, df = 6 (P = 0.22), I² = 27.8%						
Test for overall effect: Z = 6.19 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.01(0.29)	212	-0.02(0.29)	38.72	0.03 [-0.03, 0.09]
Hill 1999	89	-0.04(0.29)	103	0.00(0.29)	17.52	-0.04 [-0.12, 0.04]
Rossner 2000	241	0.04(0.29)	236	0.01(0.29)	43.76	0.03 [-0.02, 0.08]
Subtotal (95% CI)	540		551		100.00	0.02 [-0.02, 0.05]
Test for heterogeneity: Chi² = 2.29, df = 2 (P = 0.32), I² = 12.8%						
Test for overall effect: Z = 1.01 (P = 0.31)						



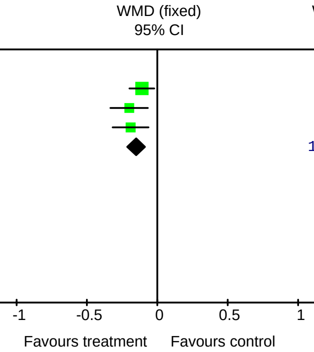
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 14 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002a	259	0.44(0.96)	263	0.17(0.96)	8.73	0.27 [0.11, 0.43]
Hauptman 2000	210	0.06(0.96)	212	-0.10(0.96)	7.06	0.16 [-0.02, 0.34]
Lindgarde 2000	190	0.18(0.96)	186	0.04(0.96)	6.29	0.14 [-0.05, 0.33]
Rossner 2000	241	-0.09(0.96)	236	-0.08(0.96)	7.98	-0.01 [-0.18, 0.16]
Sjostrom 1998	343	-0.07(0.96)	340	0.06(0.96)	11.43	-0.13 [-0.27, 0.01]
Swinburn 2005	170	0.01(0.73)	169	-0.06(0.57)	12.19	0.07 [-0.07, 0.21]
Torgerson 2004	1487	-0.12(0.96)	1295	-0.12(0.96)	46.32	0.00 [-0.07, 0.07]
Subtotal (95% CI)	2900		2701		100.00	0.04 [-0.01, 0.09]
Test for heterogeneity: Chi² = 17.20, df = 6 (P = 0.009), I² = 65.1%						
Test for overall effect: Z = 1.47 (P = 0.14)						
02 Weight maintenance						
Hauptman 2000	210	0.15(0.96)	212	0.05(0.96)	38.72	0.10 [-0.08, 0.28]
Hill 1999	89	0.02(0.96)	103	0.14(0.96)	17.52	-0.12 [-0.39, 0.15]
Rossner 2000	241	-0.01(0.96)	236	0.03(0.96)	43.76	-0.04 [-0.21, 0.13]
Subtotal (95% CI)	540		551		100.00	0.00 [-0.11, 0.11]
Test for heterogeneity: Chi² = 2.10, df = 2 (P = 0.35), I² = 4.7%						
Test for overall effect: Z = 0.00 (P = 1.00)						



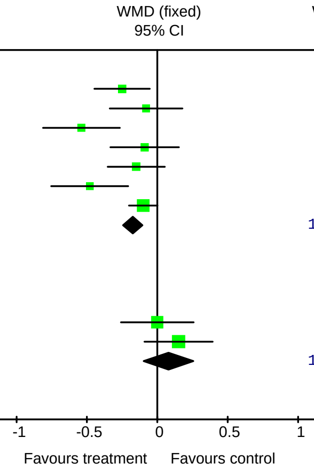
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 15 Change in HbA1c% at 12 months

Study	Orlistat + diet		Placebo + diet		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Broom 2002a	259	0.08(0.43)	263	0.19(0.58)	52.57	-0.11 [-0.20, -0.02]
Lindgarde 2000	190	-0.25(0.78)	186	-0.05(0.51)	22.77	-0.20 [-0.33, -0.07]
Swinburn 2005	170	-0.04(0.60)	169	0.15(0.60)	24.66	-0.19 [-0.32, -0.06]
Subtotal (95% CI)	619		618		100.00	-0.15 [-0.21, -0.09]
Test for heterogeneity: Chi² = 1.72, df = 2 (P = 0.42), I² = 0%						
Test for overall effect: Z = 4.64 (P < 0.00001)						
02 Weight maintenance						
Subtotal (95% CI)	0		0			Not estimable
Test for heterogeneity: not applicable						
Test for overall effect: not applicable						



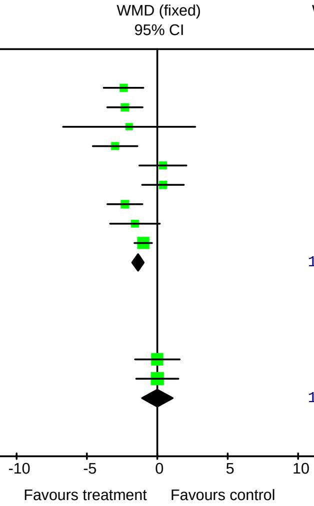
Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 16 Change in fasting plasma glucose in mmol/l at 12 months

Study	Orlistat + diet		Placebo + diet		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Broom 2002a	259	-0.19(1.26)	263	0.06(1.02)	12.41	-0.25 [-0.45, -0.05]
Hauptman 2000	210	0.03(1.35)	212	0.11(1.35)	7.25	-0.08 [-0.34, 0.18]
Lindgarde 2000	190	-0.46(1.35)	186	0.08(1.35)	6.45	-0.54 [-0.81, -0.27]
Rossner 2000	241	0.01(1.35)	236	0.10(1.35)	8.19	-0.09 [-0.33, 0.15]
Sjostrom 1998	343	-0.21(1.35)	340	-0.06(1.35)	11.73	-0.15 [-0.35, 0.05]
Swinburn 2005	170	-0.19(1.13)	169	0.29(1.42)	6.44	-0.48 [-0.75, -0.21]
Torgerson 2004	1487	0.10(1.35)	1295	0.20(1.35)	47.54	-0.10 [-0.20, 0.00]
Subtotal (95% CI)	2900		2701		100.00	-0.18 [-0.24, -0.11]
Test for heterogeneity: Chi² = 15.40, df = 6 (P = 0.02), I² = 61.0%						
Test for overall effect: Z = 4.95 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	0.13(1.35)	212	0.13(1.35)	46.94	0.00 [-0.26, 0.26]
Rossner 2000	241	0.03(1.35)	236	-0.12(1.35)	53.06	0.15 [-0.09, 0.39]
Subtotal (95% CI)	451		448		100.00	0.08 [-0.10, 0.26]
Test for heterogeneity: Chi² = 0.69, df = 1 (P = 0.41), I² = 0%						
Test for overall effect: Z = 0.88 (P = 0.38)						



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 17 Change in DBP in mmHg at 12 months

Study	Orlistat + diet		Placebo + diet		Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
Broom 2002a	259	-5.50(8.30)	263	-3.10(8.30)	8.28	-2.40 [-3.82, -0.98]
Davidson 1999	657	-1.00(8.30)	223	1.30(8.30)	10.57	-2.30 [-3.56, -1.04]
Derosa 2003	25	-4.00(8.30)	23	-2.00(8.30)	0.76	-2.00 [-6.70, 2.70]
Hauptman 2000	210	-1.00(8.30)	212	2.00(8.30)	6.70	-3.00 [-4.58, -1.42]
Lindgarde 2000	190	-0.90(8.30)	186	-1.30(8.30)	5.97	0.40 [-1.28, 2.08]
Rossner 2000	241	-0.90(8.30)	236	-1.30(8.30)	7.57	0.40 [-1.09, 1.89]
Sjostrom 1998	343	-2.10(8.30)	340	0.20(8.30)	10.84	-2.30 [-3.54, -1.06]
Swinburn 2005	170	-2.96(8.01)	169	-1.37(8.59)	5.37	-1.59 [-3.36, 0.18]
Torgerson 2004	1487	-3.60(8.30)	1295	-2.60(8.30)	43.94	-1.00 [-1.62, -0.38]
Subtotal (95% CI)	3582		2947		100.00	-1.38 [-1.79, -0.97]
Test for heterogeneity: Chi² = 21.51, df = 8 (P = 0.006), I² = 62.8%						
Test for overall effect: Z = 6.59 (P < 0.00001)						
02 Weight maintenance						
Hauptman 2000	210	2.00(8.30)	212	2.00(8.30)	46.94	0.00 [-1.58, 1.58]
Rossner 2000	241	1.30(8.30)	236	1.30(8.30)	53.06	0.00 [-1.49, 1.49]
Subtotal (95% CI)	451		448		100.00	0.00 [-1.09, 1.09]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 1.00), I² = 0%						
Test for overall effect: Z = 0.00 (P = 1.00)						

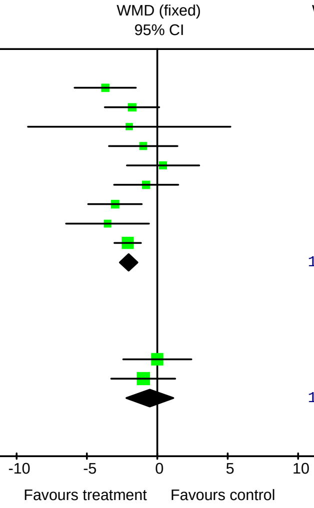


Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 18 Change in SBP in mmHg at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002a	259	-6.00(12.70)	263	-2.30(12.70)	8.36	-3.70 [-5.88, -1.52]
Davidson 1999	657	-0.80(12.70)	223	1.00(12.70)	10.66	-1.80 [-3.73, 0.13]
Derosa 2003	25	-6.00(12.70)	23	-4.00(12.70)	0.77	-2.00 [-9.19, 5.19]
Hauptman 2000	210	2.00(12.70)	212	3.00(12.70)	6.76	-1.00 [-3.42, 1.42]
Lindgarde 2000	190	-0.50(12.70)	186	-0.90(12.70)	6.02	0.40 [-2.17, 2.97]
Rossner 2000	241	-2.70(12.70)	236	-1.90(12.70)	7.64	-0.80 [-3.08, 1.48]
Sjostrom 1998	343	-2.00(12.70)	340	1.00(12.70)	10.93	-3.00 [-4.90, -1.10]
Swinburn 2005	170	-4.05(13.00)	169	-0.51(14.70)	4.54	-3.54 [-6.49, -0.59]
Torgerson 2004	1487	-7.30(12.70)	1295	-5.20(12.70)	44.33	-2.10 [-3.05, -1.15]
Subtotal (95% CI)	3582		2947		100.00	-2.04 [-2.67, -1.41]
02 Weight maintenance						
Hauptman 2000	210	2.00(12.70)	212	2.00(12.70)	46.94	0.00 [-2.42, 2.42]
Rossner 2000	241	2.10(12.70)	236	3.10(12.70)	53.06	-1.00 [-3.28, 1.28]
Subtotal (95% CI)	451		448		100.00	-0.53 [-2.19, 1.13]

01 Weight reduction: Test for heterogeneity: Chi² = 9.58, df = 8 (P = 0.30), I² = 16.5%
Test for overall effect: Z = 6.35 (P < 0.00001)

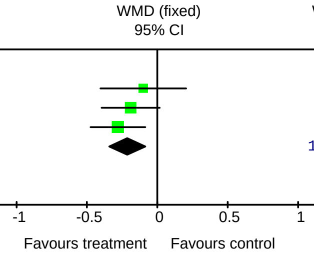
02 Weight maintenance: Test for heterogeneity: Chi² = 0.35, df = 1 (P = 0.56), I² = 0%
Test for overall effect: Z = 0.63 (P = 0.53)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 19 Change in total cholesterol in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	0.11(1.08)	89	0.21(1.08)	17.71	-0.10 [-0.40, 0.20]
Hauptman 2000	210	0.25(1.08)	212	0.44(1.08)	38.63	-0.19 [-0.40, 0.02]
Rossner 2000	241	0.03(1.08)	236	0.31(1.08)	43.66	-0.28 [-0.47, -0.09]
Subtotal (95% CI)	557		537		100.00	-0.21 [-0.34, -0.09]

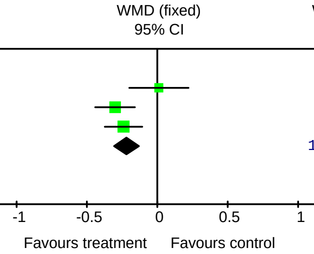
Test for heterogeneity: Chi² = 1.04, df = 2 (P = 0.60), I² = 0%
Test for overall effect: Z = 3.26 (P = 0.001)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 20 Change in LDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	104	0.05(0.74)	88	0.04(0.74)	17.50	0.01 [-0.20, 0.22]
Hauptman 2000	210	0.06(0.74)	212	0.36(0.74)	38.73	-0.30 [-0.44, -0.16]
Rossner 2000	241	0.04(0.74)	236	0.28(0.74)	43.77	-0.24 [-0.37, -0.11]
Subtotal (95% CI)	555		536		100.00	-0.22 [-0.31, -0.13]

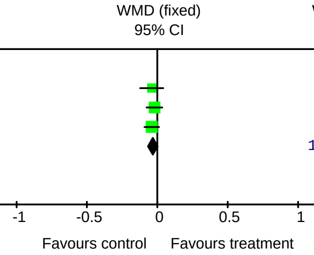
Test for heterogeneity: Chi² = 5.92, df = 2 (P = 0.05), I² = 66.2%
Test for overall effect: Z = 4.90 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 21 Change in HDL cholesterol in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	0.11(0.29)	89	0.15(0.29)	17.71	-0.04 [-0.12, 0.04]
Hauptman 2000	210	0.07(0.29)	212	0.09(0.29)	38.63	-0.02 [-0.08, 0.04]
Rossner 2000	241	0.12(0.29)	236	0.16(0.29)	43.66	-0.04 [-0.09, 0.01]
Subtotal (95% CI)	557		537		100.00	-0.03 [-0.07, 0.00]

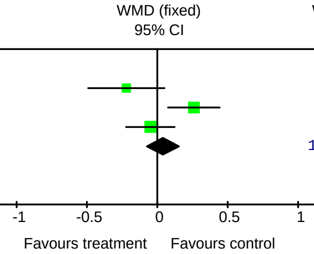
Test for heterogeneity: Chi² = 0.31, df = 2 (P = 0.86), I² = 0%
Test for overall effect: Z = 1.84 (P = 0.07)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 22 Change in triglycerides in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	-0.07(0.96)	89	0.15(0.96)	17.71	-0.22 [-0.49, 0.05]
Hauptman 2000	210	0.21(0.96)	212	-0.05(0.96)	38.63	0.26 [0.08, 0.44]
Rossner 2000	241	-0.10(0.96)	236	-0.05(0.96)	43.66	-0.05 [-0.22, 0.12]
Subtotal (95% CI)	557		537		100.00	0.04 [-0.07, 0.15]

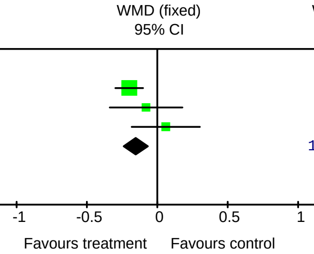
Test for heterogeneity: Chi² = 10.14, df = 2 (P = 0.006), I² = 80.3%
Test for overall effect: Z = 0.68 (P = 0.50)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 23 Change in fasting plasma glucose in mmol/l at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Davidson 1999	106	0.06(0.31)	89	0.26(0.38)	76.23	-0.20 [-0.30, -0.10]
Hauptman 2000	210	0.16(1.35)	212	0.24(1.35)	11.16	-0.08 [-0.34, 0.18]
Rossner 2000	241	0.04(1.35)	236	-0.02(1.35)	12.61	0.06 [-0.18, 0.30]
Subtotal (95% CI)	557		537		100.00	-0.15 [-0.24, -0.07]

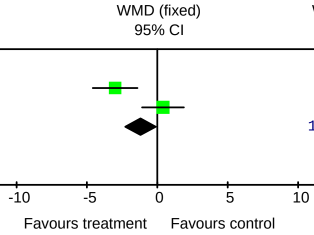
Test for heterogeneity: Chi² = 4.15, df = 2 (P = 0.13), I² = 51.8%
Test for overall effect: Z = 3.50 (P = 0.0005)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 24 Change in DBP mmHg at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	1.00(8.30)	212	4.00(8.30)	46.94	-3.00 [-4.58, -1.42]
Rossner 2000	241	0.40(8.30)	236	0.00(8.30)	53.06	0.40 [-1.09, 1.89]
Subtotal (95% CI)	451		448		100.00	-1.20 [-2.28, -0.11]

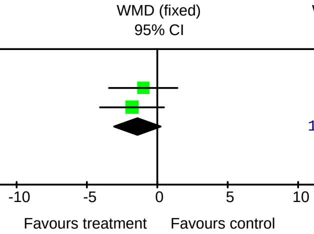
Test for heterogeneity: Chi² = 9.39, df = 1 (P = 0.002), I² = 89.4%
Test for overall effect: Z = 2.16 (P = 0.03)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 25 Change in SBP mmHg at 24 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hauptman 2000	210	4.00(12.70)	212	5.00(12.70)	46.94	-1.00 [-3.42, 1.42]
Rossner 2000	241	-0.60(12.70)	236	1.20(12.70)	53.06	-1.80 [-4.08, 0.48]
Subtotal (95% CI)	451		448		100.00	-1.42 [-3.08, 0.24]

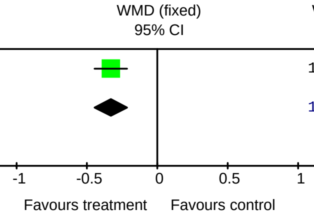
Test for heterogeneity: Chi² = 0.22, df = 1 (P = 0.64), I² = 0%
Test for overall effect: Z = 1.68 (P = 0.09)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 26 Change in total cholesterol in mmol/l at 48 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-0.46(1.08)	567	-0.13(1.08)	100.00	-0.33 [-0.44, -0.22]
Total (95% CI)	851		567		100.00	-0.33 [-0.44, -0.22]

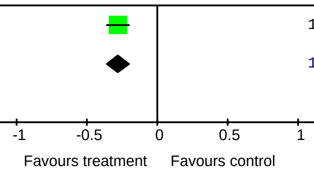
Test for heterogeneity: not applicable
Test for overall effect: Z = 5.64 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 27 Change in LDL cholesterol in mmol/l at 48 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-0.47(0.74)	567	-0.19(0.74)	100.00	-0.28 [-0.36, -0.20]
Total (95% CI)	851		567		100.00	-0.28 [-0.36, -0.20]

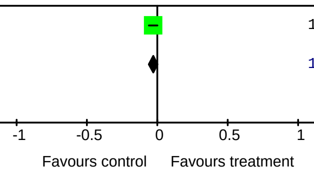
Test for heterogeneity: not applicable
Test for overall effect: Z = 6.98 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 28 Change in HDL cholesterol in mmol/l at 48 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	0.08(0.29)	567	0.11(0.29)	100.00	-0.03 [-0.06, 0.00]
Total (95% CI)	851		567		100.00	-0.03 [-0.06, 0.00]

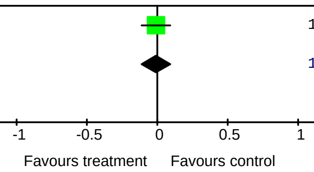
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.91 (P = 0.06)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 29 Change in triglycerides in mmol/l at 48 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	0.05(0.96)	567	0.06(0.96)	100.00	-0.01 [-0.11, 0.09]
Total (95% CI)	851		567		100.00	-0.01 [-0.11, 0.09]

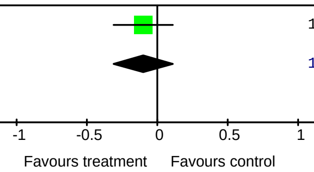
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.19 (P = 0.85)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 30 Change in fasting plasma glucose in mmol/l at 48 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	0.10(1.98)	567	0.20(1.98)	100.00	-0.10 [-0.31, 0.11]
Total (95% CI)	851		567		100.00	-0.10 [-0.31, 0.11]

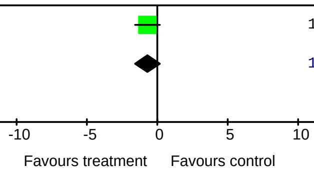
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.93 (P = 0.35)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 31 Change in DBP in mmHg at 48 months

Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-2.60(8.30)	567	-1.90(8.30)	100.00	-0.70 [-1.58, 0.18]
Total (95% CI)	851		567		100.00	-0.70 [-1.58, 0.18]

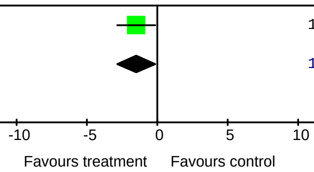
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.56 (P = 0.12)



Review: Orlistat UPDATE adults only
Comparison: 02 Orlistat 360mg/day + diet vs placebo + diet (no specific comorbidities, or mixed)
Outcome: 32 Change in SBP in mmHg at 48 months

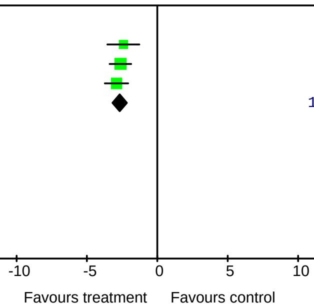
Study or sub-category	Orlistat + diet N	Orlistat + diet Mean (SD)	Placebo + diet N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
Torgerson 2004	851	-4.90(12.70)	567	-3.40(12.70)	100.00	-1.50 [-2.85, -0.15]
Total (95% CI)	851		567		100.00	-1.50 [-2.85, -0.15]

Test for heterogeneity: not applicable
Test for overall effect: Z = 2.18 (P = 0.03)



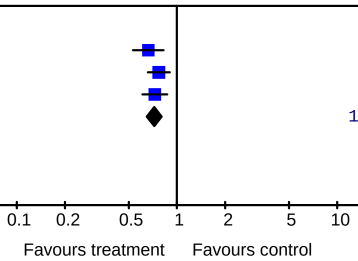
Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Hollander 1998	156	-3.84(5.00)	151	-1.43(5.10)		19.80	-2.41 [-3.54, -1.28]
Kelley 2002	266	-3.89(4.40)	269	-1.27(4.59)		43.58	-2.62 [-3.38, -1.86]
Miles 2002	250	-4.70(4.74)	254	-1.80(4.78)		36.62	-2.90 [-3.73, -2.07]
Subtotal (95% CI)	672		674			100.00	-2.68 [-3.18, -2.18]
Test for heterogeneity: Chi² = 0.51, df = 2 (P = 0.77), I² = 0%							
Test for overall effect: Z = 10.45 (P < 0.00001)							
02 Weight maintenance							
Subtotal (95% CI)	0		0				Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							



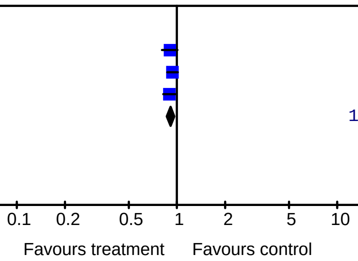
Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 02 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Hollander 1998	51/100	77/100		31.05	0.66 [0.53, 0.83]
Kelley 2002	67/100	87/100		35.08	0.77 [0.66, 0.90]
Miles 2002	61/100	84/100		33.87	0.73 [0.61, 0.87]
Subtotal (95% CI)	300	300		100.00	0.72 [0.65, 0.80]
Total events: 179 (Orlistat + diet), 248 (Placebo + diet)					
Test for heterogeneity: Chi² = 1.25, df = 2 (P = 0.54), I² = 0%					
Test for overall effect: Z = 6.04 (P < 0.00001)					



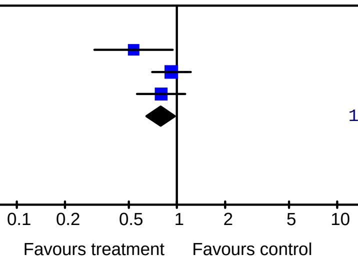
Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 03 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Hollander 1998	82/100	91/100		32.16	0.90 [0.81, 1.01]
Kelley 2002	90/100	96/100		33.92	0.94 [0.87, 1.01]
Miles 2002	86/100	96/100		33.92	0.90 [0.82, 0.98]
Subtotal (95% CI)	300	300		100.00	0.91 [0.86, 0.96]
Total events: 258 (Orlistat + diet), 283 (Placebo + diet)					
Test for heterogeneity: Chi² = 0.70, df = 2 (P = 0.70), I² = 0%					
Test for overall effect: Z = 3.41 (P = 0.0007)					



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 04 Failure to complete at 12 months

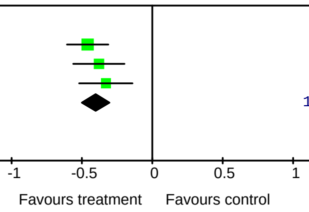
Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Hollander 1998	15/100	28/100		22.58	0.54 [0.31, 0.94]
Kelley 2002	48/100	52/100		41.94	0.92 [0.70, 1.22]
Miles 2002	35/100	44/100		35.48	0.80 [0.56, 1.13]
Subtotal (95% CI)	300	300		100.00	0.79 [0.64, 0.97]
Total events: 98 (Orlistat + diet), 124 (Placebo + diet)					
Test for heterogeneity: Chi² = 3.04, df = 2 (P = 0.22), I² = 34.2%					
Test for overall effect: Z = 2.25 (P = 0.02)					



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hollander 1998	156	-0.05(0.60)	151	0.41(0.70)	44.55	-0.46 [-0.61, -0.31]
Kelley 2002	266	-0.30(1.08)	276	0.08(1.08)	28.73	-0.38 [-0.56, -0.20]
Miles 2002	250	-0.27(1.08)	254	0.06(1.08)	26.72	-0.33 [-0.52, -0.14]
Subtotal (95% CI)	672		681		100.00	-0.40 [-0.50, -0.30]

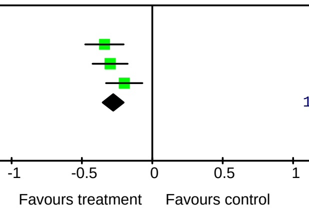
Test for heterogeneity: Chi² = 1.22, df = 2 (P = 0.54), I² = 0%
Test for overall effect: Z = 8.09 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 06 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hollander 1998	156	-0.12(0.50)	151	0.22(0.70)	30.17	-0.34 [-0.48, -0.20]
Kelley 2002	266	-0.38(0.74)	276	-0.08(0.74)	36.18	-0.30 [-0.42, -0.18]
Miles 2002	250	-0.25(0.74)	254	-0.05(0.74)	33.65	-0.20 [-0.33, -0.07]
Subtotal (95% CI)	672		681		100.00	-0.28 [-0.35, -0.20]

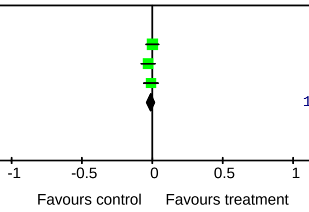
Test for heterogeneity: Chi² = 2.31, df = 2 (P = 0.31), I² = 13.5%
Test for overall effect: Z = 7.28 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 07 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hollander 1998	156	0.06(0.20)	151	0.06(0.20)	38.16	0.00 [-0.04, 0.04]
Kelley 2002	266	0.02(0.29)	276	0.05(0.29)	32.04	-0.03 [-0.08, 0.02]
Miles 2002	250	0.09(0.29)	254	0.10(0.29)	29.80	-0.01 [-0.06, 0.04]
Subtotal (95% CI)	672		681		100.00	-0.01 [-0.04, 0.02]

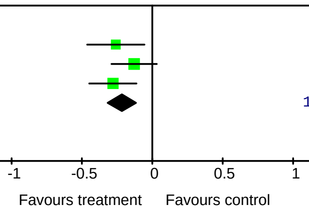
Test for heterogeneity: Chi² = 0.80, df = 2 (P = 0.67), I² = 0%
Test for overall effect: Z = 0.89 (P = 0.37)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 08 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hollander 1998	156	0.02(0.80)	151	0.28(1.00)	24.74	-0.26 [-0.46, -0.06]
Kelley 2002	266	0.18(0.96)	276	0.31(0.96)	38.99	-0.13 [-0.29, 0.03]
Miles 2002	250	-0.25(0.96)	254	0.03(0.96)	36.27	-0.28 [-0.45, -0.11]
Subtotal (95% CI)	672		681		100.00	-0.22 [-0.32, -0.12]

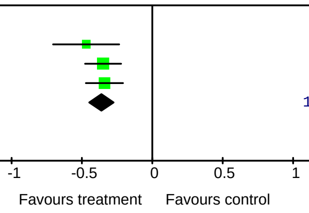
Test for heterogeneity: Chi² = 1.83, df = 2 (P = 0.40), I² = 0%
Test for overall effect: Z = 4.20 (P < 0.0001)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 09 Change in HbA1c% at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Hollander 1998	156	-0.15(1.00)	151	0.32(1.10)	13.28	-0.47 [-0.71, -0.23]
Kelley 2002	266	-0.62(0.76)	276	-0.27(0.76)	44.93	-0.35 [-0.48, -0.22]
Miles 2002	250	-0.75(0.76)	254	-0.41(0.76)	41.79	-0.34 [-0.47, -0.21]
Subtotal (95% CI)	672		681		100.00	-0.36 [-0.45, -0.28]

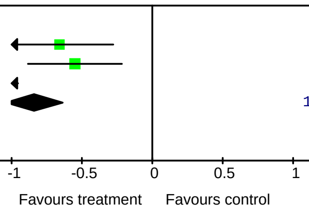
Test for heterogeneity: Chi² = 0.95, df = 2 (P = 0.62), I² = 0%
Test for overall effect: Z = 8.27 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 10 Change in fasting plasma glucose in mmol/l at 12 months

Study		Orlistat + diet		Placebo + diet	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Hollander 1998	156	0.04(1.60)	151	0.70(1.80)		28.37	-0.66 [-1.04, -0.28]
Kelley 2002	266	-1.63(1.98)	276	-1.08(1.98)		37.11	-0.55 [-0.88, -0.22]
Miles 2002	250	-2.00(1.98)	254	-0.70(1.98)		34.52	-1.30 [-1.65, -0.95]
Subtotal (95% CI)	672		681			100.00	-0.84 [-1.04, -0.64]

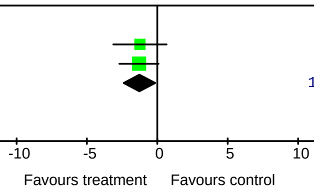
Test for heterogeneity: Chi² = 10.56, df = 2 (P = 0.005), I² = 81.1%
Test for overall effect: Z = 8.11 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 11 Change in DBP in mmHg at 12 months

Study		Orlistat + diet		Placebo + diet	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Hollander 1998	156	-1.01(8.00)	151	0.23(8.90)		35.24	-1.24 [-3.14, 0.66]
Kelley 2002	266	-2.30(8.30)	276	-1.00(8.30)		64.77	-1.30 [-2.70, 0.10]
Subtotal (95% CI)	422		427			100.00	-1.28 [-2.40, -0.15]

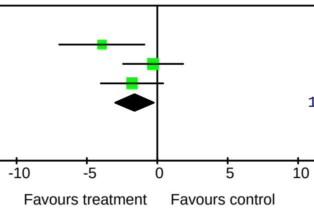
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.96), I² = 0%
Test for overall effect: Z = 2.23 (P = 0.03)



Review: Orlistat UPDATE adults only
Comparison: 03 Orlistat 360mg/day + diet vs placebo + diet (diabetes only)
Outcome: 12 Change in SBP in mmHg at 12 months

Study		Orlistat + diet		Placebo + diet	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Hollander 1998	156	0.21(12.80)	151	4.15(14.20)		20.55	-3.94 [-6.97, -0.91]
Kelley 2002	266	-1.20(12.70)	276	-0.90(12.70)		41.16	-0.30 [-2.44, 1.84]
Miles 2002	250	-2.10(12.70)	254	-0.30(12.70)		38.29	-1.80 [-4.02, 0.42]
Subtotal (95% CI)	672		681			100.00	-1.62 [-2.99, -0.25]

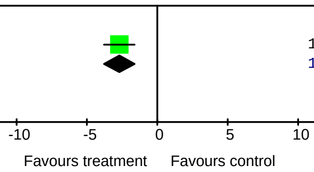
Test for heterogeneity: Chi² = 3.74, df = 2 (P = 0.15), I² = 46.6%
Test for overall effect: Z = 2.32 (P = 0.02)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 01 Weight change in kg at 12 months

Study		Orlistat + diet		Placebo + diet	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Bakris 2002	267	-5.40(6.40)	265	-2.70(6.40)		100.00	-2.70 [-3.79, -1.61]
Subtotal (95% CI)	267		265			100.00	-2.70 [-3.79, -1.61]

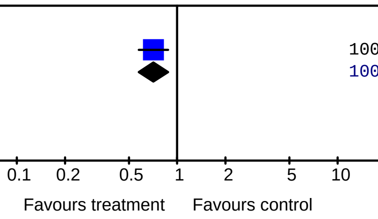
Test for heterogeneity: not applicable
Test for overall effect: Z = 4.87 (P < 0.00001)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 02 Failure to achieve at least 5% loss of initial body weight at 12 months

Study	Orlistat + diet	Placebo + diet	RR (fixed)	Weight	RR (fixed)
or sub-category	n/N	n/N	95% CI	%	95% CI
01 Weight loss					
Bakris 2002	54/100	76/100		100.00	0.71 [0.57, 0.88]
Subtotal (95% CI)	100	100		100.00	0.71 [0.57, 0.88]

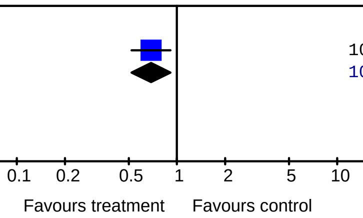
Total events: 54 (Orlistat + diet), 76 (Placebo + diet)
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.16 (P = 0.002)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 03 Failure to complete at 12 months

Study or sub-category	Orlistat + diet n/N	Placebo + diet n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Bakris 2002	42/100	61/100		100.00	0.69 [0.52, 0.91]
Subtotal (95% CI)	100	100		100.00	0.69 [0.52, 0.91]

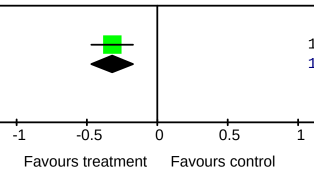
Total events: 42 (Orlistat + diet), 61 (Placebo + diet)
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.63 (P = 0.009)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 04 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Bakris 2002	267	-0.36(0.94)	265	-0.04(0.79)		100.00	-0.32 [-0.47, -0.17]
Subtotal (95% CI)	267		265			100.00	-0.32 [-0.47, -0.17]

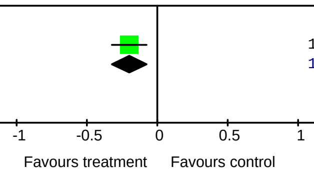
Test for heterogeneity: not applicable
Test for overall effect: Z = 4.25 (P < 0.0001)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 05 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Bakris 2002	267	-0.31(0.76)	265	-0.11(0.70)		100.00	-0.20 [-0.32, -0.08]
Subtotal (95% CI)	267		265			100.00	-0.20 [-0.32, -0.08]

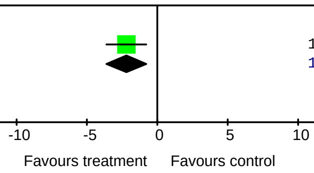
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.16 (P = 0.002)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 06 Change in DBP in mmHg at 12 months

Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Bakris 2002	267	-11.40(8.30)	265	-9.20(8.40)		100.00	-2.20 [-3.62, -0.78]
Subtotal (95% CI)	267		265			100.00	-2.20 [-3.62, -0.78]

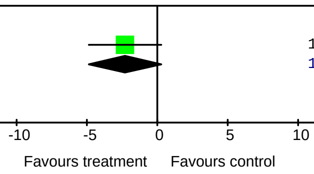
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.04 (P = 0.002)



Review: Orlistat UPDATE adults only
Comparison: 04 Orlistat 360mg/day + diet vs placebo + diet (hypertension only)
Outcome: 07 Change in SBP in mmHg at 12 months

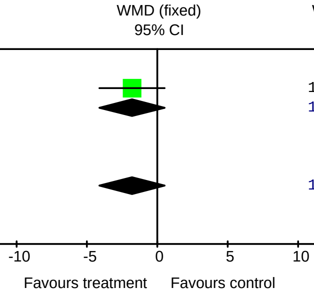
Study or sub-category	N	Orlistat + diet Mean (SD)	N	Placebo + diet Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Bakris 2002	267	-13.30(15.20)	265	-11.00(15.00)		100.00	-2.30 [-4.87, 0.27]
Subtotal (95% CI)	267		265			100.00	-2.30 [-4.87, 0.27]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.76 (P = 0.08)



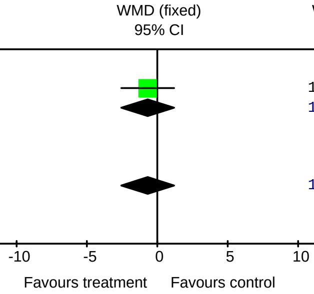
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	Orlistat N	Orlistat Mean (SD)	Placebo N	Placebo Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-4.40(7.16)	71	-2.60(6.65)	100.00	-1.80 [-4.12, 0.52]
Subtotal (95% CI)	66		71		100.00	-1.80 [-4.12, 0.52]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						
Total (95% CI)	66		71		100.00	-1.80 [-4.12, 0.52]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						



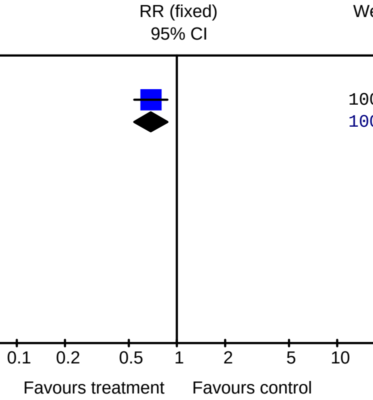
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	Orlistat N	Orlistat Mean (SD)	Placebo-orlistat N	Placebo-orlistat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-4.97(5.40)	71	-4.28(5.82)	100.00	-0.69 [-2.57, 1.19]
Subtotal (95% CI)	66		71		100.00	-0.69 [-2.57, 1.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						
Total (95% CI)	66		71		100.00	-0.69 [-2.57, 1.19]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						



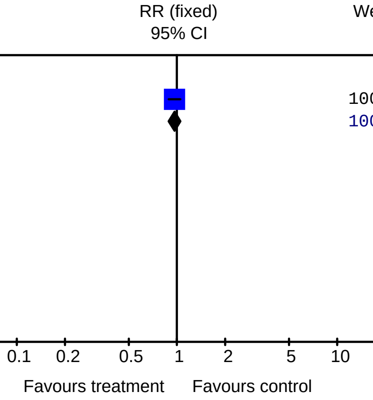
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 03 Failure to achieve at least 5% loss of initial body weight at 6 months

Study or sub-category	Orlistat n/N	Placebo n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Broom 2002b	37/66	58/71	100.00	0.69 [0.54, 0.87]
Subtotal (95% CI)	66	71	100.00	0.69 [0.54, 0.87]
Total events: 37 (Orlistat), 58 (Placebo)				
Test for heterogeneity: not applicable				
Test for overall effect: Z = 3.07 (P = 0.002)				
02 Weight maintenance				
Subtotal (95% CI)	0	0		Not estimable
Total events: 0 (Orlistat), 0 (Placebo)				
Test for heterogeneity: not applicable				
Test for overall effect: not applicable				



Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 04 Failure to achieve at least 10% loss of initial body weight at 6 months

Study or sub-category	Orlistat n/N	Placebo n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Broom 2002b	61/66	68/71	100.00	0.97 [0.89, 1.05]
Subtotal (95% CI)	66	71	100.00	0.97 [0.89, 1.05]
Total events: 61 (Orlistat), 68 (Placebo)				
Test for heterogeneity: not applicable				
Test for overall effect: Z = 0.82 (P = 0.41)				
02 Weight maintenance				
Subtotal (95% CI)	0	0		Not estimable
Total events: 0 (Orlistat), 0 (Placebo)				
Test for heterogeneity: not applicable				
Test for overall effect: not applicable				



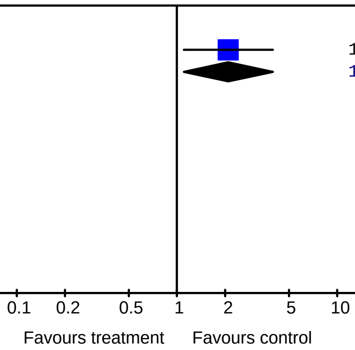
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 05 Failure to complete at 6 months

Study or sub-category	Orlistat n/N	Placebo-orlistat n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Broom 2002b	23/71	11/71		100.00	2.09 [1.10, 3.96]
Subtotal (95% CI)	71	71		100.00	2.09 [1.10, 3.96]

Total events: 23 (Orlistat), 11 (Placebo-orlistat)
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.26 (P = 0.02)

Study or sub-category	Orlistat n/N	Placebo-orlistat n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
02 Weight maintenance					
Subtotal (95% CI)	0	0			Not estimable

Total events: 0 (Orlistat), 0 (Placebo-orlistat)
Test for heterogeneity: not applicable
Test for overall effect: not applicable



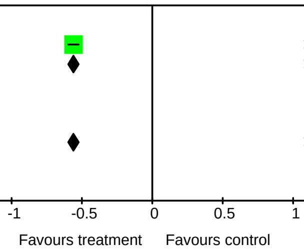
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 06 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Broom 2002b	66	-0.83(0.12)	71	-0.27(0.10)		100.00	-0.56 [-0.60, -0.52]
Subtotal (95% CI)	66		71			100.00	-0.56 [-0.60, -0.52]

Test for heterogeneity: not applicable
Test for overall effect: Z = 29.55 (P < 0.00001)

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Total (95% CI)	66		71			100.00	-0.56 [-0.60, -0.52]

Test for heterogeneity: not applicable
Test for overall effect: Z = 29.55 (P < 0.00001)



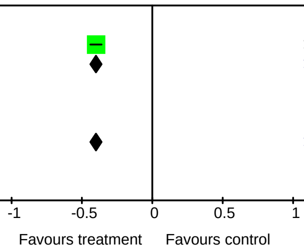
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 07 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Broom 2002b	66	-0.71(0.12)	71	-0.31(0.12)		100.00	-0.40 [-0.44, -0.36]
Subtotal (95% CI)	66		71			100.00	-0.40 [-0.44, -0.36]

Test for heterogeneity: not applicable
Test for overall effect: Z = 19.49 (P < 0.00001)

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Total (95% CI)	66		71			100.00	-0.40 [-0.44, -0.36]

Test for heterogeneity: not applicable
Test for overall effect: Z = 19.49 (P < 0.00001)



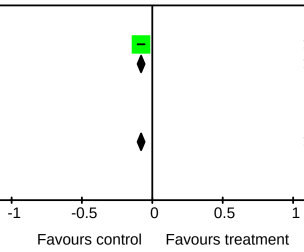
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 08 Change in HDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Broom 2002b	66	-0.19(0.10)	71	-0.11(0.03)		100.00	-0.08 [-0.11, -0.05]
Subtotal (95% CI)	66		71			100.00	-0.08 [-0.11, -0.05]

Test for heterogeneity: not applicable
Test for overall effect: Z = 6.24 (P < 0.00001)

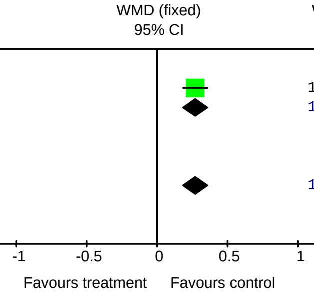
Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Total (95% CI)	66		71			100.00	-0.08 [-0.11, -0.05]

Test for heterogeneity: not applicable
Test for overall effect: Z = 6.24 (P < 0.00001)



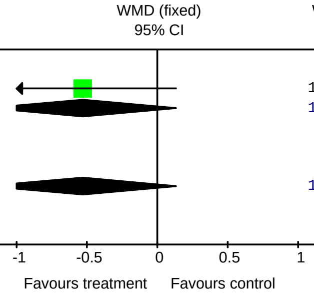
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 09 Change in triglycerides in mmol/l at 6 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-0.15(0.25)	71	-0.42(0.26)	100.00	0.27 [0.18, 0.36]
Subtotal (95% CI)	66		71		100.00	0.27 [0.18, 0.36]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 6.20 (P < 0.00001)						
Total (95% CI)	66		71		100.00	0.27 [0.18, 0.36]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 6.20 (P < 0.00001)						



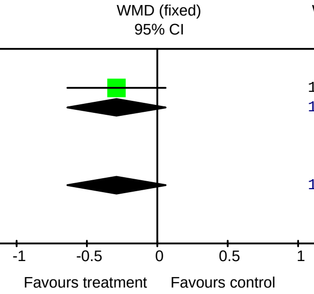
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 10 Change in fasting plasma glucose in mmol/l at 6 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo-orlistat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-0.41(1.98)	71	0.12(1.98)	100.00	-0.53 [-1.19, 0.13]
Subtotal (95% CI)	66		71		100.00	-0.53 [-1.19, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.57 (P = 0.12)						
Total (95% CI)	66		71		100.00	-0.53 [-1.19, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.57 (P = 0.12)						



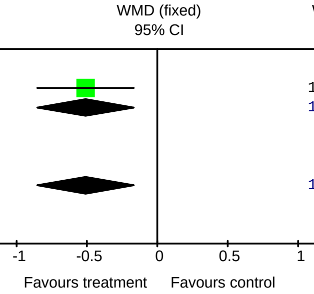
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 11 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo-orlistat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-0.96(1.04)	71	-0.67(1.04)	100.00	-0.29 [-0.64, 0.06]
Subtotal (95% CI)	66		71		100.00	-0.29 [-0.64, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.63 (P = 0.10)						
Total (95% CI)	66		71		100.00	-0.29 [-0.64, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.63 (P = 0.10)						



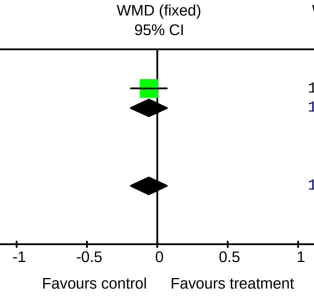
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 12 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo-orlistat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-0.91(1.00)	71	-0.40(1.05)	100.00	-0.51 [-0.85, -0.17]
Subtotal (95% CI)	66		71		100.00	-0.51 [-0.85, -0.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.91 (P = 0.004)						
Total (95% CI)	66		71		100.00	-0.51 [-0.85, -0.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.91 (P = 0.004)						



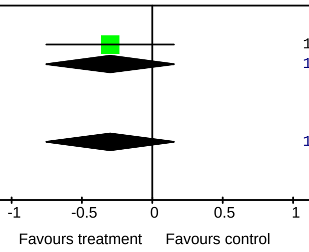
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 13 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo-orlistat Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Broom 2002b	66	-0.29(0.45)	71	-0.23(0.29)	100.00	-0.06 [-0.19, 0.07]
Subtotal (95% CI)	66		71		100.00	-0.06 [-0.19, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.92 (P = 0.36)						
Total (95% CI)	66		71		100.00	-0.06 [-0.19, 0.07]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.92 (P = 0.36)						



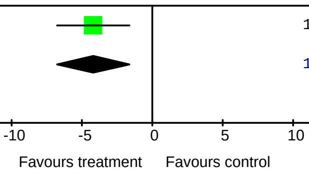
Review: Orlistat UPDATE adults only
Comparison: 05 Orlistat 360mg/day+diet vs placebo (24 weeks)+diet then orlistat 360mg/day (28 weeks) +diet (high cholester
Outcome: 14 Change in fasting plasma glucose in mmol/l at 12 months

Study or sub-category	N	Orlistat Mean (SD)	N	Placebo-orlistat Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Broom 2002b	66	-0.40(1.35)	71	-0.10(1.35)		100.00	-0.30 [-0.75, 0.15]
Subtotal (95% CI)	66		71			100.00	-0.30 [-0.75, 0.15]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.30 (P = 0.19)							
Total (95% CI)	66		71			100.00	-0.30 [-0.75, 0.15]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.30 (P = 0.19)							



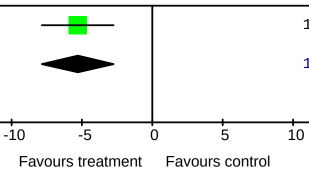
Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-5.20(7.39)	52	-1.00(6.20)		100.00	-4.20 [-6.77, -1.63]
Total (95% CI)	56		52			100.00	-4.20 [-6.77, -1.63]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.21 (P = 0.001)							



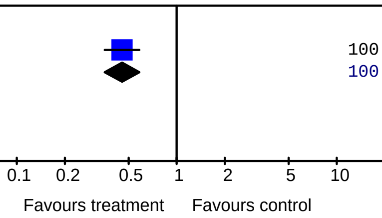
Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-5.60(7.50)	52	-0.30(6.00)		100.00	-5.30 [-7.85, -2.75]
Total (95% CI)	56		52			100.00	-5.30 [-7.85, -2.75]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 4.07 (P < 0.0001)							



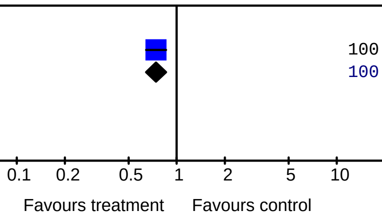
Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 03 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Intervention n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Poston 2003	40/100	88/100		100.00	0.45 [0.35, 0.58]
Subtotal (95% CI)	100	100		100.00	0.45 [0.35, 0.58]
Total events: 40 (Intervention), 88 (Control)					
Test for heterogeneity: not applicable					
Test for overall effect: Z = 6.16 (P < 0.00001)					



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 04 Failure to achieve at least 10% loss of initial body weight at 12 months

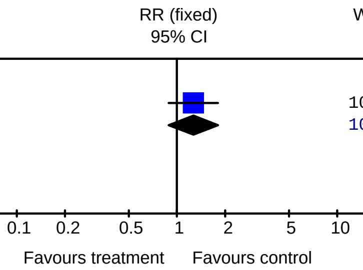
Study or sub-category	Intervention n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
01 Weight loss					
Poston 2003	69/100	93/100		100.00	0.74 [0.64, 0.86]
Subtotal (95% CI)	100	100		100.00	0.74 [0.64, 0.86]
Total events: 69 (Intervention), 93 (Control)					
Test for heterogeneity: not applicable					
Test for overall effect: Z = 4.12 (P < 0.0001)					



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 05 Failure to complete at 12 months

Study or sub-category	Intervention n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Poston 2003	43/100	34/100	100.00	1.26 [0.89, 1.80]
Subtotal (95% CI)	100	100	100.00	1.26 [0.89, 1.80]

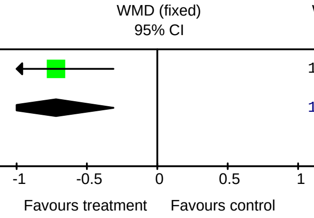
Total events: 43 (Intervention), 34 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.30 (P = 0.19)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 06 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-0.74(1.08)	52	-0.02(1.08)	100.00	-0.72 [-1.13, -0.31]
Total (95% CI)	56		52		100.00	-0.72 [-1.13, -0.31]

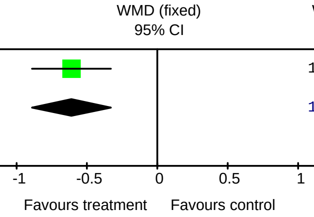
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.46 (P = 0.0005)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 07 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-0.58(0.74)	52	0.03(0.74)	100.00	-0.61 [-0.89, -0.33]
Total (95% CI)	56		52		100.00	-0.61 [-0.89, -0.33]

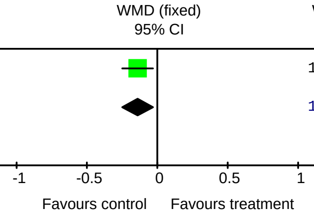
Test for heterogeneity: not applicable
Test for overall effect: Z = 4.28 (P < 0.0001)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 08 Change in HDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-0.20(0.29)	52	-0.06(0.29)	100.00	-0.14 [-0.25, -0.03]
Total (95% CI)	56		52		100.00	-0.14 [-0.25, -0.03]

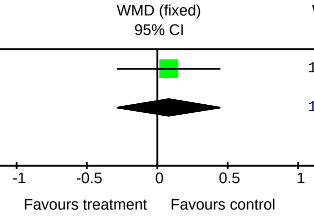
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.51 (P = 0.01)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 09 Change in triglycerides in mmol/l at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Poston 2003	56	0.09(0.96)	52	0.01(0.96)	100.00	0.08 [-0.28, 0.44]
Total (95% CI)	56		52		100.00	0.08 [-0.28, 0.44]

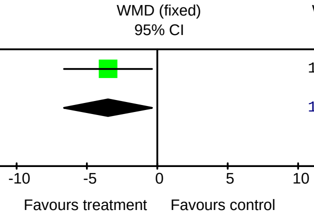
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.43 (P = 0.67)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 10 Change in DBP in mmHg at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-6.80(8.30)	52	-3.30(8.30)	100.00	-3.50 [-6.63, -0.37]
Total (95% CI)	56		52		100.00	-3.50 [-6.63, -0.37]

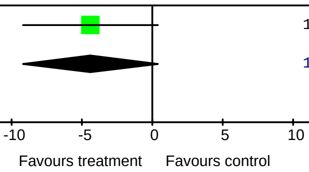
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.19 (P = 0.03)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 11 Change in SBP in mmHg at 6 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-7.20(12.70)	52	-2.80(12.70)		100.00	-4.40 [-9.19, 0.39]
Total (95% CI)	56		52			100.00	-4.40 [-9.19, 0.39]

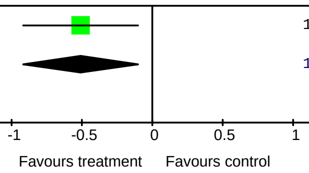
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.80 (P = 0.07)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 12 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-0.35(1.08)	52	0.16(1.08)		100.00	-0.51 [-0.92, -0.10]
Total (95% CI)	56		52			100.00	-0.51 [-0.92, -0.10]

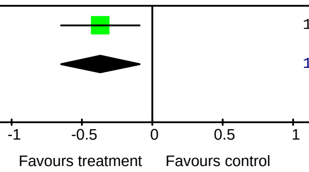
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.45 (P = 0.01)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 13 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-0.47(0.74)	52	-0.10(0.74)		100.00	-0.37 [-0.65, -0.09]
Total (95% CI)	56		52			100.00	-0.37 [-0.65, -0.09]

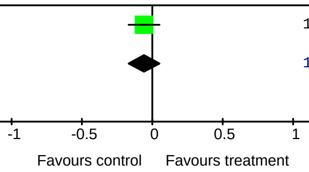
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.60 (P = 0.009)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 14 Change in HDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	0.00(0.29)	52	0.06(0.29)		100.00	-0.06 [-0.17, 0.05]
Total (95% CI)	56		52			100.00	-0.06 [-0.17, 0.05]

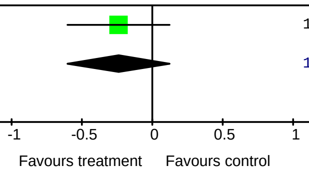
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.07 (P = 0.28)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 15 Change in triglycerides in mmol/l at 12 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	0.27(0.96)	52	0.51(0.96)		100.00	-0.24 [-0.60, 0.12]
Total (95% CI)	56		52			100.00	-0.24 [-0.60, 0.12]

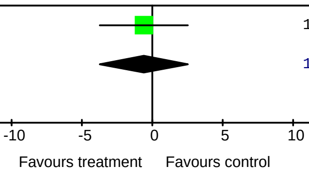
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.30 (P = 0.19)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 16 Change in DBP in mmHg at 12 months

Study or sub-category	N	Intervention Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-4.30(8.30)	52	-3.70(8.30)		100.00	-0.60 [-3.73, 2.53]
Total (95% CI)	56		52			100.00	-0.60 [-3.73, 2.53]

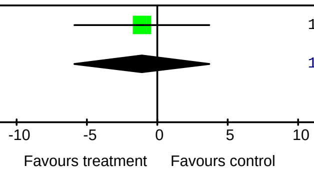
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.38 (P = 0.71)



Review: Orlistat UPDATE adults only
Comparison: 06 Orlistat 360mg/day + lifestyle modification vs control (no intervention) (no specific comorbidities)
Outcome: 17 Change in SBP in mmHg at 12 months

Study or sub-category	Intervention N	Intervention Mean (SD)	Control N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Poston 2003	56	-4.10(12.70)	52	-3.00(12.70)		100.00	-1.10 [-5.89, 3.69]
Total (95% CI)	56		52			100.00	-1.10 [-5.89, 3.69]

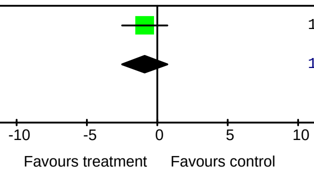
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.45 (P = 0.65)



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 01 Weight change in kg at 12 months

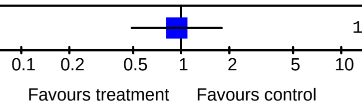
Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	-9.52(7.52)	141	-8.62(6.61)		100.00	-0.90 [-2.51, 0.71]
Total (95% CI)	154		141			100.00	-0.90 [-2.51, 0.71]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.09 (P = 0.27)



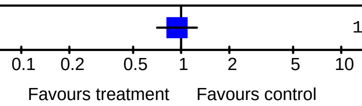
Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 02 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Orlistat + 1000kcal n/N	Orlistat + 500kcal n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
Toplak 2005	15/100	16/100		100.00	0.94 [0.49, 1.79]



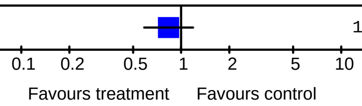
Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 03 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Orlistat + 1000kcal n/N	Orlistat + 500kcal n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
Toplak 2005	47/100	50/100		100.00	0.94 [0.71, 1.25]



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 04 Failure to complete at 12 months

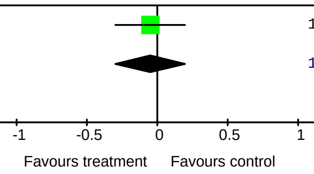
Study or sub-category	Orlistat + 1000kcal n/N	Orlistat + 500kcal n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
Toplak 2005	35/100	42/100		100.00	0.83 [0.59, 1.19]



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	-0.39(1.08)	141	-0.34(1.08)		100.00	-0.05 [-0.30, 0.20]
Total (95% CI)	154		141			100.00	-0.05 [-0.30, 0.20]

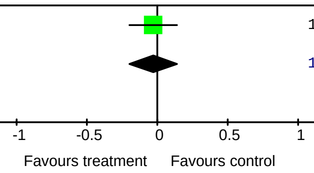
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.40 (P = 0.69)



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 06 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500 kcal N	Orlistat + 500 kcal Mean (SD)	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	-0.37(0.74)	141	-0.34(0.74)	100.00	-0.03 [-0.20, 0.14]
Total (95% CI)	154		141		100.00	-0.03 [-0.20, 0.14]

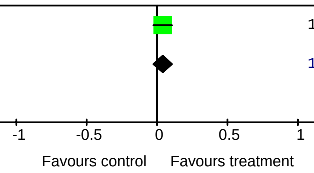
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.35 (P = 0.73)



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 07 Change in HDL cholesterol in mmol/l at 12 months

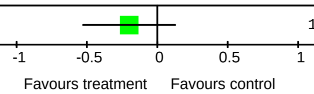
Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	0.09(0.29)	141	0.05(0.29)	100.00	0.04 [-0.03, 0.11]
Total (95% CI)	154		141		100.00	0.04 [-0.03, 0.11]

Test for heterogeneity: not applicable
Test for overall effect: Z = 1.18 (P = 0.24)



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 08 Change in FPG in mmol/l at 12 months

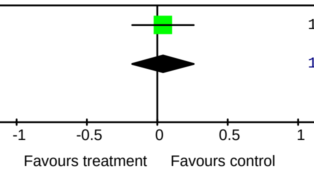
Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	-0.20(0.60)	141	0.00(1.90)	100.00	-0.20 [-0.53, 0.13]



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 09 Change in triglycerides in mmol/l at 12 months

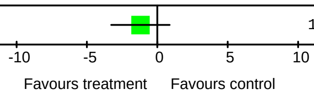
Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	0.04(0.96)	141	0.00(0.96)	100.00	0.04 [-0.18, 0.26]
Total (95% CI)	154		141		100.00	0.04 [-0.18, 0.26]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.36 (P = 0.72)



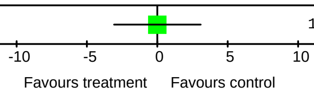
Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 10 Change in DBP in mmHg at 12 months

Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	-3.80(8.50)	141	-2.60(9.60)	100.00	-1.20 [-3.28, 0.88]



Review: Orlistat UPDATE adults only
Comparison: 07 Orlistat 360mg/day+1000kcal/day deficit diet vs orlistat 360mg/day+500kcal/day deficit diet (no spec comorb
Outcome: 11 Change in SBP in mmHg at 12 months

Study or sub-category	Orlistat + 1000kcal N	Orlistat + 1000kcal Mean (SD)	Orlistat + 500kcal N	Orlistat + 500kcal Mean (SD)	Weight %	WMD (fixed) 95% CI
Toplak 2005	154	-6.00(13.90)	141	-6.00(13.00)	100.00	0.00 [-3.07, 3.07]

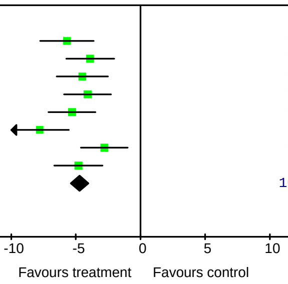


3.5 Sibutramine

Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Sibutramine Mean (SD)	N	Placebo Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	81	-5.20(7.50)	78	0.50(5.70)	10.77	-5.70 [-7.77, -3.63]
McMahon 2000	142	-4.40(7.16)	69	-0.50(6.06)	13.39	-3.90 [-5.75, -2.05]
NEW Kaukua 2004	102	-7.10(7.92)	108	-2.60(6.65)	11.68	-4.50 [-6.48, -2.52]
NEW McMahon 2002	145	-4.50(7.19)	72	-0.40(6.03)	13.88	-4.10 [-5.92, -2.28]
NEW McNulty 2003a	68	-5.50(4.95)	32	-0.20(4.00)	13.90	-5.30 [-7.12, -3.48]
NEW McNulty 2003b	62	-8.00(7.09)	32	-0.20(4.00)	9.12	-7.80 [-10.04, -5.56]
Smith 2001a	154	-4.40(7.16)	79	-1.60(6.37)	14.13	-2.80 [-4.60, -1.00]
Smith 2001b	153	-6.41(7.73)	78	-1.60(6.37)	13.13	-4.81 [-6.68, -2.94]
Subtotal (95% CI)	907		548		100.00	-4.71 [-5.38, -4.03]

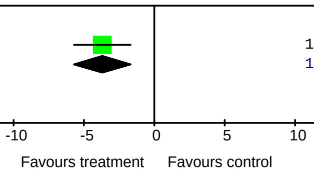
Test for heterogeneity: Chi² = 14.10, df = 7 (P = 0.05), I² = 50.4%
Test for overall effect: Z = 13.61 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 02 Weight change in kg at 15 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	81	-0.90(6.17)	78	2.80(6.71)	100.00	-3.70 [-5.71, -1.69]
Subtotal (95% CI)	81		78		100.00	-3.70 [-5.71, -1.69]

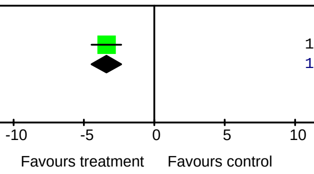
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.62 (P = 0.0003)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 03 Weight change in kg at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	350	2.80(6.00)	114	6.20(4.60)	100.00	-3.40 [-4.45, -2.35]
Subtotal (95% CI)	350		114		100.00	-3.40 [-4.45, -2.35]

Test for heterogeneity: not applicable
Test for overall effect: Z = 6.33 (P < 0.00001)



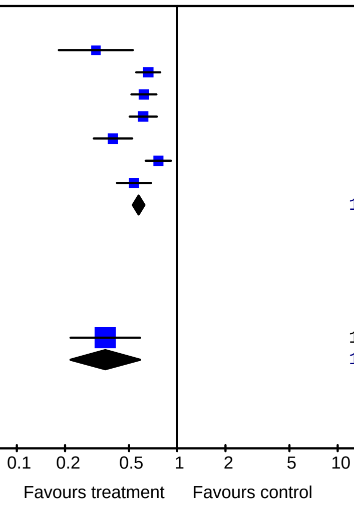
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 04 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Apfelbaum 1999	14/100	45/100	7.98	0.31 [0.18, 0.53]
McMahon 2000	60/100	91/100	16.13	0.66 [0.56, 0.78]
NEW McMahon 2002	57/100	92/100	16.31	0.62 [0.52, 0.74]
NEW McNulty 2003a	54/100	88/100	15.60	0.61 [0.51, 0.75]
NEW McNulty 2003b	35/100	88/100	15.60	0.40 [0.30, 0.52]
Smith 2001a	61/100	80/100	14.18	0.76 [0.63, 0.92]
Smith 2001b	43/100	80/100	14.18	0.54 [0.42, 0.69]
Subtotal (95% CI)	700	700	100.00	0.57 [0.53, 0.63]

Total events: 324 (Treatment), 564 (Control)
Test for heterogeneity: Chi² = 24.78, df = 6 (P = 0.0004), I² = 75.8%
Test for overall effect: Z = 12.88 (P < 0.00001)

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
02 Weight maintenance				
STORM 2000	16/100	45/100	100.00	0.36 [0.22, 0.59]
Subtotal (95% CI)	100	100	100.00	0.36 [0.22, 0.59]

Total events: 16 (Treatment), 45 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 4.06 (P < 0.0001)



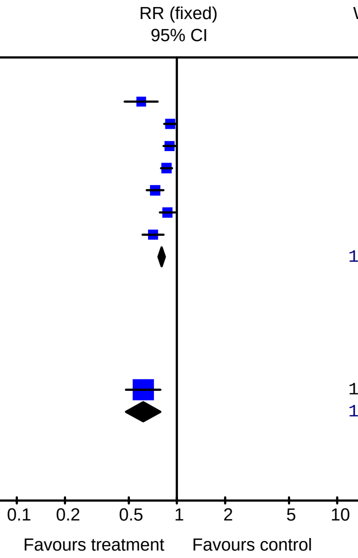
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 05 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Apfelbaum 1999	46/100	77/100	11.74	0.60 [0.47, 0.76]
McMahon 2000	87/100	96/100	14.63	0.91 [0.83, 0.99]
NEW McMahon 2002	87/100	97/100	14.79	0.90 [0.83, 0.97]
NEW McNulty 2003a	86/100	100/100	15.24	0.86 [0.79, 0.93]
NEW McNulty 2003b	73/100	100/100	15.24	0.73 [0.65, 0.82]
Smith 2001a	81/100	93/100	14.18	0.87 [0.78, 0.97]
Smith 2001b	66/100	93/100	14.18	0.71 [0.61, 0.83]
Subtotal (95% CI)	700	700	100.00	0.80 [0.77, 0.84]

Total events: 526 (Treatment), 656 (Control)
Test for heterogeneity: Chi² = 30.81, df = 6 (P < 0.0001), I² = 80.5%
Test for overall effect: Z = 9.57 (P < 0.00001)

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
02 Weight maintenance				
STORM 2000	45/100	73/100	100.00	0.62 [0.48, 0.79]
Subtotal (95% CI)	100	100	100.00	0.62 [0.48, 0.79]

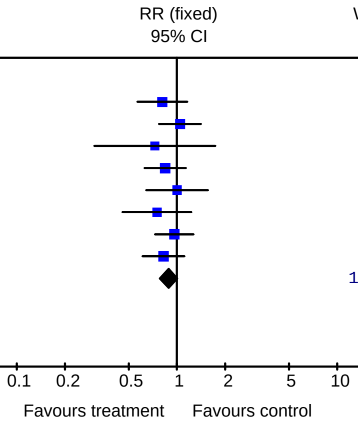
Total events: 45 (Treatment), 73 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.83 (P = 0.0001)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 06 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Apfelbaum 1999	34/100	42/100	13.68	0.81 [0.57, 1.16]
McMahon 2000	47/100	45/100	14.66	1.04 [0.77, 1.41]
NEW Kaukua 2004	8/100	11/100	3.58	0.73 [0.31, 1.73]
NEW McMahon 2002	43/100	51/100	16.61	0.84 [0.63, 1.13]
NEW McNulty 2003a	28/100	28/100	9.12	1.00 [0.64, 1.56]
NEW McNulty 2003b	21/100	28/100	9.12	0.75 [0.46, 1.23]
Smith 2001a	49/100	51/100	16.61	0.96 [0.73, 1.27]
Smith 2001b	42/100	51/100	16.61	0.82 [0.61, 1.11]
Subtotal (95% CI)	800	800	100.00	0.89 [0.78, 1.00]

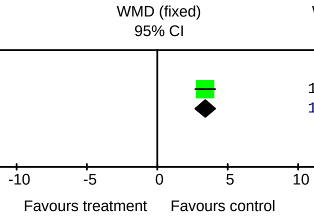
Total events: 272 (Treatment), 307 (Control)
Test for heterogeneity: Chi² = 2.98, df = 7 (P = 0.89), I² = 0%
Test for overall effect: Z = 1.89 (P = 0.06)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 07 Change in DBP (mmHg) at 6 months

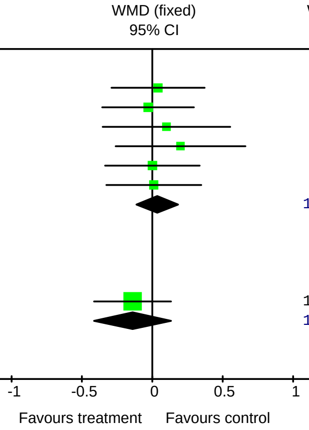
Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	73	1.50(2.00)	68	-1.90(2.20)	100.00	3.40 [2.70, 4.10]
Subtotal (95% CI)	73		68		100.00	3.40 [2.70, 4.10]

Test for heterogeneity: not applicable
Test for overall effect: Z = 9.58 (P < 0.00001)



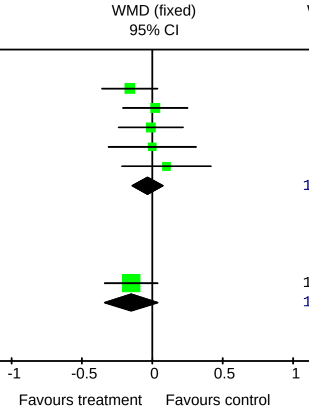
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 08 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	133	-0.03(1.08)	59	-0.07(1.08)	19.91	0.04 [-0.29, 0.37]
NEW McMahon 2002	129	-0.09(1.08)	63	-0.06(1.08)	20.62	-0.03 [-0.36, 0.30]
NEW McNulty 2003a	68	-0.10(1.08)	32	-0.20(1.08)	10.60	0.10 [-0.35, 0.55]
NEW McNulty 2003b	62	0.00(1.08)	32	-0.20(1.08)	10.28	0.20 [-0.26, 0.66]
Smith 2001a	122	0.08(1.08)	59	0.08(1.08)	19.38	0.00 [-0.34, 0.34]
Smith 2001b	123	0.09(1.08)	58	0.08(1.08)	19.20	0.01 [-0.33, 0.35]
Subtotal (95% CI)	637		303		100.00	0.03 [-0.11, 0.18]
Test for heterogeneity: Chi² = 0.79, df = 5 (P = 0.98), I² = 0%						
Test for overall effect: Z = 0.46 (P = 0.64)						
02 Weight maintenance						
STORM 2000	265	0.12(1.08)	77	0.26(1.08)	100.00	-0.14 [-0.41, 0.13]
Subtotal (95% CI)	265		77		100.00	-0.14 [-0.41, 0.13]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						



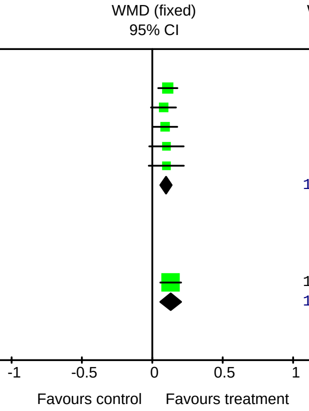
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 09 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	81	0.41(0.65)	78	0.57(0.62)	30.45	-0.16 [-0.36, 0.04]
McMahon 2000	131	-0.09(0.74)	58	-0.11(0.74)	22.68	0.02 [-0.21, 0.25]
NEW McMahon 2002	122	-0.11(0.74)	60	-0.10(0.74)	22.69	-0.01 [-0.24, 0.22]
NEW McNulty 2003a	68	-0.20(0.74)	32	-0.20(0.74)	12.28	0.00 [-0.31, 0.31]
NEW McNulty 2003b	62	-0.10(0.74)	32	-0.20(0.74)	11.91	0.10 [-0.22, 0.42]
Subtotal (95% CI)	464		260		100.00	-0.03 [-0.14, 0.07]
Test for heterogeneity: Chi² = 2.56, df = 4 (P = 0.63), I² = 0%						
Test for overall effect: Z = 0.62 (P = 0.53)						
02 Weight maintenance						
STORM 2000	265	-0.11(0.74)	77	0.04(0.74)	100.00	-0.15 [-0.34, 0.04]
Subtotal (95% CI)	265		77		100.00	-0.15 [-0.34, 0.04]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.57 (P = 0.12)						



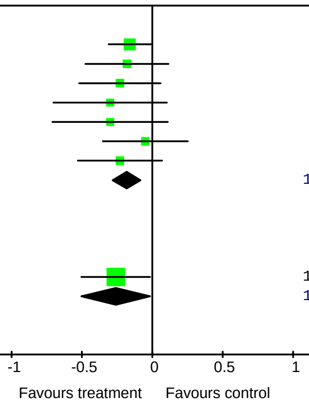
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 10 Change in HDL cholesterol (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	81	0.34(0.23)	78	0.23(0.21)	35.38	0.11 [0.04, 0.18]
McMahon 2000	133	0.14(0.29)	59	0.06(0.29)	20.95	0.08 [-0.01, 0.17]
NEW McMahon 2002	129	0.12(0.29)	63	0.03(0.29)	21.70	0.09 [0.00, 0.18]
NEW McNulty 2003a	68	0.10(0.29)	32	0.00(0.29)	11.15	0.10 [-0.02, 0.22]
NEW McNulty 2003b	62	0.10(0.29)	32	0.00(0.29)	10.82	0.10 [-0.02, 0.22]
Subtotal (95% CI)	473		264		100.00	0.10 [0.06, 0.14]
Test for heterogeneity: Chi² = 0.31, df = 4 (P = 0.99), I² = 0%						
Test for overall effect: Z = 4.68 (P < 0.00001)						
02 Weight maintenance						
STORM 2000	265	0.22(0.29)	77	0.09(0.29)	100.00	0.13 [0.06, 0.20]
Subtotal (95% CI)	265		77		100.00	0.13 [0.06, 0.20]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.46 (P = 0.0005)						



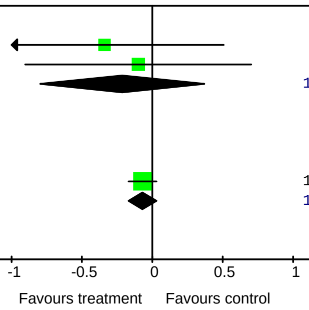
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 11 Change in triglycerides mmol/l at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	81	-0.05(0.42)	78	0.11(0.54)	43.26	-0.16 [-0.31, -0.01]
McMahon 2000	133	-0.19(0.96)	59	-0.01(0.96)	11.35	-0.18 [-0.47, 0.11]
NEW McMahon 2002	129	-0.31(0.96)	63	-0.08(0.96)	11.75	-0.23 [-0.52, 0.06]
NEW McNulty 2003a	68	-0.20(0.96)	32	0.10(0.96)	6.04	-0.30 [-0.70, 0.10]
NEW McNulty 2003b	62	-0.20(0.96)	32	0.10(0.96)	5.86	-0.30 [-0.71, 0.11]
Smith 2001a	122	-0.26(0.96)	57	-0.21(0.96)	10.79	-0.05 [-0.35, 0.25]
Smith 2001b	123	-0.44(0.96)	58	-0.21(0.96)	10.95	-0.23 [-0.53, 0.07]
Subtotal (95% CI)	718		379		100.00	-0.18 [-0.28, -0.08]
Test for heterogeneity: Chi² = 1.67, df = 6 (P = 0.95), I² = 0%						
Test for overall effect: Z = 3.62 (P = 0.0003)						
02 Weight maintenance						
STORM 2000	265	-0.01(0.96)	77	0.25(0.96)	100.00	-0.26 [-0.50, -0.02]
Subtotal (95% CI)	265		77		100.00	-0.26 [-0.50, -0.02]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.09 (P = 0.04)						



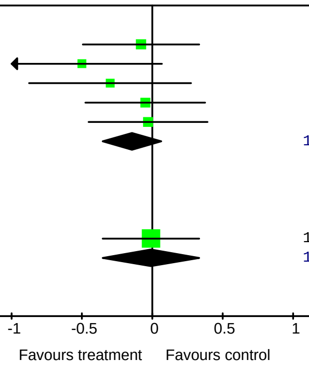
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 12 Change in HbA 1c % at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	-0.56(2.20)	32	-0.22(1.92)	47.33	-0.34 [-1.19, 0.51]
NEW McNulty 2003b	62	-0.32(1.80)	32	-0.22(1.92)	52.67	-0.10 [-0.90, 0.70]
Subtotal (95% CI)	130		64		100.00	-0.21 [-0.80, 0.37]
Test for heterogeneity: Chi² = 0.16, df = 1 (P = 0.69), I² = 0%						
Test for overall effect: Z = 0.72 (P = 0.47)						
02 Weight maintenance						
STORM 2000	265	0.16(0.71)	770	0.23(0.71)	100.00	-0.07 [-0.17, 0.03]
Subtotal (95% CI)	265		770		100.00	-0.07 [-0.17, 0.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.38 (P = 0.17)						



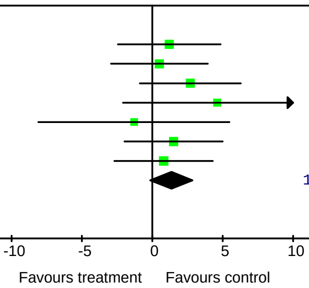
Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 13 Change in fasting plasma glucose (mmol/l) at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	133	0.23(1.35)	59	0.31(1.35)	25.23	-0.08 [-0.49, 0.33]
NEW McNulty 2003a	68	-0.30(1.35)	32	0.20(1.35)	13.43	-0.50 [-1.07, 0.07]
NEW McNulty 2003b	62	-0.10(1.35)	32	0.20(1.35)	13.03	-0.30 [-0.88, 0.28]
Smith 2001a	122	-0.21(1.35)	57	-0.16(1.35)	23.98	-0.05 [-0.47, 0.37]
Smith 2001b	123	-0.19(1.35)	58	-0.16(1.35)	24.33	-0.03 [-0.45, 0.39]
Subtotal (95% CI)	508		238		100.00	-0.15 [-0.35, 0.06]
Test for heterogeneity: Chi² = 2.36, df = 4 (P = 0.67), I² = 0%						
Test for overall effect: Z = 1.37 (P = 0.17)						
02 Weight maintenance						
STORM 2000	265	0.13(1.35)	77	0.14(1.35)	100.00	-0.01 [-0.35, 0.33]
Subtotal (95% CI)	265		77		100.00	-0.01 [-0.35, 0.33]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.06 (P = 0.95)						



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 14 Change in SBP (mmHg) at 12 months

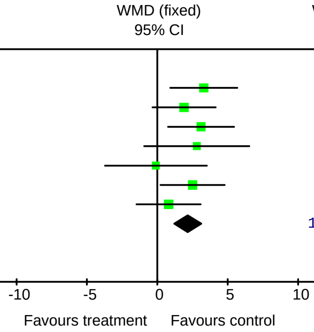
Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	142	2.70(12.70)	69	1.50(12.70)	16.83	1.20 [-2.45, 4.85]
NEW Kaukua 2004	102	4.10(12.70)	108	3.60(12.70)	19.01	0.50 [-2.94, 3.94]
NEW McMahon 2002	145	3.80(12.70)	72	1.10(12.70)	17.43	2.70 [-0.89, 6.29]
NEW McNulty 2003a	68	4.40(15.67)	32	-0.20(16.00)	5.03	4.60 [-2.08, 11.28]
NEW McNulty 2003b	62	-1.50(15.75)	32	-0.20(16.00)	4.87	-1.30 [-8.09, 5.49]
Smith 2001a	154	1.00(12.70)	76	-0.50(12.70)	18.44	1.50 [-1.99, 4.99]
Smith 2001b	149	0.30(12.70)	77	-0.50(12.70)	18.39	0.80 [-2.69, 4.29]
Subtotal (95% CI)	822		466		100.00	1.36 [-0.14, 2.86]
Test for heterogeneity: Chi² = 2.38, df = 6 (P = 0.88), I² = 0%						
Test for overall effect: Z = 1.78 (P = 0.08)						



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 15 Change in DBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	142	2.00(8.30)	69	-1.30(8.30)	16.14	3.30 [0.91, 5.69]
NEW Kaukua 2004	102	1.70(8.30)	108	-0.20(8.30)	18.23	1.90 [-0.35, 4.15]
NEW McMahon 2002	145	3.00(8.30)	72	-0.10(8.30)	16.72	3.10 [0.75, 5.45]
NEW McNulty 2003a	68	3.30(9.07)	32	0.50(8.80)	6.59	2.80 [-0.93, 6.53]
NEW McNulty 2003b	62	0.40(7.87)	32	0.50(8.80)	7.00	-0.10 [-3.72, 3.52]
Smith 2001a	154	1.60(8.30)	76	-0.90(8.30)	17.68	2.50 [0.22, 4.78]
Smith 2001b	149	-0.10(8.30)	77	-0.90(8.30)	17.64	0.80 [-1.48, 3.08]
Subtotal (95% CI)	822		466		100.00	2.16 [1.20, 3.12]

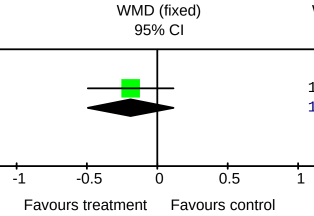
Test for heterogeneity: Chi² = 4.60, df = 6 (P = 0.60), I² = 0%
Test for overall effect: Z = 4.41 (P < 0.0001)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 16 Change in total cholesterol (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	0.15(1.08)	62	0.34(1.08)	100.00	-0.19 [-0.49, 0.11]
Subtotal (95% CI)	222		62		100.00	-0.19 [-0.49, 0.11]

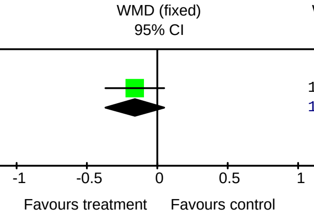
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.22 (P = 0.22)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 17 Change in LDL cholesterol (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	-0.06(0.74)	62	0.10(0.74)	100.00	-0.16 [-0.37, 0.05]
Subtotal (95% CI)	222		62		100.00	-0.16 [-0.37, 0.05]

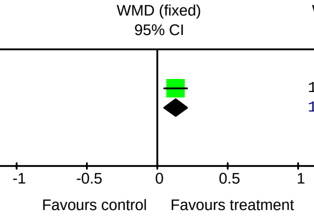
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.51 (P = 0.13)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 18 Change in HDL cholesterol (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	0.24(0.29)	62	0.11(0.29)	100.00	0.13 [0.05, 0.21]
Subtotal (95% CI)	222		62		100.00	0.13 [0.05, 0.21]

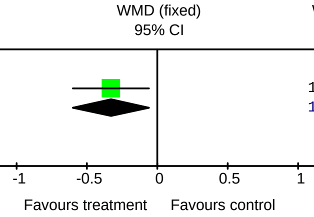
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.12 (P = 0.002)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 19 Change in triglycerides (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	-0.05(0.96)	62	0.28(0.96)	100.00	-0.33 [-0.60, -0.06]
Subtotal (95% CI)	222		62		100.00	-0.33 [-0.60, -0.06]

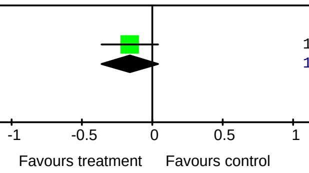
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.39 (P = 0.02)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 20 Change in HbA 1c% at 18 months

Study		Treatment		Control	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight maintenance							
STORM 2000	222	0.00(0.71)	62	0.16(0.71)		100.00	-0.16 [-0.36, 0.04]
Subtotal (95% CI)	222		62			100.00	-0.16 [-0.36, 0.04]

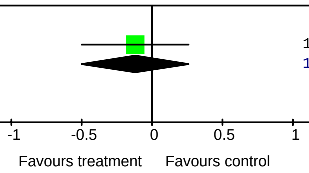
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.57 (P = 0.12)



Review: Sibutramine UPDATE adults only
Comparison: 01 Sibutramine and diet vs placebo and diet (all studies)
Outcome: 21 Change in fasting plasma glucose (mmol/l) at 18 months

Study		Treatment		Control	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight maintenance							
STORM 2000	222	0.14(1.35)	62	0.26(1.35)		100.00	-0.12 [-0.50, 0.26]
Subtotal (95% CI)	222		62			100.00	-0.12 [-0.50, 0.26]

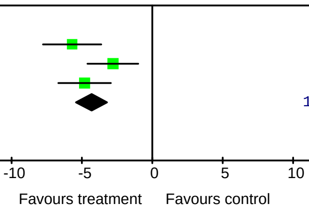
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.62 (P = 0.54)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 01 Weight change in kg at 12 months

Study		Sibutramine		Placebo	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Apfelbaum 1999	81	-5.20(7.50)	78	0.50(5.70)		28.31	-5.70 [-7.77, -3.63]
Smith 2001a	154	-4.40(7.16)	79	-1.60(6.37)		37.15	-2.80 [-4.60, -1.00]
Smith 2001b	153	-6.41(7.73)	78	-1.60(6.37)		34.53	-4.81 [-6.68, -2.94]
Subtotal (95% CI)	388		235			100.00	-4.32 [-5.41, -3.22]

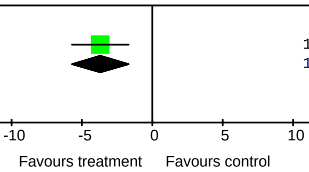
Test for heterogeneity: Chi² = 4.71, df = 2 (P = 0.10), I² = 57.5%
Test for overall effect: Z = 7.69 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 02 Weight change in kg at 15 months

Study		Treatment		Control	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight reduction							
Apfelbaum 1999	81	-0.90(6.17)	78	2.80(6.71)		100.00	-3.70 [-5.71, -1.69]
Subtotal (95% CI)	81		78			100.00	-3.70 [-5.71, -1.69]

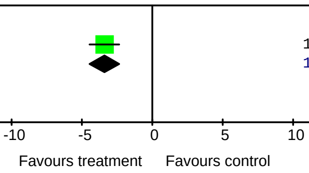
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.62 (P = 0.0003)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 03 Weight change in kg at 18 months

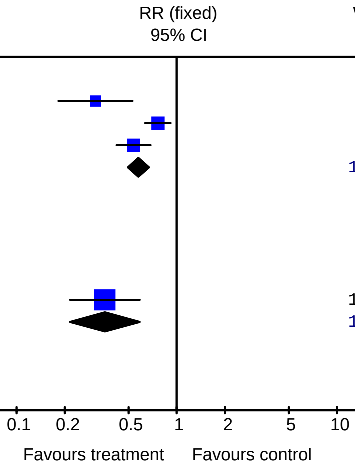
Study		Treatment		Control	WMD (fixed)	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	95% CI	%	95% CI
01 Weight maintenance							
STORM 2000	350	2.80(6.00)	114	6.20(4.60)		100.00	-3.40 [-4.45, -2.35]
Subtotal (95% CI)	350		114			100.00	-3.40 [-4.45, -2.35]

Test for heterogeneity: not applicable
Test for overall effect: Z = 6.33 (P < 0.00001)



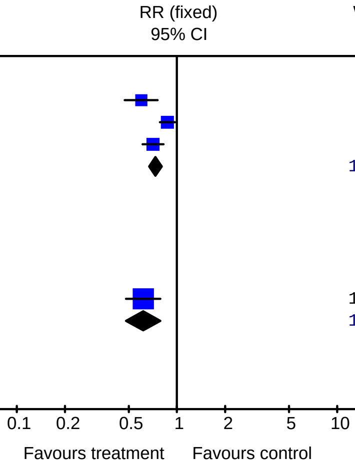
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 04 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Apfelbaum 1999	14/100	45/100	21.95	0.31 [0.18, 0.53]
Smith 2001a	61/100	80/100	39.02	0.76 [0.63, 0.92]
Smith 2001b	43/100	80/100	39.02	0.54 [0.42, 0.69]
Subtotal (95% CI)	300	300	100.00	0.58 [0.49, 0.67]
Total events: 118 (Treatment), 205 (Control)				
Test for heterogeneity: Chi² = 14.33, df = 2 (P = 0.0008), I² = 86.0%				
Test for overall effect: Z = 7.16 (P < 0.00001)				
02 Weight maintenance				
STORM 2000	16/100	45/100	100.00	0.36 [0.22, 0.59]
Subtotal (95% CI)	100	100	100.00	0.36 [0.22, 0.59]
Total events: 16 (Treatment), 45 (Control)				
Test for heterogeneity: not applicable				
Test for overall effect: Z = 4.06 (P < 0.0001)				



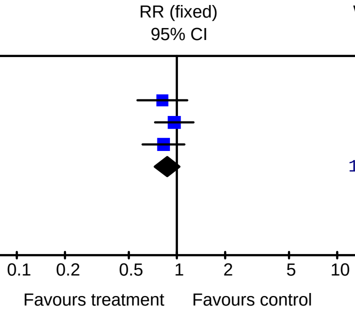
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 05 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Apfelbaum 1999	46/100	77/100	29.28	0.60 [0.47, 0.76]
Smith 2001a	81/100	93/100	35.36	0.87 [0.78, 0.97]
Smith 2001b	66/100	93/100	35.36	0.71 [0.61, 0.83]
Subtotal (95% CI)	300	300	100.00	0.73 [0.67, 0.80]
Total events: 193 (Treatment), 263 (Control)				
Test for heterogeneity: Chi² = 12.54, df = 2 (P = 0.002), I² = 84.0%				
Test for overall effect: Z = 6.60 (P < 0.00001)				
02 Weight maintenance				
STORM 2000	45/100	73/100	100.00	0.62 [0.48, 0.79]
Subtotal (95% CI)	100	100	100.00	0.62 [0.48, 0.79]
Total events: 45 (Treatment), 73 (Control)				
Test for heterogeneity: not applicable				
Test for overall effect: Z = 3.83 (P = 0.0001)				



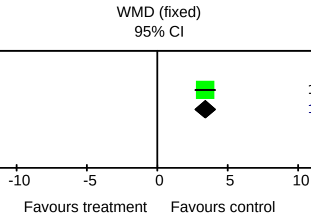
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 06 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Apfelbaum 1999	34/100	42/100	29.17	0.81 [0.57, 1.16]
Smith 2001a	49/100	51/100	35.42	0.96 [0.73, 1.27]
Smith 2001b	42/100	51/100	35.42	0.82 [0.61, 1.11]
Subtotal (95% CI)	300	300	100.00	0.87 [0.73, 1.04]
Total events: 125 (Treatment), 144 (Control)				
Test for heterogeneity: Chi² = 0.78, df = 2 (P = 0.68), I² = 0%				
Test for overall effect: Z = 1.56 (P = 0.12)				

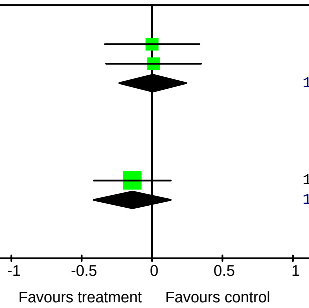


Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 07 Change in DBP (mmHg) at 6 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Apfelbaum 1999	73	1.50(2.00)	68	-1.90(2.20)	100.00	3.40 [2.70, 4.10]
Subtotal (95% CI)	73		68		100.00	3.40 [2.70, 4.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 9.58 (P < 0.00001)						

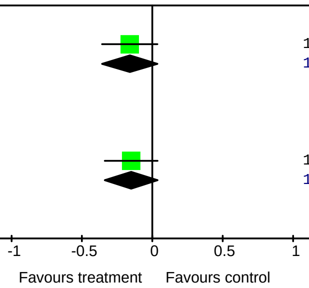


Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 08 Change in total cholesterol in mmol/l at 12 months



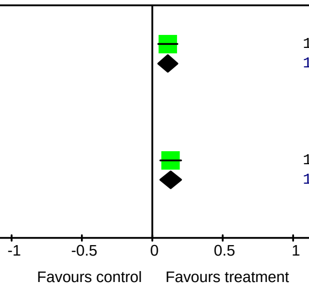
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Smith 2001a	122	0.08(1.08)	59	0.08(1.08)		50.22	0.00 [-0.34, 0.34]
Smith 2001b	123	0.09(1.08)	58	0.08(1.08)		49.78	0.01 [-0.33, 0.35]
Subtotal (95% CI)	245		117			100.00	0.00 [-0.23, 0.24]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.97), I² = 0%							
Test for overall effect: Z = 0.04 (P = 0.97)							
02 Weight maintenance							
STORM 2000	265	0.12(1.08)	77	0.26(1.08)		100.00	-0.14 [-0.41, 0.13]
Subtotal (95% CI)	265		77			100.00	-0.14 [-0.41, 0.13]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.00 (P = 0.32)							

Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 09 Change in LDL cholesterol in mmol/l at 12 months



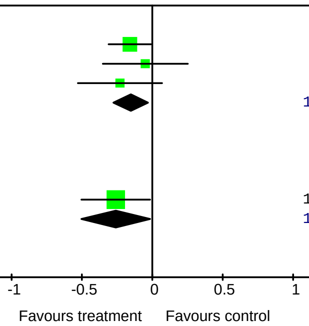
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Apfelbaum 1999	81	0.41(0.65)	78	0.57(0.62)		100.00	-0.16 [-0.36, 0.04]
Subtotal (95% CI)	81		78			100.00	-0.16 [-0.36, 0.04]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.59 (P = 0.11)							
02 Weight maintenance							
STORM 2000	265	-0.11(0.74)	77	0.04(0.74)		100.00	-0.15 [-0.34, 0.04]
Subtotal (95% CI)	265		77			100.00	-0.15 [-0.34, 0.04]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.57 (P = 0.12)							

Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 10 Change in HDL cholesterol (mmol/l) at 12 months



Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Apfelbaum 1999	81	0.34(0.23)	78	0.23(0.21)		100.00	0.11 [0.04, 0.18]
Subtotal (95% CI)	81		78			100.00	0.11 [0.04, 0.18]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.15 (P = 0.002)							
02 Weight maintenance							
STORM 2000	265	0.22(0.29)	77	0.09(0.29)		100.00	0.13 [0.06, 0.20]
Subtotal (95% CI)	265		77			100.00	0.13 [0.06, 0.20]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 3.46 (P = 0.0005)							

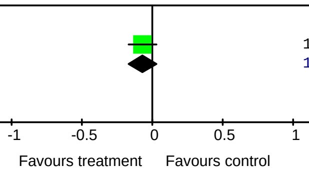
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 11 Change in triglycerides mmol/l at 12 months



Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
Apfelbaum 1999	81	-0.05(0.42)	78	0.11(0.54)		66.56	-0.16 [-0.31, -0.01]
Smith 2001a	122	-0.26(0.96)	57	-0.21(0.96)		16.60	-0.05 [-0.35, 0.25]
Smith 2001b	123	-0.44(0.96)	58	-0.21(0.96)		16.84	-0.23 [-0.53, 0.07]
Subtotal (95% CI)	326		193			100.00	-0.15 [-0.28, -0.03]
Test for heterogeneity: Chi² = 0.71, df = 2 (P = 0.70), I² = 0%							
Test for overall effect: Z = 2.45 (P = 0.01)							
02 Weight maintenance							
STORM 2000	265	-0.01(0.96)	77	0.25(0.96)		100.00	-0.26 [-0.50, -0.02]
Subtotal (95% CI)	265		77			100.00	-0.26 [-0.50, -0.02]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 2.09 (P = 0.04)							

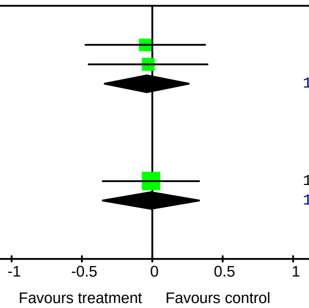
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 12 Change in HbA 1c % at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	265	0.16(0.71)	770	0.23(0.71)	100.00	-0.07 [-0.17, 0.03]
Subtotal (95% CI)	265		770		100.00	-0.07 [-0.17, 0.03]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.38 (P = 0.17)						



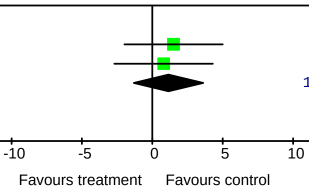
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 13 Change in fasting plasma glucose (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Smith 2001a	122	-0.21(1.35)	57	-0.16(1.35)	49.64	-0.05 [-0.47, 0.37]
Smith 2001b	123	-0.19(1.35)	58	-0.16(1.35)	50.36	-0.03 [-0.45, 0.39]
Subtotal (95% CI)	245		115		100.00	-0.04 [-0.34, 0.26]
Test for heterogeneity: Chi² = 0.00, df = 1 (P = 0.95), I² = 0%						
Test for overall effect: Z = 0.26 (P = 0.79)						
02 Weight maintenance						
STORM 2000	265	0.13(1.35)	77	0.14(1.35)	100.00	-0.01 [-0.35, 0.33]
Subtotal (95% CI)	265		77		100.00	-0.01 [-0.35, 0.33]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.06 (P = 0.95)						



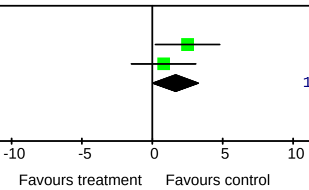
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 14 Change in SBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Smith 2001a	154	1.00(12.70)	76	-0.50(12.70)	50.06	1.50 [-1.99, 4.99]
Smith 2001b	149	0.30(12.70)	77	-0.50(12.70)	49.94	0.80 [-2.69, 4.29]
Subtotal (95% CI)	303		153		100.00	1.15 [-1.32, 3.62]
Test for heterogeneity: Chi² = 0.08, df = 1 (P = 0.78), I² = 0%						
Test for overall effect: Z = 0.91 (P = 0.36)						



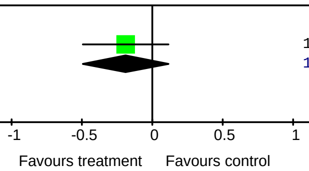
Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 15 Change in DBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
Smith 2001a	154	1.60(8.30)	76	-0.90(8.30)	50.06	2.50 [0.22, 4.78]
Smith 2001b	149	-0.10(8.30)	77	-0.90(8.30)	49.94	0.80 [-1.48, 3.08]
Subtotal (95% CI)	303		153		100.00	1.65 [0.04, 3.26]
Test for heterogeneity: Chi² = 1.07, df = 1 (P = 0.30), I² = 6.2%						
Test for overall effect: Z = 2.01 (P = 0.04)						



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 16 Change in total cholesterol (mmol/l) at 18 months

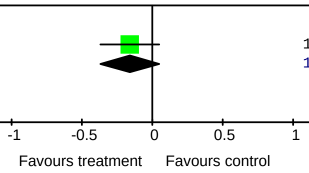
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	0.15(1.08)	62	0.34(1.08)	100.00	-0.19 [-0.49, 0.11]
Subtotal (95% CI)	222		62		100.00	-0.19 [-0.49, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.22 (P = 0.22)						



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 17 Change in LDL cholesterol (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	-0.06(0.74)	62	0.10(0.74)	100.00	-0.16 [-0.37, 0.05]
Subtotal (95% CI)	222		62		100.00	-0.16 [-0.37, 0.05]

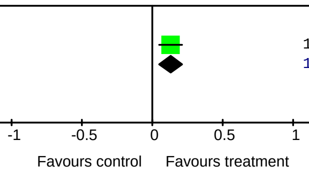
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.51 (P = 0.13)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 18 Change in HDL cholesterol (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	0.24(0.29)	62	0.11(0.29)	100.00	0.13 [0.05, 0.21]
Subtotal (95% CI)	222		62		100.00	0.13 [0.05, 0.21]

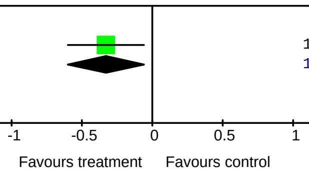
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.12 (P = 0.002)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 19 Change in triglycerides (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	-0.05(0.96)	62	0.28(0.96)	100.00	-0.33 [-0.60, -0.06]
Subtotal (95% CI)	222		62		100.00	-0.33 [-0.60, -0.06]

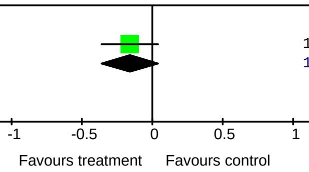
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.39 (P = 0.02)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 20 Change in HbA 1c% at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	0.00(0.71)	62	0.16(0.71)	100.00	-0.16 [-0.36, 0.04]
Subtotal (95% CI)	222		62		100.00	-0.16 [-0.36, 0.04]

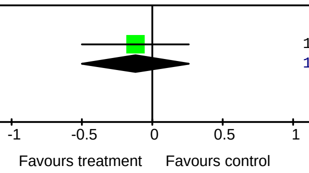
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.57 (P = 0.12)



Review: Sibutramine UPDATE adults only
Comparison: 02 Sibutramine and diet vs placebo and diet (otherwise healthy)
Outcome: 21 Change in fasting plasma glucose (mmol/l) at 18 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight maintenance						
STORM 2000	222	0.14(1.35)	62	0.26(1.35)	100.00	-0.12 [-0.50, 0.26]
Subtotal (95% CI)	222		62		100.00	-0.12 [-0.50, 0.26]

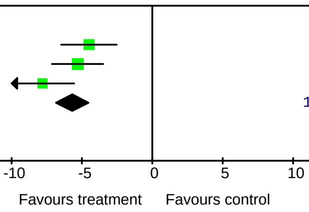
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.62 (P = 0.54)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Sibutramine Mean (SD)	N	Placebo Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Kaukua 2004	102	-7.10(7.92)	108	-2.60(6.65)	33.64	-4.50 [-6.48, -2.52]
NEW McNulty 2003a	68	-5.50(4.95)	32	-0.20(4.00)	40.06	-5.30 [-7.12, -3.48]
NEW McNulty 2003b	62	-8.00(7.09)	32	-0.20(4.00)	26.29	-7.80 [-10.04, -5.56]
Subtotal (95% CI)	232		172		100.00	-5.69 [-6.84, -4.54]

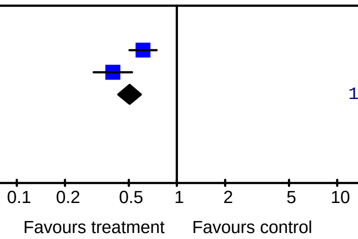
Test for heterogeneity: Chi² = 4.96, df = 2 (P = 0.08), I² = 59.6%
Test for overall effect: Z = 9.69 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 02 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW McNulty 2003a	54/100	88/100	50.00	0.61 [0.51, 0.75]
NEW McNulty 2003b	35/100	88/100	50.00	0.40 [0.30, 0.52]
Subtotal (95% CI)	200	200	100.00	0.51 [0.43, 0.60]

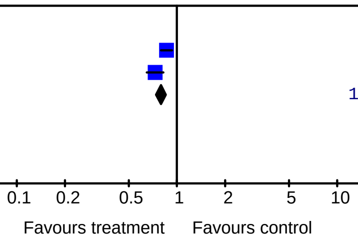
Total events: 89 (Treatment), 176 (Control)
Test for heterogeneity: Chi² = 6.68, df = 1 (P = 0.010), I² = 85.0%
Test for overall effect: Z = 8.20 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 03 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW McNulty 2003a	86/100	100/100	50.00	0.86 [0.79, 0.93]
NEW McNulty 2003b	73/100	100/100	50.00	0.73 [0.65, 0.82]
Subtotal (95% CI)	200	200	100.00	0.80 [0.74, 0.85]

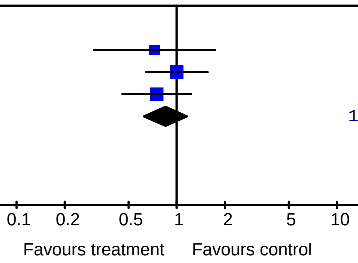
Total events: 159 (Treatment), 200 (Control)
Test for heterogeneity: Chi² = 5.76, df = 1 (P = 0.02), I² = 82.6%
Test for overall effect: Z = 6.39 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 04 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Kaukua 2004	8/100	11/100	16.42	0.73 [0.31, 1.73]
NEW McNulty 2003a	28/100	28/100	41.79	1.00 [0.64, 1.56]
NEW McNulty 2003b	21/100	28/100	41.79	0.75 [0.46, 1.23]
Subtotal (95% CI)	300	300	100.00	0.85 [0.62, 1.16]

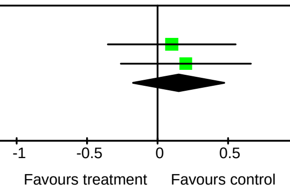
Total events: 57 (Treatment), 67 (Control)
Test for heterogeneity: Chi² = 0.88, df = 2 (P = 0.64), I² = 0%
Test for overall effect: Z = 1.03 (P = 0.30)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	-0.10(1.08)	32	-0.20(1.08)	50.76	0.10 [-0.35, 0.55]
NEW McNulty 2003b	62	0.00(1.08)	32	-0.20(1.08)	49.24	0.20 [-0.26, 0.66]
Subtotal (95% CI)	130		64		100.00	0.15 [-0.17, 0.47]

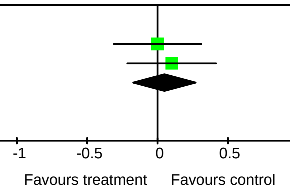
Test for heterogeneity: Chi² = 0.09, df = 1 (P = 0.76), I² = 0%
Test for overall effect: Z = 0.90 (P = 0.37)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 06 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	-0.20(0.74)	32	-0.20(0.74)	50.76	0.00 [-0.31, 0.31]
NEW McNulty 2003b	62	-0.10(0.74)	32	-0.20(0.74)	49.24	0.10 [-0.22, 0.42]
Subtotal (95% CI)	130		64		100.00	0.05 [-0.17, 0.27]

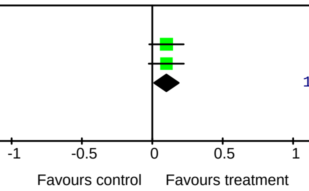
Test for heterogeneity: Chi² = 0.20, df = 1 (P = 0.66), I² = 0%
Test for overall effect: Z = 0.44 (P = 0.66)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 07 Change in HDL cholesterol (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	0.10(0.29)	32	0.00(0.29)	50.76	0.10 [-0.02, 0.22]
NEW McNulty 2003b	62	0.10(0.29)	32	0.00(0.29)	49.24	0.10 [-0.02, 0.22]
Subtotal (95% CI)	130		64		100.00	0.10 [0.01, 0.19]

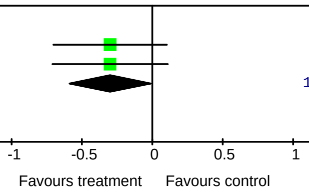
Test for heterogeneity: Chi^2 = 9.81E-32, df = 1 (P = 1.00), I^2 = 0%
Test for overall effect: Z = 2.26 (P = 0.02)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 08 Change in triglycerides mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	-0.20(0.96)	32	0.10(0.96)	50.76	-0.30 [-0.70, 0.10]
NEW McNulty 2003b	62	-0.20(0.96)	32	0.10(0.96)	49.24	-0.30 [-0.71, 0.11]
Subtotal (95% CI)	130		64		100.00	-0.30 [-0.59, -0.01]

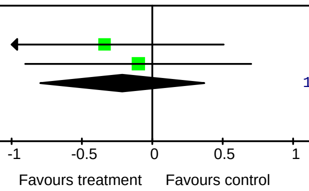
Test for heterogeneity: Chi^2 = 1.43E-31, df = 1 (P = 1.00), I^2 = 0%
Test for overall effect: Z = 2.05 (P = 0.04)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 09 Change in HbA 1c % at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	-0.56(2.20)	32	-0.22(1.92)	47.33	-0.34 [-1.19, 0.51]
NEW McNulty 2003b	62	-0.32(1.80)	32	-0.22(1.92)	52.67	-0.10 [-0.90, 0.70]
Subtotal (95% CI)	130		64		100.00	-0.21 [-0.80, 0.37]

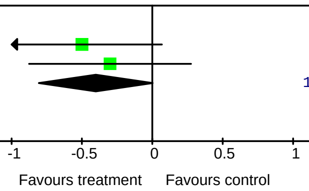
Test for heterogeneity: Chi^2 = 0.16, df = 1 (P = 0.69), I^2 = 0%
Test for overall effect: Z = 0.72 (P = 0.47)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 10 Change in fasting plasma glucose (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW McNulty 2003a	68	-0.30(1.35)	32	0.20(1.35)	50.76	-0.50 [-1.07, 0.07]
NEW McNulty 2003b	62	-0.10(1.35)	32	0.20(1.35)	49.24	-0.30 [-0.88, 0.28]
Subtotal (95% CI)	130		64		100.00	-0.40 [-0.81, 0.00]

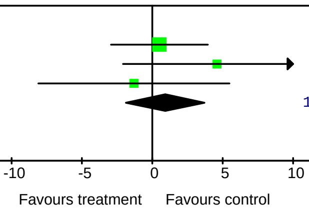
Test for heterogeneity: Chi^2 = 0.24, df = 1 (P = 0.63), I^2 = 0%
Test for overall effect: Z = 1.95 (P = 0.05)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 11 Change in SBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Kaukua 2004	102	4.10(12.70)	108	3.60(12.70)	65.75	0.50 [-2.94, 3.94]
NEW McNulty 2003a	68	4.40(15.67)	32	-0.20(16.00)	17.41	4.60 [-2.08, 11.28]
NEW McNulty 2003b	62	-1.50(15.75)	32	-0.20(16.00)	16.84	-1.30 [-8.09, 5.49]
Subtotal (95% CI)	232		172		100.00	0.91 [-1.88, 3.70]

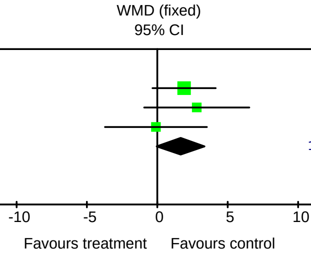
Test for heterogeneity: Chi^2 = 1.63, df = 2 (P = 0.44), I^2 = 0%
Test for overall effect: Z = 0.64 (P = 0.52)



Review: Sibutramine UPDATE adults only
Comparison: 03 Sibutramine and diet vs placebo and diet (type 2 diabetes)
Outcome: 12 Change in DBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Kaukua 2004	102	1.70(8.30)	108	-0.20(8.30)	57.28	1.90 [-0.35, 4.15]
NEW McNulty 2003a	68	3.30(9.07)	32	0.50(8.80)	20.72	2.80 [-0.93, 6.53]
NEW McNulty 2003b	62	0.40(7.87)	32	0.50(8.80)	22.00	-0.10 [-3.72, 3.52]
Subtotal (95% CI)	232		172		100.00	1.65 [-0.05, 3.35]

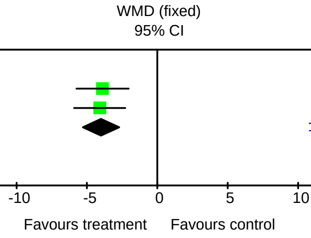
Test for heterogeneity: Chi² = 1.31, df = 2 (P = 0.52), I² = 0%
Test for overall effect: Z = 1.90 (P = 0.06)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Sibutramine Mean (SD)	N	Placebo Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	142	-4.40(7.16)	69	-0.50(6.06)	49.10	-3.90 [-5.75, -2.05]
NEW McMahon 2002	145	-4.50(7.19)	72	-0.40(6.03)	50.90	-4.10 [-5.92, -2.28]
Subtotal (95% CI)	287		141		100.00	-4.00 [-5.30, -2.70]

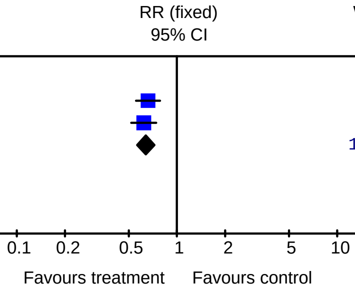
Test for heterogeneity: Chi² = 0.02, df = 1 (P = 0.88), I² = 0%
Test for overall effect: Z = 6.04 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 02 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
McMahon 2000	60/100	91/100	49.73	0.66 [0.56, 0.78]
NEW McMahon 2002	57/100	92/100	50.27	0.62 [0.52, 0.74]
Subtotal (95% CI)	200	200	100.00	0.64 [0.56, 0.72]

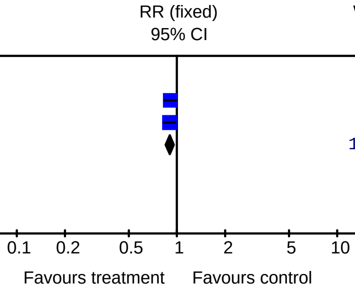
Total events: 117 (Treatment), 183 (Control)
Test for heterogeneity: Chi² = 0.24, df = 1 (P = 0.62), I² = 0%
Test for overall effect: Z = 7.06 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 03 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
McMahon 2000	87/100	96/100	49.74	0.91 [0.83, 0.99]
NEW McMahon 2002	87/100	97/100	50.26	0.90 [0.83, 0.97]
Subtotal (95% CI)	200	200	100.00	0.90 [0.85, 0.96]

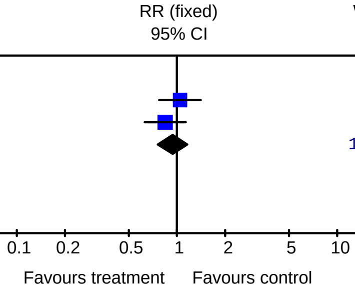
Total events: 174 (Treatment), 193 (Control)
Test for heterogeneity: Chi² = 0.03, df = 1 (P = 0.86), I² = 0%
Test for overall effect: Z = 3.40 (P = 0.0007)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 04 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
McMahon 2000	47/100	45/100	46.88	1.04 [0.77, 1.41]
NEW McMahon 2002	43/100	51/100	53.13	0.84 [0.63, 1.13]
Subtotal (95% CI)	200	200	100.00	0.94 [0.76, 1.16]

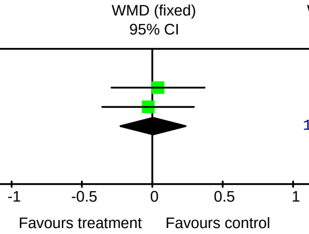
Total events: 90 (Treatment), 96 (Control)
Test for heterogeneity: Chi² = 0.99, df = 1 (P = 0.32), I² = 0%
Test for overall effect: Z = 0.60 (P = 0.55)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 05 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	133	-0.03(1.08)	59	-0.07(1.08)	49.12	0.04 [-0.29, 0.37]
NEW McMahon 2002	129	-0.09(1.08)	63	-0.06(1.08)	50.88	-0.03 [-0.36, 0.30]
Subtotal (95% CI)	262		122		100.00	0.00 [-0.23, 0.24]

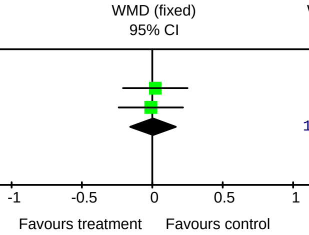
Test for heterogeneity: Chi² = 0.09, df = 1 (P = 0.77), I² = 0%
Test for overall effect: Z = 0.04 (P = 0.97)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 06 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	131	-0.09(0.74)	58	-0.11(0.74)	49.99	0.02 [-0.21, 0.25]
NEW McMahon 2002	122	-0.11(0.74)	60	-0.10(0.74)	50.01	-0.01 [-0.24, 0.22]
Subtotal (95% CI)	253		118		100.00	0.01 [-0.16, 0.17]

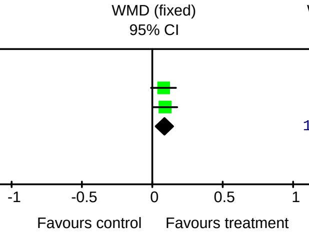
Test for heterogeneity: Chi² = 0.03, df = 1 (P = 0.86), I² = 0%
Test for overall effect: Z = 0.06 (P = 0.95)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 07 Change in HDL cholesterol (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	133	0.14(0.29)	59	0.06(0.29)	49.12	0.08 [-0.01, 0.17]
NEW McMahon 2002	129	0.12(0.29)	63	0.03(0.29)	50.88	0.09 [0.00, 0.18]
Subtotal (95% CI)	262		122		100.00	0.09 [0.02, 0.15]

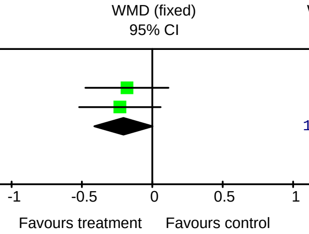
Test for heterogeneity: Chi² = 0.02, df = 1 (P = 0.88), I² = 0%
Test for overall effect: Z = 2.68 (P = 0.007)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 08 Change in triglycerides mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	133	-0.19(0.96)	59	-0.01(0.96)	49.12	-0.18 [-0.47, 0.11]
NEW McMahon 2002	129	-0.31(0.96)	63	-0.08(0.96)	50.88	-0.23 [-0.52, 0.06]
Subtotal (95% CI)	262		122		100.00	-0.21 [-0.41, 0.00]

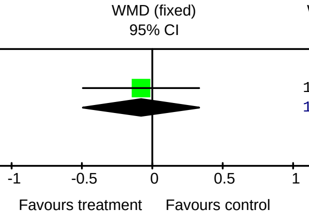
Test for heterogeneity: Chi² = 0.06, df = 1 (P = 0.81), I² = 0%
Test for overall effect: Z = 1.95 (P = 0.05)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 09 Change in fasting plasma glucose (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	133	0.23(1.35)	59	0.31(1.35)	100.00	-0.08 [-0.49, 0.33]
Subtotal (95% CI)	133		59		100.00	-0.08 [-0.49, 0.33]

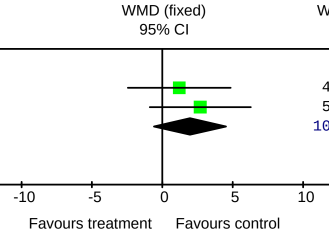
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.38 (P = 0.70)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 10 Change in SBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	142	2.70(12.70)	69	1.50(12.70)	49.11	1.20 [-2.45, 4.85]
NEW McMahon 2002	145	3.80(12.70)	72	1.10(12.70)	50.89	2.70 [-0.89, 6.29]
Subtotal (95% CI)	287		141		100.00	1.96 [-0.60, 4.52]

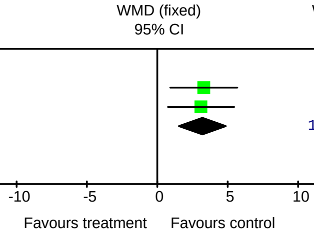
Test for heterogeneity: Chi² = 0.33, df = 1 (P = 0.57), I² = 0%
Test for overall effect: Z = 1.50 (P = 0.13)



Review: Sibutramine UPDATE adults only
Comparison: 04 Sibutramine and diet vs placebo and diet (hypertension)
Outcome: 11 Change in DBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
McMahon 2000	142	2.00(8.30)	69	-1.30(8.30)	49.11	3.30 [0.91, 5.69]
NEW McMahon 2002	145	3.00(8.30)	72	-0.10(8.30)	50.89	3.10 [0.75, 5.45]
Subtotal (95% CI)	287		141		100.00	3.20 [1.53, 4.87]

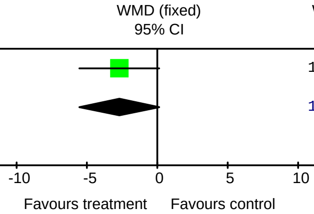
Test for heterogeneity: Chi² = 0.01, df = 1 (P = 0.91), I² = 0%
Test for overall effect: Z = 3.75 (P = 0.0002)



Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 01 Weight change in kg at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
NEW Sanchez-Reyes 20	44	-4.10(7.08)	42	-1.40(6.31)	100.00	-2.70 [-5.53, 0.13]
Total (95% CI)	44		42		100.00	-2.70 [-5.53, 0.13]

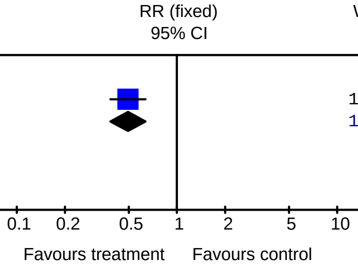
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.87 (P = 0.06)



Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 02 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Sanchez-Reyes 20	41/100	83/100	100.00	0.49 [0.38, 0.64]
Subtotal (95% CI)	100	100	100.00	0.49 [0.38, 0.64]

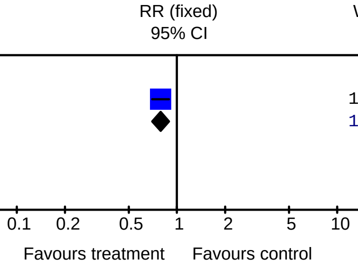
Total events: 41 (Treatment), 83 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 5.50 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 03 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Sanchez-Reyes 20	75/100	95/100	100.00	0.79 [0.70, 0.89]
Subtotal (95% CI)	100	100	100.00	0.79 [0.70, 0.89]

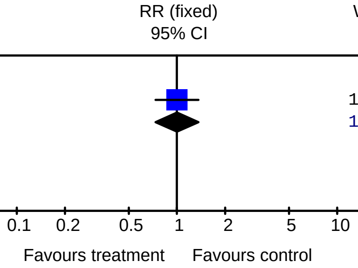
Total events: 75 (Treatment), 95 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.80 (P = 0.0001)



Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 04 Failure to complete at 12 months

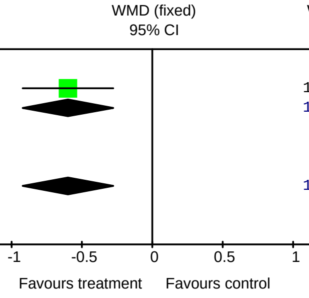
Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Sanchez-Reyes 20	45/100	45/100	100.00	1.00 [0.74, 1.36]
Subtotal (95% CI)	100	100	100.00	1.00 [0.74, 1.36]

Total events: 45 (Treatment), 45 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



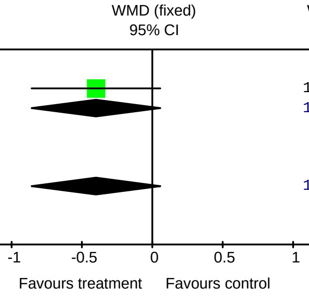
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 05 Change in HbA 1c % at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	-0.60(0.76)	42	0.00(0.76)	100.00	-0.60 [-0.92, -0.28]
Subtotal (95% CI)	44		42		100.00	-0.60 [-0.92, -0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.66 (P = 0.0003)						
Total (95% CI)	44		42		100.00	-0.60 [-0.92, -0.28]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 3.66 (P = 0.0003)						



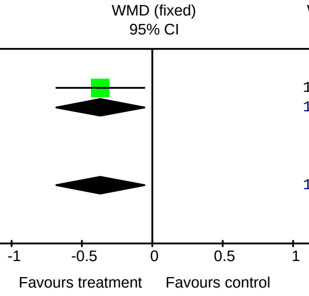
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 06 Change in total cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	-0.10(1.08)	42	0.30(1.08)	100.00	-0.40 [-0.86, 0.06]
Subtotal (95% CI)	44		42		100.00	-0.40 [-0.86, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.72 (P = 0.09)						
Total (95% CI)	44		42		100.00	-0.40 [-0.86, 0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.72 (P = 0.09)						



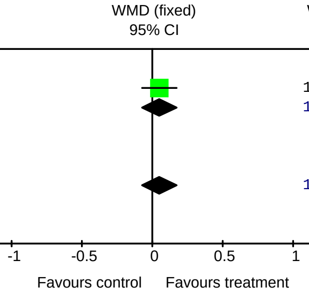
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 07 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	-0.07(0.74)	42	0.30(0.74)	100.00	-0.37 [-0.68, -0.06]
Subtotal (95% CI)	44		42		100.00	-0.37 [-0.68, -0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.32 (P = 0.02)						
Total (95% CI)	44		42		100.00	-0.37 [-0.68, -0.06]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 2.32 (P = 0.02)						



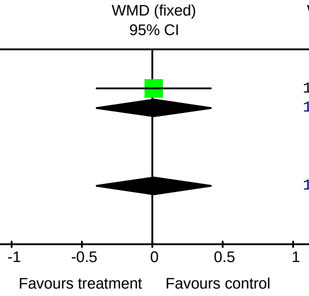
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 08 Change in HDL cholesterol (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	0.02(0.29)	42	-0.03(0.29)	100.00	0.05 [-0.07, 0.17]
Subtotal (95% CI)	44		42		100.00	0.05 [-0.07, 0.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.80 (P = 0.42)						
Total (95% CI)	44		42		100.00	0.05 [-0.07, 0.17]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.80 (P = 0.42)						



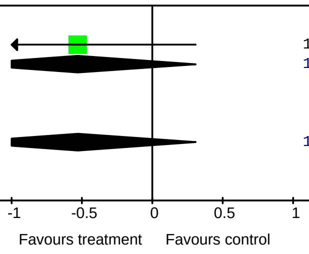
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 09 Change in triglycerides mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	-0.19(0.96)	42	-0.20(0.96)	100.00	0.01 [-0.40, 0.42]
Subtotal (95% CI)	44		42		100.00	0.01 [-0.40, 0.42]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.05 (P = 0.96)						
Total (95% CI)	44		42		100.00	0.01 [-0.40, 0.42]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.05 (P = 0.96)						



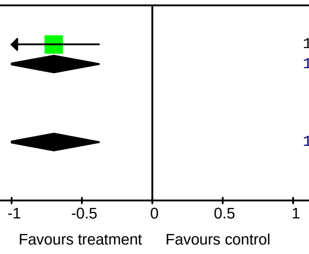
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 10 Change in fasting plasma glucose (mmol/l) at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	-1.46(1.98)	42	-0.93(1.98)	100.00	-0.53 [-1.37, 0.31]
Subtotal (95% CI)	44		42		100.00	-0.53 [-1.37, 0.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.24 (P = 0.21)						
Total (95% CI)	44		42		100.00	-0.53 [-1.37, 0.31]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.24 (P = 0.21)						



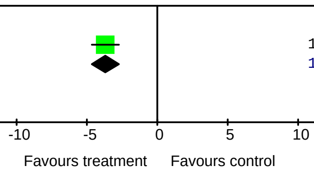
Review: Sibutramine UPDATE adults only
Comparison: 05 Sibutramine+D and PA, vs placebo+D and PA
Outcome: 11 Change in HbA 1c % at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Sanchez-Reyes 20	44	-0.60(0.76)	42	0.10(0.76)	100.00	-0.70 [-1.02, -0.38]
Subtotal (95% CI)	44		42		100.00	-0.70 [-1.02, -0.38]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.27 (P < 0.0001)						
Total (95% CI)	44		42		100.00	-0.70 [-1.02, -0.38]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 4.27 (P < 0.0001)						



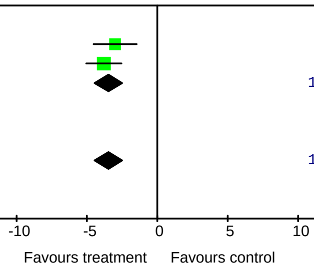
Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	-6.80(5.50)	220	-3.10(5.40)	100.00	-3.70 [-4.66, -2.74]
Subtotal (95% CI)	281		220		100.00	-3.70 [-4.66, -2.74]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 7.55 (P < 0.00001)						



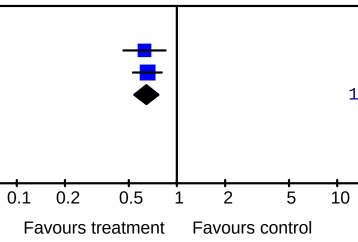
Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	-8.10(7.74)	174	-5.10(6.73)	40.42	-3.00 [-4.52, -1.48]
NEW Porter 2004	281	-6.30(7.70)	220	-2.50(6.62)	59.58	-3.80 [-5.06, -2.54]
Subtotal (95% CI)	455		394		100.00	-3.48 [-4.45, -2.51]
Test for heterogeneity: Chi² = 0.63, df = 1 (P = 0.43), I² = 0%						
Test for overall effect: Z = 7.03 (P < 0.00001)						
Total (95% CI)	455		394		100.00	-3.48 [-4.45, -2.51]
Test for heterogeneity: Chi² = 0.63, df = 1 (P = 0.43), I² = 0%						
Test for overall effect: Z = 7.03 (P < 0.00001)						



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 03 Failure to achieve at least 5% loss of initial body weight at 12 months

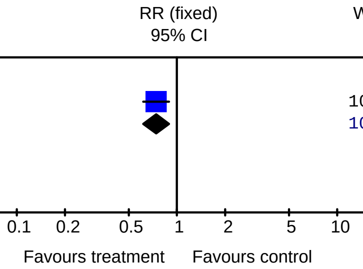
Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Hauner 2004	37/100	59/100	42.14	0.63 [0.46, 0.85]
NEW Porter 2004	53/100	81/100	57.86	0.65 [0.53, 0.81]
Subtotal (95% CI)	200	200	100.00	0.64 [0.54, 0.77]
Total events: 90 (Treatment), 140 (Control)				
Test for heterogeneity: Chi² = 0.05, df = 1 (P = 0.82), I² = 0%				
Test for overall effect: Z = 4.95 (P < 0.00001)				



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 04 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Hauner 2004	60/100	81/100	100.00	0.74 [0.61, 0.89]
Subtotal (95% CI)	100	100	100.00	0.74 [0.61, 0.89]

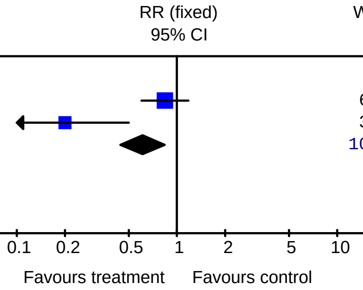
Total events: 60 (Treatment), 81 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 3.16 (P = 0.002)



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 05 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Hauner 2004	37/100	44/100	63.77	0.84 [0.60, 1.18]
NEW Porter 2004	5/100	25/100	36.23	0.20 [0.08, 0.50]
Subtotal (95% CI)	200	200	100.00	0.61 [0.44, 0.84]

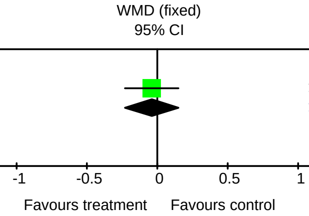
Total events: 42 (Treatment), 69 (Control)
Test for heterogeneity: Chi² = 9.14, df = 1 (P = 0.003), I² = 89.1%
Test for overall effect: Z = 3.07 (P = 0.002)



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 06 Change in total cholesterol in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	0.01(1.08)	220	0.05(1.08)	100.00	-0.04 [-0.23, 0.15]
Subtotal (95% CI)	281		220		100.00	-0.04 [-0.23, 0.15]

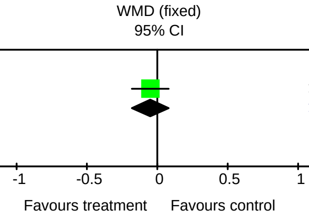
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.41 (P = 0.68)



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 07 Change in LDL cholesterol in mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	0.02(0.74)	220	0.07(0.74)	100.00	-0.05 [-0.18, 0.08]
Subtotal (95% CI)	281		220		100.00	-0.05 [-0.18, 0.08]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.75 (P = 0.45)

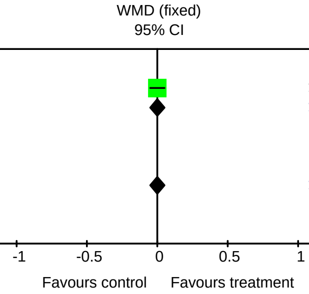


Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 08 Change in HDL cholesterol (mmol/l) at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	0.01(0.29)	220	0.01(0.29)	100.00	0.00 [-0.05, 0.05]
Subtotal (95% CI)	281		220		100.00	0.00 [-0.05, 0.05]
Total (95% CI)	281		220		100.00	0.00 [-0.05, 0.05]

Test for heterogeneity: not applicable (Subtotal)
Test for overall effect: Z = 0.00 (P = 1.00)

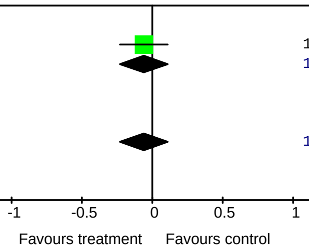
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 09 Change in triglycerides mmol/l at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	-0.15(0.96)	220	-0.09(0.96)	100.00	-0.06 [-0.23, 0.11]
Subtotal (95% CI)	281		220		100.00	-0.06 [-0.23, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.69 (P = 0.49)						
Total (95% CI)	281		220		100.00	-0.06 [-0.23, 0.11]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.69 (P = 0.49)						

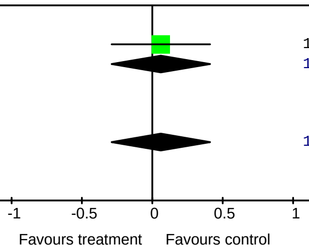
WMD (fixed)
95% CI



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 10 Change in fasting plasma glucose (mmol/l) at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	-0.04(1.98)	220	-0.10(1.98)	100.00	0.06 [-0.29, 0.41]
Subtotal (95% CI)	281		220		100.00	0.06 [-0.29, 0.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.34 (P = 0.74)						
Total (95% CI)	281		220		100.00	0.06 [-0.29, 0.41]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.34 (P = 0.74)						

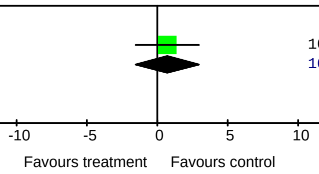
WMD (fixed)
95% CI



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 11 Change in SBP (mmHg) at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	-1.40(12.70)	220	-2.10(12.70)	100.00	0.70 [-1.54, 2.94]
Subtotal (95% CI)	281		220		100.00	0.70 [-1.54, 2.94]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.61 (P = 0.54)						

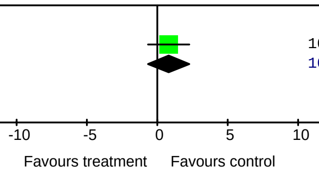
WMD (fixed)
95% CI



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 12 Change in DBP (mmHg) at 6 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Porter 2004	281	-0.90(8.30)	220	-1.70(8.30)	100.00	0.80 [-0.66, 2.26]
Subtotal (95% CI)	281		220		100.00	0.80 [-0.66, 2.26]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.07 (P = 0.28)						

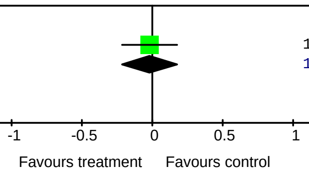
WMD (fixed)
95% CI



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 13 Change in total cholesterol in mmol/l at 12 months

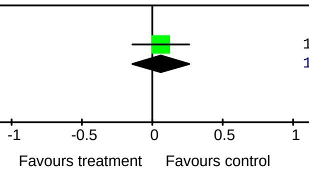
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	-0.06(0.88)	174	-0.04(0.98)	100.00	-0.02 [-0.22, 0.18]
Subtotal (95% CI)	174		174		100.00	-0.02 [-0.22, 0.18]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.20 (P = 0.84)						

WMD (fixed)
95% CI



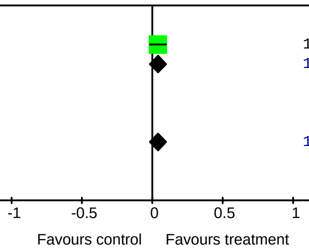
Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 14 Change in LDL cholesterol in mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	-0.16(0.79)	174	-0.22(1.10)	100.00	0.06 [-0.14, 0.26]
Subtotal (95% CI)	174		174		100.00	0.06 [-0.14, 0.26]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.58 (P = 0.56)						



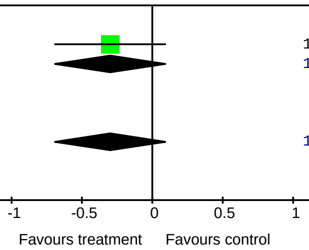
Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 15 Change in HDL cholesterol (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	0.14(0.26)	174	0.10(0.29)	100.00	0.04 [-0.02, 0.10]
Subtotal (95% CI)	174		174		100.00	0.04 [-0.02, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.35 (P = 0.18)						
Total (95% CI)	174		174		100.00	0.04 [-0.02, 0.10]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.35 (P = 0.18)						



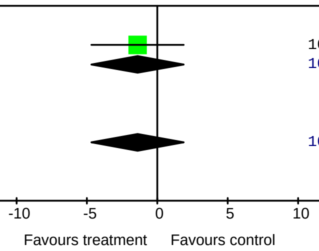
Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 16 Change in triglycerides mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	-0.11(0.79)	174	0.19(2.51)	100.00	-0.30 [-0.69, 0.09]
Subtotal (95% CI)	174		174		100.00	-0.30 [-0.69, 0.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.50 (P = 0.13)						
Total (95% CI)	174		174		100.00	-0.30 [-0.69, 0.09]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 1.50 (P = 0.13)						



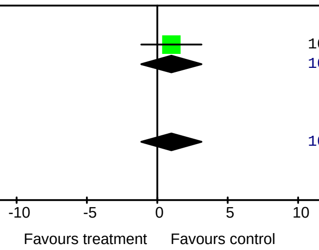
Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 17 Change in SBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	-2.90(14.70)	174	-1.50(16.40)	100.00	-1.40 [-4.67, 1.87]
Subtotal (95% CI)	174		174		100.00	-1.40 [-4.67, 1.87]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.84 (P = 0.40)						
Total (95% CI)	174		174		100.00	-1.40 [-4.67, 1.87]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.84 (P = 0.40)						



Review: Sibutramine UPDATE adults only
Comparison: 06 Sibutramine+D, PA, and BT vs placebo+D, PA, and BT
Outcome: 18 Change in DBP (mmHg) at 12 months

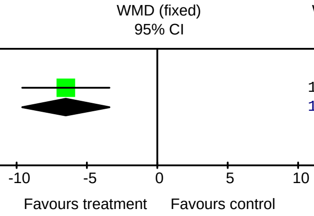
Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Hauner 2004	174	-0.30(10.50)	174	-1.30(9.90)	100.00	1.00 [-1.14, 3.14]
Subtotal (95% CI)	174		174		100.00	1.00 [-1.14, 3.14]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.91 (P = 0.36)						
Total (95% CI)	174		174		100.00	1.00 [-1.14, 3.14]
Test for heterogeneity: not applicable						
Test for overall effect: Z = 0.91 (P = 0.36)						



Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 01 Weight change in kg at 12 months

Study		Sibutramine		Placebo	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
NEW Redmon 2003	27	-7.30(6.75)	27	-0.80(4.68)	100.00	-6.50 [-9.60, -3.40]
Subtotal (95% CI)	27		27		100.00	-6.50 [-9.60, -3.40]

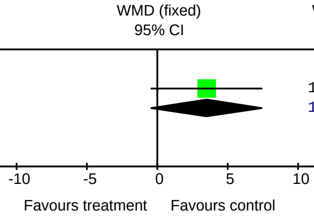
Test for heterogeneity: not applicable
Test for overall effect: Z = 4.11 (P < 0.0001)



Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 02 Weight change in kg at 24 months

Study		Sibutramine		Placebo	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
NEW Redmon 2003	23	-4.60(5.75)	25	-8.10(8.00)	100.00	3.50 [-0.42, 7.42]
Subtotal (95% CI)	23		25		100.00	3.50 [-0.42, 7.42]

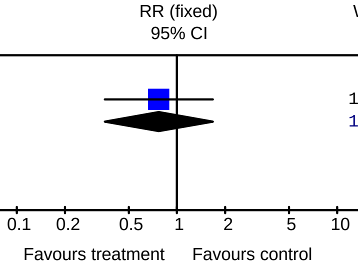
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.75 (P = 0.08)



Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 03 Failure to complete at 12 months

Study	Treatment	Control	Weight	RR (fixed)
or sub-category	n/N	n/N	%	95% CI
01 Weight loss				
NEW Redmon 2003	10/100	13/100	100.00	0.77 [0.35, 1.67]
Subtotal (95% CI)	100	100	100.00	0.77 [0.35, 1.67]

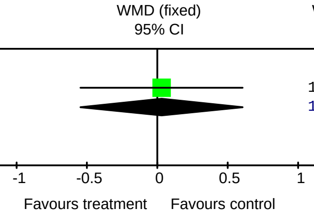
Total events: 10 (Treatment), 13 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.66 (P = 0.51)



Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 04 Change in total cholesterol in mmol/l at 12 months

Study		Treatment		Control	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
NEW Redmon 2003	27	-0.41(1.08)	27	-0.44(1.08)	100.00	0.03 [-0.55, 0.61]
Subtotal (95% CI)	27		27		100.00	0.03 [-0.55, 0.61]

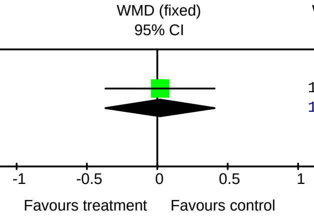
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.10 (P = 0.92)



Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 05 Change in LDL cholesterol in mmol/l at 12 months

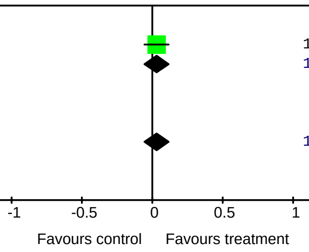
Study		Treatment		Control	Weight	WMD (fixed)
or sub-category	N	Mean (SD)	N	Mean (SD)	%	95% CI
01 Weight reduction						
NEW Redmon 2003	27	-0.31(0.67)	27	-0.33(0.78)	100.00	0.02 [-0.37, 0.41]
Subtotal (95% CI)	27		27		100.00	0.02 [-0.37, 0.41]

Test for heterogeneity: not applicable
Test for overall effect: Z = 0.10 (P = 0.92)



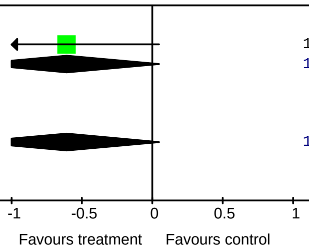
Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 06 Change in HDL cholesterol (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
NEW Redmon 2003	27	0.05(0.16)	27	0.02(0.16)		100.00	0.03 [-0.06, 0.12]
Subtotal (95% CI)	27		27			100.00	0.03 [-0.06, 0.12]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.69 (P = 0.49)							
Total (95% CI)	27		27			100.00	0.03 [-0.06, 0.12]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.69 (P = 0.49)							



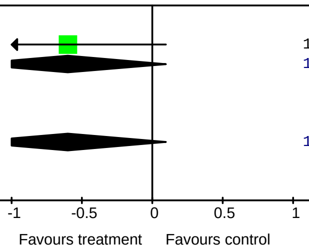
Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 07 Change in triglycerides mmol/l at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
NEW Redmon 2003	27	-0.52(1.40)	27	0.09(1.04)		100.00	-0.61 [-1.27, 0.05]
Subtotal (95% CI)	27		27			100.00	-0.61 [-1.27, 0.05]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.82 (P = 0.07)							
Total (95% CI)	27		27			100.00	-0.61 [-1.27, 0.05]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.82 (P = 0.07)							



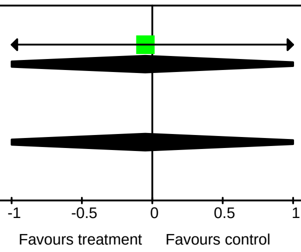
Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 08 Change in HbA 1c % at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
NEW Redmon 2003	27	-0.60(1.55)	27	0.00(1.00)		100.00	-0.60 [-1.30, 0.10]
Subtotal (95% CI)	27		27			100.00	-0.60 [-1.30, 0.10]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.69 (P = 0.09)							
Total (95% CI)	27		27			100.00	-0.60 [-1.30, 0.10]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 1.69 (P = 0.09)							



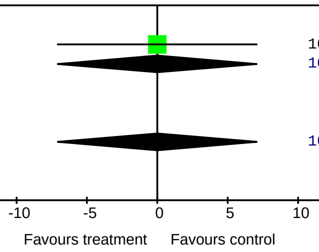
Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 09 Change in fasting plasma glucose (mmol/l) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
NEW Redmon 2003	27	-0.66(2.59)	27	-0.61(2.59)		100.00	-0.05 [-1.43, 1.33]
Subtotal (95% CI)	27		27			100.00	-0.05 [-1.43, 1.33]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.07 (P = 0.94)							
Total (95% CI)	27		27			100.00	-0.05 [-1.43, 1.33]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.07 (P = 0.94)							



Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 10 Change in SBP (mmHg) at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Weight reduction							
NEW Redmon 2003	27	-6.00(15.59)	27	-6.00(10.39)		100.00	0.00 [-7.07, 7.07]
Subtotal (95% CI)	27		27			100.00	0.00 [-7.07, 7.07]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.00 (P = 1.00)							
Total (95% CI)	27		27			100.00	0.00 [-7.07, 7.07]
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.00 (P = 1.00)							

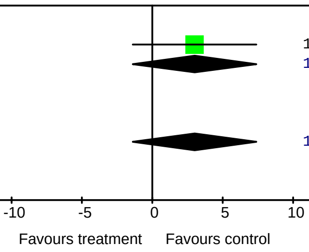


Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 11 Change in DBP (mmHg) at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Redmon 2003	27	-3.00(5.20)	27	-6.00(10.39)	100.00	3.00 [-1.38, 7.38]
Subtotal (95% CI)	27		27		100.00	3.00 [-1.38, 7.38]
Total (95% CI)	27		27		100.00	3.00 [-1.38, 7.38]

Subtotal: Test for heterogeneity: not applicable
Test for overall effect: Z = 1.34 (P = 0.18)

Total: Test for heterogeneity: not applicable
Test for overall effect: Z = 1.34 (P = 0.18)

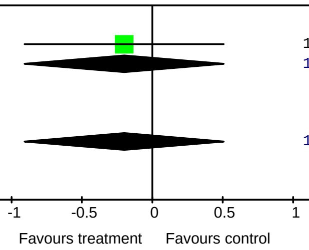


Review: Sibutramine UPDATE adults only
Comparison: 07 Sibutramine and lifestyle vs lifestyle alone THEN sibutramine and lifestyle for all participants
Outcome: 12 Change in HbA 1c % at 24 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
01 Weight reduction						
NEW Redmon 2003	23	-0.50(1.44)	25	-0.30(1.00)	100.00	-0.20 [-0.91, 0.51]
Subtotal (95% CI)	23		25		100.00	-0.20 [-0.91, 0.51]
Total (95% CI)	23		25		100.00	-0.20 [-0.91, 0.51]

Subtotal: Test for heterogeneity: not applicable
Test for overall effect: Z = 0.55 (P = 0.58)

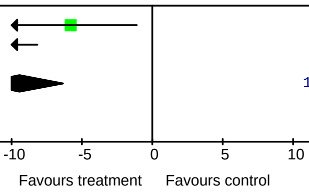
Total: Test for heterogeneity: not applicable
Test for overall effect: Z = 0.55 (P = 0.58)



Review: Sibutramine UPDATE adults only
Comparison: 08 Sibutramine + LCD + exercise + behaviour therapy vs sibutramine + LCD + exercise
Outcome: 01 Weight change in kg at 6 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wadden 2001a	17	-11.40(7.10)	9	-5.60(5.00)	43.82	-5.80 [-10.50, -1.10]
Wadden 2001b	17	-17.90(5.80)	10	-5.60(5.00)	56.18	-12.30 [-16.45, -8.15]
Total (95% CI)	34		19		100.00	-9.45 [-12.56, -6.34]

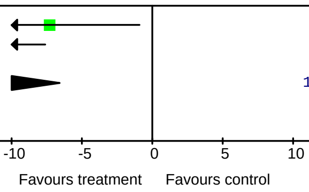
Test for heterogeneity: Chi² = 4.13, df = 1 (P = 0.04), I² = 75.8%
Test for overall effect: Z = 5.96 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 08 Sibutramine + LCD + exercise + behaviour therapy vs sibutramine + LCD + exercise
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
Wadden 2001a	17	-11.10(10.50)	9	-3.80(6.10)	39.83	-7.30 [-13.69, -0.91]
Wadden 2001b	17	-16.60(7.50)	10	-3.80(6.10)	60.17	-12.80 [-18.00, -7.60]
Total (95% CI)	34		19		100.00	-10.61 [-14.64, -6.58]

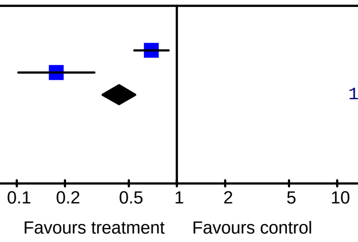
Test for heterogeneity: Chi² = 1.71, df = 1 (P = 0.19), I² = 41.7%
Test for overall effect: Z = 5.16 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 08 Sibutramine + LCD + exercise + behaviour therapy vs sibutramine + LCD + exercise
Outcome: 03 Failure to achieve at least 5% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Wadden 2001a	47/100	68/100	50.00	0.69 [0.54, 0.89]
Wadden 2001b	12/100	68/100	50.00	0.18 [0.10, 0.31]
Subtotal (95% CI)	200	200	100.00	0.43 [0.34, 0.55]

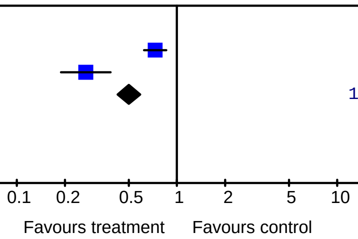
Total events: 59 (Treatment), 136 (Control)
Test for heterogeneity: Chi² = 23.94, df = 1 (P < 0.00001), I² = 95.8%
Test for overall effect: Z = 6.98 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 08 Sibutramine + LCD + exercise + behaviour therapy vs sibutramine + LCD + exercise
Outcome: 04 Failure to achieve at least 10% loss of initial body weight at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Wadden 2001a	65/100	89/100	50.00	0.73 [0.62, 0.86]
Wadden 2001b	24/100	89/100	50.00	0.27 [0.19, 0.38]
Subtotal (95% CI)	200	200	100.00	0.50 [0.43, 0.59]

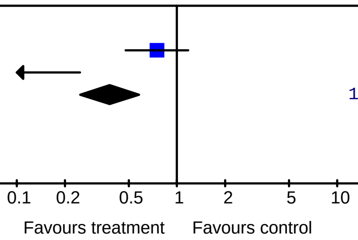
Total events: 89 (Treatment), 178 (Control)
Test for heterogeneity: Chi² = 33.27, df = 1 (P < 0.00001), I² = 97.0%
Test for overall effect: Z = 8.37 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 08 Sibutramine + LCD + exercise + behaviour therapy vs sibutramine + LCD + exercise
Outcome: 05 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
Wadden 2001a	24/100	32/100	49.61	0.75 [0.48, 1.18]
Wadden 2001b	0/100	32/100	50.39	0.02 [0.00, 0.25]
Subtotal (95% CI)	200	200	100.00	0.38 [0.25, 0.58]

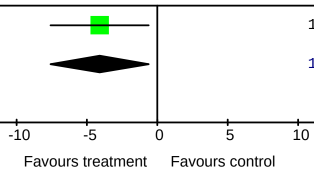
Total events: 24 (Treatment), 64 (Control)
Test for heterogeneity: Chi² = 13.86, df = 1 (P = 0.0002), I² = 92.8%
Test for overall effect: Z = 4.49 (P < 0.00001)



Review: Sibutramine UPDATE adults only
Comparison: 09 Sibutramine and diet vs placebo and diet (4 months) then open label sibutramine for all participants
Outcome: 01 Weight change in kg at 4 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
NEW Hainer 2005	38	-9.00(8.46)	42	-4.90(7.30)	100.00	-4.10 [-7.58, -0.62]
Total (95% CI)	38		42		100.00	-4.10 [-7.58, -0.62]

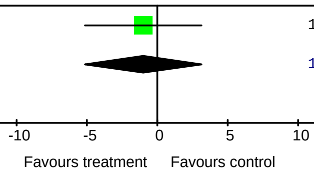
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.31 (P = 0.02)



Review: Sibutramine UPDATE adults only
Comparison: 09 Sibutramine and diet vs placebo and diet (4 months) then open label sibutramine for all participants
Outcome: 02 Weight change in kg at 12 months

Study or sub-category	N	Treatment Mean (SD)	N	Control Mean (SD)	Weight %	WMD (fixed) 95% CI
NEW Hainer 2005	38	-12.90(9.57)	42	-11.90(9.28)	100.00	-1.00 [-5.14, 3.14]
Total (95% CI)	38		42		100.00	-1.00 [-5.14, 3.14]

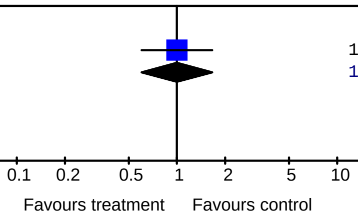
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.47 (P = 0.64)



Review: Sibutramine UPDATE adults only
Comparison: 09 Sibutramine and diet vs placebo and diet (4 months) then open label sibutramine for all participants
Outcome: 03 Failure to complete at 12 months

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI
01 Weight loss				
NEW Hainer 2005	23/100	23/100	100.00	1.00 [0.60, 1.66]
Subtotal (95% CI)	100	100	100.00	1.00 [0.60, 1.66]

Total events: 23 (Treatment), 23 (Control)
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



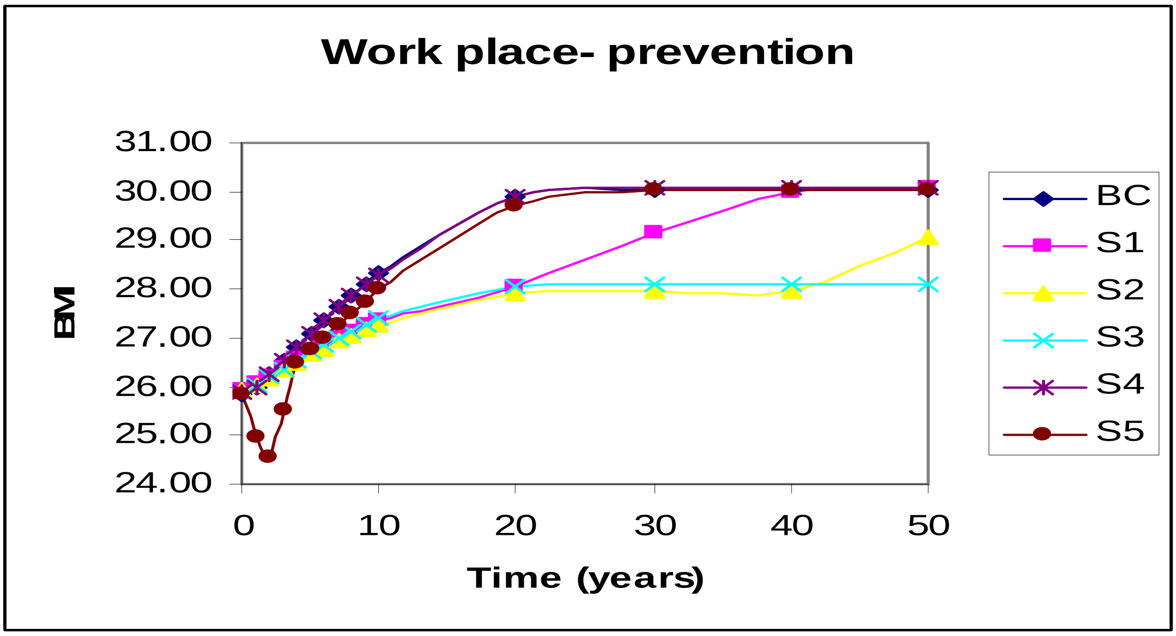
Appendix 18

HEALTH ECONOMICS: PUBLIC HEALTH

Table 1. Mortality by age and sex

Age (years)	Male	Female	Age (years)	Male	Female
0	0.005725	0.004715	**51**	0.004243	0.002774
1	0.000414	0.000364	**52**	0.004652	0.002925
2	0.000243	0.000204	**53**	0.004981	0.003281
3	0.000182	0.000139	**54**	0.005400	0.003502
4	0.000145	0.000143	**55**	0.005933	0.003839
5	0.000114	0.000114	**56**	0.006375	0.004209
6	0.000122	0.000113	**57**	0.007333	0.004551
7	0.000101	0.000090	**58**	0.007923	0.005022
8	0.000106	0.000080	**59**	0.008772	0.005568
9	0.000117	0.000075	**60**	0.010084	0.006298
10	0.000106	0.000100	**61**	0.011025	0.006754
11	0.000122	0.000080	**62**	0.012525	0.007445
12	0.000142	0.000122	**63**	0.013254	0.008134
13	0.000173	0.000107	**64**	0.014909	0.009035
14	0.000192	0.000132	**65**	0.016209	0.009820
15	0.000254	0.000137	**66**	0.017756	0.010953
16	0.000321	0.000210	**67**	0.019749	0.012030
17	0.000486	0.000229	**68**	0.022014	0.013572
18	0.000644	0.000250	**69**	0.024525	0.014919
19	0.000613	0.000303	**70**	0.026694	0.016276
20	0.000738	0.000253	**71**	0.030018	0.018466
21	0.000666	0.000270	**72**	0.033499	0.021096
22	0.000778	0.000274	**73**	0.037136	0.023658
23	0.000760	0.000297	**74**	0.041829	0.026625
24	0.000716	0.000279	**75**	0.046822	0.030265
25	0.000820	0.000318	**76**	0.052029	0.033726
26	0.000786	0.000348	**77**	0.057773	0.037443
27	0.000766	0.000331	**78**	0.063690	0.042188
28	0.000815	0.000352	**79**	0.071991	0.046527
29	0.000851	0.000397	**80**	0.078723	0.052626
30	0.000923	0.000438	**81**	0.087252	0.058660
31	0.000938	0.000461	**82**	0.095888	0.066367
32	0.001038	0.000476	**83**	0.102962	0.072231
33	0.001027	0.000510	**84**	0.112893	0.081454
34	0.001052	0.000596	**85**	0.125632	0.092885
35	0.001124	0.000590	**86**	0.145341	0.107513
36	0.001218	0.000658	**87**	0.160356	0.120096
37	0.001303	0.000695	**88**	0.176224	0.134309
38	0.001280	0.000843	**89**	0.192971	0.149487
39	0.001458	0.000882	**90**	0.204588	0.166094
40	0.001596	0.000939	**91**	0.222805	0.183601
41	0.001649	0.000997	**92**	0.247299	0.206840
42	0.001824	0.001144	**93**	0.272060	0.229441
43	0.002134	0.001301	**94**	0.287803	0.252408
44	0.002147	0.001458	**95**	0.326015	0.272554
45	0.002348	0.001549	**96**	0.342374	0.299233
46	0.002626	0.001794	**97**	0.368259	0.323896
47	0.002960	0.001992	**98**	0.396878	0.349627
48	0.003206	0.002159	**99**	0.417557	0.376015
49	0.003560	0.002275	**100**	0.443119	0.407128
50	0.003909	0.002578			

Figure 1. **Body mass index (BMI; kg/m^2) vs. time for work place counselling**



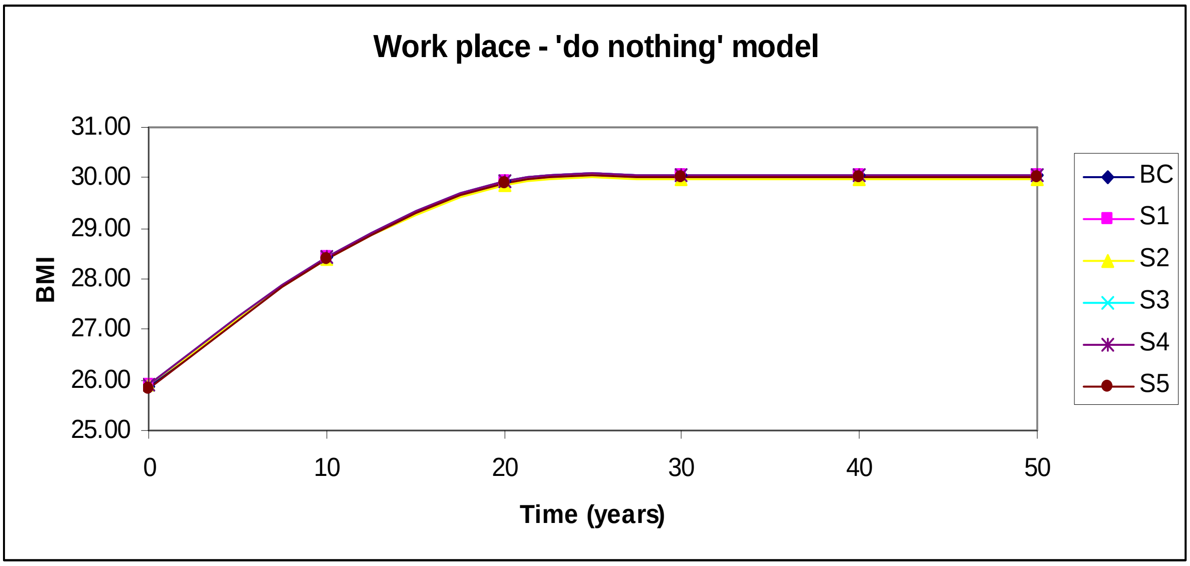
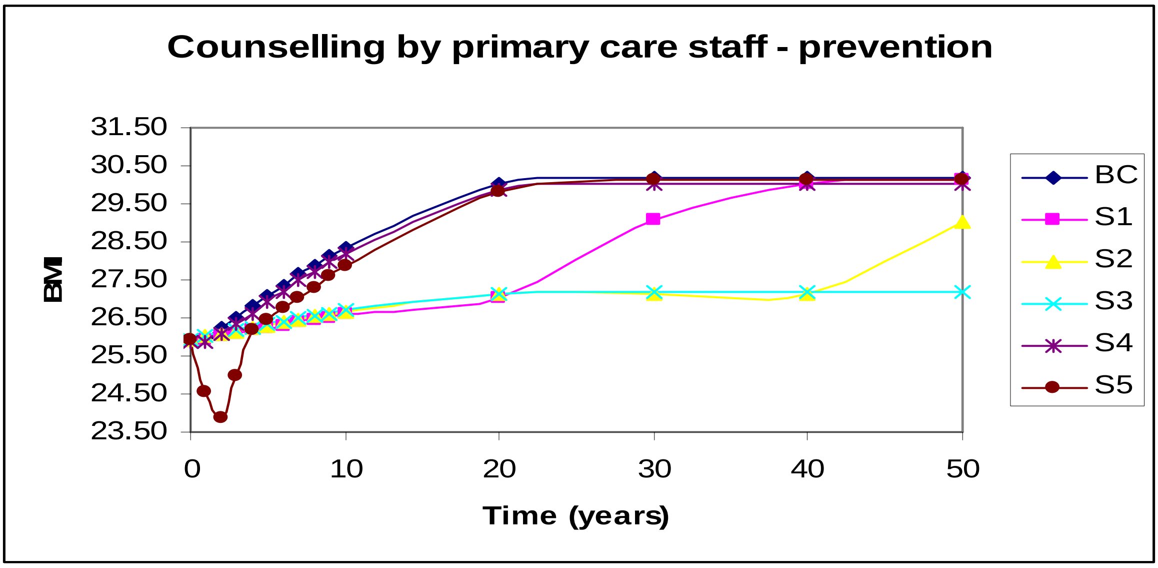


Figure 2. Body mass index (BMI; kg/m^2) vs. time for counselling by primary care staff



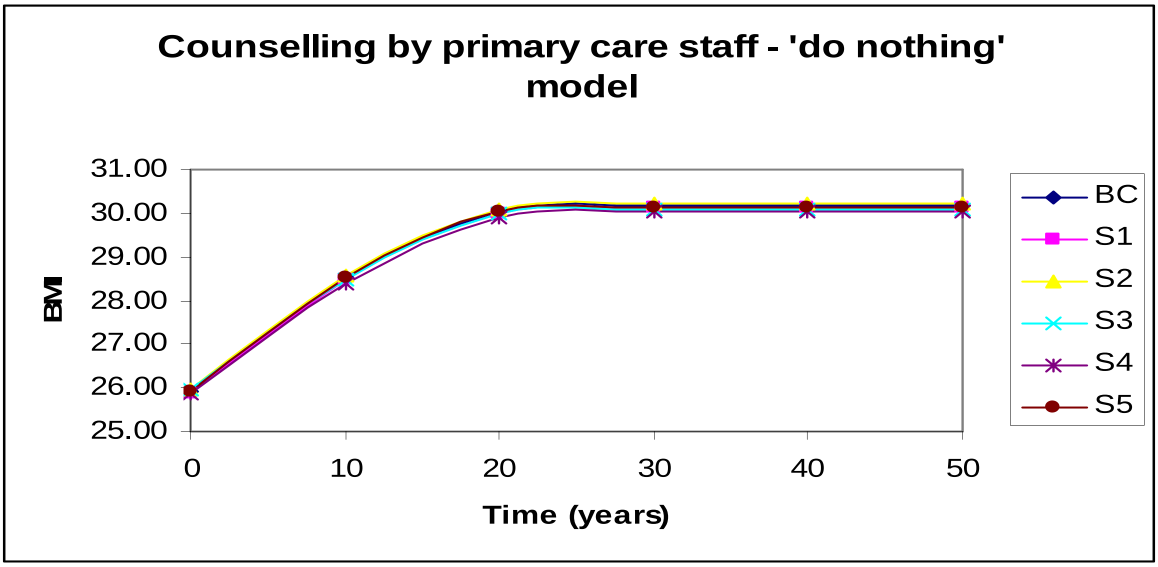
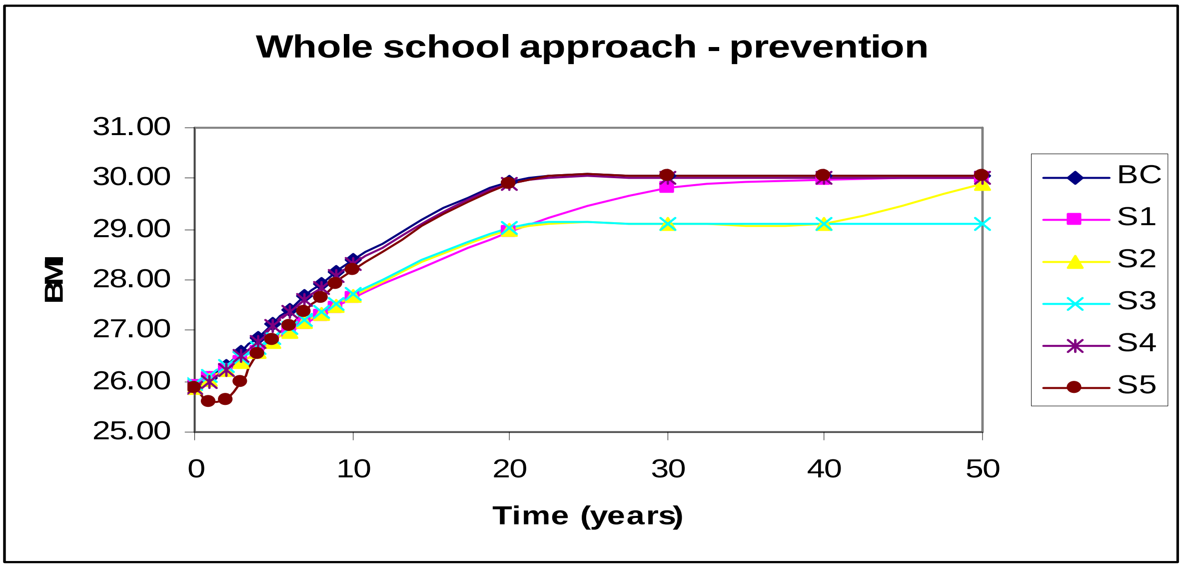
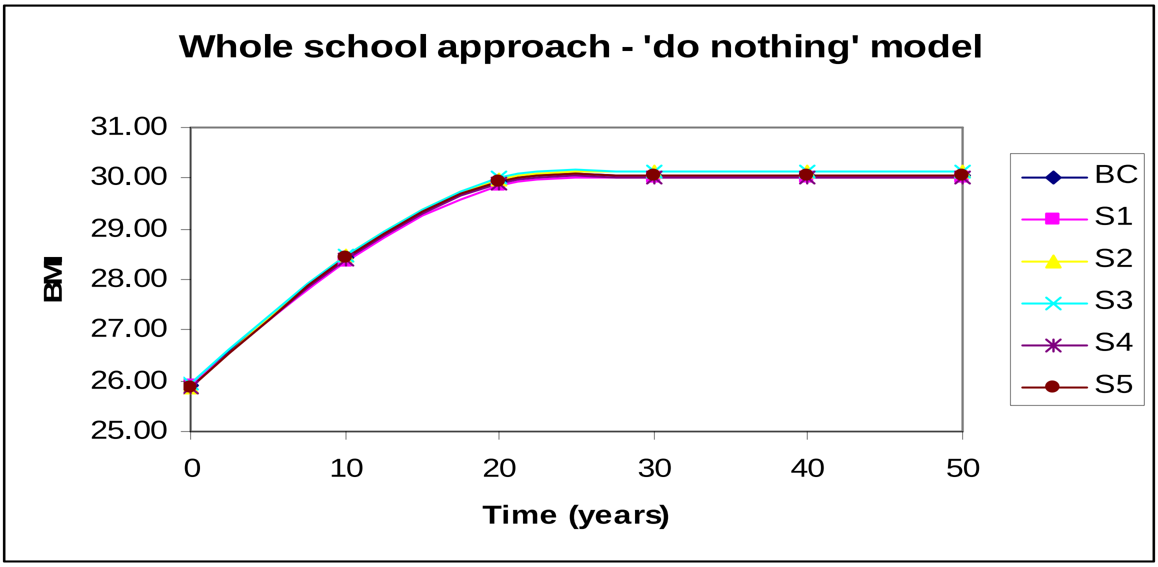


Figure 3. **Body mass index (BMI; kg/m^2) vs. time for the whole school approach**





First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design** (include power calculation if available)	**Length of follow-up**	**Main results** (include effect size(s)/confidence intervals for each outcome if available)	**Confounders** (potential sources of bias)/ **Comments**
Evidence of efficacy (internal validity) for weight maintenance/reduction								
Dzator 2004 [1]	Randomised controlled trial (RCT)	1	+	The study population included Perth couples who were cohabiting for the first time, had not been living together for more than 2 years, intended to stay in Perth for the 2 years and were not planning a pregnancy. Average age 29.4 (SD 8.2) years. Individuals were excluded if they suffered from heart disease, diabetes or severe asthma. 137 couples entered the study, 111 completed the testing at the end of the programme and 81 attended follow-up after 1 year.	**Aim:** To investigate the effect that diet and PA programmes have on couples. Couples were randomised to one of two interventions or a control. The low-level intervention group received an initial introductory group workshop, followed by mail outs. The high-level intervention group received mail outs alternated with interactive sessions, with a dietitian and the exercise physiologist. Control patients were invited for measurement (they were offered the programme at the end of the study).	16-week intervention 8-month follow-up (1 year after baseline)	Intervention is more effective than doing nothing. The high intervention group showed substantial marginal improvement compared to the low intervention group. This was particularly the case for blood cholesterol, blood pressure, fat intake and fitness. There was no significant difference in body mass index (BMI) at either 4 or 12 months.	**Limitations:** No allocation concealment. Potential for bias caused by the over representation of higher socio-economic status (SES). Participants were chosen who responded to an advertisement, these were potentially more motivated to begin with. Intention to treat (ITT) analysis was used.

					Programme delivered by health promotion professionals. **Power calculation:** $p = 0.05$ with a power of 80% as a minimum.			
Israel 1985 (included in McLean 2003 systematic review) [9]	Randomised controlled trial (RCT)			Thirty-three families, children aged between 8–12 years and at least 20% over IBW; mean age 11 years and 4 months. Behavioural weight reduction only group, *n* = 12 (nine girls, three boys, range 9–12 years). Behavioural weight reduction plus parent training group, *n* = 12 (eight girls, four boys, range 8–13 years). Wait list control group, *n* = 9 (six girls, three boys, range 9–12 years).	To evaluate the effect of explicit and additional training in general child management skills in the context of a behavioural treatment programme for overweight children.	Behavioural weight reduction only group and behavioural weight reduction plus parent training group received identical treatment consisting of stimulus control cues, exercise, food intake and rewards; responsibility for monitoring was divided between parent and child, also included homework. Behavioural weight reduction plus parent training group also received 2-hour-long sessions of	Changes in weight at 1-year behavioural weight reduction plus parent training vs. behavioural weight reduction only: 5.2 (*n* = 11) vs. 4.8 kg (*n* = 9). Change in % overweight at 1 year behavioural weight reduction plus parent training vs. behavioural weight reduction only: –10.2 (*n* = 11) % vs. –1.3% (*n* = 9). No significant difference between two active treatment groups.	Thirty-three families, children aged between 8–12 years and at least 20% over IBW; mean age 11 years and 4 months. Behavioural weight reduction only group, *n* = 12 (nine girls, three boys, range 9–12 years). Behavioural weight reduction plus parent training group, *n* = 12 (eight girls, four boys, range 8–13 years). Wait list control group, *n* = 9 (six girls, three boys, range 9–12 years).

						instruction in behavioural child management skills prior to start of programme, understanding was tested in three quizzes and concepts were referred to in treatment programme. Nine × 90 min sessions then brief problem-solving discussions at 1, 2, 4, 6, 9 and 12 months including telephone calls.		

Overall strength of evidence of efficacy for weight outcomes = 1+

Evidence of efficacy (internal validity) for diet outcomes								
Aldana et al. 2005 [2]	Before and after study	2	–	The study population was employees and retirees of the Washoe County School District (WCSD) in 1997 to 2002. Participants were eligible if they had	**Aim:** To assess the effect the WCSD Wellness Programme on employee healthcare costs and the rates of absenteeism. There were 11 different programmes offered to all participants. The	2 years	Of the eligible employees 1407 participated in either 2001 or 2002, and 1264 in both. The majority were >50 years, female, had a certified job classification, worked at least 6 years and had not participated in any of the wellness programmes. The results for each of the	There was no control group to compare the results with.

				been employed full time by the district for ≥3 years, including 2001 and 2002. 6246 were eligible; of this 1441 were retired. Participants enrolled on line or at any of the different district schools or facilities.	programmes were promoted over the internet and email. The programmes were: 1) Brighten your smile – participants were encouraged to brush and floss their teeth twice per day; 2) Holiday weight challenge – this encouraged responsible energy intake and expenditure during the holiday season; 3) Water challenge – promoted dehydration awareness; 4) Tame the TV – encouraged the substituted of healthier activities for TV; 5) March nutrition mystery – by eating five portions of fruit and vegetables per day clues to a mystery became available; 6) Mount Everest fitness challenge – teams moved up a web-based map of Mount Everest by exercising; 7) Test your rest – 7–9 hours sleep per night was encouraged; 8) Iron man triathlon fitness challenge – the teams moved up a course by exercising, drinking		programmes are as follows: 1) 166 participants, there was a significant increase in brushing and flossing; 2) 1761 participants, 91% reported no weight gain. For those who lost weight, they lost 2.5 lb (1.13 kg) on average; 3), 4), 5), 7), 9) and 11) had 2736 participants; 6) and 8) had 3288 participants, and reported a 90% compliance to dietary and exercise recommendations. Programme completion rates ranged from 62 to 82% The number of days missed of work increased with age and years worked and was higher among males and classified employees. The days of work significantly decreased with the level of wellness participation.	

					water and eating fruits and vegetables; 9) Train your brain – encouraged participants to read for a few minutes each day; 10) Exercise for life – participants committed to 8 weeks of exercise; 11) Buckle up America – the wearing of seatbelts was encouraged.			
Proper 2004 [3]	RCT individual	1	+	The study population was recruited from three municipal services of a Dutch town. To be included participants had to be a civil servant; perform office work; work at least 24 hours per week at the local municipal service of Enschde; and have a contract until at least the end of the post-test. The mean age of the intervention group was 43.8 years and for the control group was 43.7 years.	**Aim:** To investigate the efficacy of physical activity (PA) counselling at a worksite. Cost benefit and cost-effectiveness were looked at. Costs of the intervention were compared to the monetary benefits from a reduction in sick leave. Patients were randomised to either the intervention group or a control group. Participants in the intervention group were offered seven consultations, which took place at the worksite. The counselling promoted PA and healthy dietary habits. Standardised protocols and the individual's stage of behaviour change were used as guides. Stage of development was determined using baseline	The intervention lasted 9 months. Outcomes were investigated during the same 9 months 1 year after the intervention.	The results of the study show that 'a significant positive intervention effect was observed for energy expenditure'. Participants in the intervention group expended more energy per day. The controls decreased their energy expenditure. The mean energy expenditure was 64 kcal (268 kJ)/day, for the intervention group, and –129 kcal (–540 kJ)/day for the control group. The fitness level of the intervention group improved, compared with the controls. The effect on the proportion of subjects meeting public health recommendation for moderate-intensity PA was not significant. The prevalence of upper extremity symptoms decreases more in the intervention group; no significant effect was found.	The authors' note that several potential benefits were not included in the study. These included employee turnover, productivity, commitment to the company and improved corporate image. Healthcare costs, due to medical consumption or therapy, were not taken on to account.

					measurements. Advice offered was tailored to the individual. The counsellor and the employee devised a plan to improve PA and nutrition. Both the intervention group and the control group received written information about lifestyle factors (PA, nutrition, alcohol, smoking, [work] stress, and musculoskeletal symptoms).			
Rajgopal 2002 [4]	Before and after study	2	–	The study population consisted of 3100 homemakers, who had graduated from Virginia Expanded Food and Nutrition Education Programme (EFNEP), i.e. were included in the 1996 sample study. EFNEP teaches homemakers recommended food-related behaviours and food nutrient intakes.	**Aim:** To evaluate the economic efficacy of the Virginia EFNEP. The monetised health benefits were compared with the programme implementation costs. The study was split into three phases. The first investigated behaviours taught in EFNEP that might 'contribute to delay or avoidance of diet-related chronic diseases and conditions that are believed to be most prevalent among the low-income population'. In the second phase SPSS was used to select participants from the 3100 graduated homemakers who had met the selected criteria for	1 year	The perspective adopted was that of the programme sponsors, including the federal leaders and legislators who determine the funding and direction of the programme. The initial benefit/cost ratio was US$10.64/US$1.00, indicating that for every one dollar spent more than ten dollars may be saved in future healthcare costs. Sensitivity analysis on the initial assumptions and the lack of incidence data for some disease areas gives a benefit/cost ratio ranging from US$2.66/US$1.00 to US$17.04/US$1.00. Reducing in the number of graduates to achieve the optimal behaviours by 75%, the ratio is US$2.66/US$1.00, and when it is reduced by 50% the ratio is US$5.32/US$1.00. Assuming 50% is the portion of osteoporosis due to dietary factors, the ratio is	This was a general dietary initiative and was not targeted at obesity. The authors note that data on disease incidence rates for low-income populations and treatment costs for diet-related diseases were not available for several diseases. Some available treatment costs did not reflect total economic costs of the diseases. There was a lack of data on the portion of some diseases and conditions that could be attributed to diet.

					optimal nutritional behaviour (ONB). The final phase gleaned the data from the previous phases in to a controlled before and after (CBA) formula.		US$5.91/US$1.00. Using only estimated disease incidence rates for low-income populations the ratio is US$17.01/US$1.00.	
Roux 2004 [5]	Markov model	1	+	The study population included adults; further details of the study population were not provided.	**Aim:** To assess the cost-effectiveness of population wide strategies to promote PA in adults. A Markov model was developed to estimate the costs, health gains and cost-effectiveness. Four public health strategies that had been strongly recommended by the US Task Force for Preventative Services were investigated. Further details of the interventions were not provided. The efficacy estimates were obtained from RCTs. A systematic review of disease burden by exercise status was used to obtain the relative risk of five diseases (coronary heart disease, ischaemic stroke, colorectal cancer, breast cancer and type 2 diabetes), for inactive, regularly active, and sufficiency active PA levels.	10, 20, 30 and 40 years time horizons were used.	A societal perspective was used. PA access intervention was the most effective. Social support was the most cost-effective intervention at US$9,000 per quality-adjusted life-year (QALY), assuming a 40-year time horizon. All physical activities were cost effective (ranging from $9,000/QALY to $30,000/QALY) The results were sensitive to intervention costs and efficacy and analytic time horizon.	The information provided is taken from an abstract presentation at NAASO's 2004 annual meeting.

					The Quality of Well Being Scale was used for data on quality of life.			
Wang 2003 [6]	RCT Individual	1	+	310 female middle school children in Boston, MA, USA, metropolitan area. The children appear to be 14 years old.	**Aim:** To investigate the effect of Planet Health, a school-based intervention was designed to reduce obesity in the youth of middle school children. Children were randomly assigned to the intervention group or a control group.	2 years (fall 1995 to spring 1997)	Planet Health would prevent an estimated 1.9% of the female students from becoming overweight adults. Obesity prevalence declined from 23.6 to 20.4% during the intervention. This compares with an increase from 21.5 to 23.7% in the control group. When baseline covariates were controlled the prevalence of obesity in girls from the intervention group was reduced significantly compared to the control girls (odds ratio [OR] 0.47, 95% CI 0.24 to 0.93, $p = 0.03$). There were no significant differences found among boys.	No allocation concealment.
Wang *et al.* 2004 [7]	CCT	2	+	The study population included third graders in Augusta, GA, USA, were included in the study.	The aim was to investigate the cost-effectiveness of an after school obesity prevention programme called MCG FitKid Project. Nine elementary schools were included in the study.	3 years. Only the first year results are presented here.	A societal perspective was adopted. The cost of the programme was US$546 per student (US$174,070 per programme). There was a 0.5% ($p = 0.07$) body fat reduction in the intervention students. When comparing the intervention with the control, there was a saving of US$451 per student in costs of usual after-school care. The cost-effectiveness ratio was US$190 per 1% body fat reduction.	The information provided is taken from an abstract presentation at NAASO's (The Obesity Society's) 2004 annual meeting.

							For students who attended at least 40 and 80% of the sessions, the programme resulted in an average 0.8% ($p < 0.01$) and 1.2% ($p < 0.01$) body fat reduction respectively. This was achieved at a cost of US$634 and US$839 per student in after-school care costs. Resulting in a per capita net savings of US$88 and US$293 respectively.	

Evidence of efficacy (internal validity) for physical activity outcomes

Overall strength of evidence of efficacy for physical activity outcomes = 1+

Overall strength of evidence of efficacy for diet outcomes = 1+

Evidence of corroboration (external validity)

Evidence of salience – Is it appropriate for the UK?

First author	Study design	Research type	Research quality	Study population	Research question and design	Length of follow-up	Main results	Confounders/comments

Evidence for implementation – Will it work in the UK?

First author	Study design	Research type	Research quality	Study population	Research question and design	Length of follow-up	Main results	Confounders/ comments
Aldana et al. 2005 [2]	Before and after study	2	–	The study population was employees and retirees of the Washoe County School District (WCSD) for the 1997 to 2002. Participants were eligible if they had been employed full	Aim: To see the effect the WCSD Wellness Programme had on employee healthcare costs and the rates of absenteeism. There were 11 different programmes offered to all participants.	2 years	Of the eligible employees 1407 participated in either 2001 or 2002, and 1264 in both. The majority were ≥50 years, female, had a certified job classification, worked at least 6 years and had not participated in any of the wellness programmes. The results for each of the programmes are as follows:	There was no control group to compare the results with. This was carried out in the USA, there is not evidence to suggest that similar programmes would not work in the UK.

				time by the district for three or more years, including 2001 and 2002. 6246 were eligible, of this 1441 were retired. Participants enrolled on line or at any of the different district schools or facilities.	The programmes were promoted over the Internet and email. The programmes were: 1) Brighten your smile – where participants were encouraged to brush and floss their teeth twice a day; 2) Holiday weight challenge – this encouraged responsible energy intake and expenditure during the holiday season; 3) Water challenge – promoted dehydration awareness; 4) Tame the television – encouraged the substituted of healthier activities for television; 5) March nutrition mystery – by eating five portions of fruit and vegetables per day clues to a mystery became available; 6) Mount Everest fitness challenge – teams moved up a web-based map of		1) 166 participants, there was a significant increase in brushing and flossing; 2) 1761 participants, 91% reported no weight gain. For those who lost weight, they lost 2.5 lb on average; 3), 4), 5), 7), 9) and 11) had 2736 participants; 6) and 8) had 3288 participants, reporting a 90% compliance to dietary and exercise recommendations. Programme completion rates ranged from 62 to 82% The number of days missed of work increased with age and years worked and was higher among males and classified employees. The days of work significantly decreased with the level of wellness participation.	

					Mount Everest by exercising; 7) Test your rest – 7 to 9 hours sleep per night was encouraged; 8) Iron man triathlon fitness challenge – the teams moved up a course by exercising, drinking water and eating fruits and vegetables; 9) Train your brain – encouraged participants to read for a few minutes each day; 10) Exercise for life – participants committed to 8 weeks of exercise; 11) Buckle up America – the wearing of seatbelts was encouraged.			
Dzator 2004 [1]	RCT	1	+	The study population included Perth couples who were cohabiting for the first time, had not been living together for more than 3 years, intended to stay in Perth for the 3 years and were not planning a pregnancy.	**Aim:** To investigate the effect that diet and PA programmes have on couples. Couples were randomised to one of two interventions or a control. The low-level intervention group received an initial introductory group	16-week intervention 8-month follow-up (1 year after baseline)	Intervention is more effective than doing nothing. The high-intervention group showed substantial marginal improvement compared with the low-intervention group. This was particularly the case for blood cholesterol, blood pressure, fat intake and fitness. There was no significant difference in BMI at either 4 or 12 months.	The study was carried out in Perth. All topics presented in participants are generalisable to all countries (i.e. the benefits of good nutrition, how to start an exercise programme, injury prevention, recognising signs of overexertion, back care and cultivating exercise partners).

				Average age 29.4 (SD 8.2) years. Individuals were excluded if they suffered from heart disease, diabetes or severe asthma. 137 couples entered the study, 111 completed the testing at the end of the programme and 81 attended follow-up after one year.	workshop, followed by mail outs. The high-level intervention group received mail outs alternated with interactive sessions, with a dietitian and the exercise physiologist. Control patients were invited for measurement (they were offered the programme at the end of the study). Programme delivered by health promotion professionals. **Power calculation:** *p* = 0.05 with a power of 80% as a minimum.			**Limitations:** There is a potential for bias caused by the over representation of higher socioeconomic status (SES). Participants were chosen who responded to an advertisement, these were potentially more motivated to begin with.
Proper 2004 [3]	RCT individual	1	+	The study population was recruited from three municipal services, of a Dutch town. To be included participants had to be a civil servant; perform office work; work at least 24 hours per week at the local	Aim: To investigate the efficacy of PA counselling at a worksite. Cost–benefit and cost-effectiveness were looked at. Costs of the intervention were compared with the monetary benefits from a reduction in sick leave.	The intervention lasted 9 months. Outcomes were investigated during the same 9 months 1 year after the intervention.	The results of the study show that ‘a significant positive intervention effect was observed for energy expenditure’. Participants in the intervention group expended more energy per day. The controls decreased their energy expenditure. The fitness level of the intervention group improved, compared with the controls.	This study was carried out in a Dutch town therefore may not be generalisable to the UK. The public health recommendations may not be the same as those given in the UK. The authors’ note that several potential benefits were not included in the study. These included employee turnover,

				municipal service of Enschde; and have a contract until at least the end of the post-test. The mean age of the intervention group was 43.8 years and for the control group was 43.7 years.	Patients were randomised to either the intervention group or a control group. Participants in the intervention group were offered seven consultations, which took place at the worksite. The counselling promoted PA and healthy dietary habits. Standardised protocols and the individual's stage of behaviour change were used as guides. Stage of development was determined using baseline measurements. Advice offered was tailored to the individual. The counsellor and the employee devised a plan to improve PA and nutrition. Both the intervention group and the control group received written information about life style factors (PA, nutrition, alcohol,		The effect on the proportion of subjects meeting public health recommendation for moderate-intensity PA was not significant. The prevalence of upper extremity symptoms decreased more in the intervention group; no significant effect was found.	productivity, commitment to the company and improved corporate image. Healthcare costs, due to medical consumption or therapy, were not taken into account.

					smoking, [work] stress, and musculoskeletal symptoms).			
Rajgopal 2002 [4]	Before and after study	2	–	The study population consisted of 3100 homemakers, who had graduated from the Virginia Expanded Food and Nutrition Education Programme (EFNEP), i.e. were included in the 1996 sample study. EFNEP teaches limited resource homemakers recommended food-related behaviours and food nutrient intakes.	The aim of the study was to evaluate the economic efficacy of the Virginia EFNEP. The monetised health benefits were compared with the programme implementation costs. The study was split into three phases. The first investigated behaviours taught in EFNEP that might 'contribute to delay or avoidance of diet-related chronic diseases and conditions that are believed to be most prevalent among the low-income population'. In the second phase SPSS was used to select participants from the 3100 graduate homemakers who had met the selected criteria for ONB. The final phase gleaned the data from the previous phases in to a CBA formula.	1 year	The perspective adopted was that of the programme sponsors, including the federal leaders and legislators who determine the funding and direction of the programme.	This was a general dietary initiative and was not targeted at obesity. This study investigates the cost benefit of the EFNEP programme in the USA, as such it might not be generalisable to the UK. Limited resource homemakers in the USA may not have the same characteristics as limited resource homemakers in the UK.

Roux 2004 [8]	Discrete choice experiment (non-randomised experimental design)	3	+	Members of a community weight loss programme in the spring of 2001, Calgary, Alberta, Canada. Participants were ≥25 years, overweight or obese (BMI ≥25 kg/m^2), had recently enrolled on the scheme, were not pregnant or nursing and were absence of clinical co-morbidities.	**Aim:** To investigate factors that impact on individual's decision to adhere to a community weight loss programme.	N/A	Attributes with a positive coefficient (participants were willing to give up something else to move up a level) were amount of doctor time, programme components emphasised, and the programme focus. Attributes with a negative coefficient (i.e. become less preferable as the absolute magnitude of the coefficients rises) were the programme cost for 3 months and one-way travel time. Service attributes do play a marked role in the decisions that users of a weight loss programme make.	This study investigated what influences Canadians' decisions to adhere to a community weight loss programme. These may not be generalisable to different settings. **Limitations:** The sample was self-selecting and therefore may not be representative of the general weight loss population; the sample size was small.
Wang 2003 [6]	RCT	1	+	310 female middle school children in Boston, MA, USA, metropolitan area.	**Aim:** To investigate the effect of Planet Health, a school-based intervention was designed to reduce obesity in the youth of middle school children. Children were randomly assigned to the intervention group or a control group	2 years (fall 1995 to spring 1997)	Planet Health would prevent an estimated 1.9% of the female students from becoming overweight adults. Obesity prevalence declined from 23.6 to 20.4% during the intervention. This compares with an increase of 21.5 to 23.7% in the control group. When baseline covariates were controlled the prevalence of obesity in girls from the intervention group was reduced significantly compared with the control girls (OR 0.47, 95% CI 0.24 to 0.93, *p* = 0.03). There were no significant differences	The curricula and amount of physical education classes the control group received is likely to be different than the amount typically received by a UK middle-school child.

							found among boys.	
Wang et al. 2004 [7]	CCT	2	+	The study population included third graders in Augusta, GA, USA, were included in the study.	**Aim:** To investigate the cost-effectiveness of an after school obesity prevention programme called MCG FitKid Project. Nine elementary schools were included in the study.	3 years. Only the first year results are presented here.	A societal perspective was adopted. The cost of the programme was US$546 per student (US$174,070 per programme). There was a 0.5% ($p = 0.07$) body-fat reduction in the intervention students. When comparing the intervention to the control, there was a saving of US$451 per student in costs of usual after-school care. The cost-effectiveness ratio was US$190 per 1% body-fat reduction. For students who attended at least 40% and 80% of the sessions, the programme resulted in an average 0.8% ($p < 0.01$) and 1.2% ($p < 0.01$) body-fat reduction respectively. This was achieved at a cost of US$634 and US$839 per student in after-school care costs. Resulting in a per capita net savings of US$88 and US$293 respectively.	The information provided is taken from an abstract presentation at NAASO's 2004 annual meeting. This is a US study and as such details about the school day and after care facility may not be generalisable to the UK.
Overall strength of evidence of corroboration = none of the studies were UK studies. All the studies investigated different interventions.								
Evidence of cost-effectiveness								
First author	**Study design**	**Research type**	**Research quality**	**Study population**	**Research question and design**	**Length of follow-up**	**Main results**	**Confounders/comments**

Aldana et al. 2005 [2]	Before and after study	2	–	The study population was employees and retirees of the Washoe County School District (WCSD) for 1997 to 2002. Participants were eligible if they had been employed full time by the district for ≥3 years, including 2001 and 2002. 6246 were eligible, of this 1441 were retired. Participants enrolled online or at any of the different district schools or facilities.	Aim: To see the effect the WCSD Wellness Programme had on employee healthcare costs and the rates of absenteeism. There were 11 different programmes offered to all participants. The programmes were promoted over the Internet and email. The programmes were: 1) Brighten your smile – participants were encouraged to brush and floss their teeth twice per day; 2) Holiday weight challenge – this encouraged responsible energy intake and expenditure during the holiday season; 3) Water challenge – promoted dehydration awareness; 4) Tame the television – encouraged the substituted of healthier activities for television; 5) March nutrition mystery – by eating five portions of fruits and vegetables per day clues to a mystery became available; 6) Mount Everest fitness challenge – teams moved up a web-based map of Mount Everest by exercising; 7) Test your rest – 7 to 9 hours sleep per night was	2 years	Of the eligible employees 1407 participated in either 2001 or 2002, and 1264 in both. The majority were 50 years plus, female, had a certified job classification, worked at least 6 years and had not participated in any of the wellness programmes. The results for each of the programmes were as follows: For every certified and classified employee who was absent from work, on average, the WCSD paid US$231/day and US$103/day respectively. The cost per day of a substitute was US$75. Programme participation was associated with a US$3,041,290 difference in absenteeism cost during 2001 and 2002, compared with non-participants. This is '… 15.6 times greater than the total cost for all wellness programmes during the same time period'. The programme costs included the costs of wellness staff,	There was no control group to compare the results with.

					encouraged; 8) Iron man triathlon fitness challenge – the teams moved up a course by exercising, drinking water and eating fruits and vegetables; 9) Train your brain – encouraged participants to read for a few minutes each day; 10) Exercise for life – participants committed to 8 weeks of exercise; 11) Buckle up America – the wearing of seatbelts was encouraged.		benefits, programme costs, and any other associated costs. 'These savings translate into a cost saving of US$15.6 for every dollar spent on programming.'	
Dzator 2004 [1]	RCT	1	+	The study population included Perth couples who were cohabiting for the first time, had not been living together for more than 2 years, intended to stay in Perth for the 2 years and were not planning a pregnancy. Average age 29.4 (SD 8.2) years. Individuals were excluded if they suffered from heart disease, diabetes or severe asthma. 137 couples	**Aim:** To investigate the effect that diet and PA programmes have on couples. Couples were randomised to one of two interventions or a control. The low-level intervention group received 'initial introductory group workshop, after which modules were mailed at intervals of 2 to 3 weeks'. The high-level intervention group received 'mail outs alternated with interactive sessions of about eight couples per group, at which the dietitian and the exercise physiologist explained nutritional and exercise techniques, answered questions and reviewed progress'. Control patients were invited for	16-week intervention 8-month follow-up (1 year after baseline)	Direct intervention costs were included. Intervention is more effective than doing nothing. The high-intervention group showed substantial marginal improvement compared with the low-intervention group. This was particularly the case for blood cholesterol, blood pressure, fat intake and fitness. The total cost for the high-intervention group was US$41,854.34 (US$445.30 per participant, US$111.33 per month). The total cost for the	**Limitations:** There is a potential for bias caused by the over representation of higher SES. Participants were chosen who responded to an advertisement, these were potentially more motivated to begin with.

				entered the study, 111 completed the testing at the end of the programme and 81 attended follow-up after 1 year.	measurement (they were offered the programme at the end of the study). Programme delivered by health promotion professionals. **Power calculation:** *p* = 0.05 with a power of 80% as a minimum.		low-intervention group was US$41,847.26 (US$445.18 per participant, US$111.30 per month). At 12-month follow-up the total and average incremental costs were US$43,282.10 ($460.44 per participant, $38.37 per month) for the high-intervention group and $431,09.43 ($458.61 per participant, $38.22 per month) for the low-intervention group. 'The results show that the high intervention group achieved greater marginal effectiveness and cost-effectiveness than the low level intervention.' The average cost of having interactive workshops every two to three weeks post-intervention was US$445.50 per unit change in the outcome variable; for the high-intervention group; this is US$445.18 for the low-intervention group. This shows that the high-intervention group costs US$0.12 per participant at the end of the	

							programme and US$1.84 at the 12-months follow-up, to 'achieve an additional average unit of improvement (increase or decrease) in the outcomes additional to that achieved in the low intervention group.'	
Proper 2004 [3]	RCT individual	1	+	The study population were recruited from three municipal services, of a Dutch town. To be included participants had to be a civil servant; perform office work; work at least 24 hours per week at the local municipal service of Enschde; and have a contract until at least the end of the post-test. The mean age of the intervention group was 43.8 years and for the control group was 43.7 years.	The aim was to investigate the efficacy of PA counselling at a worksite. Cost–benefit and cost-effectiveness were looked at. Costs of the intervention were compared with the monetary benefits from a reduction in sick leave. Patients were randomised to either the intervention group or a control group. Participants in the intervention group were offered seven consultations, which took place at the worksite. The counselling promoted PA and healthy dietary habits. Standardised protocols and the individual's stage of behaviour change were used as guides. Stage of development was determined using baseline measurements. Advice offered was tailored to the individual. The counsellor and the employee devised a plan to improve PA and	The intervention lasted 9 months. Outcomes were investigated during the same 9 months 1 year after the intervention.	The company perspective was used for the economic evaluation. The intervention costs were €430 per participant. There were no statistically significant differences between the total costs or the sick leave costs between the two groups. During the intervention the costs due to sick leave were lower in the intervention group by €125 (95% CI –1386 to –1062) (€1915 compared with €2040). During the intervention the mean total cost were higher in the intervention group by €305 (95% CI –1029 to –1419) (€2345 compared with €2040). The year after the intervention the costs due to sick leave were lower in the intervention group	The authors' note that several potential benefits were not included in the study. These included employee turnover, productivity, commitment to the company and improved corporate image. Healthcare costs, due to medical consumption or therapy, were not taken on to account.

					nutrition. Both the intervention group and the control group received written information about life style factors (PA, nutrition, alcohol, smoking, [work] stress, and musculoskeletal symptoms).		by € –635 (95% CI –1885 to –814) (€1830 compared with €2465). For public health recommendations met the cost-effectiveness ratio was €–1030 (95% CI –36,535 to –591) per kcal per day per employee. Cost for the intervention group was €2508, compared with a cost of €1947 for the control. The effect for the intervention group was –6.62, compared with an effect of –6.0 for the control. For energy expenditure the cost-effectiveness ratio was €5.2 (95% CI –4.9 to 27.4)/kcal per day per employee. Cost for the intervention group was €2583, compared with a cost of €1578 for the control. The effect for the intervention group was 64.2, compared with an effect of –129 for the control. For cardio-respiratory fitness the cost-effectiveness ratio was €235 (95% CI –10.0 to –830) per beats/min decrease in sub-maximal heart rate. Cost for the	

							intervention group was €2223, compared with a cost of €1118 for the control. The effect for the intervention group was –2.2, compared with an effect of 2.5 for the control. For upper-extremity symptoms the cost-effectiveness ratio was €53.6 (95% CI –101 to –810). Cost for the intervention group was €2461, compared with a cost of €1829 for the control. The effect for the intervention group was –17.9, compared with an effect of –6.2 for the control.	
Rajgopal 2002 [4]	Before and after study	2	–	The study population consisted of 3100 homemakers, who had graduated from the Virginia Expanded Food and Nutrition Education Programme (EFNEP), i.e. were included in the 1996 sample study. EFNEP teaches homemakers recommended food-related behaviours and	The aim of the study was to evaluate the economic efficacy of the Virginia EFNEP. The monetised health benefits were compared to the programme implementation costs. The study was split into three phases. The first investigated behaviours taught in EFNEP that might 'contribute to delay or avoidance of diet-related chronic diseases and conditions that are believed to be most prevalent among the low-income population'. In the second phase SPSS	1 year.	The perspective adopted was that of the programme sponsors, including the federal leaders and legislators who determine the funding and direction of the programme. The initial benefit/cost ratio was US$10.64/US$1.00, indicating that for every one dollar spent more than ten dollars may be saved in future healthcare costs.	This is a general dietary initiative and is not targeted at obesity. The authors note that data on disease incidence rates for low-income populations and treatment costs for diet related diseases was not available for several diseases. Some available treatment costs did not reflect total economic costs of the diseases. There was a lack of data on the portion of some diseases and conditions

				food nutrient intakes.	was used to select participants from the 3100 graduated homemakers who had met the selected criteria for ONB. The final phase gleaned the data from the previous phases in to a CBA formula.		Sensitivity analysis on the initial assumptions and the lack of incidence data for some disease areas gave a benefit/cost ratio ranging from US$2.66/$1.00 to US$17.04/$1.00. Reducing in the number of graduates to achieve the optimal behaviours by 75%, the ratio was US$2.66/$1.00, and when it was reduced by 50% the ratio was $5.32/$1.00. Assuming 50% is the portion of osteoporosis due to dietary factors, the ratio is US$5.91/US$1.00. Using only estimated disease incidence rates for low-income populations the ratio is US$17.01/US$1.00.	that could be attributed to diet.
Roux 2004 [8]	Discrete choice experiment (non-randomised experimental design)	3	+	Members of a community weight loss programme in the spring of 2001, Calgary Alberta, Canada. Participants were ≥25 years, overweight or obese (BMI ≥25 kg/m^2), had recently enrolled on the scheme, were not pregnant or nursing and	**Aim:** To investigate factors that impact on an individual's decision to adhere to a community weight loss programme.	N/A	Participants were willing to pay an extra US$600 out-of-pocket for a 3-month weight loss programme that was more accessible, comprehensive and tailored when compared to the current available programme. Service attributes do play a marked role in the decisions, users of a weight loss programme make.	**Limitations:** The sample was self-selecting and therefore may not be representative of the general weight loss population; the sample size was small.

				were absent of clinical co-morbidities.				
Roux 2004 [5]	Markov model	1	+	The study population included adults, further details of the study population were not provided.	**Aim:** To assess the cost-effectiveness of population wide strategies to promote PA in adults. A Markov model was developed to estimate the costs, health gains and cost-effectiveness. Four public health strategies that had been strongly recommended by the US Task Force for Preventative Services were investigated. Further details of the interventions were not provided. The efficacy estimates were obtained from RCTs. A systematic review of disease burden by exercise status was used to obtain the relative risk of five diseases (coronary heart disease, ischaemic stroke, colorectal cancer, breast cancer and type 2 diabetes), for inactive, regularly active and sufficiency active PA levels. The Quality of Well Being Scale was used for data on quality of life.	10-, 20-, 30- and 40-year time horizons were used.	A societal perspective was used. PA access intervention was the most effective. Social support was the most cost-effective intervention at US$9,000 per QALY, assuming a 40-year time horizon. All PAs were cost-effective (ranging from US$9,000 to US$30,000 per QALY). The results were sensitive to intervention costs and efficacy and analytic time horizon.	The information provided is taken from an abstract presentation at NAASO's 2004 annual meeting.
Wang 2003 [6]	RCT	1	+	310 female middle school children in	**Aim:** To investigate the effect of	2 years (fall 1995 to	A societal perspective was used in the study.	The authors note that there is concern about

				Boston, MA, USA, metropolitan area.	Planet Health, a school-based intervention was designed to reduce obesity in middle-school children. Children were randomly assigned to the intervention group or a control group.	spring 1997)	Planet health would prevent an estimated 1.9% of the female students from becoming overweight adults. For the five schools in the study the total intervention cost over the 2 years, was US$33,677. This is US$14 per student. 4.1 QALYs would be saved; society would save an estimated US$15,887 in medical costs and US$25,104 in productivity costs. The gives US$4,305 per QALY saved and a net saving of US$7,313 to society. Sensitivity analysis showed that the cost-effectiveness of the programme was relatively unaffected by changes to most parameters but was more sensitive to changes in the discount rate.	possible bias in estimates of the probability of an overweight young woman 21 to 29 years of age being overweight by 40 years old and the probability of a non-overweight young woman aged 21 to 29 years being overweight by 40 years old. This is due to the 'elimination of women with missing data'. **Limitation of the model:** Intervention costs were estimated and not prospectively measured; modelling was used for the number of adulthood overweight cases prevented; only a single data source was available for most of the parameters; overweight relapses were not considered; intervention effectiveness was based on 310 female students who were included in the baseline and follow-up analysis but costs were estimated on all 1203 students; not all direct and indirect costs were included, i.e. medical costs associated with obesity during adolescence were not

								included.
Wang et al. 2004 [7]	CCT	2	+	The study population included 3rd graders in Augusta, GA, USA, were included in the study.	**Aim:** To investigate the cost-effectiveness of an after school obesity prevention programme called MCG FitKid Project. Nine elementary schools were included in the study.	3 years. Only the first year results are presented here.	A societal perspective was adopted. The cost of the programme was US$546 per student (US$174,070 per programme). There was a 0.5% ($p = 0.07$) body fat reduction in the intervention students. When comparing the intervention to the control, there was a saving of US$451 per student in costs of usual after-school care. The cost effectiveness ratio was US$190 per 1% body-fat reduction. For students who attended at least 40% and 80% of the sessions, the programme resulted in an average 0.8% ($p < 0.01$) and 1.2% ($p < 0.01$) body-fat reduction respectively. This was achieved at a cost of US$634 and US$839 per student in after-school care costs, resulting in per capita net savings of US$88 and US$293 respectively.	The information provided is taken from an abstract presentation at NAASO's 2004 annual meeting.
Cost-effectiveness summary = 1+								

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