Managing overweight and obese adults: update review

The clinical effectiveness of long-term weight management schemes for adults (Review 1a)

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Declarations of interest: Paul Aveyard is an author of one included study (Jolly 2011) and Susan Jebb is an author of one included study (Jebb 2011). Paul Aveyard and Susan Jebb are currently involved in another two trials, one of which has treatment courses donated by Weight Watchers and the other which involves treatment courses donated by Slimming World and Rosemary Conley. Paul Aveyard and Susan Jebb have been out for meals courtesy of Weight Watchers and Nestle (owners of Jenny Craig). Susan Jebb writes for a magazine published by Rosemary Conley Enterprises and receives a fee.

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Executive summary

Introduction

This review assesses the effects of multicomponent behavioural weight management programmes (BWMPs) in overweight and obese adults which may be applicable in the UK. To be considered a multicomponent BWMP, the components of the programme had to include diet, physical activity, and behavioural therapy (for example, counselling sessions). The scope included commercial weight loss programmes and non-commercial programmes, such as those delivered in primary care settings (for example, in GP practices).

Methods

This review is an update and expansion of an existing review published in 2011 (Loveman 2011[1]) and the methods used closely follow those used by Loveman et al. We ran systematic searches of ten electronic databases and also screened reference lists and considered references submitted to NICE in a call for evidence. One reviewer screened titles and abstracts using an inclusion criteria checklist that had been agreed before screening. Two reviewers independently assessed full text articles and extracted data from included studies. Any disagreements were resolved by discussion or consulting a third reviewer. Results were presented in a number of ways, including evidence tables for each included study, listing key study characteristics and results, and forest plots showing pooled study effects on mean weight. Included studies presented weight data using a variety of analytical approaches: some did not include participants with missing data whereas others made various assumptions about missing data. So that we could pool studies and compare their effects, we used a common method to calculate the effects of each intervention. We assumed that anyone missing data at a follow-up point weighed the same amount that they did at the start of the study (baseline observation carried forward approach).

The review work for NICE is split into three parts. Review 1 looks at the effectiveness of BWMPs, and is split into review 1a, which looks only at randomized controlled trials that compare a BWMP with a control (ranging from no contact to multiple contacts regarding weight loss with someone who is not trained in weight management), and review 1b, which looks at randomized controlled trials which compare multicomponent BWMPs with other multicomponent BWMPs and with BWMPs that gave diet or physical activity only interventions. Review 1a aims to determine if BWMPs work, whereas review 1b focuses on what components of BWMPs are more effective than others. Review 2 answers specific sub-questions and does not use the same methods as Reviews 1a and 1b. It is not restricted to randomized controlled trials.

[1] Loveman E, Frampton GK, Shepher J, Picot J, Cooper K, Bryant J, et al. The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review. *Health Technology Assessment* 2011;15(2).

Results

Not including Loveman, we screened 1935 references, 34 of which met our inclusion criteria. We included a further nine studies from the original Loveman review (43 total). Of these, 30 involved a comparison between a multicomponent BWMP and a control, and these are included in this review (1a). The other 13 studies will be included in review 1b.

The 30 studies tested 44 interventions versus control and included 14,169 participants in total, 69% of whom were female. The mean age was 49 years. Only 15 of the 30 included studies reported data on ethnicity. Of these, the percentage of the study population made up of ethnic minorities ranged from 0 to 100%, and the mean percentage ethnic minority group was 27%. Overall, studies were judged to be of high quality and externally valid, with conclusions unlikely to change and likely to be applicable in other settings and to other population groups.

The 30 studies represent 44 intervention arms overall (12 studies involved more than one intervention arm). Fourteen intervention arms tested programmes delivered in both group and individual sessions, 12 tested interventions delivered via group sessions, and 18 tested interventions delivered on an individual level only. Thirty-nine included at least some element of face-to-face contact. The interventions were delivered by a range of people, though most interventions were delivered by more than one professional. The total number of sessions offered to participants varied greatly between studies, from a minimum of two to a maximum of 216. On average, interventions were 18 months long, with contact decreasing in intensity over time in a number of studies.

Results from 29 of the 30 studies (representing 40 of 44 intervention arms) could be combined in a meta-analysis. At 12 to 18 months, the meta-analysis showed a statistically significant effect of BWMPs on weight loss when compared to control (mean difference -2.59 kg, with 95% confidence intervals (CI) -2.78 to -2.41). This effect was found to continue over time (in the four studies with results at 36 months, the mean difference was -2.21, 95% CI -2.66 to -1.75). Though the vast majority of studies induced more weight loss in the intervention than in the control arm, the size of the effect varied substantially between studies. This could not be explained by programme components such as length, intensity, and face-to-face contact alone. Subgroup analyses showed that programmes that were six months or longer, and that involved supervised exercise, set energy goals (e.g. calorie counting), face-to-face contact, and group and individual sessions, tended to produce greater weight loss than other interventions, but again the size of the effect varied substantially within these groups. Effects of interventions did not appear to be dependent on age, race, or ethnicity, though data in these areas were limited. A separate analysis of those interventions currently available in the UK found that some but not all programmes had statistically significant effects on weight loss, though interventions conducted by generalists trained in weight management in general practice settings resulted in less weight loss than commercial programmes. However, there were few trials of UK-based weight loss programmes so the conclusions are tentative.

The majority of studies did not report on adverse events. Based on the nine included studies that reported any information on adverse events, multicomponent BWMPs appear to cause few adverse events and no serious ones have been detected. Eleven studies reported on dietary behaviour, and in eight the intervention group showed significant changes towards a healthier diet when compared

to the control group, but this included a variety of measures. Eleven of the 16 studies which included data or comment on physical activity outcomes detected a significant positive effect of the intervention at least one time point. The three studies that included cost-effectiveness analyses found the BWMPs to be cost-effective.

Conclusions

Multicomponent BWMPs produce modest weight loss at 12 to 18 months and in the longer-term, though the weight difference with untreated comparison groups diminishes over time. The effectiveness of programmes varies and this is not fully explained by features relating only to how they are delivered. BWMPs appear to be safe, causing few adverse events.

Findings are comparable to those in Loveman 2011 to the extent that Loveman 2011 found, overall, that BWMPs can lead to greater weight loss than control arms and found limited cost-effectiveness data. As Loveman 2011 did not pool data from included studies, did not report on effects by demographic group, and did not report on outcomes other than weight loss, further comparisons cannot be drawn.

Summary of evidence statements

Please see the final agreed evidence statements for this guideline which are contained in a separate document on the NICE website. The final statements reflect conclusions drawn from reviews 1a, 1b, 1c and 2 (as appropriate)

Conclusions from evidence statements are summarised below (full evidence statements can be see n in 'Evidence statements'). All evidence was directly applicable to the UK and comes from randomized controlled trials. Control includes arms with no contact through to arms with multiple weight related contacts delivered by a generalist with no specialist training in weight management. Unless stated otherwise, data is for weight loss at 12 to 18 months.

- Strong evidence indicates that BWMPs can lead to greater weight-loss over a 12 to 18 month period than control arms and that this effect persists over 18 to 24 months and at 36 months. The effectiveness of these programmes varies. (Statements 1.1 and 1.2)
- There is strong evidence that BWMPs currently available in the UK can lead to greater weight-loss over a 12 to 18 month period than usual care control arms. There is moderate evidence to suggest commercial BWMP's lead to greater weight-loss than BWMPs delivered in primary care but this should be interpreted with caution due to the limited number of studies and programmes included. (Statement 1.3)
- There was inconsistent evidence that men achieve slightly more weight loss than women on BWMPs and there was moderate evidence that older participants (> 60) lose more weight than younger participants from two studies that reported results by age group. There is inconsistent evidence that European Americans lose more weight than African Americans on the same BWMP. There is no evidence as to whether the effectiveness of BWMPs varies based on the sexual orientation, disability, religion, place of residence, occupation, education, socioeconomic position or social capital of participants. There is no evidence that one type of BWMP suits one demographic group more than another. (Statements 1.4, 1.5, 1.6, 1.7)

- There is moderate evidence that BWMPs have a positive influence on diet and physical activity outcomes at 12 to 18 months. (Statement 1.8)
- There is moderate evidence that BWMPs cause few adverse events and no serious adverse events. In the studies that reported adverse events, results suggest adverse events associated with BWMPs are likely to be due to participation in exercise, and were primarily musculoskeletal events that were not serious. (Statement 1.9)
- There was weak evidence that BWMPs are cost effective. (Statement 1.10)

Commonly used terms and abbreviations

Adverse events: An adverse outcome that occurs during or after participation in an intervention but is not necessarily caused by it.

Blinding: The process of preventing those involved in a trial from knowing to which comparison group a particular participant belongs.

BMI – Body Mass Index: A simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m^2)

BOCF - Baseline observation carried forward: a method to handle missing data from treatment discontinuation, where people with missing data at follow-up are assumed to weigh the same amount as they did at the start of the study (for detailed explanation, see Appendix 1).

BWMPs - Multicomponent behavioural weight management programmes: To be considered a multicomponent BWMP, a programme must include diet, physical activity, and behavioural therapy components (for example, counselling sessions).

CI - Confidence Interval: A measure of the uncertainty around the main finding of a statistical analysis. It provides an estimated range of values within which the population parameter lies for a set percentage of certainty.

Control: A participant in the arm that acts as a comparator for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention. (For control classifications see the Methods section.)

Completer: An individual who provides, in the context of this report, weight-loss data at the follow-up examination being assessed.

External validity: The extent to which results provide a correct basis for generalisations to other circumstances.

Follow-up: The observation over a period of time of study/trial participants to measure outcomes under investigation

HEI – Healthy Eating Index: measure of diet quality that assesses conformance to federal dietary guidance (US)

Heterogeneity: The quality of diversity, or differences, within a set of data.

Intention-to-treat: A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of

participants, which may disrupt the baseline equivalence established by randomisation and which may reflect non-adherence to the protocol.

Kcal – kilocalories (Calories)

OECD - Organisation for Economic Co-operation and Development: A multidisciplinary international body made up of 30 member countries that offers a structure/forum for governments to consult and co-operate with each other in order to develop and refine economic and social policy.

LTPA – leisure time physical activity: exercise, sports, recreation or hobbies not associated with an individual's job, transportation, or household duties.

MET – Metabolic Equivalent of Task: measure of energy expended during physical activity (ratio of metabolic rate to a reference metabolic rate)

Quality: A notion of the methodological strength of a study, indicating the extent of bias prevention (judgement criteria outlined in Methods section)

Randomisation: The process of randomly allocating participants into one of the arms of a controlled trial. There are two components to randomisation: the generation of a random sequence, and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence.

RCT - Randomised Control Trial: An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. It is considered the Gold standard experimental design for clinical studies.

SD - Standard deviation: A statistic that describes the spread or dispersion of a set of observations around the mean value, calculated as the average difference from the mean value in the sample.

SE - Standard error: Like standard deviation this is a measure of the spread of data around the mean; however, it considers variation in the sample statistic over all possible samples of the same size. The standard error decreases as the sample size increases. (p19 – needs full wording added)

Statistical significant: A result that is unlikely to have happened by chance. The usual threshold for this judgement is a result would occur by chance with a probability of less than 0.05 (5%).

Sub-group analysis: An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial.

Systematic review: A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies

TEE – total energy expenditure: A calculation based on a number of parameters to calculate how many kcal a person expends in a day.

VO_2 max: maximum capacity of a person's body to transport and use oxygen during exercise, a measure of physical fitness.

GLOSSARY OF SEARCH DATABASES

BIOSIS: An electronic database of life sciences and biomedical literature covering 5,000 journals, as well as non-journal literature from 100 countries. Years of coverage – 1926 to present.

EMBASE - Excerpta Medica database: A European-based electronic database of pharmacological and biomedical literature covering 3,500 journals from 110 countries. Years of coverage - 1974 to present.

MEDLINE (MEDlars onLINE): An electronic database produced by the United States National Library of Medicine. It indexes millions of articles in selected (about 3,700) journals. It is available through most medical libraries, and can be accessed on CD-ROM, the Internet and by other means. Years of coverage - 1966 to present.

Cochrane Database of Systematic Reviews (CDSR): One of the databases in The Cochrane Library. It brings together all the currently available Cochrane Reviews and Protocols for Cochrane Reviews. It is updated quarterly, and is available via the Internet and CD-ROM.

Cochrane Central Register of Controlled Trials (CENTRAL): An electronic database that includes details of published articles taken from bibliographic databases (notably MEDLINE and EMBASE), and other published and unpublished sources. These include a collection of controlled trials and other items from each Cochrane Review Group.

Conference Proceedings Citation Index (CPCI): An electronic database of proceedings of international conferences, symposia, seminars, colloquia, workshops, and conventions. Years of coverage - 1990 to present.

Database of Abstracts of Reviews and Effects (DARE): An electronic database of systematic reviews that evaluate the effects of health care interventions and the delivery and organisation of health services

Health Technology Assessment database (HTA): An electronic database of completed and on-going health technology assessments. A resource of for identifying grey literature as much of the information it contains is generally only available directly from individual funding agencies.

PsychInfo: An electronic database of behavioural science and mental health literature. Years of comprehensive coverage - 1880 to present.

Science Citation Index (SCI): An electronic database of literature from 150 disciplines. Years of coverage - 1900 to present.

Introduction

Clarification of scope

This review aims to examine the efficacy of multi-component lifestyle interventions for the treatment of obesity and the relative importance of elements of these interventions. This review therefore covers only those interventions that include diet, exercise, and behavioural therapy components, which from here on will be described as multi-component behavioural interventions. Interventions which include referral to individual clinicians, management of associated conditions, surgery, and pharmacological treatments are excluded. The review is restricted to interventions that are judged to be feasible for implementation in the UK.

For the remainder of the document, multi-component behaviour weight management programs (BWMPs) will be defined as those which focus on reducing energy intake, increasing physical activity and changing behaviour. These may include weight management programmes, courses or clubs:

- specifically designed for adults who are obese or overweight
- that accept adults through self-referral or referral from a health practitioner
- provided by the public, private or voluntary sector
- based in the community, workplaces, primary care or online.

Review questions

The review of effectiveness has been split into two components, Review 1a and Review 1b. Review 1a is presented here.

Review 1a (ie this review) addresses the primary question of review 1, namely:

- How effective and cost-effective are multi-component lifestyle weight management programmes for adults?

It also seeks to answer secondary questions relating to these programmes, should data be available:

- How does effectiveness vary for different population groups (for example, men, black and minority ethnic or low-income groups)?
- How does effectiveness and cost effectiveness vary based on the components of the individual programmes?
- Are there any adverse or unintended effects associated with the use of BWMPs?

To answer the above questions, Review 1a focuses only on those studies which involve a comparison of intervention versus control. Review 1a addresses the question how does effectiveness and cost effectiveness vary based on the components of the individual programmes in a limited way. It addresses this by comparing types of programmes. Specifically, review 1a will consider the effect of programme aim (weight loss, diabetes prevention, etc.), set energy goals, supervised exercised, in person versus remote modes of delivery, and intensity of intervention. Review 1b (to be considered at PDG2) will expand upon the question, “How does effectiveness and cost effectiveness vary based

on the components of the individual programmes?" It will examine a larger number of components than those covered in Review 1a, including behavioural change techniques, and will also include studies that do not have a control arm as fits our definition (namely, those that compare a BWMP with a diet or exercise programme, or those that compare two or more BWMPs; this represents nine additional studies - three from database searches and six included studies from Loveman - and additional arms from six of the studies included in Review 1a).

Factors which influence the effectiveness, implementation or sustainability of initiatives may be either positive ('facilitators') or negative ('barriers'), and will also be explored when assessing the included studies. However, detailed questions about key components of BWMPs, their implementation, user experience, and facilitators and barriers (overall and for specific population groups) will be addressed separately in review 2 (to be considered at PDG3). Review 1 will focus only on the effectiveness of the BWMPs.

Existing systematic reviews in this area

A systematic review of multi-component behavioural weight loss programmes

Together, reviews 1a and b an update of a previously published review (Loveman 2011[2]). Though included studies from Loveman 2011 have been incorporated into the findings of this update review, rather than treated separately, Loveman 2011 is briefly summarised and appraised below.

Loveman 2011 aimed to assess the clinical and cost-effectiveness of multi-component weight management programmes (BWMPs) in overweight and obese adults. These programmes include diet, exercise and behavioural components. Loveman conducted a sensitive search strategy used in 10 electronic databases, and the authors also screened reference lists and contacted experts in the field. The most recent search was run in December 2009. Screening of titles and abstracts was done by two reviewers, with inclusion criteria agreed before screening started. Following screening, 12 randomized controlled trials were included. The review did not pool studies due to heterogeneity, and hence results are reported as narrative descriptions only. In general, BWMPs tended to produce greater weight loss than in comparator groups, though differences were modest and the authors note further work is needed to determine if the weight lost was clinically significant. Where measured, it appeared that most groups began to regain weight at longer follow-ups. The authors also ran a separate search for cost-effectiveness studies, but none were found that met the inclusion criteria. Two cost effectiveness papers found BWMPs to be cost effective, but methodological quality was deemed to be poor.

Despite being a relatively robust review in terms of searches, data extraction, and data synthesis, there are limitations to the methods used by Loveman et al. Firstly, the review did not include

[2] Loveman E, Frampton GK, Shepher J, Picot J, Cooper K, Bryant J, et al. The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review. *Health Technology Assessment* 2011;15(2).

studies with less than 18 months follow-up. As many weight loss studies follow-up participants only for 12 months, our review incorporates findings from these studies, as well (see methods section for further discussion). Loveman et al also does not include those behavioural interventions whose primary aim is diabetes prevention. As weight management is central to these studies, and as many diabetes prevention initiatives incorporate the same approaches to dietary and physical activity as seen in weight loss interventions, our update review incorporates such studies. Loveman also reported the weight loss data as presented in each study report. However, all studies suffer loss to follow up and how these losses are dealt with affects the apparent weight loss and difference between intervention and control. In our update review, we have converted outcome data to weight change in kilograms using a baseline observation carried forward approach to enable pooling and comparison of included studies (described further below). Finally, Loveman narratively reported results from included studies but does not pool results or present a meta-analysis. This limits the ability of the review to draw conclusions or make comparisons between studies. Our expanded inclusion criteria resulted in an additional eight studies, published prior to the Loveman search, being included in this update review. A further 11 recent studies included in our review would have been excluded according to Loveman's original criteria.

Other systematic reviews

As part of our review process, we screened 39 further systematic reviews for relevant references. The aims of some were not relevant to this review (e.g., the effect of workplace health interventions on employee presenteeism). Key findings from the 33 reviews that evaluated behavioural programmes (with or without pharmacotherapy) and reported on one or more health outcomes are summarised below.

Citation	Key findings
Al-Zadjali, M., Keller, C., Larkey, L.K., Albertini, L., & Center for Healthy Outcomes in Aging 2010. Evaluation of intervention research in weight reduction in post menopausal women. *Geriatric Nursing*, 31, (6) 419-434	All 15 included studies to reduce weight in post-menopausal women resulted in a positive weight management outcome, though external validity was limited. Overall, varying intensities of exercise when combined with reduced energy or meal replacement diets were shown to be effective.
Anderson, L.M., et al. 2009. The Effectiveness of Worksite Nutrition and Physical Activity Interventions for Controlling Employee Overweight and Obesity A Systematic Review. *American Journal of Preventive Medicine*, 37, (4) 340-357	At six to twelve months follow-up, worksite weight loss and physical activity programs can achieve modest weight loss in both men and women, across a range of worksite settings. Most of the studies used informational and behavioural strategies to influence diet and physical activity, and fewer studies modified the work environment.
Armstrong, M.J., Mottershead, T.A., Ronksley, P.E., Sigal, R.J., Campbell, T.S., & Hemmelgarn, B.R. 2011. Motivational interviewing to improve weight loss in overweight and/or obese patients: a systematic review and meta-analysis of randomized controlled trials. *Obesity Reviews*, 12, (9) 709-723	Motivational interviewing was associated with greater weight loss than in controls in a meta-analysis of 11 studies, and appears to enhance weight loss in overweight and obese patients.
Baker, M.K., Simpson, K., Lloyd, B., Bauman, A.E., Fiatarone Sigh, M.A. 2011. Behavioural strategies in diabetes prevention programs: a systematic review of randomized controlled trials. Diabetes Research and Clinical Practice, 91, 1-12.	Lifestyle interventions were successful overall in reducing the incidence of type 2 diabetes. A robust behavioural change strategy is an essential part of a lifestyle modification program, as opposed to an 'information only' or general advice program.

Citation	Key findings
Dombrowski, S.U., Avenell, A., & Sniehotta, F.F. 2010. Behavioural interventions for obese adults with additional risk factors for morbidity: systematic review of effects on behaviour, weight and disease risk factors. [Review]. *Obesity Facts*, 3, (6) 377-396	Behavioural interventions in obese adults with additional risk factors for morbidity were found to have a consistent and modest effect on behavioural outcomes, weight loss, and cardiovascular risk factors over time. There is room for improvement and further research should aim to identify the most effective means of inducing behaviour change in at-risk populations.
Dyson, P.A. 2010. The therapeutics of lifestyle management on obesity. *Diabetes Obesity & Metabolism*, 12, (11) 941-946	Lifestyle interventions have a modest but significant effect on weight loss, but there is little evidence to indicate what interventions are most effective. The combination of diet, exercise and behavioural interventions appears to be most effective for treatment and prevention of obesity.
Fortier, M.S., Duda, J.L., Guerin, E., & Teixeira, P.J. 2012. Promoting physical activity: development and testing of self-determination theory-based interventions. [Review]. *International Journal of Behavioral Nutrition & Physical Activity*, 9, 20	Three randomized controlled trials that focussed on increasing physical activity through interventions based on self-determination theory support the use of this model for behavioural weight loss interventions. There were a number of limitations in each of the included studies, and the authors call for further quantitative research in this area.
Gillies, C.L. et al. 2007. Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: systematic review and meta-analysis. BMJ, 334, (7588) 299.	Lifestyle and pharmacological interventions can reduce the rate of progression to type 2 diabetes, and lifestyle interventions can be at least as effective as drug treatment.
Groeneveld, I.F., Proper, K.I., van der Beek, A.J., Hildebrandt, V.H., & van Mechelen, W. 2010. Lifestyle-focused interventions at the workplace to reduce the risk of cardiovascular disease - a systematic review. *Scandinavian Journal of Work Environment & Health*, 36, (3) 202-215	Strong evidence from 31 randomized controlled trials was found for the effect of lifestyle interventions delivered at the workplace on body fat, a strong predictor of cardiovascular disease risk. Among 'at risk' populations there was strong evidence for a positive effect on body weight. Supervised exercise interventions appeared to be the least effective workplace intervention strategy.
Han, T., Tajar, A., & Lean, M. 2011. Obesity and weight management in the elderly. *British Medical Bulletin*, 97, (1) 169-196	A combination of exercise and modest energy restriction appears to be the best method of reducing fat mass and preserving muscle mass in the elderly. Age is not an obstacle to the delivery of such interventions.
Harrington, M., Gibson, S., & Cottrell, R.C. 2009. A review and meta-analysis of the effect of weight loss on all-cause mortality risk. *Nutrition Research Reviews*, 22, (1) 93-108	Data from 26 prospective studies monitoring subsequent weight loss by diet and lifestyle change showed that intentional weight loss had a neutral effect on all-cause mortality. Data showed a small benefit for individuals with an obesity related risk factor, and a particularly strong benefit in obese people with additional risk factors. Intentional weight loss appeared to be associated with slightly increased mortality for individuals without obesity related risk factors and for those who were overweight but not obese. There was no evidence for weight loss having an effect on mortality among healthy obese people.
Jinks et al. 2011. Obesity interventions for people with a learning disability: an integrative literature review. Journal of Advanced Nursing, 67, (3) 460-471	Of 12 studies of non-surgical and non-pharmacological weight loss interventions aimed at people with a learning disability, eight detected an effect on BMI, but studies were variable and a meta-analysis was not possible. The authors conclude that behavioural interventions are important to ensure success of weight loss interventions in people with learning disabilities.
Khoo, S. & Morris, T. 2012. Physical Activity and Obesity Research in the Asia-Pacific: A Review. *Asia-Pacific Journal of Public Health*, 24, (3) 435-449	No conclusions could be drawn on the impact of behavioural interventions for weight loss in the Asia-Pacific region. The authors conclude more research is needed.
Kirk, S.F.L., Penney, T.L., McHugh, T.-L.F., & Sharma, A.M. 2012. Effective weight management practice: a review of the lifestyle intervention evidence. [References]. *International Journal of Obesity*, 36, (2) 178-185	Multi-component interventions are likely to be the most effective strategies for weight management. Interventions should be delivered over the long term and should be tailored to individuals. The use of web-based technologies to support traditional models of care is a promising practice.

Citation	Key findings
Kodama, S., Saito, K., Tanaka, S., Horikawa, C., Fujiwara, K., Hirasawa, R., Yachi, Y., Iida, K.T., Shimano, H., Ohashi, Y., Yamada, N., & Sone, H. 2012. Effect of web-based lifestyle modification on weight control: A meta-analysis. [References]. *International Journal of Obesity*, 36, (5) 675-685	Overall, evidence from 23 studies showed that using the internet had a modest but significant effect on weight loss compared to non-web user control groups. Stratified analyses indicated that using the internet as an adjunct to traditional care was effective, but that using it as a substitute for face-to-face interactions was unfavourable. The effect was diminished in studies with longer educational periods. The internet appeared to be more effective for initial weight loss than for subsequent weight maintenance.
Laddu, D., Dow, C., Hingle, M., Thomson, C., & Going, S. 2011. A Review of Evidence-Based Strategies to Treat Obesity in Adults. *Nutrition in Clinical Practice*, 26, (5) 512-525 available from: WOS:000295222800003	Many individuals lose 5-10% of their baseline weight through behavioural weight loss interventions that combine diet and exercise. There was evidence of similar success with weight loss prescriptions, but not with over-the-counter medications and supplements. Commercial weight loss programs have been shown to be effective but a lack of comparable evidence limits recommendations of one program over another.
Leao, L.S.C.D., de Moraes, M.M., de Carvalho, G.X., & Koifman, R.J. 2011. Nutritional Interventions in Metabolic Syndrome A Systematic Review. *Arquivos Brasileiros de Cardiologia*, 97, (3) 260-265 available from: WOS:000297311900018	Data from 15 studies showed that interventions involving low-calorie diets and exercise were more effective for treating metabolic syndrome than diet alone or diets that did not involve energy restriction, with or without an exercise component.
Lo, P.R., Lai, J., Hildebrandt, T., & Loeb, K.L. 2010. Psychological treatments for obesity in youth and adults. *Mount Sinai Journal of Medicine.77 (5) (pp 472-487), 2010.Date of Publication: September 2010.* (5) 472-487	Data supports the use of behavioural weight loss interventions and family-based interventions. Despite limitations in generalizability across demographic variables, including age and severity of overweight status, overall the evidence shows that psychological interventions play an important role in achieving and maintaining weight loss.
McCombie L, Lean MEJ, Haslam D. 2012. Effective UK weight management services for adults. Clinical Obesity 2(3-4):96-102	The effectiveness of evidence-based approaches for weight loss varies based on setting and the stage of disease process of obesity. In individuals with relatively low BMIs and few medical complications, self-referral to commercial agencies is a reasonable first step. For more severely obese people (BMI>35), evidence is largely lacking for commercial services, but the community-based Counterweight programme was found to be effective and cost-effective in maintaining weight loss. For more complicated and resistant obesity, referral to secondary care can generate weight loss in the short term but evidence is lacking on longer-term effectiveness.
Moutzouri, E., Tsimihodimos, V., Rizos, E., & Elisaf, M. 2011. Prediabetes: To treat or not to treat? *European Journal of Pharmacology.672 (1-3) (pp 9-19), 2011.Date of Publication: 15 Dec 2011.* (1-3) 9-19	Both metformin and lifestyle interventions can prevent the development of type 2 diabetes in subjects in with pre-diabetes. More research is needed to establish if the biochemical improvement translates into actual clinical benefit.
Mulholland, Y., Nicokavoura, E., Broom, J., & Rolland, C. 2012. Very-low-energy diets and morbidity: a systematic review of longer-term evidence. *British Journal of Nutrition*, 108, (5) 832-851 available from: WOS:000308365600009	Evidence from 32 trials demonstrates that significant weight loss and improvements in blood pressure, waist circumference and lipid profile can persist in the longer term (12 months to 5 years) following use of a very-low-energy diet. Heterogeneity between studies limits the ability to guide best practice.
Norris, S.L., Zhang, X., Avenell, A., Gregg, E., Schmid, C.H., & Lau, J. 2005. Long-term non-pharmacological weight loss interventions for adults with prediabetes. *Cochrane Database of Systematic Reviews* (2)	Studies of weight loss interventions using dietary, physical activity, or behavioural interventions produced significant weight loss and prevention of type 2 diabetes in people with pre-diabetes. Pooled together, four studies comparing an intervention to usual care found a significant decrease in weight at 12 months. This effect persisted in three studies measuring weight at two years.
Osei-Assibey, G., Kyrou, I., Adi, Y., Kumar, S., & Matyka, K. 2010. Dietary and lifestyle interventions for weight management in adults from minority ethnic/non-White groups: A systematic review. *Obesity Reviews* (11) 769-776	Nineteen studies were identified that investigated weight management interventions in adults from minority groups. Most of the interventions proved effective, but the quality of the evidence was limited, and the authors conclude that better and long-term studies are needed.

Citation	Key findings
Paulweber, B., et al. 2010. A European Evidence-Based Guideline for the Prevention of Type 2 Diabetes. *Hormone and Metabolic Research*, 42, (Suppl. 1) S3-S36	Obesity and sedentary lifestyle are the main modifiable factors for prevention of type 2 diabetes. Lifestyle interventions and strategies that create health promoting environments should be considered first line options. There are a number of pharmacotherapies that are second line options. Prevention using lifestyle modification in high-risk populations is cost-effective.
Pearson, E.S. 2012. Goal setting as a health behavior change strategy in overweight and obese adults: a systematic literature review examining intervention components. [Review]. *Patient Education & Counseling*, 87, (1) 32-42	Goal setting can be useful for changing behaviour in overweight and obese adults. However, data from the 18 included studies was limited as different intervention components were often implemented concurrently. The authors were unable to judge which were independently responsible for positive changes.
Renzaho, A.M., Mellor, D., Boulton, K., & Swinburn, B. 2010. Effectiveness of prevention programmes for obesity and chronic diseases among immigrants to developed countries - a systematic review. [Review] [27 refs]. *Public Health Nutrition*, 13, (3) 438-450	Overall, findings from the 13 included studies showed that culturally tailored interventions can prevent the development of type 2 diabetes and produce better outcomes than generalised interventions. Of the six studies that reported anthropometric data, only two detected improvement in weight or body fat measures. The authors conclude more research is needed.
Sanderson, P.W., Clemes, S.A., & Biddle, S.J. 2011. The correlates and treatment of obesity in military populations: a systematic review. [Review]. *Obesity Facts*, 4, (3) 229-237	There is a deficit in knowledge concerning treatment and lack of engagement with lifestyle correlates to obesity in military populations. Successful treatment interventions were supported by trained personnel and involved exercise, information on healthy eating, behaviour modification, self-monitoring, relapse prevention and structured follow-up.
Stehr, M.D. & von, L.T. 2012. Preventing weight gain through exercise and physical activity in the elderly: a systematic review. [Review]. *Maturitas*, 72, (1) 13-22	Exercise was associated with weight loss in all intervention studies conducted in the elderly overweight, and was associated with weight maintenance in most observational studies. Physical activity interventions can also preserve lean body mass in this population and are therefore important for the balance between positive and negative effects of weight reduction later in life.
Venditti, E.M. & Kramer, M.K. 2012. Necessary Components for Lifestyle Modification Interventions to Reduce Diabetes Risk. *Current Diabetes Reports*, 12, (2) 138-146	Behavioural interventions for diabetes prevention require a minimum of four to six months of frequent intervention contact to induce weight loss of at least 5% of initial body weight. Weekly contact during the first several months, followed by regular but less frequent contact, appeared necessary for participants to adopt and enact behavioural self-regulatory skills. Feedback and social support are crucial components of lifestyle modification programs. In-person contact was associated with the largest effect size but may not be a necessary component.
Vetter, M.L., Faulconbridge, L.F., Webb, V.L., & Wadden, T.A. 2010. Behavioral and pharmacologic therapies for obesity. *Nature Reviews Endocrinology*, 6, (10) 578-588	Lifestyle interventions including diet, physical activity and behaviour therapy can induce a mean loss of 7-10% initial body weight in obese people, which can reduce the risk of developing type 2 diabetes in people with impaired glucose tolerance. In some patients, pharmacotherapy is recommended as an adjunct to lifestyle modification.
Wieland, L.S., Falzon, L., Sciamanna, C.N., Trudeau, K.J., Brodney, S., Schwartz, J.E., & Davidson, K.W. 2012. Interactive computer-based interventions for weight loss or weight maintenance in overweight or obese people. *Cochrane Database of Systematic Reviews* (8)	Compared to no intervention or minimal contact controls, interactive computer-based interventions are effective for weight loss and weight maintenance, but are less effective than in-person interventions. However, the difference in weight loss between in-person and computer-based interventions is relatively small and brief, and the clinical significance is unclear.
Witham, M.D. & Avenell, A. 2010. Interventions to achieve long-term weight loss in obese older people: a systematic review and meta-analysis. [Review] [27 refs]. *Age & Ageing*, 39, (2) 176-184	Meta-analysis of seven studies aiming to achieve long-term weight loss in obese older people found a modest but significant effect on weight loss at one year. Overall, there is a lack of high quality evidence to support the efficacy of weight loss programmes in this population.

Citation	Key findings
Yoong S et al. 2012. A systematic review of behavioural weight-loss interventions involving primary-care physicians in overweight and obese primary-care patients (1999–2011). Public Health Nutrition, Oct 26, 1-17 (epub ahead of print).	High-intensity weight loss counselling delivered by primary care physicians was found to induce moderate but not clinically significant weight loss. High-intensity interventions delivered by non-physicians, meal replacements delivered alongside dietician counselling, and referral to commercial weight loss programmes accompanied by regular monitoring in primary care produced clinically significant weight loss. Interventions delivered by dietitians appeared effective regardless of intensity. Overall, there was a lack of evidence and the quality of some of the 16 included studies was poor.

Understanding how weight loss is presented

All studies suffer loss to follow up, which means that participants who are enrolled in a study do not turn up to be weighed at the end of the study or at various interim points. Individual trials vary in what they do about this and adopt different practices. One option is to present data only on people who do turn up to be weighed. In weight control literature, this is usually called a completer analysis, which might be taken to imply these are people who completed the intervention, but this is not actually the case. The only other option is to impute a weight for people who fail to turn up. This has various attractive properties because it preserves what is known as the intention to treat approach and is unbiased, whereas the completer approach is potentially biased. However, there is no absolutely best way to impute data on the people whose data are missing and studies vary in how they do this. The imputation or decision not to impute data can have important consequences on how much weight loss a programme appears to achieve and hence its effectiveness and cost-effectiveness. In this review we used a method of imputation called baseline observation carried forward (BOCF), which assumes that the weight of everyone who did not turn up for follow up did not change from their weight at the beginning of the study. There are strong reasons to believe that people who do well in programmes are more likely to turn up at follow up.

Unlike Loveman and, to our knowledge, most reviews, we calculated BOCF figures from reports which used other approaches to presenting the data. This means that all weight loss data presented in this report are presented on a like-for-like basis. A fuller and more detailed explanation of different methods of imputation is shown in Appendix 1.

Methods

The review protocol was agreed with NICE prior to commencing work and can be found in Appendix 2. Key methods are summarised below. This review is an update of an existing review, published in 2011, and therefore follows as closely as possible the scope and format of the original review.[3] Methods used were in line with those specified by NICE in 'Methods of the development of NICE public health guidance (second edition, 2009).'

Inclusion and exclusion criteria

We followed similar criteria for including and excluding studies as used in the Loveman 2011 report, with two key changes: we did not include BWMPs that involved medications for obesity of any type, unless their use was not part of the BWMP and was comparable in both intervention and control groups, and we included studies with 12 month follow-up or longer (Loveman required a minimum of 18 months follow-up). The revised inclusion criteria are listed below.

Population

- Adults (≥ 18 years) classified as overweight or obese, i.e. people with a BMI of ≥ 25 kg/m2 and ≥ 30 kg/m2, respectively, or a BMI of ≥ 23 kg/m^2 in Asian populations.[4] *Where overweight or obesity was not an inclusion criterion, we included studies where greater than 80% of each arm was overweight/obese (note, this differs from Loveman, who did not specify guidelines for dealing with such studies).*
- Studies in children, pregnant women, and people with eating disorders were not included, nor were studies specifically in people with a pre-existing medical condition such as diabetes, heart failure, uncontrolled hypertension or angina. *We did, however, include studies in specific at-risk populations, most notably studies aiming for diabetes prevention, conducted in populations with elevated fasting glucose or impaired glucose tolerance (but without diabetes mellitus). This also differs from Loveman's approach: Loveman excluded diabetes prevention studies.*

Intervention

- Structured, sustained multi-component weight management programmes (i.e. the intervention had to be a combination of diet and physical activity with a behaviour change strategy to influence lifestyle).
- Components of the programme had to be clearly specified (i.e. details provided of the diet, behavioural definition, and exercise components; see below).
- Programmes that included a long-term follow-up of more than 12 months. *Unlike Loveman, who required follow-up of 18 months or longer.*

[3] Loveman

[4] The inclusion of BMI ≥ 23 kg/m^2 in Asian populations differs slightly from existing NICE guidance on identification of obesity (recommendation 1.2.2.8, http://publications.nice.org.uk/obesity-cg43/guidance#clinical-recommendations). There is also some guidance in development on BMI for BMEGs (see http://guidance.nice.org.uk/PHG/69). These minor discrepancies do affect the applicability of our results.

- The programme was delivered in the health sector, in the community or commercially.
- Multi-component programmes that involved the use of any surgery or medication, over-the-counter or otherwise, were excluded.
    - Interventions incorporating other lifestyle changes such as efforts at smoking cessation or reduction of alcohol intake were not included.

Unlike Loveman, we excluded studies which only looked at a specific component of an intervention so that comparator interventions differed only by a single element, for example presence or absence of self monitoring, or differences in dietary composition.

Comparators

The comparator had to fit into one of the following groups

1. No intervention at all or leaflet/s only[5]
2. Discussion/advice/counselling in one-off session +/-leaflet
3. Seeing someone more than once for discussion of something other than weight loss.
4. Seeing someone more than once for weight management, person untrained +/- leaflets

This is in contrast to Loveman, where the control condition was normal practice (as defined by the study).

In a later review (1b) we will also compare multicompent behavioural weight loss programmes to

- Single-component weight management strategies, and other structured multi-component weight management programmes.

Outcomes

- Studies were required to include a measure of weight loss. Where BMI, waist circumference or adverse events are also reported, this is recorded in the evidence tables.

Types of studies

- Randomized controlled trials (RCTs) only.
- Studies published as abstracts or conference presentations were only included if sufficient details were presented to allow an appraisal of the methodology and the assessment of results to be undertaken.

Location

- Undertaken in any setting (i.e. community, commercial, primary care, online).
- Studies conducted in Organisation for Economic Co-operation and Development (OECD) countries were considered for inclusion. In the instance that a study was conducted in an OECD country but the reviewers and advisory panel judged that the intervention would not be feasible for implementation in the UK, the reviewers consulted with CPHE regarding its inclusion.
- Studies conducted in non OECD countries were excluded.

[5] Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

Specification of components of intervention

Loveman et al required that, in order for a study to be included, at least two items under each of the below components (diet, exercise, and behaviour modification) had to be specified.

Diet

- type of diet
- calories
- proportion of diet (e.g. proportion of diet made up of fats, protein, carbohydrate)
- monitoring

Exercise

- mode
- type
- frequency/length sessions
- delivered by
- level of supervision
- monitoring

Behaviour modification

- mode
- type
- content
- frequency/length sessions
- delivered by.

We required these same criteria, but we modified them as follows. Where studies were multicomponent but the study report did not meet the above criteria, we followed the approach below:

- If the study reported on the effectiveness of a weight loss programme , we searched online for details of the weight loss programme and used these to classify the study components. Where insufficient details were available online, we contacted the programme directly, specifying that a response would be needed by 20 December 2012.
- If the details of the programme were not available online we emailed study authors with a template email asking them to provide any details they have on the above elements, specifying that a response was needed by 20 December 2012.
- Where authors did not respond by the deadline specified, provided insufficient information, or where we could not find a current e-mail address, the study was excluded, with the reason for exclusion clearly identified.
- For consistency, we followed this same approach for studies that Loveman had listed as excluded on the basis of insufficient intervention detail.

Search methods for identification of studies

Database searches

We searched BIOSIS, the Cochrane Database of Systematic Reviews, CENTRAL, the Conference Proceedings Citation Index, the Database of Abstracts of Reviews and Effects (DARE), Embase, the Health Technology Assessment database, Medline, PsychInfo, and Science Citation Index for references relating to weight loss programmes. This is an update of an existing review and as such the existing search strategy as published in Loveman 2011 was used, but with some minor changes and with results restricted to those added after the date at which Loveman conducted their most recent search.

The literature search was run on November 14, 2012 by NICE with input from one reviewer. Full search strategies can be found in Appendix 3. The only significant deviation from Loveman's strategy was minor adjustments to the Embase search, as described in Appendix 3. In summary, after Loveman conducted their final search in 2010, Embase imported a large number of records from Medline. This meant that running Loveman's search on Embase returned over 11,000 records. Therefore, in order to increase the specificity of the search, we replaced Loveman's original study type filter with an RCT filter designed by the Cochrane Collaboration[6] and a systematic review filter developed by the Scottish Intercollegiate Guidelines Network.[7]

Non-database searches

In addition to the database searches described above, we also screened references from three additional sources: reference lists in systematic reviews, documents received via the NICE call for evidence, and studies excluded from Loveman that we wished to re-examine (described below). We used the same approach to screening and extraction as we did for those references found in our database searches.

Studies excluded from Loveman

There were three categories of studies which Loveman et al excluded but that we wished to re-examine, namely:

- Those with 12 to 18 months follow up from baseline. Loveman set their minimum follow-up period as 18 months. We moved this to 12 months because a large number of studies that were relevant to the UK had 12 month follow up. To account for this, we screened all of the studies that Loveman had listed as excluded on the basis of length of follow-up.
- Diabetes prevention studies. These were not explicitly excluded from Loveman and hence there was no means of gathering a quick list of these studies. Instead, to ensure we had not missed major trials in this area published prior to the period of our updated search, we used published systematic reviews of diabetes prevention trials to identify relevant studies.

[6] http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/chapter_6/6_3_2_2_what_is_in_the_cochrane_central_register_of_controlled.htm

[7] http://www.sign.ac.uk/methodology/filters.html#systematic

- Studies which reported limited intervention detail in the published report. To ensure consistency of approach, for all studies which Loveman had excluded on this basis, we followed the approach detailed above (searching for additional information, e-mailing study authors, etc).

Study selection process

Assessment for inclusion was initially undertaken at title and/or abstract level (to identify potential papers/reports for inclusion) by a single reviewer (and a sample of over 10% checked by a second reviewer), and then by examination of full papers. A third reviewer was used to help adjudicate inclusion decisions in cases of disagreement. Where the research methods used or type of initiative evaluated were not clear from the abstract, assessment was based upon a reading of the full paper, conducted by two reviewers.

Quality assessment

We critically appraised the literature for inclusion using a checklist based on the York CRD approach and as described in the CPHE manual, but did not evaluate included studies on the basis of blinding. Internal and external validity were graded ++, + or – for each study based on the following criteria.

Internal validity (study quality)

Studies were rated ++ if all or most of checklist criteria were fulfilled and conclusions were judged very unlikely to alter; + if some criteria were fulfilled and conclusions were unlikely to alter; and - if few or no criteria were fulfilled and conclusions were likely or very likely to alter. This was based on:

- Randomization and allocation procedures
- Evidence of selective reporting
- Attrition (at 12 months, or at the closest point after 12 months if 12 months was not reported , if either arm had <50% followed up or the difference in percentage followed up between arms was >20%, we reduced the quality score)

External validity

As for internal validity, studies were rated ++, + or –. This was based on:

- If the participants were representative of the general population of people who are overweight (in part through assessing the number of those screened who were enrolled, where this information was provided)
- If the intervention required no extraordinary efforts to implement broadly in the UK. This meant, for example, that it required no special infrastructure or that the therapists were available in the UK and did not require lengthy training. It was not based upon judgements about whether the intensity of the intervention was likely to be funded or broadly acceptable in the UK.

Data extraction

Data extraction was conducted using a pre-specified data extraction form, which was piloted by two reviewers before its use. Data extraction and quality assessment were done independently by two reviewers, who then compared data extraction forms. Any discrepancies were resolved by discussion or, where needed, by referral to a third reviewer.

We had originally planned to rely on the data extraction conducted by Loveman et al for studies included in the 2011 review, but to ensure consistency across our analyses, we conducted full and duplicate data extraction on all Loveman included studies as well.

Extracting and calculating weight loss data

For each study, we extracted weight change as complete case data and baseline observation carried forward (BOCF) data reporting the mean, standard deviations (SD), and number of participants contributing. Where SDs were not presented we calculated them from 95% confidence intervals or standard errors (SEs). In most cases, BOCF was not presented and we calculated it from completer data as described recently.[8] In a few cases, neither BOCF nor completer data were presented and in this case we wrote to authors for the data. If authors did not respond, we strove to try to get data that was as comparable as possible to one or other of these ways of presenting data. We classified multiple imputed data as similar to completer data because it is primarily based on the weight of people that were followed up. We used the number followed up and treated these data as completer data in the standard calculation of BOCF. In a few cases, some useful data were missing that would allow us to calculate the mean weight change, SD, or know the number followed up. Where possible, we made reasonable assumptions to calculate these data and noted these assumptions in the evidence tables. Any such deviations from our standard calculation methods are listed in the evidence tables for individual studies. Where authors provided additional intervention or outcome data, this has been noted in the evidence tables.

Where weight, but not weight change, was provided, we calculated weight change and its SD using the information given, and noted this in the evidence tables. Where weight change was not published, mean weight change was calculated as follow up weight minus baseline weight. Standard deviation of weight change was also calculated by the reviewers using a standard formula. The formula requires a correlation coefficient for the correlation between end weight and starting weight. We derived this from complete datasets (Jebb 2011 and Jolly 2010)[9]. These correlations were used with the published mean and standard deviations for weight at baseline and follow-up to estimate the standard deviation of weight change.[10]

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[8] Kaiser KA, Affuso O, Beasley TM, Allison DB. Getting carried away: a note showing baseline observation carried forward (BOCF) results can be calculated from published complete-cases results. Int J Obes 2012; 36(6):886-889.

[9] For the intervention, the correlation between baseline weight and short follow up was r = 0.96 and long term follow up r = 0.88. For usual care arms, the correlation between baseline weight and short term follow up was r=0.97 and long-term follow up r=0.93.

[10] Using the following formula: SD (C) = √((SD (B)2 + SD (F)2) - (2 X r X SD (B) X SD (F)) [r= correlation coefficient, SD= standard deviation for the changes in means, B= baseline, F= final measurement, and C= change in mean weight measurement.]

Control coding

We grouped studies by the nature of the comparison, including the nature of the control group. The groupings are described below. We classified comparisons 1 through 4 as 'control', including them in Review 1a. Studies which only investigated 6 versus 5 or 6 versus 6 are not addressed in Review 1a and rather will be covered in Review 1b. The coding we used for weight loss interventions was:

1. No intervention at all or leaflet/s only[11]
2. Discussion/advice/counselling in one-off session +/-leaflet
3. Seeing someone more than once for discussion of something other than weight loss.
4. Seeing someone more than once for weight management, person untrained +/- leaflets
5. Behavioural weight loss programme comprising one of either diet or physical activity plus behavioural programme. 5 also includes seeing a health professional with special training on more than one occasion, such as a dietitian, who, because of their training will naturally create a weight loss programme with (in this case) dietary and behavioural elements (unless explicitly stated that they did not create a weight loss programme, in which case coded as 4). 5 also included seeing a professional with no basic training in weight loss management but who has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.
6. Behavioural weight loss programme comprising diet and physical activity plus behavioural programme. 6 also includes seeing a professional has no basic training in weight loss management but has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.

Data synthesis and presentation, including evidence statements

We presented evidence tables summarising key features of each included study, and narratively summarised the characteristics of the studies overall. We presented forest plots of mean difference for weight.

Quantitative data synthesis

We conducted meta-analyses in Review Manager 5.2 using 12 month BOCF weight change data where available, comparing intervention to control. Where 12 month data was not available, we used data from the closest follow-up point to 12 months available (10-18 months). Results are presented as mean difference and 95% confidence interval using a fixed effect model.

We present forest plots for each comparison and subgroup analysis. We also present a separate forest plot of those interventions that are widely available in the UK, and a forest plot of outcomes at 18 to 24 months. Weight change data at all available time points are displayed using weight curves for those studies which report weight at more than one follow-up point.

[11] Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

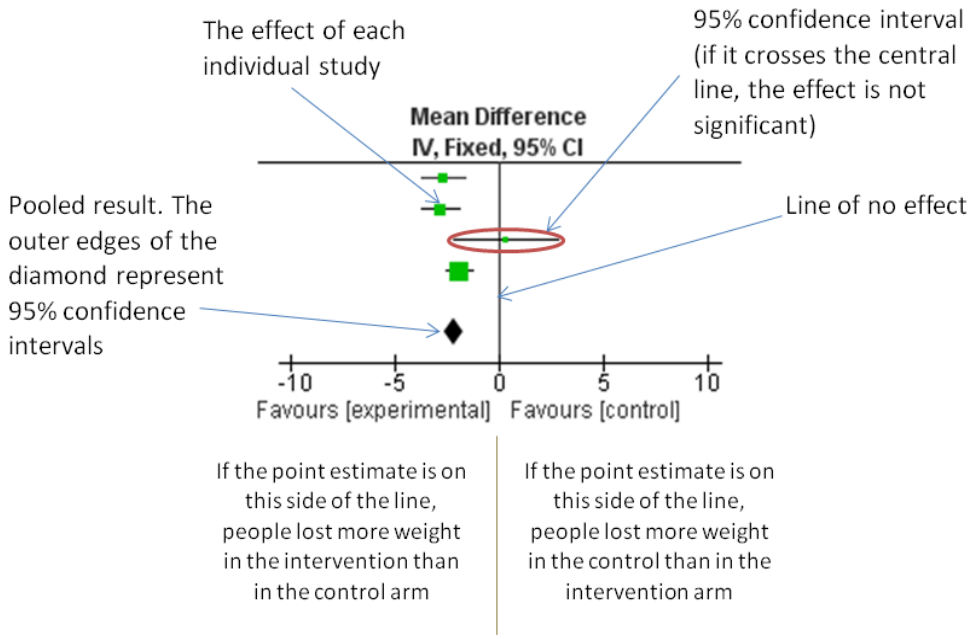
Subgroup analyses

Though reviews 1b and 2 will look in more depth at specific aspect of BWMPs, in review 1a we examined the effect of a number of variables through subgroup analyses in the below areas:

- Aim of programme (weight loss, diabetes prevention, other)
- Presence or absence of a specific energy goal
- Presence or absence of supervised exercise sessions
- Group versus individual versus group + individual delivery
- In-person versus remote delivery (with any intervention involving at least some face-to-face interaction coded as in-person)
- Length of intervention (up to 3 months, 4 to 6 months, and longer than 6 months; for analyses at 18 months, 6 to 12 months and greater than 12 months)
- Frequency of contact : weekly, fortnightly, monthly, every two months, less than every two months (calculated as number of sessions in first 12 months divided by number of weeks up to 52, unless a programme decreased in intensity over time and the most intensive phase lasted 2 months or longer, in which case code as that frequency)
- Nature of the control group (see control coding)

Interpreting forest plots

Forest plots display mean differences between intervention and control arms along with 95% confidence intervals. The mean difference (in this case, the difference in weight change between the intervention and control arms calculated using BOCF) is represented by a square for each study (the point estimate). The size of the square is dependent on the weight of the study: the bigger the square, the larger the number of participants in the study. The horizontal line running through the point estimate displays the confidence interval: this represents the range of values in which the actual effect size is likely to be located (95% probability that the actual effect size is somewhere along this line). The central vertical line in each forest plot is called the line of no effect. If a study's confidence interval crosses the line of no effect, it means we cannot say the difference in weight change between the intervention and control arm is likely not to be due to chance alone. If the point estimate and confidence interval lies to the left of the line of no effect, it means that significantly more weight was lost in the intervention arm than in the control arm, and if it lies to the right of the line of no effect, it means that significantly more weight was lost in the control arm than in the intervention arm. A diamond is used to represent where results from studies have been pooled. The width of the diamond shows the 95% confidence intervals of the pooled estimate. This is interpreted in the same way as explained for individual point estimates and confidence intervals above. The below diagram identifies key elements of a forest plot.


The effect of each individual study
95% confidence interval (if it crosses the central line, the effect is not significant)
Mean Difference
IV, Fixed, 95% CI
Pooled result. The outer edges of the diamond represent 95% confidence intervals
Line of no effect
-10
-5
0
5
10
Favours [experimental]
Favours [control]
If the point estimate is on this side of the line, people lost more weight in the intervention than in the control arm
If the point estimate is on this side of the line, people lost more weight in the control than in the intervention arm

Results

Description of studies

Results of the search

A flow chart detailing the search and screening process can be found in Figure 1. Our search retrieved 1935 references in total, 1691 of which were retrieved through database searches and 244 of which were retrieved from other sources. 1761 studies were excluded during title and abstract screening. Full text was retrieved and screened for 174 references. Of these, 74 were excluded (see

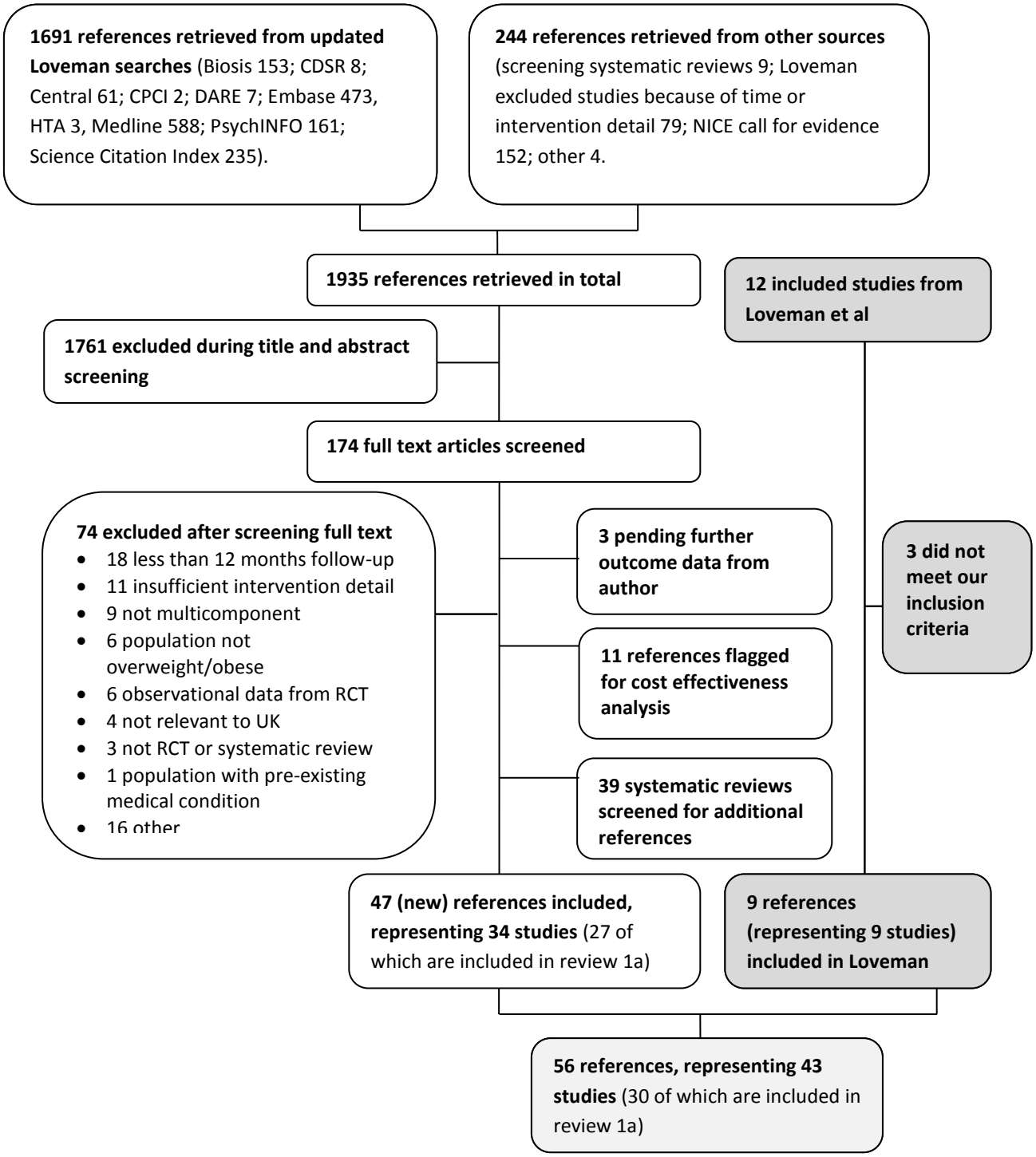
Excluded studies for further detail). Thirty-nine systematic reviews were screened for additional references, 11 references were flagged for cost-effectiveness analysis, three reference are pending due to the need for further outcome data from the author, and 47 references were included, representing 34 studies. Of these, 27 included a comparison of a behavioural weight management program versus a control (defined as no contact through to seeing someone with no training in weight management more than once, but excluding conditions where a health professional with relevant training was seen on one or more occasion or behavioural interventions with diet or exercise were delivered). No included studies were identified from the NICE call for evidence, though some references provided related to studies already retrieved via Loveman and database searches.

Included studies from Loveman 2011

In addition to the studies retrieved through our searches, we also re-evaluated (and re-extracted where relevant) the included studies from Loveman et al.[12] Of the 12 studies included in Loveman et al, three did not meet our inclusion criteria: two were tests of specific components of an intervention, rather than of the efficacy of a behavioural weight management programme itself[13,14], and one did not meet our criteria for the population being overweight or obese (50% of participants had a BMI <24).[15] We classified three of Loveman's included studies as testing intervention versus control, and these are included in the results reported below.[16,17,18] The remaining studies in Loveman were classified as testing one BWMP against another and will be presented in review 1b.

[12] LOVEMAN
[13] Burke 2008
[14] Tate 2007
[15] Simkin-Silverman 1998
[16] Stevens 2001
[17] Jeffery and Wing 1995
[18] Stevens 1993

Figure 1. Diagram of study flow[19]



[19] The three references pending further outcome data are: McConnon, A., et al. 2007. The internet for weight control in an obese sample: results of randomised controlled trial. BMC Health Services Research, 7, 206; Moore, H. et al. 2003. Improving management of obesity in primary care: cluster randomised trial. BMJ, 327, 1085; and Truby, H., et al. 2006. Randomised controlled trial of four commercial weight loss programmes in the UK: initial findings from the BBC 'diet trials.' BMJ, 332, 1309–14.

Excluded studies

The main reasons for excluding studies at full-text stage was that they reported less than 12 months follow-up, reported insufficient intervention detail (and author contact was not fruitful), were not multicomponent (i.e. had no arm which included diet, exercise and behavioural approaches), or the population was not overweight or obese at baseline (defined as 80% of each arm having a BMI >25, or >23 in Asian populations). Four studies were excluded as they were conducted in special populations judged not relevant to the UK, including two studies conducted in non-OECD countries. Other studies were excluded for not testing the efficacy of behavioural weight management programs (for example, testing efficacy of specific diet or tool), on the basis that the intervention was inpatient, because they measured weight maintenance rather than weight loss, and because they were subreports of existing studies or systematic reviews that fell outside the scope of this review. A full list of studies excluded at full text stage, along with reasons for exclusion, can be found in Appendix 4.

Characteristics of included studies

An overview of the 30 included studies (27 new references, 3 from Loveman 2011) can be seen in Table 1, and further details on each study can be found in Appendix 5.

Population

Of the 30 studies that tested intervention versus control, 15 were conducted in the USA, three were conducted in the UK, two each were conducted in Netherlands and Sweden, and one each were conducted in Australia, Belgium, Canada, Finland, New Zealand, Portugal, and Switzerland. The remaining study was a multicentre study conducted in the UK, Germany, and Australia[20].

The studies include 14,169 participants in total. The number of participants in each study ranged from 65 to over 2000, with a median of 398 participants and a mean of 472. Two studies recruited men only and six studies recruited only women (two specified postmenopausal women, one specified premenopausal women, and one recruited women at 8 to 12 weeks postpartum). One study did not provide gender information. In all but three of the remaining studies, the majority of participants were female. Overall, females represented 9,738 of the included participants (69%). This is representative of weight loss studies overall, in which the majority of participants have been found to be female[21]. All studies required that participants be at least 18 years or older. The average mean age was 49, with mean age ranging from 32 years to 70 years old. Two studies recruited only older adults (one in people 60 or older and one in people 65 or older). Only 15 of the 30 included studies reported data on ethnicity. Of these, the percentage of the study population made up of ethnic minorities ranged from 0 to 100% (one study recruited only African-Americans[22]). Of those studies that reported ethnicity data, the mean percentage ethnic minority group was 27%. There was no standard reporting for socioeconomic data, though when reported the most common

[20] Jebb 2011

[21] Pagoto, S.L., Schneider, K.L., Oleski, J.L., Luciani, J.M., Bodenlos, J.S., & Whited, M.C. 2012. Male Inclusion in Randomized Controlled Trials of Lifestyle Weight Loss Interventions. *Obesity*, 20, (6) 1234-1239

[22] Fitzgibbon 2010

variable was years of education. Where available, this information is recorded in the evidence tables for each study.

In all but two of the studies, overweight or obesity was an inclusion criterion. In two diabetes prevention studies, participants were not required to be overweight or obese, but reported data indicated that greater than 80% of participants in each study arm were overweight or obese.[23] Three studies required that participants were at increased risk of cardiovascular disease,[24] two studies required that baseline blood pressure be in the elevated but normal range,[25] and five required some measure of elevated risk for developing type 2 diabetes beyond overweight/obesity (family history, elevated fasting glucose, impaired glucose tolerance, etc).[26]

The mean BMI across all studies was 33 (the median was also 33), ranging from 29 (Vermunt 2011) to 40 (Fitzgibbon 2012). Thirteen of the 30 included studies had a maximum BMI as an inclusion criteria; this ranged from 35 to 50 (average 40). The other 17 included studies had no maximum cut off for baseline BMI.

Interventions

The 30 included studies represent 44 intervention arms overall (12 studies involved more than one intervention arm).

Of these 44 intervention arms, 31 had weight loss as their primary aim and one had weight loss and improved physical function as primary aims. Seven aimed to prevent the development of type 2 diabetes, two aimed to lower blood pressure, one was designed to prevent cardiovascular disease, and one was designed to increase mobility in an elderly population. The remaining intervention was originally designed to slow progression of subclinical atherosclerosis among women on hormone replacement therapy, but when much of the population discontinued use of hormone replacement therapy because of new knowledge of the risks involved, the study's aim was changed to weight loss.

Fourteen intervention arms tested programmes delivered in both group and individual sessions, 12 tested interventions delivered via group sessions, and 18 tested interventions delivered on an individual level only. Thirty-nine included at least some element of face-to-face contact, and the remaining 5 involved remote contact only (phone, e-mail, and/or website). There was a range in terms of who delivered the interventions though most interventions were delivered by more than one professional: in 22 a dietitian was involved, 18 involved an exercise physiologist, exercise trainer, or physiotherapist, and eight involved lay people.

The total number of sessions offered to participants varied greatly between studies, from a minimum of two to a maximum of 216. The median number of sessions offered was 39, and the mean was 58. To some extent, the variation in number of sessions offered is a product of variation in the length of the intervention itself, which ranged from three months to three years. On average,

[23] Eriksson 2009 and Dale 2008
[24] Wadden 2011, Erikkson 2009, Appel 2011
[25] Stevens 2001 and Stevens 1993
[26] DPP, Mensink 2003, Penn 2009, Dale 2008, Lindstrom 2003, Vermunt 2011

interventions were 18 months long, with contact decreasing in intensity over time in a number of studies. The majority of studies did not report on session length, but of those 14 that did, the average session was approximately an hour long. Sixteen of the 40 intervention arms involved some element of supervised exercise.

Comparisons

The inclusion criteria ensured that all 30 studies involved some comparison of intervention (behavioural weight management programme) versus control (defined as 1-4 below). The number of interventions tested against each control category is described below:

1. No intervention or one off written advice only, 14
2. One-off contact regarding weight loss, 11
3. Multiple contacts, not focussing on weight loss, 4
4. Multiple contacts focussing on weight loss, delivered by someone with no specialist training, 11

Of these 30 studies, five also included one or more arms in which a diet or exercise only programme was tested (these arms are excluded from this first report but are presented in review 1b), and eight included more than one BWMP arm (most commonly varying in intensity or delivery mode; comparisons with the control are included in this report).

Outcomes

All studies either provided data on weight change or provided sufficient information that reviewers were able to calculate weight change from the information provided (where non standard methods were used to calculate weight change, these are noted in the evidence tables). In one case, though weight change data were available, reviewers were unable to calculate BOCF or standard deviations.[27] All but six studies provided these data at 12 months from baseline, and for those that did not, data from 18 month follow-ups were used in its place. Average length of follow-up was 24 months from baseline, with ten studies having a longest follow-up of 12 months (these would have been excluded from Loveman 2011). Seven studies provided data at three years or longer. Twenty studies reported information sufficient to calculate BMI change, and 12 studies reported information sufficient to calculate change in waist circumference.

Only nine of the 30 included studies reported any information on adverse events. Of those that did, information was for the most part sparse and limited to reporting the presence or absence of adverse events possibly or definitely related to study treatment. In terms of intermediate outcomes, 12 studies reported some measure of dietary intake and 15 recorded some measure of physical activity.

Internal and external validity of included studies

The majority of studies were judged as ++ (high) for both internal validity (study quality) and external validity. Any reasons for study downgrading are detailed in the evidence tables.

[27] Jeffery 1995

Eighteen studies were judged to be of high quality: all or most quality checklist criteria were fulfilled and conclusions were judged unlikely to alter. Nine studies were awarded only one +, most commonly because randomization and/or allocation procedures were not described or were judged to not be sufficiently robust; in these cases, conclusions were still judged unlikely to alter. Two studies were rated as -, with few or no criteria fulfilled and conclusions judged likely to alter. One was downgraded as the randomisation process was not defined, groups were not similar at study outset, and an imbalance in dropouts between arms was not accounted for. [28] This was a relatively small study, however, and its inclusion is unlikely to affect the overall quality of the evidence base. The second study had a larger sample size and was downgraded as randomisation procedures were not described and follow up was less than 50% at 12 months.[29] Quality checklist results are reported for each study in Appendix 6.

Eighteen studies were rated as ++ on external validity, the extent to which the findings of the study were judged to be generalisable to the population in question. The remaining 12 studies were rated as + for external validity, with the most common reason for downgrading being that the majority of participants initially screened were not enrolled.

Table 1. Overview of included studies

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Comparison [30]	Outcomes	Adverse events (AEs)
Appel 2011 *Aim:* Weight loss	*Total n:* 415 *Country:* USA Notes: One or more CVD risk factors	Quality score: ++ External validity score: +	Group and individual *Delivered by:* weight loss coaches, HealthWays call centre *Mode of delivery:* Phone, web, in-person *Number of sessions:* 61 *Duration:* 24 months *Session length:* 55 mins	6 vs 2 6 vs 6	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	One AE intervention possibly related to study treatment. No difference in total hospitalizations
Bertz 2012 *Aim:* Weight loss	*Total n:* 68 *Country:* Sweden Notes: Women 8-12 weeks post partum	Quality score: ++ External validity score: ++	Individual *Delivered by:* dietitians and physical therapists *Mode of delivery:* in-person *Number of sessions:* 2 *Duration:* 12 months *Session length:* 135 mins	6 vs 1 6 vs 5 6 vs 6	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	Significant effect of diet on introducing non breastfeeding (all voluntary)

[28] Munsch 2003
[29] Hersey 2012
[30] (1) no intervention or one off written advice only, (2) one-off contact regarding weight loss, (3) multiple contacts, not focussing on weight loss, (4) multiple contacts focussing on weight loss, delivered by someone with no specialist training, (5) intervention involving diet only or exercise only (with or without behavioural counselling), (6) BWMP.

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Comparison [30]	Outcomes	Adverse events (AEs)
Dale 2008 *Aim:* diabetes prevention	*Total n:* 79 *Country:* New Zealand Impaired insulin sensitivity . Overweight/ obese not an inclusion criteria.	Quality score: + External validity score: +	Group and individual *Delivered by:* dietitians, exercise consultants and researchers *Mode of delivery:* phone and in-person *Number of sessions:* 36 *Duration:* 4 months *Session length:* NR	6 vs 4 6 vs 6	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR
DPP *Aim:* diabetes prevention	*Total n:* 2161 *Country:* USA Impaired glucose tolerance required	Quality score: ++ External validity score: ++	Group and individual *Delivered by:* dietitians, plus people with MA in exercise physiology, behavioural psychology or health education *Mode of delivery:* phone and in-person *Number of sessions:* NR *Duration:* NR *Session length:* 40 mins	6 vs 4	*Longest follow-up:* 48 months (plus extrapolated data at 10 years) *Change reported:* Weight: Yes BMI: No Waist circumference: No	By 3 year follow-up, fewer GI symptoms/events in intervention than in control group, other events similar.
Eriksson 2009 *Aim:* CVD prevention	*Total n:* 151 *Country:* Sweden obesity not entrance criteria but 90% obese at study entry	Quality score: ++ External validity score: ++	Group *Delivered by:* physiotherapist and dietitians *Mode of delivery:* in-person *Number of sessions:* 53 *Duration:* 36 months *Session length:* NR	6 vs 2	*Longest follow-up:* 36 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	None attributed to study treatment
Fitzgibbon 2010 (ORBIT trial) *Aim:* Weight loss	*Total n:* 213 *Country:* USA African American women	Quality score: ++ External validity score: +	Group and individual *Delivered by:* trained interventionists and lay people *Mode of delivery:* in-person and phone *Number of sessions:* 134 *Duration:* 18 months *Session length:* 75 mins	6 vs 3	*Longest follow-up:* 18 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	NR
Foster-Schubert 2012 (NEW trial) *Aim:* Weight loss	*Total n:* 439 *Country:* USA post menopausal women	Quality score: ++ External validity score: +	Group and individual *Delivered by:* dietitians and exercise physiologist *Mode of delivery:* Phone, web, in-person *Number of sessions:* 194 *Duration:* 12 months *Session length:* NR	6 vs 1 6 vs 5	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR
Hersey 2012 *Aim:* weight loss	*Total n:* 1755 *Country:* USA	Quality score: - External validity score: ++	Individual *Delivered by:* Undergraduate degree *Mode of delivery:* phone and web *Number of sessions:* 39 *Duration:* 18 months *Session length:* 20 mins	6 vs 2 6 vs 6	*Longest follow-up:* 18 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Comparison [30]	Outcomes	Adverse events (AEs)
Heshka 2006 *Aim:* weight loss	*Total n:* 433 *Country:* USA	Quality score: ++ External validity score: ++	Group *Delivered by:* trained lay people *Mode of delivery:* in-person and web *Number of sessions:* 104 *Duration:* 24 months *Session length:* 60 mins	6 vs 4	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR
Jebb 2011 *Aim:* Weight loss	*Total n:* 772 *Country:* UK, Germany and Australia	Quality score: + External validity score: ++	Group *Delivered by:* trained lay people *Mode of delivery:* phone, web, and in-person *Number of sessions:* 52 *Duration:* 12 months *Session length:* 60 mins	6 vs 4	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	No adverse events attributable to trial participation
Jeffery and Wing 1995 *Aim:* weight loss	*Total n:* 202 *Country:* USA	Quality score: + External validity score: +	Group *Delivered by:* trained interventionists with advanced degrees in nutrition or behavioural sciences *Mode of delivery:* in-person *Number of sessions:* 33 *Duration:* 18 months *Session length:* NR	6 vs 1 6 vs 6	*Longest follow-up:* 30 months *Change reported:* Weight: Y BMI: Y Waist circumference: N	NR
Kuller 2012 (WOMAN study) *Aim:* slow subclinical athleroscleriosis in women on HRT	*Total n:* 508 *Country:* USA post menopausal women	Quality score: ++ External validity score: ++	Group *Delivered by:* nutritionists, psychologists, exercise physiologists *Mode of delivery:* in-person *Number of sessions:* 64 *Duration:* 36 months *Session length:* NR	6 vs 3	*Longest follow-up:* 48 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR
Jolly 2011 (Lighten Up) *Aim:* weight loss	*Total n:* 640 *Country:* UK	Quality score: + External validity score: ++	Differs by intevention arm, see evidence table *Delivered by:* Differs by intevention arm, see evidence table *Mode of delivery:* in-person *Number of sessions:* 12 *Duration:* 3 months *Session length:* 60 mins	6 vs 1 6 vs 6	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	NR
Lindstrom 2003 (Finnish DPS) *Aim:* diabetes prevention	*Total n:* 522 *Country:* Finland people at high risk for type 2 diabetes	Quality score: ++ External validity score: ++	Group and individual *Delivered by:* dietitian, nutritionist, physician *Mode of delivery:* phone and in-person *Number of sessions:* 15 *Duration:* 36 months *Session length:* NR	6 vs 2	*Longest follow-up:* 36 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Comparison [30]	Outcomes	Adverse events (AEs)
Mensink 2003 *Aim:* diabetes prevention	*Total n:* 114 *Country:* Netherlands Non diabetic subjects with elevated fasting glucose	Quality score: + External validity score: ++	Individual *Delivered by:* dietitian and exercise trainers *Mode of delivery:* in-person *Number of sessions:* 216 *Duration:* 24 months *Session length:* 30 mins	6 vs 2	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	Authors state no serious adverse events were observed. No other details reported
Morgan 2011 (SHED-IT trial) *Aim:* Weight loss	*Total n:* 65 *Country:* Australia male university staff and students	Quality score: ++ External validity score: +	Group and individual *Delivered by:* researcher *Mode of delivery:* in-person and web *Number of sessions:* 8 *Duration:* 3 months *Session length:* NR	6 vs 2	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR
Munsch 2003 *Aim:* Weight loss	*Total n:* 122 *Country:* Switzerland	Quality score: - External validity score: ++	Group *Delivered by:* GP trained by psychologist and dietitian *Mode of delivery:* in-person *Number of sessions:* 16 *Duration:* 4 months *Session length:* 90 mins	6 vs 4 6 vs 6	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	NR
Nanchahal 2012 (CAMWEL) *Aim:* Weight loss	*Total n:* 381 *Country:* UK	Quality score: ++ External validity score: ++	Individual *Delivered by:* Health trainers, who are lay people trained by the NHS in behaviour change counselling *Mode of delivery:* in-person *Number of sessions:* 14 *Duration:* 8 months *Session length:* 30 mins	6 vs 1	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR
Patrick 2011 *Aim:* Weight loss	*Total n:* 441 *Country:* USA Men only	Quality score: ++ External validity score: +	Group and individual *Delivered by:* dietitian, exercise trainer and physiologist *Mode of delivery:* web *Number of sessions:* 52 *Duration:* 12 months *Session length:* NR	6 vs 1	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR
Penn 2009 *Aim:* diabetes prevention	*Total n:* 102 *Country:* UK Non diabetic subjects with impaired glucose tolerance	Quality score: + External validity score: ++	Group and individual *Delivered by:* dietitian and physiotherapist *Mode of delivery:* in-person *Number of sessions:* 20 *Duration:* 12 months *Session length:* 30 mins	6 vs 2	*Longest follow-up:* 60 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR
Rejeski 2011 *Aim:* increased mobility	*Total n:* 288 *Country:* USA older adults with evidence of CVD or metabolic syndrome and self-reported mobility limitation	Quality score: + External validity score: +	Group and individual *Delivered by:* professional interventionists and Cooperative Extension Agencts *Mode of delivery:* in-person and phone *Number of sessions:* 48 *Duration:* 18 months *Session length:* 50 mins	6 vs 3 6 vs 5	*Longest follow-up:* 18 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	SAEs possibly or definitely related to study treatment: intervention 6, exercise only (PA) 3, control 0. More AEs in total in intervention and PA arms than in control

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Comparison [30]	Outcomes	Adverse events (AEs)
Rock 2010 *Aim:* Weight loss	*Total n:* 442 *Country:* USA women only	Quality score: ++ External validity score: ++	Individual *Delivered by:* trained lay people *Mode of delivery:* Phone, web, in-person *Number of sessions:* 104 *Duration:* 24 months *Session length:* NR	6 vs 4 6 vs 6	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR
Ross 2012 *Aim:* Weight loss	*Total n:* 490 *Country:* Canada	Quality score: ++ External validity score: ++	Individual *Delivered by:* Health educations with degree in kinesiology and training in behavioural counselling *Mode of delivery:* in-person *Number of sessions:* 33 *Duration:* 24 months *Session length:* NR	6 vs 2	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	300 musculoskeletal injuries during exercise in intervention group, 311 in control group. No differences in non-study related AEs.
Silva 2010 *Aim:* Weight loss	*Total n:* 239 *Country:* Portugal premenopausal women	Quality score: ++ External validity score: +	Group *Delivered by:* dietitians, nutritionists, exercise physiologists *Mode of delivery:* in-person *Number of sessions:* 30 *Duration:* 12 months *Session length:* 120 mins	6 vs 3	*Longest follow-up:* 36 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR
Stevens 1993 *Aim:* Lowering blood pressure	*Total n:* 564 *Country:* USA baseline blood pressure in high normal range	Quality score: ++ External validity score: +	Group and individual *Delivered by:* dietitian, exercise physiologist, psychologist *Mode of delivery:* Phone, web, in-person *Number of sessions:* 45 *Duration:* 18 months *Session length:* NR	6 vs 1	*Longest follow-up:* 18 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR
Stevens 2001 *Aim:* Lowering blood pressure	*Total n:* 1191 *Country:* USA baseline blood pressure in high normal range	Quality score: ++ External validity score: +	Group and individual *Delivered by:* dietitians, psychologists, MA level counsellors *Mode of delivery:* in-person, phone, fax, post *Number of sessions:* 47 *Duration:* 36 months *Session length:* NR	6 vs 1	*Longest follow-up:* 36 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	NR
Vermunt 2011 *Aim:* diabetes prevention	*Total n:* 925 *Country:* Netherlands risk of developing type 2 diabetes	Quality score: + External validity score: ++	Individual *Delivered by:* Nurse practitioner, dietitian and GP *Mode of delivery:* in-person *Number of sessions:* 17 *Duration:* 36 months *Session length:* NR	6 vs 2	*Longest follow-up:* 18 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: Yes	NR

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Comparison [30]	Outcomes	Adverse events (AEs)
Villareal 2011 *Aim:* weight loss and improved physical function	*Total n:* 107 *Country:* USA aged 65 years or older; mild to moderate frailty	Quality score: ++ External validity score: ++	Group *Delivered by:* dietitian and physical therapist *Mode of delivery:* in-person *Number of sessions:* 208 *Duration:* 12 months *Session length:* NR	6 vs 4 6 vs 5	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: No Waist circumference: No	One participant in the intervention group fell during exercise training, no other study related Aes reported
Vissers 2010 *Aim:* weight loss	*Total n:* 79 *Country:* Belgium	Quality score: + External validity score: ++	Individual *Delivered by:* dietitian and physiotherapist *Mode of delivery:* in-person *Number of sessions:* 12 *Duration:* 12 months *Session length:* NR	6 vs 1 6 vs 5 6 vs 6	*Longest follow-up:* 12 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	NR
Wadden 2011 *Aim:* Weight loss	*Total n:* 261 *Country:* USA 2 or more criteria for the metabolic syndrome	Quality score: ++ External validity score: +	Individual *Delivered by:* lifestyle coach *Mode of delivery:* phone and in-person *Number of sessions:* 25 *Duration:* 24 months *Session length:* NR	6 vs 4	*Longest follow-up:* 24 months *Change reported:* Weight: Yes BMI: Yes Waist circumference: No	NR

Effects of interventions

Weight loss

At 12 months (or if 12 month data was not provided, at up to 18 months), pooled results from 29 studies[31] comparing intervention with control yielded a mean difference of -2.59 kg in favour of the intervention group, with 95% confidence intervals (CI) of -2.78 to -2.41.[32] This represents 40 intervention arms in total, with 7,540 participants in the intervention arms and 5,913 in the control arms. As was to be expected given the clinical heterogeneity of the interventions involved, results indicated a high level of statistical heterogeneity (I^2 = 93%). As seen in Figure 2, the direction of the effect was fairly consistent amongst all included studies: the control group lost more than the intervention arm in only four cases (representing two studies), and in none of these cases was the result statistically significant. A further ten studies had confidence intervals crossing the line of no effect (suggesting the possibility that the intervention was equally as effective as the control).

This effect was decreased but still significant in a meta-analysis of 19 intervention arms where results were reported at 18 to 24 months (mean difference -1.54 kg, 95% CI -1.79 to -1.30, Figure 3). Pooled results from the four studies with follow-up at 36 months from baseline also detected statistically significant evidence of an effect (mean difference -2.21, 95% CI -2.66 to -1.75, Figure 4). Results were still substantially statistically heterogeneous at both of these longer follow ups, with I^2 values of 91% at 18 to 24 months and 59% at 36 months.

The study that could not be included in the meta-analysis because of lack of data (Jeffery 1995) had five arms: standard behavioural therapy (SBT), SBT with food provision, SBT with incentives, SBT with food provision and incentives, and a no contact control. At 12 and 18 months, those arms with food provision showed significantly higher weight loss than those without, and all intervention arms were superior to control. At 30 month follow-up, food provision was no longer found to have a significant effect over standard SBT and intervention arms maintained only slightly more weight loss than the control arm.

Weight loss curves shed further light on weight change in both intervention and control groups over time.[33] As can be observed in Figure 5, an initial weight-loss was achieved in all BWMPs with subsequent regain over time. In no intervention arm did mean weight at any follow-up period exceed mean weight at baseline. Some initial weight-loss was observed in the majority of controls (Figure 6). As per the interventions, this was followed by weight regain for the remainder of follow-up. Some fluctuations in weight can be seen in studies with extended follow-up periods (DPP, Pen 2009, Morgan 2011). Unexpected weight-loss was observed in Dale 2008's control group between

[31] Note, this excludes Jeffery 1995, for which BOCF data could not be calculated

[32] Across all intervention arms, mean (unweighted) weight change was -3.8 kg (standard deviation 6.02) at 12 to 18 months (results were highly heterogeneous, ranging from -10.1 kg to -0.5 kg). This figure should not be interpreted as the amount of weight typically lost on a particular programme because it is the average across many programmes of different types. Across all control arms, mean (unweighted) weight loss was -1.0 kg (standard deviation 4.8) at 12-18 months. Again this figure should be interpreted with caution.

[33] Note, Weight loss curves only included those studies where weight was reported at two or more follow-up points

months 8 to 12. This control group were asked to continue their normal diet and exercise for the four month intervention period. Due to ethical purposes they were then offered a two week lifestyle intervention. The timing of this intervention is not clearly defined and therefore 'take-up' may overlap with the period of weight-loss observed in Figure 6. Weight loss curves for studies with data available at three years or longer can be seen in Figures 7 and 8. Even in these with longer term follow-up, at no point did any of the intervention arms have a mean weight exceeding that at baseline. Weight loss maintenance and weight regain will be investigated further in Review 1b.

Figure 2. Forest plot of behavioural weight loss programme (BWMP) versus control, outcome weight change at 12 months (BOCF), subgroup analysis by mode of delivery: group, individual, or group + individual

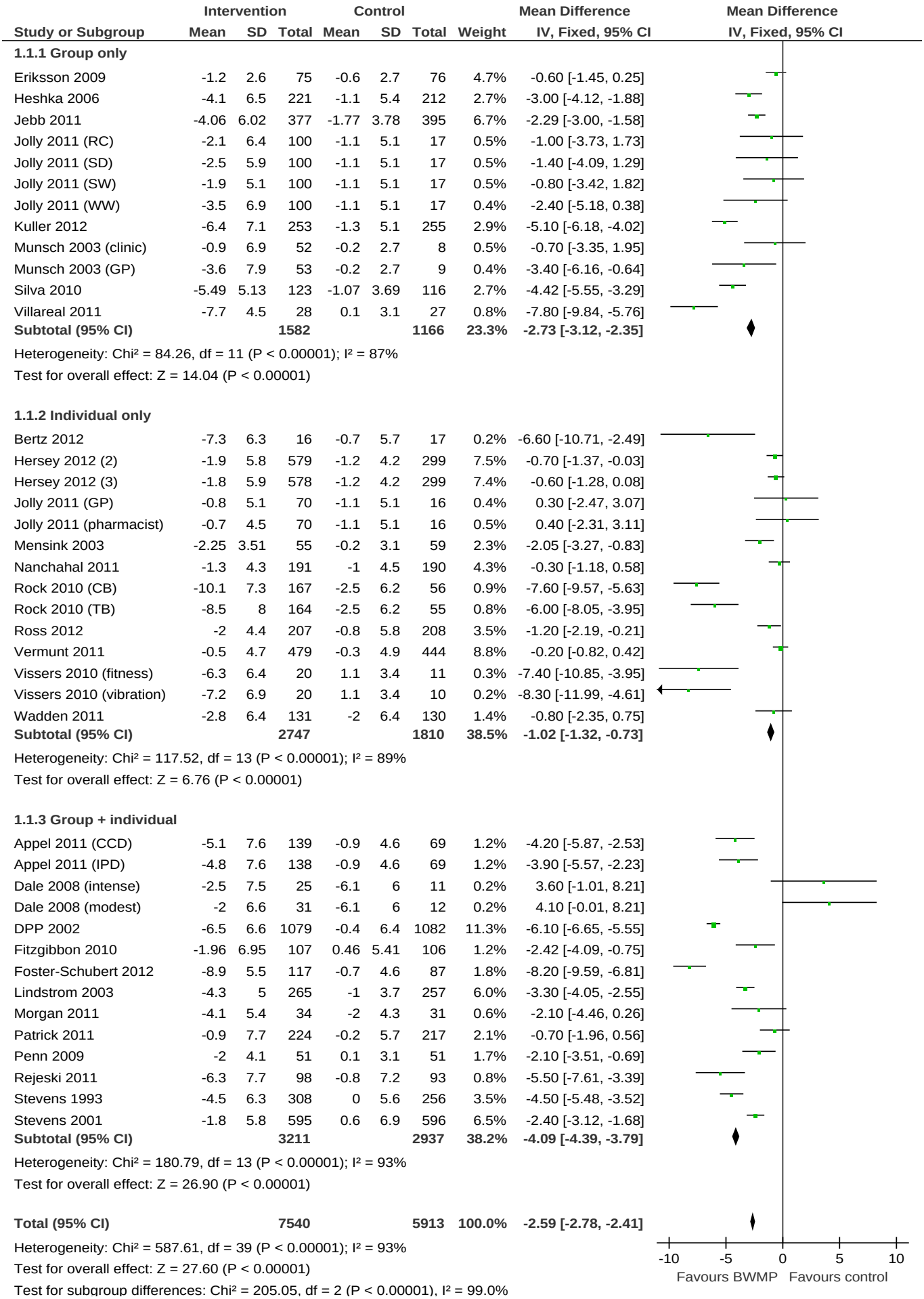


Figure 3. Forest plot of BWMP versus control, outcome weight change at 18 to 24 months (BOCF), subgroup analysis by length of intervention

Study or Subgroup	BWMP Mean	BWMP SD	BWMP Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
1.10.2 4 to 6 months								
Dale 2008 (intense)	-2.1	6.9	25	-3.7	5.5	11	0.3%	1.60 [-2.63, 5.83]
Dale 2008 (modest)	-2.2	5.7	31	-3.7	5.5	12	0.4%	1.50 [-2.20, 5.20]
Subtotal (95% CI)			**56**			**23**	**0.8%**	**1.54 [-1.24, 4.33]**
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.97); I² = 0%								
Test for overall effect: Z = 1.09 (P = 0.28)								
1.10.3 6 to 12 months								
Penn 2009	-1.7	4.1	51	-0.9	5.4	51	1.7%	-0.80 [-2.66, 1.06]
Subtotal (95% CI)			**51**			**51**	**1.7%**	**-0.80 [-2.66, 1.06]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.84 (P = 0.40)								
1.10.4 Greater than 12 months								
Appel 2011 (CCD)	-4.5	8.3	139	-0.8	7.7	69	1.2%	-3.70 [-5.98, -1.42]
Appel 2011 (IPD)	-4.9	9.1	138	-0.8	7.7	69	1.1%	-4.10 [-6.47, -1.73]
Fitzgibbon 2010	-1.96	6.95	107	0.46	5.41	106	2.2%	-2.42 [-4.09, -0.75]
Hersey 2012 (2)	-1	4.9	579	-1	4	299	16.5%	0.00 [-0.60, 0.60]
Hersey 2012 (3)	-1.5	5.6	578	-1	4	299	14.5%	-0.50 [-1.14, 0.14]
Heshka 2006	-2.1	6.1	221	0	6.1	212	4.6%	-2.10 [-3.25, -0.95]
Kuller 2012	-6.4	7.1	253	-1.3	5.1	255	5.2%	-5.10 [-6.18, -4.02]
Mensink 2003	-1.8	3.9	55	-0.1	3.2	59	3.5%	-1.70 [-3.01, -0.39]
Rejeski 2011	-6.3	7.7	98	-0.8	7.2	93	1.3%	-5.50 [-7.61, -3.39]
Rock 2010 (CB)	-7.4	8.4	167	-1.9	7.2	56	1.2%	-5.50 [-7.78, -3.22]
Rock 2010 (TB)	-6.3	9.3	164	-1.9	7.2	55	1.1%	-4.40 [-6.78, -2.02]
Ross 2012	-0.9	5.5	249	-0.5	5.7	241	6.1%	-0.40 [-1.39, 0.59]
Stevens 1993	-3.7	5	308	0	4.3	256	10.2%	-3.70 [-4.47, -2.93]
Stevens 2001	-1.8	5.8	595	0.6	6.9	596	11.5%	-2.40 [-3.12, -1.68]
Vermunt 2011	-0.5	4.7	479	-0.3	4.9	444	15.6%	-0.20 [-0.82, 0.42]
Wadden 2011	-2.4	7.4	131	-1.5	7.4	130	1.9%	-0.90 [-2.70, 0.90]
Subtotal (95% CI)			**4261**			**3239**	**97.5%**	**-1.58 [-1.83, -1.33]**
Heterogeneity: Chi² = 176.94, df = 15 (P < 0.00001); I² = 92%								
Test for overall effect: Z = 12.48 (P < 0.00001)								
Total (95% CI)			**4368**			**3313**	**100.0%**	**-1.54 [-1.79, -1.30]**
Heterogeneity: Chi² = 182.36, df = 18 (P < 0.00001); I² = 90%								
Test for overall effect: Z = 12.34 (P < 0.00001)								
Test for subgroup differences: Chi² = 5.42, df = 2 (P = 0.07), I² = 63.1%								

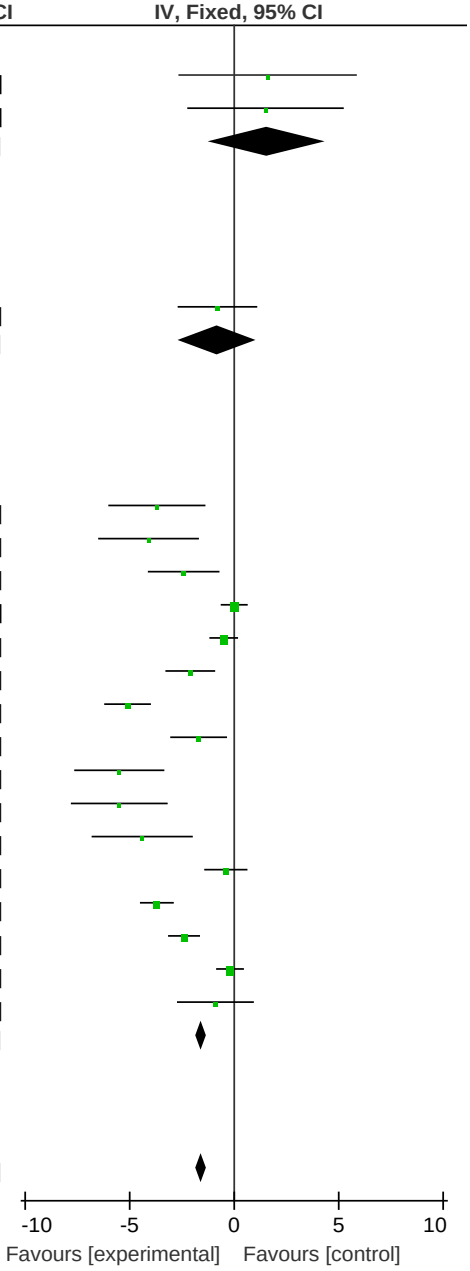


Figure 4. Forest plot of BWMP versus control, outcome weight change at 36 months

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Kuller 2012	-2.9	6.7	253	-0.2	5.3	255	18.6%	-2.70 [-3.75, -1.65]
Lindstrom 2003	-3.5	5.6	265	-0.7	4.8	257	25.7%	-2.80 [-3.69, -1.91]
Penn 2009	-2.5	5.9	51	-2.8	6.9	51	3.3%	0.30 [-2.19, 2.79]
Stevens 2001	-0.2	5.8	595	1.7	5.2	596	52.4%	-1.90 [-2.53, -1.27]
Total (95% CI)			**1164**			**1159**	**100.0%**	**-2.21 [-2.66, -1.75]**
Heterogeneity: Chi² = 7.35, df = 3 (P = 0.06); I² = 59%								
Test for overall effect: Z = 9.55 (P < 0.00001)								

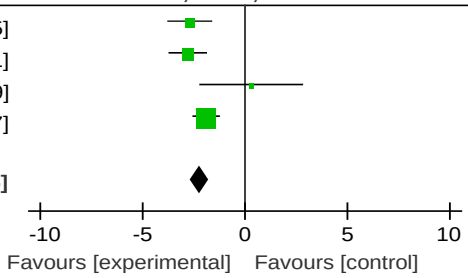


Figure 5. BWMP weight-change (BOCF) from baseline over follow-up in all interventions (five years)

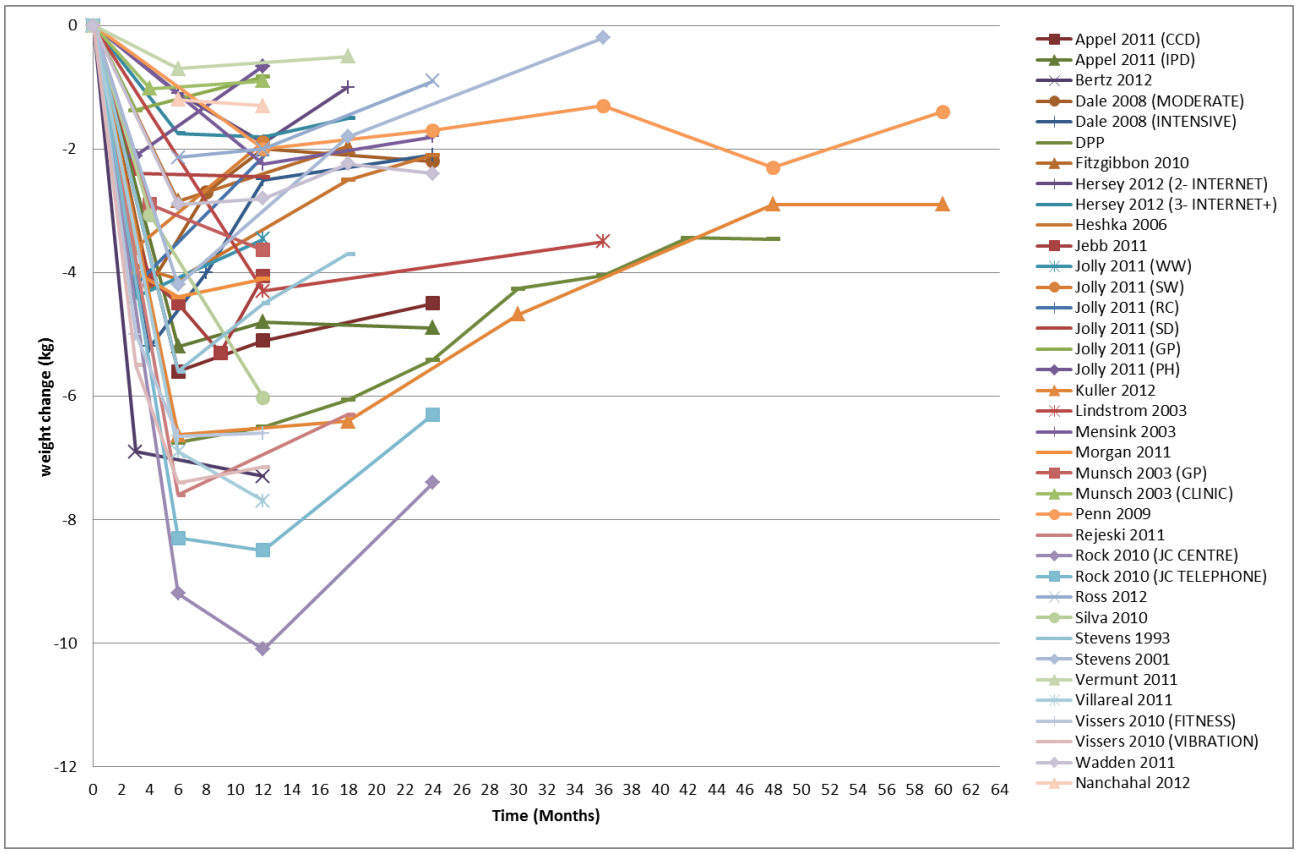


Figure 6. Control weight-change (BOCF) from baseline over time (five years)

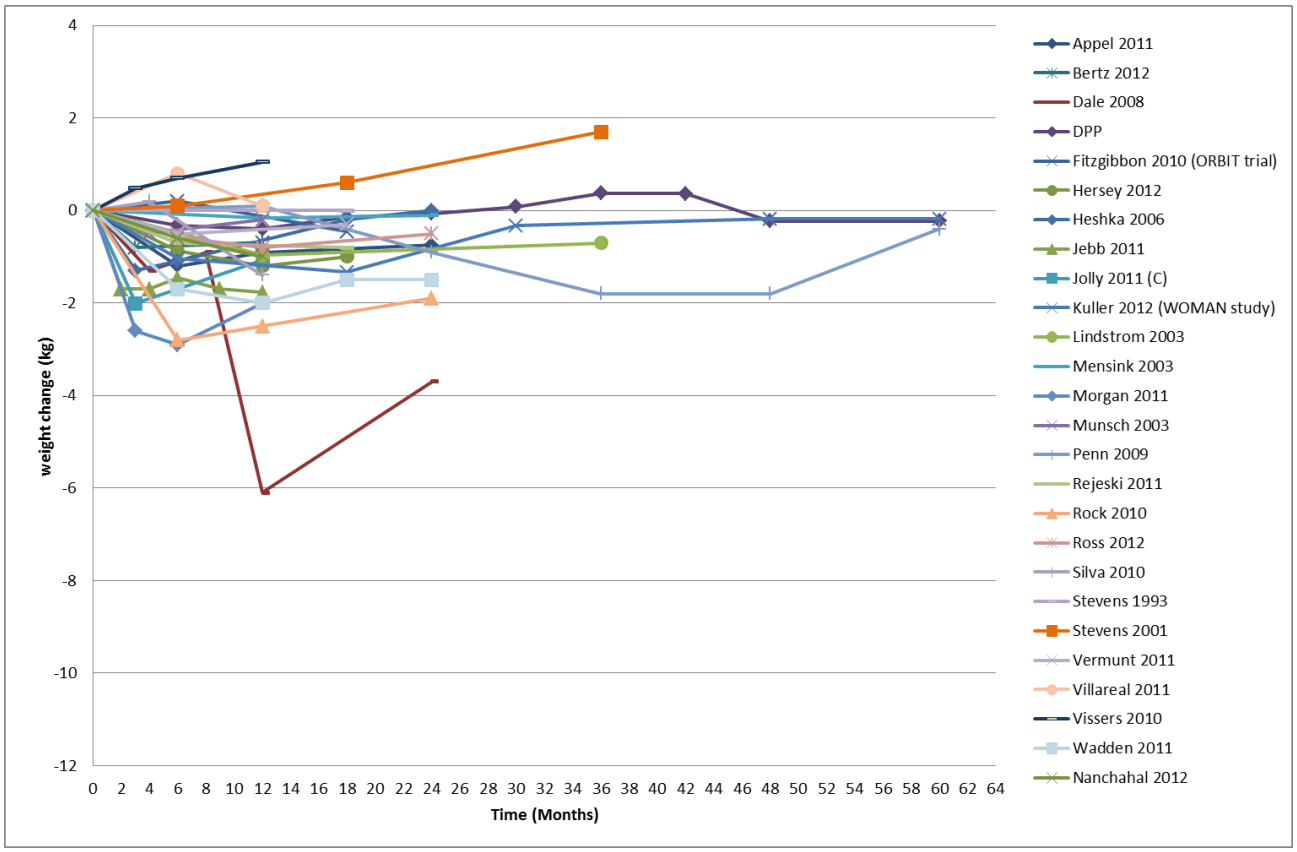


Figure 7. BWMP weight-change (BOCF) from baseline over follow-up, studies with at least 3 years follow-up

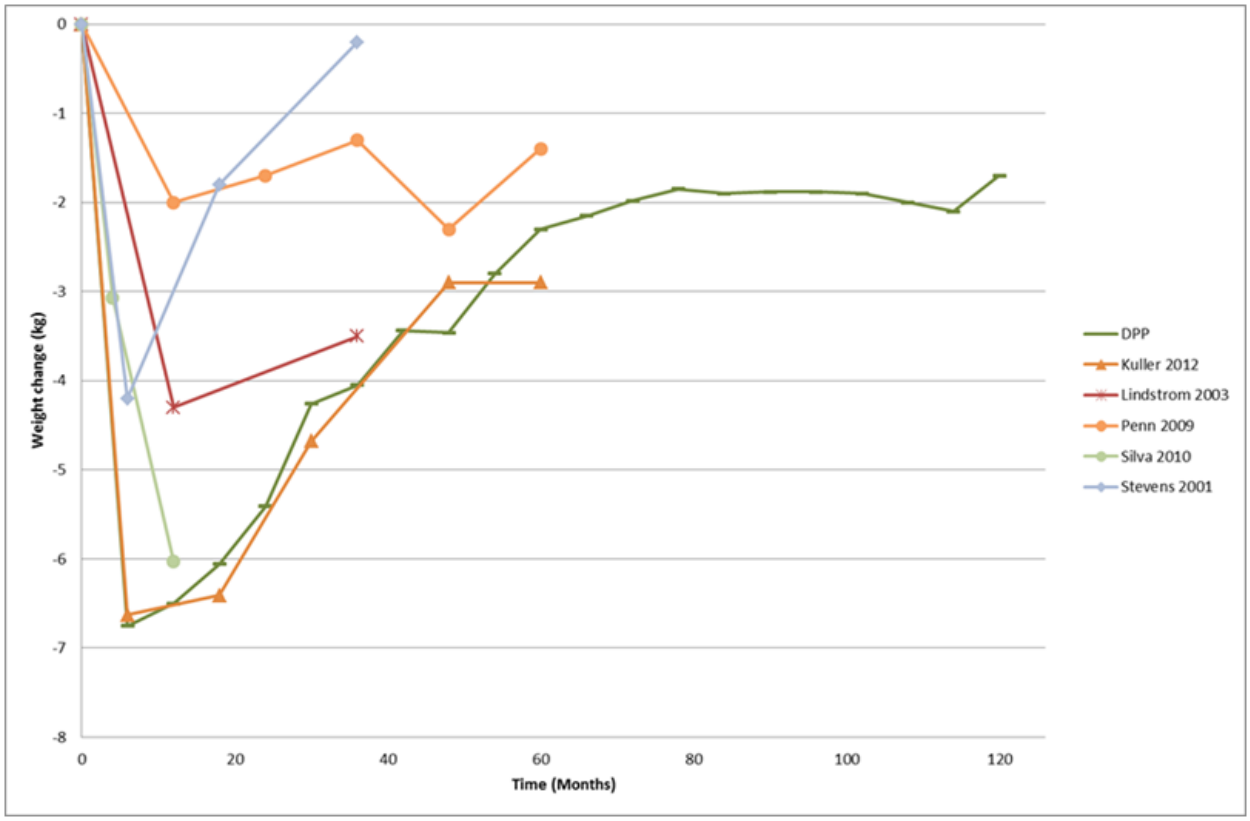
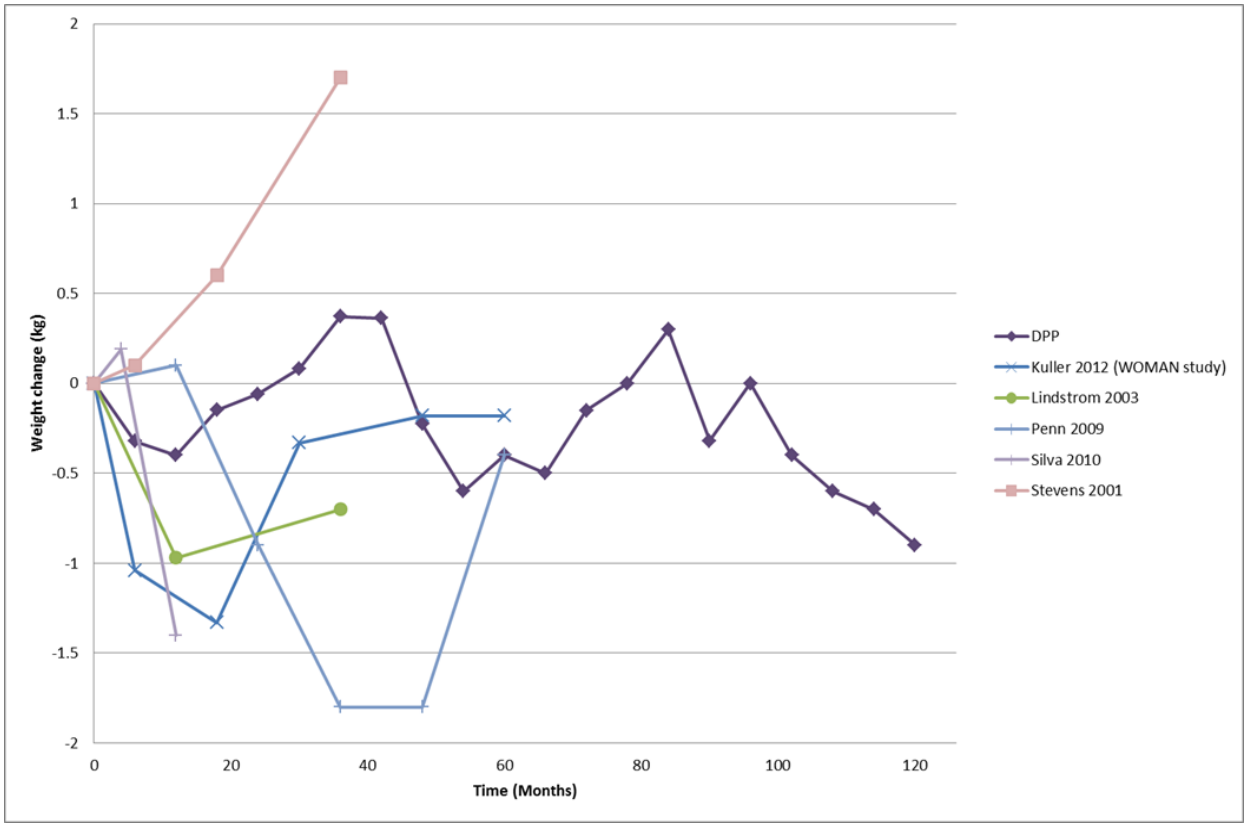


Figure 8. Control weight-change (BOCF) from baseline over follow-up, studies with at least 3 years follow-up



Subgroup analyses

Given the high level of statistical and clinical heterogeneity amongst studies and study arms, it is difficult to draw firm conclusions from the meta-analyses and from further subgroup analyses. The high levels of statistical heterogeneity within subgroups suggest that none of the characteristics investigated on their own accounted for between study heterogeneity. The analyses below are therefore exploratory, and though they may not explain between study differences, point to further avenues for exploration in reviews 1b and 2. All subgroup analyses reported below use mean difference for BOCF weight change data at 12 months or the closest point to 12 months up to 18 months, unless stated otherwise.

Programme aim

A subgroup analysis (see Figure 9) suggested no significant effect of program aim (weight loss, diabetes prevention, or other[34]). Though confidence intervals did not overlap, point estimates were relatively close and there were high levels of statistical heterogeneity ($I^2 \geq 90\%$ within each group). The point estimate for weight change in programmes aiming to prevent diabetes was higher (mean difference -3.19 kg, 95% -3.53 to -2.86) than that aiming at weight loss or with another aim (weight loss -2.13 kg, 95% CI -2.38 to -1.87; other -2.89 kg, 95% CI -3.32 to -2.47), but this is substantially influenced by the DPP, which had the highest mean difference for weight loss in this group of studies (-6.10 kg). In a sensitivity analysis removing DPP, the mean difference for the diabetes prevention studies declined to -1.48 kg (95% CI -1.90 to -1.06).

Programme delivery

As seen in Figure 2, programmes delivered in group and individual formats had the highest pooled mean difference for weight loss (-4.09 kg, 95% CI -4.39 to -3.79), followed by programmes delivered in group format only (-2.73 kg, 95% CI -3.12 to -2.35). Programmes without a group component (individual contact only) had the lowest point estimate, at -1.02 kg (95% CI -1.32 to -0.73). Though this suggests combined group and individual programmes are the most effective for weight loss at 12 months, levels of statistical heterogeneity were still high in each group.

A large majority of studies provided some degree of face-to-face contact. In a subgroup analysis comparing these to interventions with remote contact only (phone or web based), interventions involving face-to-face contact led to significantly more weight loss than those with remote contact only (-2.94 kg, 95% CI -3.15 to -2.74, compared to -1.11 kg, 95% CI -1.53 to -0.69, see Figure 10). Again, these results should be cautiously interpreted due to the high level of heterogeneity within both groups. Two of the remote contact only studies (both of which also had a face-to-face arm) had effects significantly higher than that of the pooled face-to-face studies (Appel 2011 and Rock 2010).

Due to wide variation in who delivered the interventions (most interventions were delivered by a variety of health professionals, and it is not clear who the primary person delivering the intervention would have been in each case) we did not conduct a subgroup analysis on this variable. As described below, Figure 18 includes a subset of interventions delivered by generalists in primary care settings.

[34] Other = cardiovascular disease prevention or increased mobility

Programme elements

In a subgroup analysis (see Figure 11), programmes that involved supervised exercise were shown to be more effective than those that only recommended exercise (-4.10 kg, 95% CI -4.40 to -3. 80, compared with -1.71 kg, 95% CI -1.94 to -1.47). However, here again heterogeneity was very high. Within the supervised exercise category, programmes ranged from those with most exercise being recommended to those with all exercise being supervised.

Similarly, studies in which participants were prescribed a set daily energy intake appeared to be more effective than those which prescribed other diets (either energy restricted but with no detail given, or low fat, etc). As seen in Figure 12, the point estimate for programmes with a set daily energy intake was -3.76 kg (95% CI -4.06 to -3.46) compared to -1.90 kg (95% CI -2.13 to -1.67) in studies without a set energy target. Again, levels of statistical heterogeneity were high in both groups.

Programme intensity

As seen in Figure 13, at one year interventions lasting longer than six months appeared to be significantly more effective (with a mean difference of -2.67 kg, 95% CI -2.86 to -2.48) than those lasting four to six months (-0.35 kg, 95% CI 1.97 to 1.27) and those lasting up to three months (-1.36 kg, 95% CI -2.33 to -0.38). Though heterogeneity is lower in the 'up to three months' group and the '4 to 6 months' group, these results must be interpreted with caution due to the small number of studies in these two arms (3 studies 'up to 3 months,' 2 studies '4 to 6 months'). Figure 3 shows this same pattern at longer follow-up (18 to 24 months), though again results must be interpreted cautiously due to the presence of only two studies in this group in which the intervention was less than 12 months. As seen in weight curves, maximum weight-loss is observed at three months for the majority of interventions lasting 'up to three months' (Figure 14) and at four months for the majority of interventions lasting '4 to 6 months' (Figure 15). The nadir (i.e. the lowest point) of weight loss curves for interventions of 'greater than 6 months' is more variable but maximum weight loss is observed most frequently between 6 and 12 months (Figure 16). In six interventions (Bertz 2012, Jolly 2010 (SD)[35], Munsch 2003, Nanchahal 2012, Silva 2010, Villareal 2011), no regain occurred during the studies' follow-up periods. These results must be interpreted with caution due to the influence of the frequency and duration of follow-up examinations on the curve.

We also investigated the effect of frequency of contact on weight loss at 12 months (defined as highest frequency sustained over two months or number of sessions in first year/length in weeks of programme up to 52). As seen in Figure 17, confidence intervals overlapped for groups of studies with weekly contact (-3.24 kg, 95% CI -3.54 to -2.95), contact at least fortnightly (-2.72 kg, -3.02 to -2.44), and contact at least once every two months (-3.41 kg, 95% CI -4.15 to -2.67). Interventions which involved contact at least monthly or contact less than every two months had point estimates that were significantly less effective, but this represented only four studies in total, and is likely to be due to chance due to the non-linear nature of the results.

[35] Here SD represents the arm of the study which received Size Down as an intervention

Control category

Finally, a subgroup analysis by control category (Figure 18) did not suggest that the level of control intensity affected the resulting difference in weight loss between intervention and control arms. Point estimates were highest in those studies in which the control group received multiple non-weight related contacts (control group 3, -4.47 kg, 95% CI -5.14 to -3.80) or multiple weight related contacts with generalists (control group 4, -4.32 kg, 95% CI -4.68 to -3.96), and lowest in those with no or only one weight-related contact (control group 1, -2.59 kg, 95% CI -2.99 to -2.20; control group 2, -1.28 kg, 95% CI -1.56 to -1.01). Weight change for studies in the four control categories can be seen in Figure 19, and do not show clear differences between groups. There is a trend towards greater weight loss in control group 4, but this may be due to chance.

Interventions currently available in the UK

We conducted a separate analysis of those interventions currently available in the UK. These included four commercial programmes and six studies conducted in general practice or general pharmacy settings and delivered by a generalist (e.g. a GP, nurse, pharmacist, healthcare assistant, or health educator/trainer). As seen in Figure 20, pooled results within each subgroup suggest each programme has a statistically significant effect on weight loss. The number of studies for commercial providers is small, though, and hence results should be treated with caution. Pooled results from the studies conducted by generalists in general practice settings were lower than for the commercial programmes (-0.44 kg, 95% CI -0.85 to -0.04, six studies total).

Note that these interventions are compared separately with control and it would be a mistake to use the data to try to assess the differences between treatment programmes. The programmes varied in the length to which participants were able to use the programmes as part of the trials, which varied from three months to two years. In Review 1b we will compare programme effectiveness.

Funding

The majority of studies received public sector funding only. Five received some or all of their funding from outside the public sector.[36] In a subgroup analysis (not shown), when pooled, studies which received some commercial funding showed a small but significant increase in weight loss over those which received public sector funding only (-3.37 kg, 95% CI -3.79 to -2.96, compared with -2.39 kg, 95% CI -2.59 to -2.18). Levels of statistical heterogeneity within groups were high (I^2 > 85%) and, as no studies compared like with like (i.e. studies of the same intervention delivered over the same amount of time, with one study receiving funding from the commercial sector and the other receiving no commercial funding), it is difficult to draw any conclusions from the analysis. Differences in effects between a commercial arm in Jolly 2011 (delivered over 12 weeks, no commercial funding) and two commercially-funded studies evaluating the same program (delivered over a longer period) were not significant.

[36] Heshka 2006, Jebb 2011, Lindstrom 2003, Rock 2010, Silva 2010

Figure 9. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by programme aim

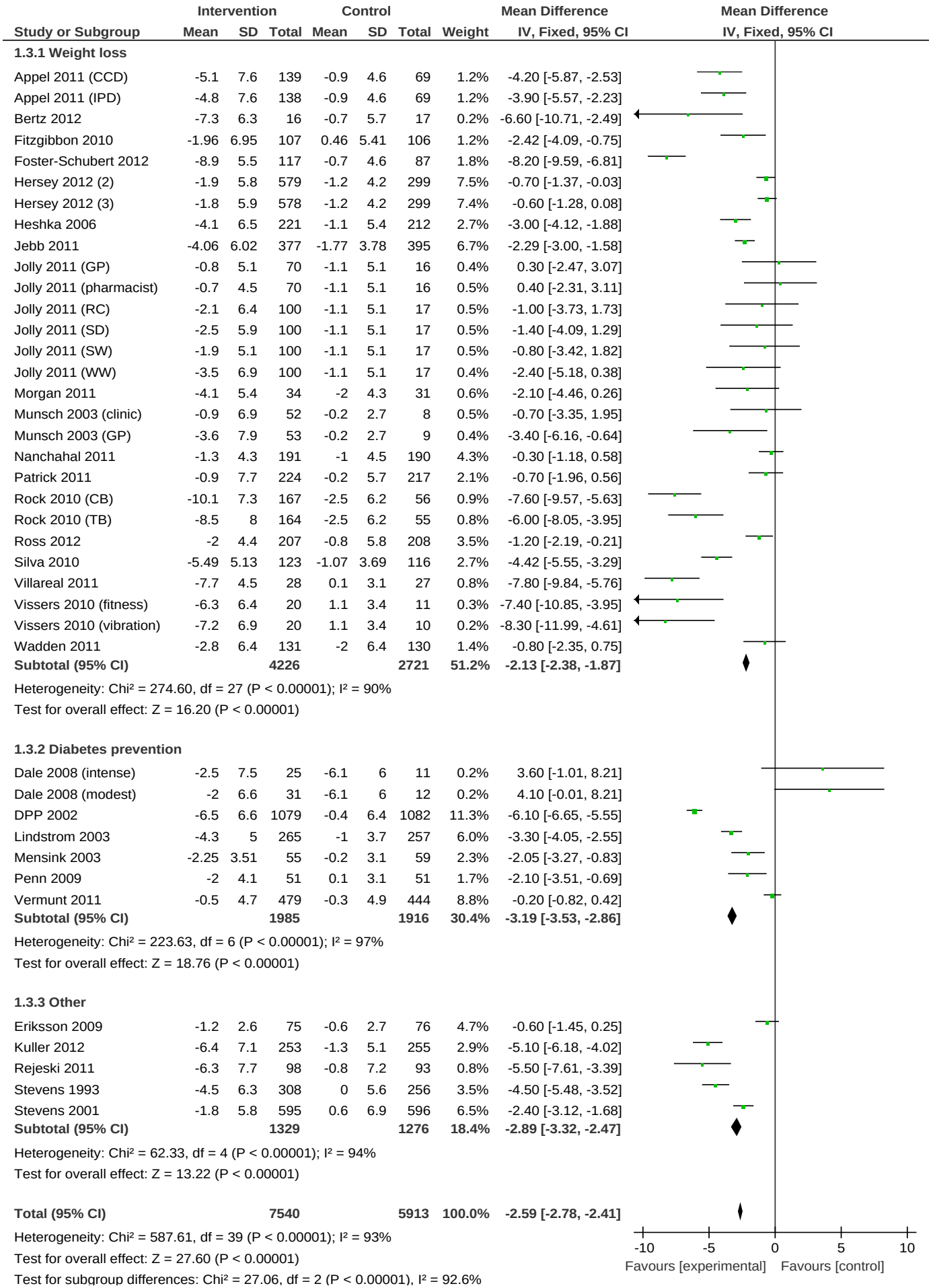


Figure 10. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by remote versus face-to-face contact

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.4.1 Face-to-face contact								
Appel 2011 (IPD)	-4.8	7.6	138	-0.9	4.6	69	1.2%	-3.90 [-5.57, -2.23]
Bertz 2012	-7.3	6.3	16	-0.7	5.7	17	0.2%	-6.60 [-10.71, -2.49]
Dale 2008 (intense)	-2.5	7.5	25	-6.1	6	11	0.2%	3.60 [-1.01, 8.21]
Dale 2008 (modest)	-2	6.6	31	-6.1	6	12	0.2%	4.10 [-0.01, 8.21]
DPP 2002	-6.5	6.6	1079	-0.4	6.4	1082	11.3%	-6.10 [-6.65, -5.55]
Eriksson 2009	-1.2	2.6	75	-0.6	2.7	76	4.7%	-0.60 [-1.45, 0.25]
Fitzgibbon 2010	-1.96	6.95	107	0.46	5.41	106	1.2%	-2.42 [-4.09, -0.75]
Foster-Schubert 2012	-8.9	5.5	117	-0.7	4.6	87	1.8%	-8.20 [-9.59, -6.81]
Heshka 2006	-4.1	6.5	221	-1.1	5.4	212	2.7%	-3.00 [-4.12, -1.88]
Jebb 2011	-4.06	6.02	377	-1.77	3.78	395	6.7%	-2.29 [-3.00, -1.58]
Jolly 2011 (GP)	-0.8	5.1	70	-1.1	5.1	16	0.4%	0.30 [-2.47, 3.07]
Jolly 2011 (pharmacist)	-0.7	4.5	70	-1.1	5.1	16	0.5%	0.40 [-2.31, 3.11]
Jolly 2011 (RC)	-2.1	6.4	100	-1.1	5.1	17	0.5%	-1.00 [-3.73, 1.73]
Jolly 2011 (SD)	-2.5	5.9	100	-1.1	5.1	17	0.5%	-1.40 [-4.09, 1.29]
Jolly 2011 (SW)	-1.9	5.1	100	-1.1	5.1	17	0.5%	-0.80 [-3.42, 1.82]
Jolly 2011 (WW)	-3.5	6.9	100	-1.1	5.1	17	0.4%	-2.40 [-5.18, 0.38]
Kuller 2012	-6.4	7.1	253	-1.3	5.1	255	2.9%	-5.10 [-6.18, -4.02]
Lindstrom 2003	-4.3	5	265	-1	3.7	257	6.0%	-3.30 [-4.05, -2.55]
Mensink 2003	-2.25	3.51	55	-0.2	3.1	59	2.3%	-2.05 [-3.27, -0.83]
Morgan 2011	-4.1	5.4	34	-2	4.3	31	0.6%	-2.10 [-4.46, 0.26]
Munsch 2003 (clinic)	-0.9	6.9	52	-0.2	2.7	8	0.5%	-0.70 [-3.35, 1.95]
Munsch 2003 (GP)	-3.6	7.9	53	-0.2	2.7	9	0.4%	-3.40 [-6.16, -0.64]
Nanchahal 2011	-1.3	4.3	191	-1	4.5	190	4.3%	-0.30 [-1.18, 0.58]
Penn 2009	-2	4.1	51	0.1	3.1	51	1.7%	-2.10 [-3.51, -0.69]
Rejeski 2011	-6.3	7.7	98	-0.8	7.2	93	0.8%	-5.50 [-7.61, -3.39]
Rock 2010 (CB)	-10.1	7.3	167	-2.5	6.2	56	0.9%	-7.60 [-9.57, -5.63]
Ross 2012	-2	4.4	207	-0.8	5.8	208	3.5%	-1.20 [-2.19, -0.21]
Silva 2010	-5.49	5.13	123	-1.07	3.69	116	2.7%	-4.42 [-5.55, -3.29]
Stevens 1993	-4.5	6.3	308	0	5.6	256	3.5%	-4.50 [-5.48, -3.52]
Stevens 2001	-1.8	5.8	595	0.6	6.9	596	6.5%	-2.40 [-3.12, -1.68]
Vermunt 2011	-0.5	4.7	479	-0.3	4.9	444	8.8%	-0.20 [-0.82, 0.42]
Villareal 2011	-7.7	4.5	28	0.1	3.1	27	0.8%	-7.80 [-9.84, -5.76]
Vissers 2010 (fitness)	-6.3	6.4	20	1.1	3.4	11	0.3%	-7.40 [-10.85, -3.95]
Vissers 2010 (vibration)	-7.2	6.9	20	1.1	3.4	10	0.2%	-8.30 [-11.99, -4.61]
Wadden 2011	-2.8	6.4	131	-2	6.4	130	1.4%	-0.80 [-2.35, 0.75]
Subtotal (95% CI)			**5856**			**4974**	**80.9%**	**-2.94 [-3.15, -2.74]**
Heterogeneity: Chi² = 489.66, df = 34 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 28.18 (P < 0.00001)								
1.4.2 Remote contact only								
Appel 2011 (CCD)	-5.1	7.6	139	-0.9	4.6	69	1.2%	-4.20 [-5.87, -2.53]
Hersey 2012 (2)	-1.9	5.8	579	-1.2	4.2	299	7.5%	-0.70 [-1.37, -0.03]
Hersey 2012 (3)	-1.8	5.9	578	-1.2	4.2	299	7.4%	-0.60 [-1.28, 0.08]
Patrick 2011	-0.9	7.7	224	-0.2	5.7	217	2.1%	-0.70 [-1.96, 0.56]
Rock 2010 (TB)	-8.5	8	164	-2.5	6.2	55	0.8%	-6.00 [-8.05, -3.95]
Subtotal (95% CI)			**1684**			**939**	**19.1%**	**-1.11 [-1.53, -0.69]**
Heterogeneity: Chi² = 39.20, df = 4 (P < 0.00001); I² = 90%								
Test for overall effect: Z = 5.16 (P < 0.00001)								
Total (95% CI)			**7540**			**5913**	**100.0%**	**-2.59 [-2.78, -2.41]**
Heterogeneity: Chi² = 587.61, df = 39 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 27.60 (P < 0.00001)								
Test for subgroup differences: Chi² = 58.75, df = 1 (P < 0.00001), I² = 98.3%								

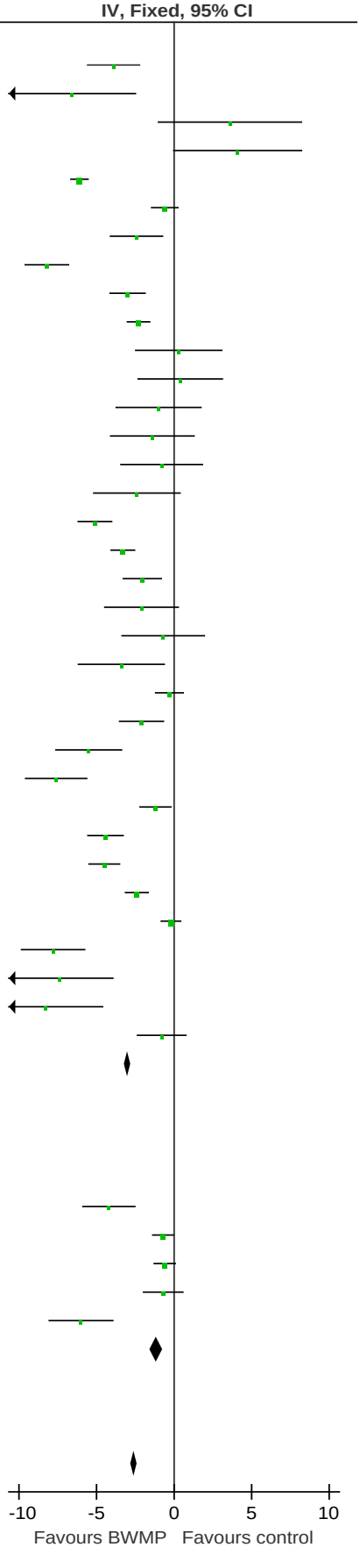


Figure 11. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by supervised versus recommended exercise

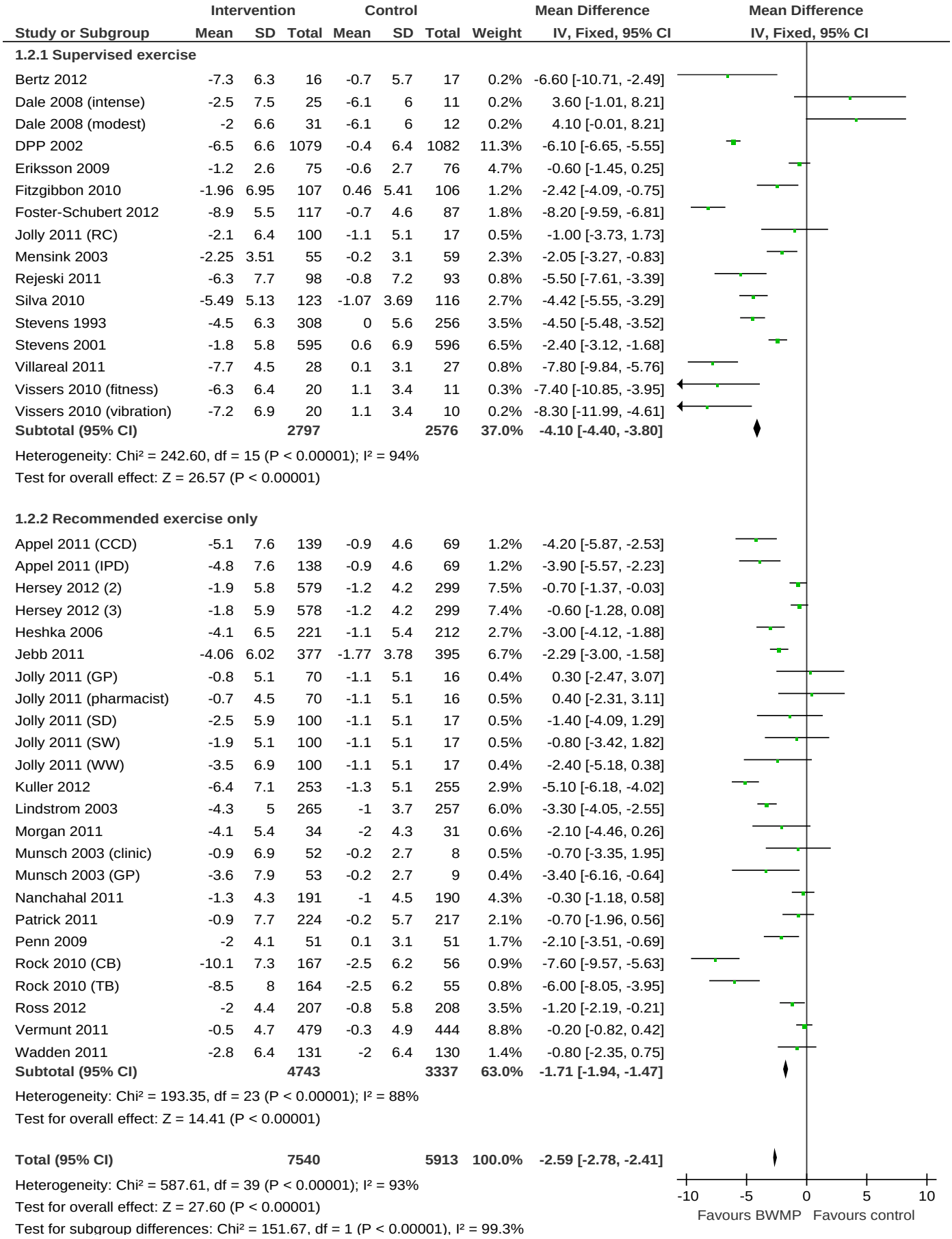


Figure 12. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by set energy intake

Study or Subgroup	BWMP Mean	BWMP SD	BWMP Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
1.7.1 No set daily calorie intake								
Dale 2008 (intense)	-2.5	7.5	25	-6.1	6	11	0.2%	3.60 [-1.01, 8.21]
Dale 2008 (modest)	-2	6.6	31	-6.1	6	12	0.2%	4.10 [-0.01, 8.21]
DPP 2002	-6.5	6.6	1079	-0.4	6.4	1082	11.3%	-6.10 [-6.65, -5.55]
Eriksson 2009	-1.2	2.6	75	-0.6	2.7	76	4.7%	-0.60 [-1.45, 0.25]
Hersey 2012 (2)	-1.9	5.8	579	-1.2	4.2	299	7.5%	-0.70 [-1.37, -0.03]
Hersey 2012 (3)	-1.8	5.9	578	-1.2	4.2	299	7.4%	-0.60 [-1.28, 0.08]
Jolly 2011 (GP)	-0.8	5.1	70	-1.1	5.1	16	0.4%	0.30 [-2.47, 3.07]
Jolly 2011 (pharmacist)	-0.7	4.5	70	-1.1	5.1	16	0.5%	0.40 [-2.31, 3.11]
Jolly 2011 (SD)	-2.5	5.9	100	-1.1	5.1	17	0.5%	-1.40 [-4.09, 1.29]
Jolly 2011 (SW)	-1.9	5.1	100	-1.1	5.1	17	0.5%	-0.80 [-3.42, 1.82]
Lindstrom 2003	-4.3	5	265	-1	3.7	257	6.0%	-3.30 [-4.05, -2.55]
Mensink 2003	-2.25	3.51	55	-0.2	3.1	59	2.3%	-2.05 [-3.27, -0.83]
Munsch 2003 (clinic)	-0.9	6.9	52	-0.2	2.7	8	0.5%	-0.70 [-3.35, 1.95]
Munsch 2003 (GP)	-3.6	7.9	53	-0.2	2.7	9	0.4%	-3.40 [-6.16, -0.64]
Nanchahal 2011	-1.3	4.3	191	-1	4.5	190	4.3%	-0.30 [-1.18, 0.58]
Patrick 2011	-0.9	7.7	224	-0.2	5.7	217	2.1%	-0.70 [-1.96, 0.56]
Penn 2009	-2	4.1	51	0.1	3.1	51	1.7%	-2.10 [-3.51, -0.69]
Ross 2012	-2	4.4	207	-0.8	5.8	208	3.5%	-1.20 [-2.19, -0.21]
Vermunt 2011	-0.5	4.7	479	-0.3	4.9	444	8.8%	-0.20 [-0.82, 0.42]
Subtotal (95% CI)			**4284**			**3288**	**62.8%**	**-1.90 [-2.13, -1.67]**
Heterogeneity: Chi² = 342.86, df = 18 (P < 0.00001); I² = 95%								
Test for overall effect: Z = 16.02 (P < 0.00001)								
1.7.2 Set daily calorie intake								
Appel 2011 (CCD)	-5.1	7.6	139	-0.9	4.6	69	1.2%	-4.20 [-5.87, -2.53]
Appel 2011 (IPD)	-4.8	7.6	138	-0.9	4.6	69	1.2%	-3.90 [-5.57, -2.23]
Bertz 2012	-7.3	6.3	16	-0.7	5.7	17	0.2%	-6.60 [-10.71, -2.49]
Fitzgibbon 2010	-1.96	6.95	107	0.46	5.41	106	1.2%	-2.42 [-4.09, -0.75]
Foster-Schubert 2012	-8.9	5.5	117	-0.7	4.6	87	1.8%	-8.20 [-9.59, -6.81]
Heshka 2006	-4.1	6.5	221	-1.1	5.4	212	2.7%	-3.00 [-4.12, -1.88]
Jebb 2011	-4.06	6.02	377	-1.77	3.78	395	6.7%	-2.29 [-3.00, -1.58]
Jolly 2011 (RC)	-2.1	6.4	100	-1.1	5.1	17	0.5%	-1.00 [-3.73, 1.73]
Jolly 2011 (WW)	-3.5	6.9	100	-1.1	5.1	17	0.4%	-2.40 [-5.18, 0.38]
Kuller 2012	-6.4	7.1	253	-1.3	5.1	255	2.9%	-5.10 [-6.18, -4.02]
Morgan 2011	-4.1	5.4	34	-2	4.3	31	0.6%	-2.10 [-4.46, 0.26]
Rejeski 2011	-6.3	7.7	98	-0.8	7.2	93	0.8%	-5.50 [-7.61, -3.39]
Rock 2010 (CB)	-10.1	7.3	167	-2.5	6.2	56	0.9%	-7.60 [-9.57, -5.63]
Rock 2010 (TB)	-8.5	8	164	-2.5	6.2	55	0.8%	-6.00 [-8.05, -3.95]
Silva 2010	-5.49	5.13	123	-1.07	3.69	116	2.7%	-4.42 [-5.55, -3.29]
Stevens 1993	-4.5	6.3	308	0	5.6	256	3.5%	-4.50 [-5.48, -3.52]
Stevens 2001	-1.8	5.8	595	0.6	6.9	596	6.5%	-2.40 [-3.12, -1.68]
Villareal 2011	-7.7	4.5	28	0.1	3.1	27	0.8%	-7.80 [-9.84, -5.76]
Vissers 2010 (fitness)	-6.3	6.4	20	1.1	3.4	11	0.3%	-7.40 [-10.85, -3.95]
Vissers 2010 (vibration)	-7.2	6.9	20	1.1	3.4	10	0.2%	-8.30 [-11.99, -4.61]
Wadden 2011	-2.8	6.4	131	-2	6.4	130	1.4%	-0.80 [-2.35, 0.75]
Subtotal (95% CI)			**3256**			**2625**	**37.2%**	**-3.76 [-4.06, -3.46]**
Heterogeneity: Chi² = 152.80, df = 20 (P < 0.00001); I² = 87%								
Test for overall effect: Z = 24.44 (P < 0.00001)								
Total (95% CI)			**7540**			**5913**	**100.0%**	**-2.59 [-2.78, -2.41]**
Heterogeneity: Chi² = 587.61, df = 39 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 27.60 (P < 0.00001)								
Test for subgroup differences: Chi² = 91.96, df = 1 (P < 0.00001), I² = 98.9%								

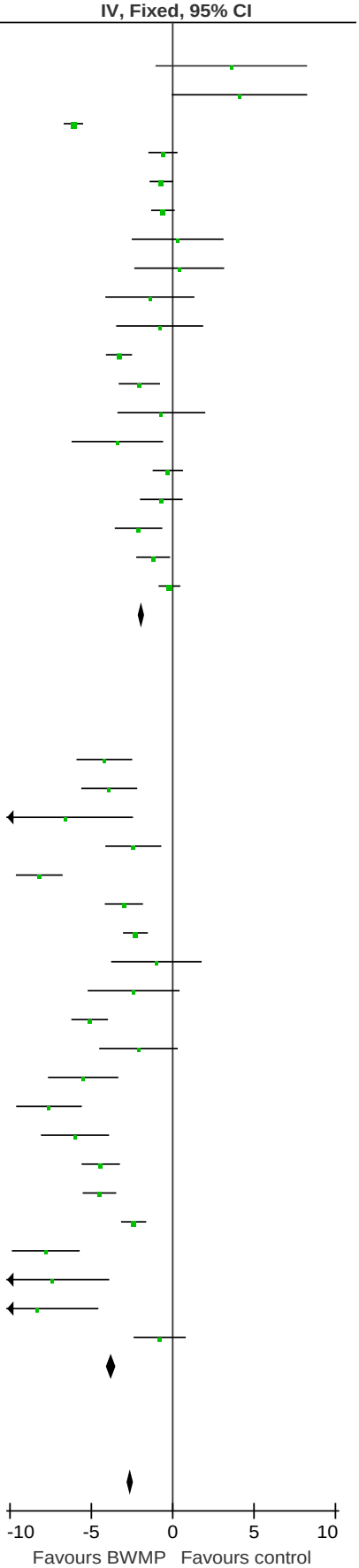


Figure 13. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by programme length

Study or Subgroup	BWMP Mean	BWMP SD	BWMP Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
1.6.1 Up to 3 months								
Bertz 2012	-7.3	6.3	16	-0.7	5.7	17	0.2%	-6.60 [-10.71, -2.49]
Jolly 2011 (GP)	-0.8	5.1	70	-1.1	5.1	16	0.4%	0.30 [-2.47, 3.07]
Jolly 2011 (pharmacist)	-0.7	4.5	70	-1.1	5.1	16	0.5%	0.40 [-2.31, 3.11]
Jolly 2011 (RC)	-2.1	6.4	100	-1.1	5.1	17	0.5%	-1.00 [-3.73, 1.73]
Jolly 2011 (SD)	-2.5	5.9	100	-1.1	5.1	17	0.5%	-1.40 [-4.09, 1.29]
Jolly 2011 (SW)	-1.9	5.1	100	-1.1	5.1	17	0.5%	-0.80 [-3.42, 1.82]
Jolly 2011 (WW)	-3.5	6.9	100	-1.1	5.1	17	0.4%	-2.40 [-5.18, 0.38]
Morgan 2011	-4.1	5.4	34	-2	4.3	31	0.6%	-2.10 [-4.46, 0.26]
Subtotal (95% CI)			**590**			**148**	**3.6%**	**-1.36 [-2.33, -0.38]**
Heterogeneity: Chi² = 10.41, df = 7 (P = 0.17); I² = 33%								
Test for overall effect: Z = 2.73 (P = 0.006)								
1.6.2 4 to 6 months								
Dale 2008 (intense)	-2.5	7.5	25	-6.1	6	11	0.2%	3.60 [-1.01, 8.21]
Dale 2008 (modest)	-2	6.6	31	-6.1	6	12	0.2%	4.10 [-0.01, 8.21]
Munsch 2003 (clinic)	-0.9	6.9	52	-0.2	2.7	8	0.5%	-0.70 [-3.35, 1.95]
Munsch 2003 (GP)	-3.6	7.9	53	-0.2	2.7	9	0.4%	-3.40 [-6.16, -0.64]
Subtotal (95% CI)			**161**			**40**	**1.3%**	**-0.35 [-1.97, 1.27]**
Heterogeneity: Chi² = 12.07, df = 3 (P = 0.007); I² = 75%								
Test for overall effect: Z = 0.42 (P = 0.67)								
1.6.3 Longer than 6 months								
Appel 2011 (CCD)	-5.1	7.6	139	-0.9	4.6	69	1.2%	-4.20 [-5.87, -2.53]
Appel 2011 (IPD)	-4.8	7.6	138	-0.9	4.6	69	1.2%	-3.90 [-5.57, -2.23]
DPP 2002	-6.5	6.6	1079	-0.4	6.4	1082	11.3%	-6.10 [-6.65, -5.55]
Eriksson 2009	-1.2	2.6	75	-0.6	2.7	76	4.7%	-0.60 [-1.45, 0.25]
Fitzgibbon 2010	-1.96	6.95	107	0.46	5.41	106	1.2%	-2.42 [-4.09, -0.75]
Foster-Schubert 2012	-8.9	5.5	117	-0.7	4.6	87	1.8%	-8.20 [-9.59, -6.81]
Hersey 2012 (2)	-1.9	5.8	579	-1.2	4.2	299	7.5%	-0.70 [-1.37, -0.03]
Hersey 2012 (3)	-1.8	5.9	578	-1.2	4.2	299	7.4%	-0.60 [-1.28, 0.08]
Heshka 2006	-4.1	6.5	221	-1.1	5.4	212	2.7%	-3.00 [-4.12, -1.88]
Jebb 2011	-4.06	6.02	377	-1.77	3.78	395	6.7%	-2.29 [-3.00, -1.58]
Kuller 2012	-6.4	7.1	253	-1.3	5.1	255	2.9%	-5.10 [-6.18, -4.02]
Lindstrom 2003	-4.3	5	265	-1	3.7	257	6.0%	-3.30 [-4.05, -2.55]
Mensink 2003	-2.25	3.51	55	-0.2	3.1	59	2.3%	-2.05 [-3.27, -0.83]
Nanchahal 2011	-1.3	4.3	191	-1	4.5	190	4.3%	-0.30 [-1.18, 0.58]
Patrick 2011	-0.9	7.7	224	-0.2	5.7	217	2.1%	-0.70 [-1.96, 0.56]
Penn 2009	-2	4.1	51	0.1	3.1	51	1.7%	-2.10 [-3.51, -0.69]
Rejeski 2011	-6.3	7.7	98	-0.8	7.2	93	0.8%	-5.50 [-7.61, -3.39]
Rock 2010 (CB)	-10.1	7.3	167	-2.5	6.2	56	0.9%	-7.60 [-9.57, -5.63]
Rock 2010 (TB)	-8.5	8	164	-2.5	6.2	55	0.8%	-6.00 [-8.05, -3.95]
Ross 2012	-2	4.4	207	-0.8	5.8	208	3.5%	-1.20 [-2.19, -0.21]
Silva 2010	-5.49	5.13	123	-1.07	3.69	116	2.7%	-4.42 [-5.55, -3.29]
Stevens 1993	-4.5	6.3	308	0	5.6	256	3.5%	-4.50 [-5.48, -3.52]
Stevens 2001	-1.8	5.8	595	0.6	6.9	596	6.5%	-2.40 [-3.12, -1.68]
Vermunt 2011	-0.5	4.7	479	-0.3	4.9	444	8.8%	-0.20 [-0.82, 0.42]
Villareal 2011	-7.7	4.5	28	0.1	3.1	27	0.8%	-7.80 [-9.84, -5.76]
Vissers 2010 (fitness)	-6.3	6.4	20	1.1	3.4	11	0.3%	-7.40 [-10.85, -3.95]
Vissers 2010 (vibration)	-7.2	6.9	20	1.1	3.4	10	0.2%	-8.30 [-11.99, -4.61]
Wadden 2011	-2.8	6.4	131	-2	6.4	130	1.4%	-0.80 [-2.35, 0.75]
Subtotal (95% CI)			**6789**			**5725**	**95.1%**	**-2.67 [-2.86, -2.48]**
Heterogeneity: Chi² = 551.02, df = 27 (P < 0.00001); I² = 95%								
Test for overall effect: Z = 27.72 (P < 0.00001)								
Total (95% CI)			**7540**			**5913**	**100.0%**	**-2.59 [-2.78, -2.41]**
Heterogeneity: Chi² = 587.61, df = 39 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 27.60 (P < 0.00001)								
Test for subgroup differences: Chi² = 14.11, df = 2 (P = 0.0009), I² = 85.8%								

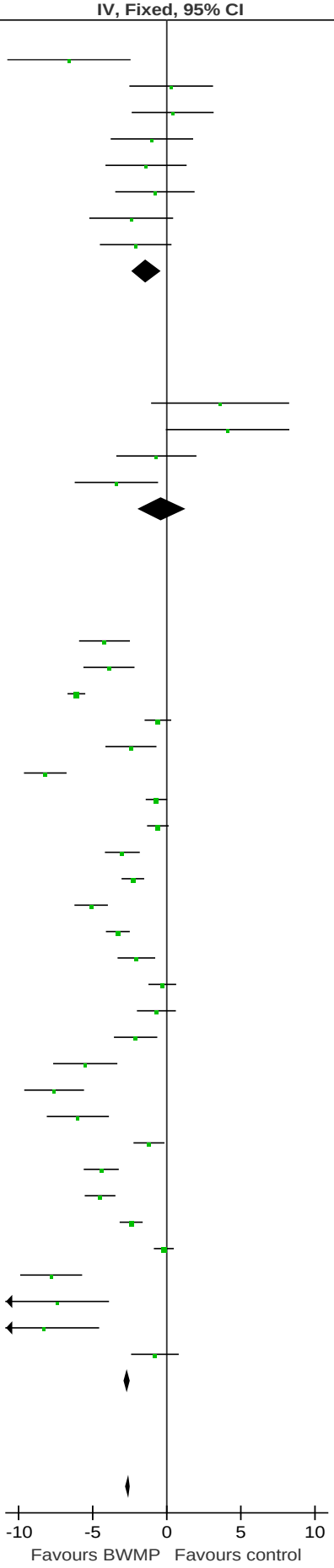


Figure 14. BWMP weight change from baseline, subgroup analysis by programme length (<3 month interventions)

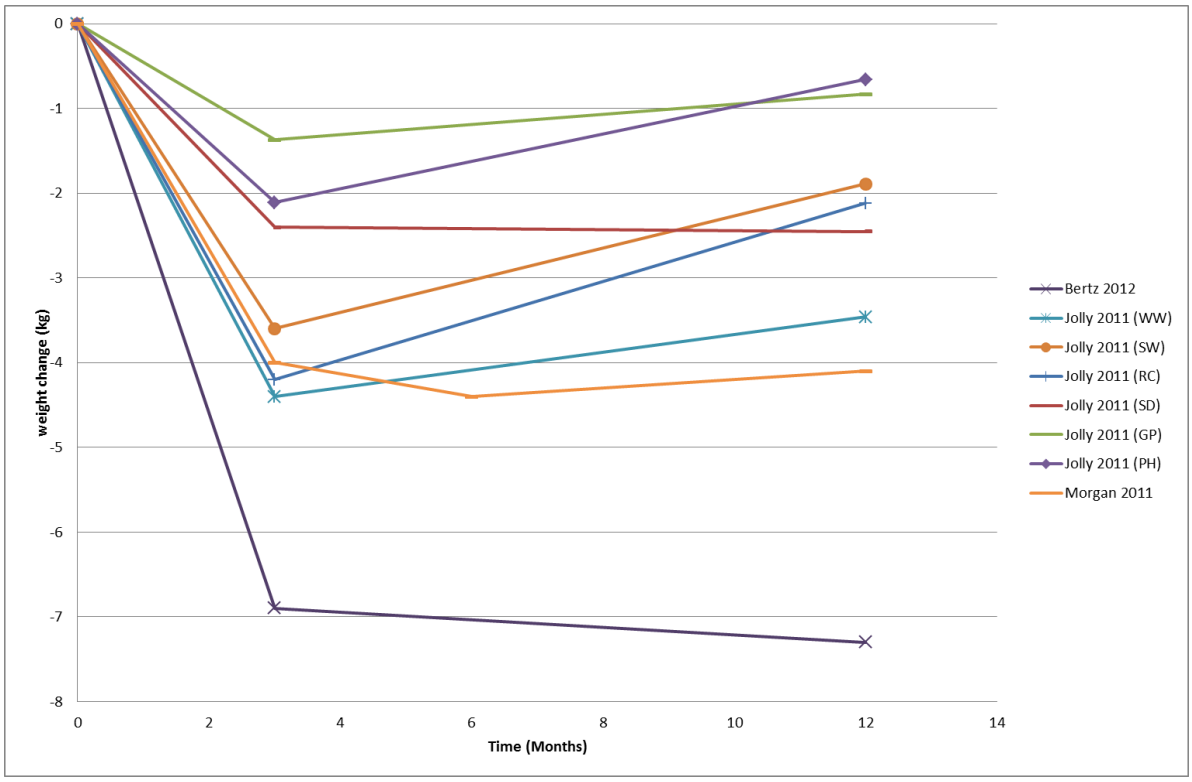


Figure 15. BWMP weight change from baseline, subgroup analysis by programme length (4-6 month interventions)

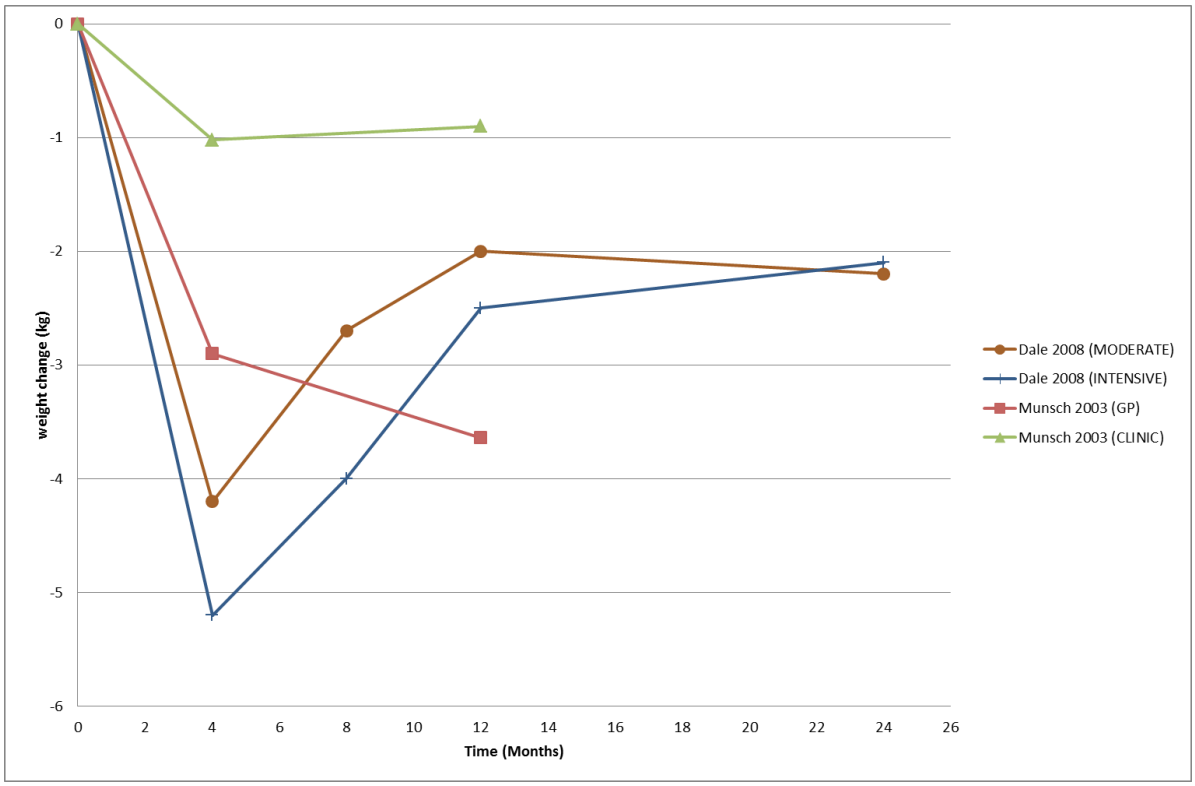


Figure 16. BWMP weight change from baseline, subgroup analysis by programme length (>6 month interventions)

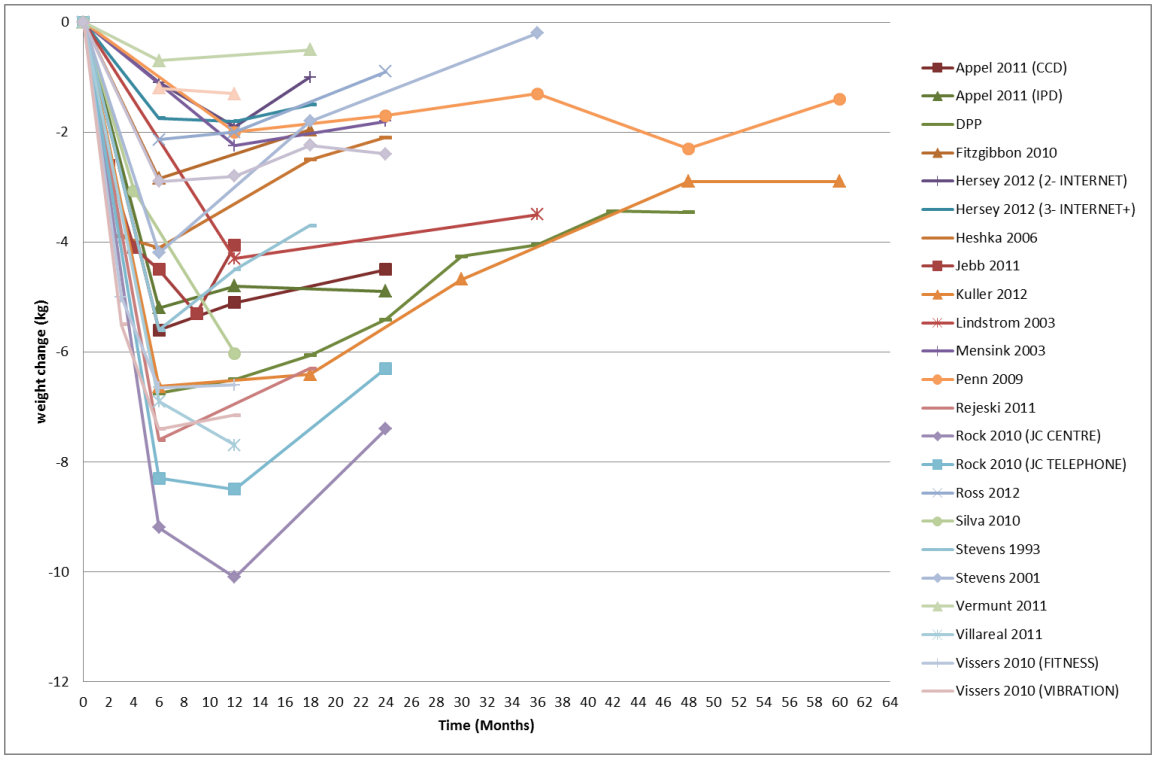


Figure 17. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by contact frequency

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.8.1 At least weekly								
Appel 2011 (IPD)	-4.8	7.6	138	-0.9	4.6	69	1.2%	-3.90 [-5.57, -2.23]
Dale 2008 (intense)	-2.5	7.5	25	-6.1	6	11	0.2%	3.60 [-1.01, 8.21]
Dale 2008 (modest)	-2	6.6	31	-6.1	6	12	0.2%	4.10 [-0.01, 8.21]
Fitzgibbon 2010	-1.96	6.95	107	0.46	5.41	106	1.2%	-2.42 [-4.09, -0.75]
Foster-Schubert 2012	-8.9	5.5	117	-0.7	4.6	87	1.8%	-8.20 [-9.59, -6.81]
Heshka 2006	-4.1	6.5	221	-1.1	5.4	212	2.7%	-3.00 [-4.12, -1.88]
Jebb 2011	-4.06	6.02	377	-1.77	3.78	395	6.7%	-2.29 [-3.00, -1.58]
Jolly 2011 (GP)	-0.8	5.1	70	-1.1	5.1	16	0.4%	0.30 [-2.47, 3.07]
Jolly 2011 (pharmacist)	-0.7	4.5	70	-1.1	5.1	16	0.5%	0.40 [-2.31, 3.11]
Jolly 2011 (RC)	-2.1	6.4	100	-1.1	5.1	17	0.5%	-1.00 [-3.73, 1.73]
Jolly 2011 (SD)	-2.5	5.9	100	-1.1	5.1	17	0.5%	-1.40 [-4.09, 1.29]
Jolly 2011 (SW)	-1.9	5.1	100	-1.1	5.1	17	0.5%	-0.80 [-3.42, 1.82]
Jolly 2011 (WW)	-3.5	6.9	100	-1.1	5.1	17	0.4%	-2.40 [-5.18, 0.38]
Kuller 2012	-6.4	7.1	253	-1.3	5.1	255	2.9%	-5.10 [-6.18, -4.02]
Mensink 2003	-2.25	3.51	55	-0.2	3.1	59	2.3%	-2.05 [-3.27, -0.83]
Munsch 2003 (clinic)	-0.9	6.9	52	-0.2	2.7	8	0.5%	-0.70 [-3.35, 1.95]
Munsch 2003 (GP)	-3.6	7.9	53	-0.2	2.7	9	0.4%	-3.40 [-6.16, -0.64]
Patrick 2011	-0.9	7.7	224	-0.2	5.7	217	2.1%	-0.70 [-1.96, 0.56]
Rejeski 2011	-6.3	7.7	98	-0.8	7.2	93	0.8%	-5.50 [-7.61, -3.39]
Rock 2010 (CB)	-10.1	7.3	167	-2.5	6.2	56	0.9%	-7.60 [-9.57, -5.63]
Rock 2010 (TB)	-8.5	8	164	-2.5	6.2	55	0.8%	-6.00 [-8.05, -3.95]
Stevens 1993	-4.5	6.3	308	0	5.6	256	3.5%	-4.50 [-5.48, -3.52]
Stevens 2001	-1.8	5.8	595	0.6	6.9	596	6.5%	-2.40 [-3.12, -1.68]
Villareal 2011	-7.7	4.5	28	0.1	3.1	27	0.8%	-7.80 [-9.84, -5.76]
Subtotal (95% CI)			**3553**			**2623**	**38.2%**	**-3.21 [-3.51, -2.91]**
Heterogeneity: Chi² = 194.79, df = 23 (P < 0.00001); I² = 88%								
Test for overall effect: Z = 21.13 (P < 0.00001)								
1.8.2 At least fortnightly								
Appel 2011 (CCD)	-5.1	7.6	139	-0.9	4.6	69	1.2%	-4.20 [-5.87, -2.53]
DPP 2002	-6.5	6.6	1079	-0.4	6.4	1082	11.3%	-6.10 [-6.65, -5.55]
Hersey 2012 (2)	-1.9	5.8	579	-1.2	4.2	299	7.5%	-0.70 [-1.37, -0.03]
Hersey 2012 (3)	-1.8	5.9	578	-1.2	4.2	299	7.4%	-0.60 [-1.28, 0.08]
Morgan 2011	-4.1	5.4	34	-2	4.3	31	0.6%	-2.10 [-4.46, 0.26]
Nanchahal 2011	-1.3	4.3	191	-1	4.5	190	4.3%	-0.30 [-1.18, 0.58]
Ross 2012	-2	4.4	207	-0.8	5.8	208	3.5%	-1.20 [-2.19, -0.21]
Silva 2010	-5.49	5.13	123	-1.07	3.69	116	2.7%	-4.42 [-5.55, -3.29]
Vissers 2010 (fitness)	-6.3	6.4	20	1.1	3.4	11	0.3%	-7.40 [-10.85, -3.95]
Vissers 2010 (vibration)	-7.2	6.9	20	1.1	3.4	10	0.2%	-8.30 [-11.99, -4.61]
Subtotal (95% CI)			**2970**			**2315**	**39.0%**	**-2.72 [-3.02, -2.43]**
Heterogeneity: Chi² = 284.32, df = 9 (P < 0.00001); I² = 97%								
Test for overall effect: Z = 18.12 (P < 0.00001)								
1.8.3 At least monthly								
Eriksson 2009	-1.2	2.6	75	-0.6	2.7	76	4.7%	-0.60 [-1.45, 0.25]
Penn 2009	-2	4.1	51	0.1	3.1	51	1.7%	-2.10 [-3.51, -0.69]
Wadden 2011	-2.8	6.4	131	-2	6.4	130	1.4%	-0.80 [-2.35, 0.75]
Subtotal (95% CI)			**257**			**257**	**7.8%**	**-0.96 [-1.62, -0.30]**
Heterogeneity: Chi² = 3.25, df = 2 (P = 0.20); I² = 38%								
Test for overall effect: Z = 2.87 (P = 0.004)								
1.8.4 At least once every 2 months								
Bertz 2012	-7.3	6.3	16	-0.7	5.7	17	0.2%	-6.60 [-10.71, -2.49]
Lindstrom 2003	-4.3	5	265	-1	3.7	257	6.0%	-3.30 [-4.05, -2.55]
Subtotal (95% CI)			**281**			**274**	**6.2%**	**-3.41 [-4.15, -2.67]**
Heterogeneity: Chi² = 2.40, df = 1 (P = 0.12); I² = 58%								
Test for overall effect: Z = 9.02 (P < 0.00001)								
1.8.5 Less than once every two months								
Vermunt 2011	-0.5	4.7	479	-0.3	4.9	444	8.8%	-0.20 [-0.82, 0.42]
Subtotal (95% CI)			**479**			**444**	**8.8%**	**-0.20 [-0.82, 0.42]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.63 (P = 0.53)								
Total (95% CI)			**7540**			**5913**	**100.0%**	**-2.59 [-2.78, -2.41]**
Heterogeneity: Chi² = 587.61, df = 39 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 27.60 (P < 0.00001)								
Test for subgroup differences: Chi² = 102.86, df = 4 (P < 0.00001), I² = 96.1%								

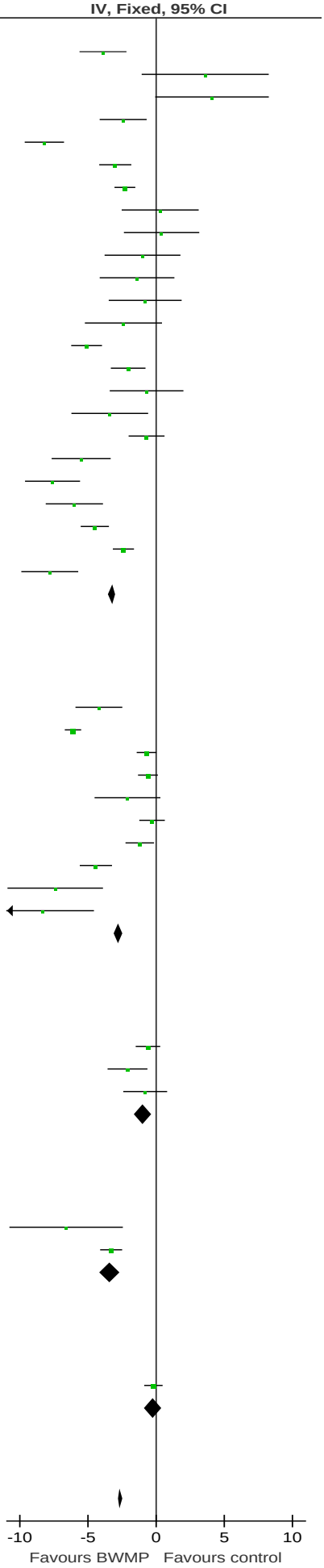


Figure 18. Forest plot of BWMP versus control, weight change at 12 months, subgroup analysis by control category

Study or Subgroup	BWMP Mean	BWMP SD	BWMP Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
1.5.1 Control 1								
Bertz 2012	-7.3	6.3	16	-0.7	5.7	17	0.2%	-6.60 [-10.71, -2.49]
Foster-Schubert 2012	-8.9	5.5	117	-0.7	4.6	87	1.8%	-8.20 [-9.59, -6.81]
Jolly 2011 (GP)	-0.8	5.1	70	-1.1	5.1	16	0.4%	0.30 [-2.47, 3.07]
Jolly 2011 (pharmacist)	-0.7	4.5	70	-1.1	5.1	16	0.5%	0.40 [-2.31, 3.11]
Jolly 2011 (RC)	-2.1	6.4	100	-1.1	5.1	17	0.5%	-1.00 [-3.73, 1.73]
Jolly 2011 (SD)	-2.5	5.9	100	-1.1	5.1	17	0.5%	-1.40 [-4.09, 1.29]
Jolly 2011 (SW)	-1.9	5.1	100	-1.1	5.1	17	0.5%	-0.80 [-3.42, 1.82]
Jolly 2011 (WW)	-3.5	6.9	100	-1.1	5.1	17	0.4%	-2.40 [-5.18, 0.38]
Nanchahal 2011	-1.3	4.3	191	-1	4.5	190	4.3%	-0.30 [-1.18, 0.58]
Patrick 2011	-0.9	7.7	224	-0.2	5.7	217	2.1%	-0.70 [-1.96, 0.56]
Stevens 1993	-4.5	6.3	308	0	5.6	256	3.5%	-4.50 [-5.48, -3.52]
Stevens 2001	-1.8	5.8	595	0.6	6.9	596	6.5%	-2.40 [-3.12, -1.68]
Vissers 2010 (fitness)	-6.3	6.4	20	1.1	3.4	11	0.3%	-7.40 [-10.85, -3.95]
Vissers 2010 (vibration)	-7.2	6.9	20	1.1	3.4	10	0.2%	-8.30 [-11.99, -4.61]
Subtotal (95% CI)			**2031**			**1484**	**21.7%**	**-2.59 [-2.99, -2.20]**
Heterogeneity: Chi² = 144.97, df = 13 (P < 0.00001); I² = 91%								
Test for overall effect: Z = 12.86 (P < 0.00001)								
1.5.2 Control 2								
Appel 2011 (CCD)	-5.1	7.6	139	-0.9	4.6	69	1.2%	-4.20 [-5.87, -2.53]
Appel 2011 (IPD)	-4.8	7.6	138	-0.9	4.6	69	1.2%	-3.90 [-5.57, -2.23]
Eriksson 2009	-1.2	2.6	75	-0.6	2.7	76	4.7%	-0.60 [-1.45, 0.25]
Hersey 2012 (2)	-1.9	5.8	579	-1.2	4.2	299	7.5%	-0.70 [-1.37, -0.03]
Hersey 2012 (3)	-1.8	5.9	578	-1.2	4.2	299	7.4%	-0.60 [-1.28, 0.08]
Lindstrom 2003	-4.3	5	265	-1	3.7	257	6.0%	-3.30 [-4.05, -2.55]
Mensink 2003	-2.25	3.51	55	-0.2	3.1	59	2.3%	-2.05 [-3.27, -0.83]
Morgan 2011	-4.1	5.4	34	-2	4.3	31	0.6%	-2.10 [-4.46, 0.26]
Penn 2009	-2	4.1	51	0.1	3.1	51	1.7%	-2.10 [-3.51, -0.69]
Ross 2012	-2	4.4	207	-0.8	5.8	208	3.5%	-1.20 [-2.19, -0.21]
Vermunt 2011	-0.5	4.7	479	-0.3	4.9	444	8.8%	-0.20 [-0.82, 0.42]
Subtotal (95% CI)			**2600**			**1862**	**44.9%**	**-1.28 [-1.56, -1.01]**
Heterogeneity: Chi² = 73.11, df = 10 (P < 0.00001); I² = 86%								
Test for overall effect: Z = 9.15 (P < 0.00001)								
1.5.3 Control 3								
Fitzgibbon 2010	-1.96	6.95	107	0.46	5.41	106	1.2%	-2.42 [-4.09, -0.75]
Kuller 2012	-6.4	7.1	253	-1.3	5.1	255	2.9%	-5.10 [-6.18, -4.02]
Rejeski 2011	-6.3	7.7	98	-0.8	7.2	93	0.8%	-5.50 [-7.61, -3.39]
Silva 2010	-5.49	5.13	123	-1.07	3.69	116	2.7%	-4.42 [-5.55, -3.29]
Subtotal (95% CI)			**581**			**570**	**7.6%**	**-4.47 [-5.14, -3.80]**
Heterogeneity: Chi² = 8.01, df = 3 (P = 0.05); I² = 63%								
Test for overall effect: Z = 13.09 (P < 0.00001)								
1.5.4 Control 4								
Dale 2008 (intense)	-2.5	7.5	25	-6.1	6	11	0.2%	3.60 [-1.01, 8.21]
Dale 2008 (modest)	-2	6.6	31	-6.1	6	12	0.2%	4.10 [-0.01, 8.21]
DPP 2002	-6.5	6.6	1079	-0.4	6.4	1082	11.3%	-6.10 [-6.65, -5.55]
Heshka 2006	-4.1	6.5	221	-1.1	5.4	212	2.7%	-3.00 [-4.12, -1.88]
Jebb 2011	-4.06	6.02	377	-1.77	3.78	395	6.7%	-2.29 [-3.00, -1.58]
Munsch 2003 (clinic)	-0.9	6.9	52	-0.2	2.7	8	0.5%	-0.70 [-3.35, 1.95]
Munsch 2003 (GP)	-3.6	7.9	53	-0.2	2.7	9	0.4%	-3.40 [-6.16, -0.64]
Rock 2010 (CB)	-10.1	7.3	167	-2.5	6.2	56	0.9%	-7.60 [-9.57, -5.63]
Rock 2010 (TB)	-8.5	8	164	-2.5	6.2	55	0.8%	-6.00 [-8.05, -3.95]
Villareal 2011	-7.7	4.5	28	0.1	3.1	27	0.8%	-7.80 [-9.84, -5.76]
Wadden 2011	-2.8	6.4	131	-2	6.4	130	1.4%	-0.80 [-2.35, 0.75]
Subtotal (95% CI)			**2328**			**1997**	**25.8%**	**-4.32 [-4.68, -3.96]**
Heterogeneity: Chi² = 156.25, df = 10 (P < 0.00001); I² = 94%								
Test for overall effect: Z = 23.38 (P < 0.00001)								
Total (95% CI)			**7540**			**5913**	**100.0%**	**-2.59 [-2.78, -2.41]**
Heterogeneity: Chi² = 587.61, df = 39 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 27.60 (P < 0.00001)								
Test for subgroup differences: Chi² = 205.27, df = 3 (P < 0.00001), I² = 98.5%								

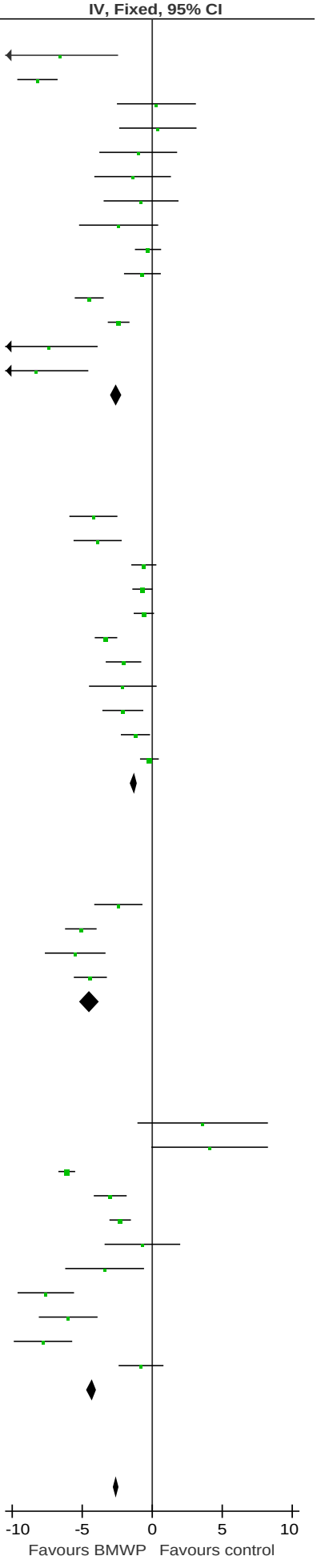
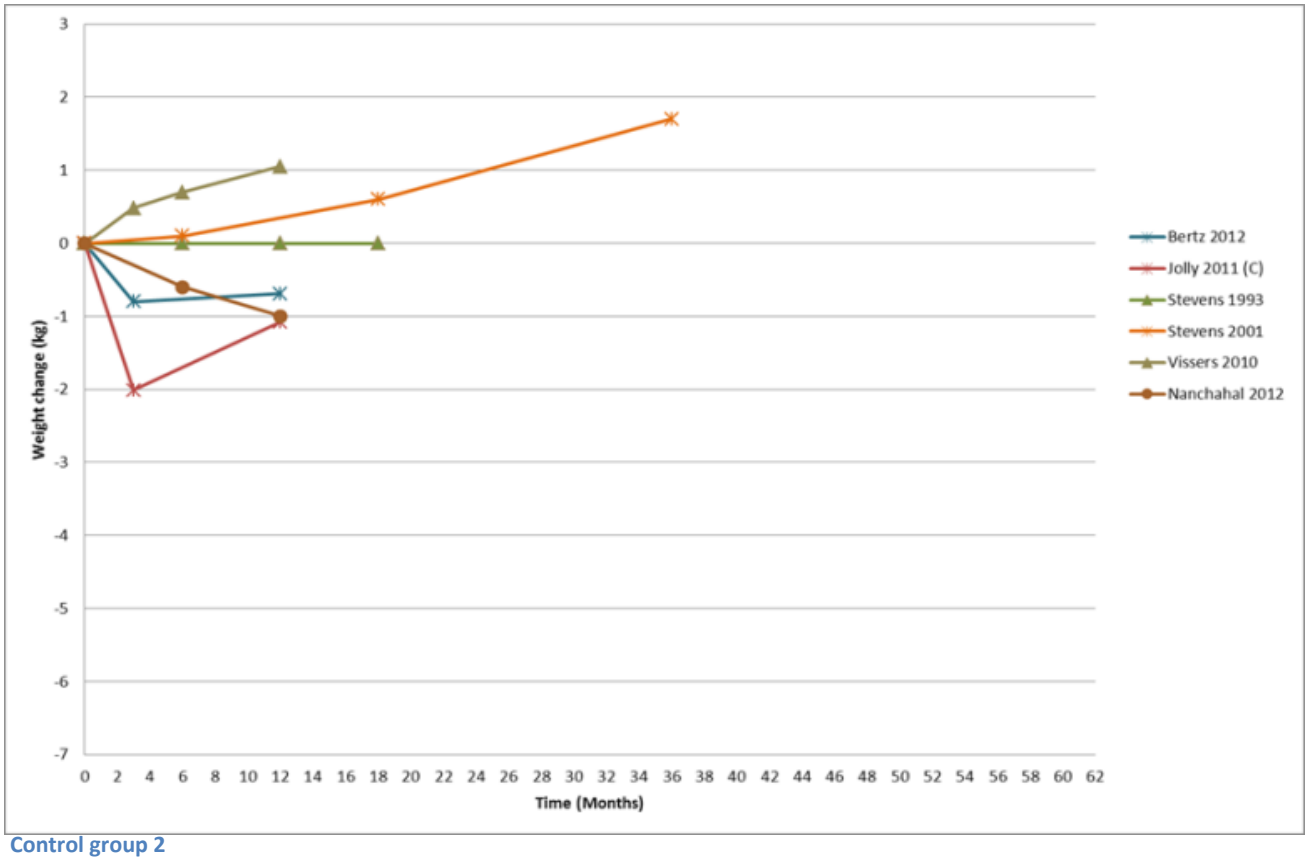
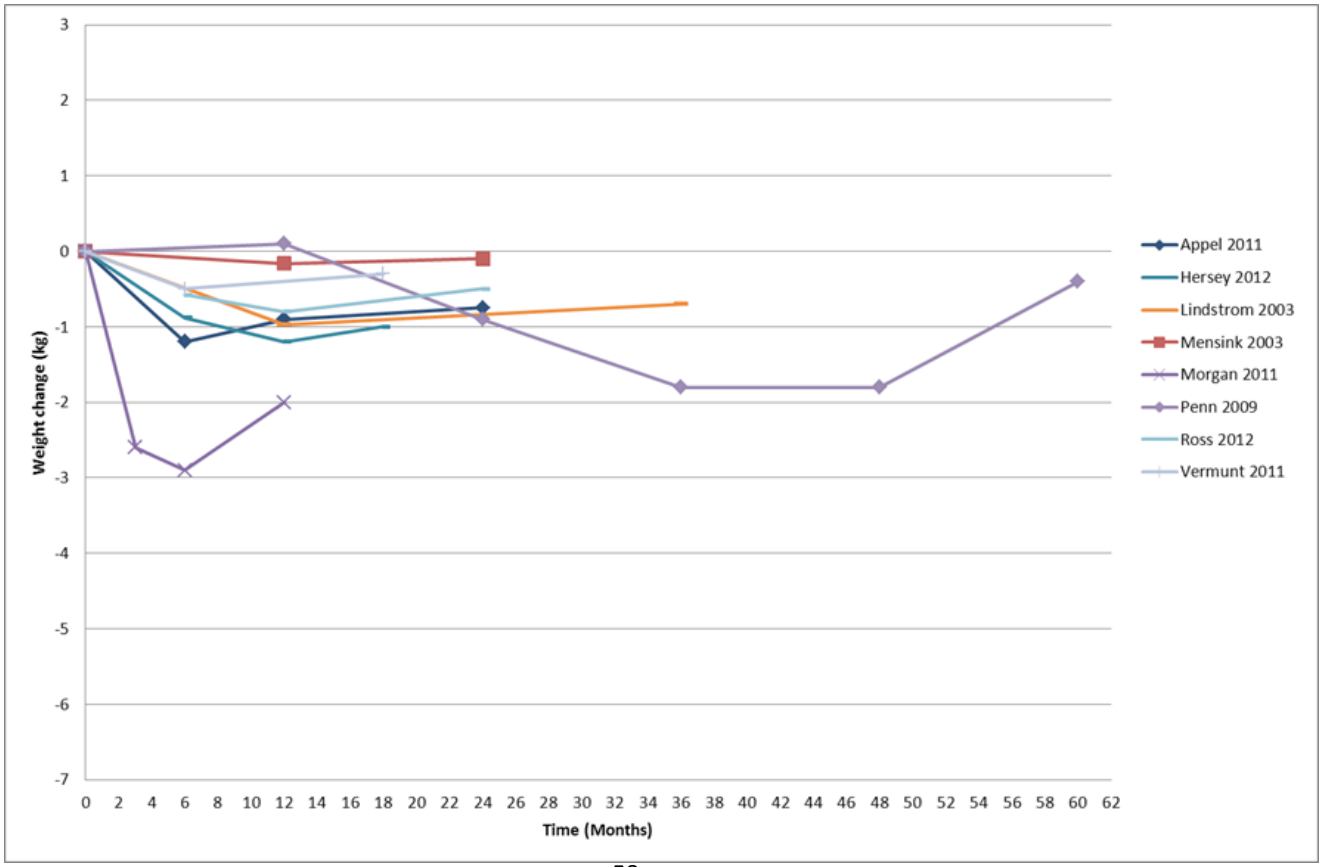


Figure 19. Control weight change from baseline, subgroup analysis by control category

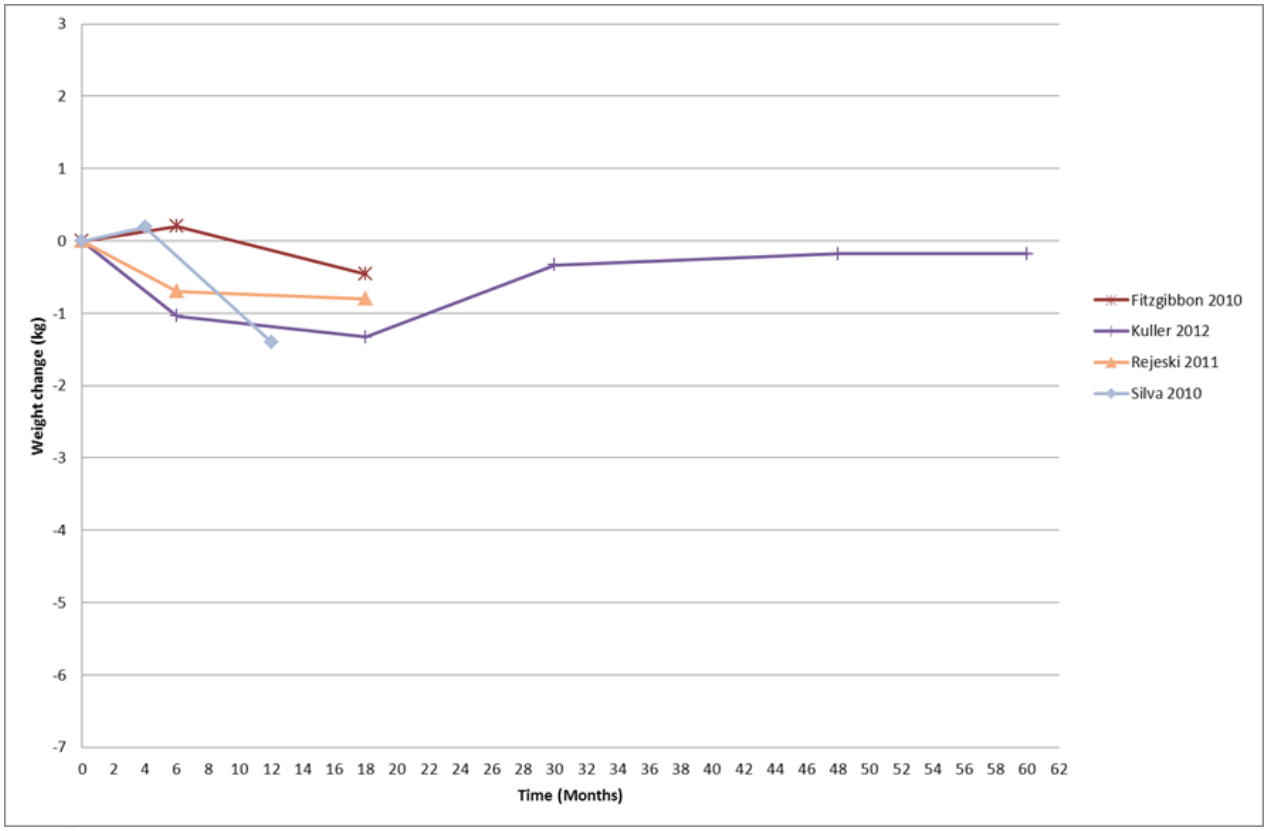
Control group 1



Control group 2



Control group 3



Control group 4

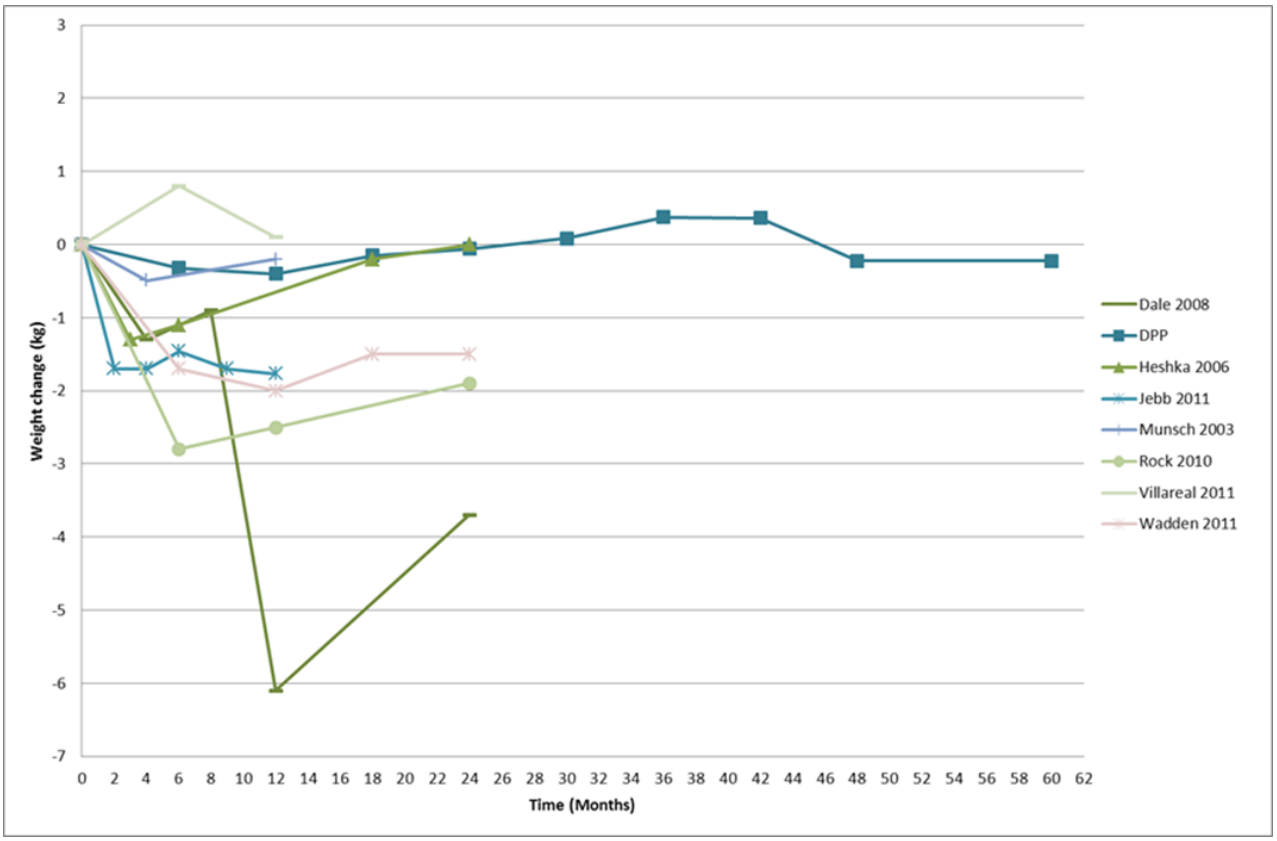
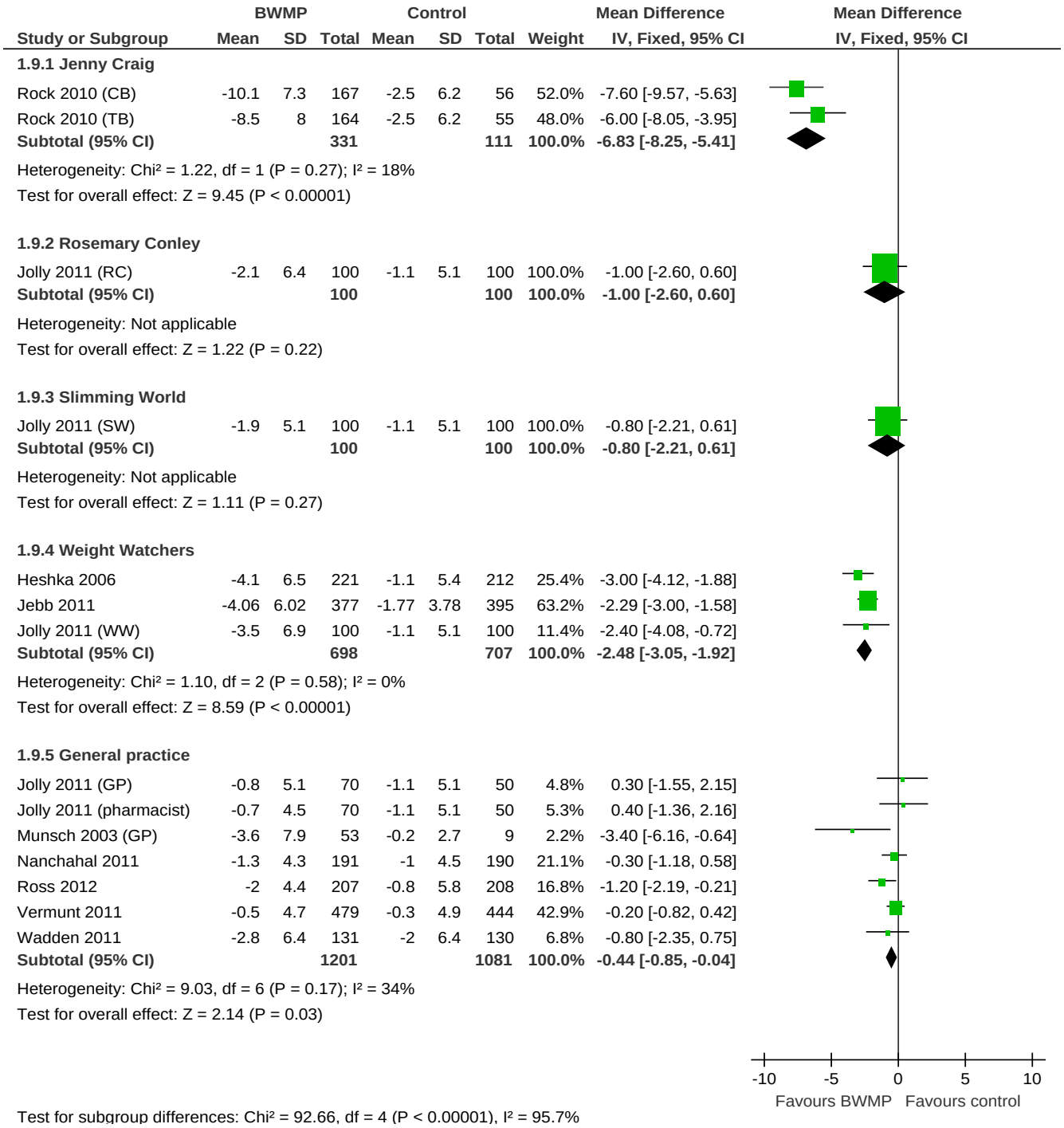


Figure 20. Forest plot of BWMP versus control, weight change at 12 months, interventions currently available in the UK



Test for subgroup differences: Chi² = 92.66, df = 4 (P < 0.00001), I² = 95.7%

Intermediate outcomes

Reporting of diet and/or physical activity measures was inconsistent in included studies. Eleven of the 30 included studies presented data or comment on diet and 16 included studies presented data on physical activity. Data on dietary and physical activity outcomes may be subject to selective reporting, especially as they were not the primary outcome of the included studies, and therefore findings below should be interpreted with caution.

Table 2 Intermediate outcomes: changes in diet and physical activity

Study	12 months (or nearest follow-up), presented as BWMP vs control			Comments
	Weight difference (kg)	Difference in change in energy intake	Difference in physical activity	
Bertz 2012	-6.60 [-10.71, -2.49]	-526 kcal (-858±665 v -332±446kcal)	Change in steps/day: No significant difference (1588±2652 v 766±3247 steps/day)) Change in TEE: No significant difference (-136±326 v 140±376 kcal/d)	
Dale 2009	Intense: 3.60 [-1.01, 8.21] Modest: 4.10 [-0.01, 8.21]	No significant difference (24 months) +206kcal (-753 v -959kcal)	Change in VO_2 max: No significant difference (24 months) -1 (0.5 v 1.5ml/min/kg)	Only combined intervention data is available for Diet and Exercise
DPP	-6.10 [-6.66, -5.54]	-201kcal (-450±26 v -249±27kcal)	Change in MET hr/wk: +6 MET (7.3 v1.3 MET)	Significantly greater decrease in fat intake. A greater increase in physical activity was maintained at 2, 3 and 4 years.
Eriksson 2009	-0.60 [-1.45, 0.25]	NR	VO_2max (30 months) +0.1l/min (2.2; 95% CI 2.11–2.29 v 2.1; 95% CI 2.00–2.19 l/min)	Greater improvement after 3 months (VO_2max 0.3 l/min; p = 0.006) then gradual decline in improvement to 30 months
Fitzgibbon 210	-2.42 [-4.09, -0.75]	No significant difference (18 months) (Data: NR)	No significant difference (70.6 v 81.4 min/day; *P* =0.4)	HEI: adjusted difference between groups was 5.16; 95% CI 2.03–8.30, *P* = 0.001
Foster-Schubert 2012	-8.20 [-9.59, -6.81]	No significant difference -26kcal (-273 v -247kcal)	Change in steps/day: +2858 steps/day (3,408±3,001 v 550±NR steps/day) Change in VO_2max: + 0.10 l/min (0.12±0.34 v -0.02±NR l/min)	Significantly greater reduction in percentage energy intake from fat
Jebb 2011	-2.29 [-3.00, -1.58]	-178kcal (±NR)	NR	Significantly greater decrease in total fat, saturated fat and greater increase in fibre density.
Jeffery 1995	NR	NR	NR	Greater improvement in fat intake and nutrition knowledge at 18 months. No difference at 30 months.

Study	12 months (or nearest follow-up), presented as BWMP vs control			Comments
	Weight difference (kg)	Difference in change in energy intake	Difference in physical activity	
Jolly 2010	WW: -2.40 [-5.18, 0.38]; SW: -0.80 [-3.42, 1.82]; RC: -1.00 [-3.73, 1.73]; SD: -1.40 [-4.09, 1.29]; GP: 0.30 [-2.47, 3.07]; Pharmacist: 0.40 [-2.31, 3.11]	NR	Change in physical activity (kcal/week): WW: +282** (2048; 95%CI 1262-2834 v 1766; 95%CI 1044-2487kcal/wk); SW:-404 (1362; 95%CI 645-2078 v 1766; 95%CI 1044-2487kcal/wk); RC: -337 (1429; 95%CI 657-2202 v 1766; 95%CI 1044-2487kcal/wk); SD: -337 (1429; 95% CI 644-2213 v 1766; 95%CI 1044-2487kcal/wk); GP: -905* (861; 95%CI 256-1467 v 1766; 95%CI 1044-2487kcal/wk); Pharmacist: -293 (1473 (95%CI 742-2203 v 1766; 95%CI 1044-2487kcal/wk)	** <0.001 *<0.05
Kuller 2012	-5.10 [-6.18, -4.02]	No significant difference (18 months) (14% reduction in both groups)	Change in MET hr/wk (18 months): -5.4 MET (5.9±10.9 v 0.6±13.0 MET)	
Lindstrom 2003	-3.30 [-4.05, -2.55]	-108 kcal (-247 ± 438kcal v -108 ± 464kcal)	Change in moderate to vigorous LTPA: +35min/wk (49; 95% CI -41-140 v 14; 95% CI -47-90 min/wk) Change in total LTPA (min/week): No significant difference (16; 95% CI -126-115 v 21; 95% CI -133-138 min/wk)	Greater increase in percentage energy from carbohydrate and fibre density and greater reduction in energy intake from total fat, saturated fat and monounsaturated fat. At 3 years differences remained significantly different. Significant increase in moderate to vigorous maintained at 3 years.
Mensink 2003	-2.05 [-3.27, -0.83]	No significant difference -165kcal (-186 v -21kcal)		Significantly greater increase in carbohydrate and fibre intake and reduction in total fatty acid and saturated fatty acid intake.
Patrick 2011	-0.70 [-1.96, 0.56]	NR	Change in total walking (min/day): 15.3 min/day (-24.0 v 8.7) (P = 0.049) Change in MET (min/week): No significant difference 4.4min/wk (5.4 v 1.0)	Significantly greater reduction in percentage of energy intake from fat and an increase in fibre density and servings of fruit and vegetables
Penn 2009	-2.10 [-3.51, -0.69]	NR	No Significant difference (Data: NR)	No significant difference in change in percentage of energy intake from fat and carbohydrate and the intake of dietary fibre
Rejeski 2011	-5.50 [-7.61, -3.39]	NR	400m walk time (18 months) -16s (321.4±56.6 v 337.1±56.8s)	Significant improvement in 400m walking time -18.0s (95% CI, 7.5-28.5) maintained at 18 months
Ross 2012	-1.20 [-2.19, -0.21]	NR	No significant difference (24 months) (Data: NR)	
Silva 2010	-4.42 [-5.55, -3.29]	NR	Steps per day: +2,049 ± 571 (p<0.0001) Moderate and vigorous PA (min/week): +138 ± 26 (p<0.0001)	

Study	12 months (or nearest follow-up), presented as BWMP vs control			Comments
	Weight difference (kg)	Difference in change in energy intake	Difference in physical activity	
Stevens 1993	-4.50 [-5.48, -3.52]	NR	x week of exercise resulting in perspiration: +1.14 (1.15 v 0.01; p<0.001)	
Vermunt 2011	-0.20 [-0.82, 0.42]	No significant difference (18 months) -81kcal (-278 ±466 v -197±449kcal)	Physical activity (min/wk) (18 months): Significant decrease in both groups but Intervention group decreased significantly less than control. (-84 v -290 min/week; p = 0.02)	

In summary, in eight of the eleven studies, the intervention group showed significant changes in dietary behaviour when compared to the control group, but this included parameters as varied as fruit intake, energy intake, and healthy eating index scores. In the 16 studies that reported physical activity, 14 reported improvements in physical activity with 11 observing significantly greater improvement in physical activity in BWMPs. Of the six studies that measured physical activity outcomes at more than one time point (typically during or immediately after the intervention and then at a later follow-up), three found the significant difference remained at a longer follow-up period.

Effectiveness by population group

Only seven of the 30 included studies considered whether the effects of interventions varied based on population characteristics. This section summarises relevant information from those seven studies, as well as information from studies with pre-specified populations. Specific information on age, gender, and ethnicity is covered below. No studies considered the effects of sexual orientation, disability, religion, place of residence, occupation, education, socioeconomic position or social capital on the efficacy of BWMPs.

Age

The only study to break down results by age was DPP, where weight loss curves by age are presented over the course of 10 years in three groups: participants aged 25 to 44 at randomization, those aged 45 to 59 at randomization, and those age 60 years and older. The information is only reported graphically; hence exact figures cannot be given. Extrapolating from the graph, weight loss was greatest in those 60 and over at all time points, in both the intervention and control groups. Approximate figures (from extrapolating) are given in Table 3.

Table 3. Mean weight loss in DPP, broken down by age group (extrapolated from graph[37])

Age at randomization	One year		Two years		Four years	
	Intervention	Control	Intervention	Control	Intervention	Control
25 to 44	-6.0	-0.2	-4.8	-0.2	-2.0	+1.0
45 to 59	-7.0	-0.5	-5.0	+0.2	-2.8	-0.8
60+	-7.2	-0.2	-6.5	-0.2	-5.2	-1.5

Stevens 2001 also investigated the effect of age on programme efficacy. The authors used linear multiple regression analyses to test the interaction of weight loss with a number of demographic characteristics, and found that age was associated with greater weight loss at the 36 month follow-up, but not at 6 or 18 month follow ups (figures not provided).

Two studies recruited only older participants: Rejeski 2011 had an age range of 60 to 79 years old, and in Villareal 2011 participants had to be 65 or older. Both of these studies detected evidence of an effect: in the case of Rejeski 2011, at 18 months the mean difference for weight change was -5.50 kg (95% CI -7.61 to -3.39), and in Villareal, the mean difference at 12 months was -7.80 kg (95% CI -9.84 to -5.76).

No studies examined whether the effectiveness of a programme depended upon age.

In summary, two studies suggest that older participants who join BWLP lose a little more weight than younger participants.

Gender

Five studies reported on the weight loss achieved in each programme split by gender. Heshka 2006 found no significant difference in weight change between men and women, and Jolly 2011 reported no effect of sex on weight loss at programme end or at one year. The authors also reported that they detected no statistically significant interaction between sex and weight loss programme. Jeffery and Wing 1995 found that men lost more weight than women, but as sex did not have a significant effect on BMI change, suggested the difference was due only to differences in stature at baseline.

Both Stevens studies (1993 and 2001) reported results separately for men and women. Stevens 1993 found that men lost significantly more weight than women at each time point ($P<0.01$). Differences in percentage change from baseline weight and change in BMI between men and women also remained statistically significant at all time points (though the level of significance was diminished at later follow-ups). The interaction of weight loss with sex remained statistically significant when controlled for age, race and baseline weight. In Stevens 2001, the authors report that in the intervention group, men had a greater net weight loss than women at 6, 18 and 36 months (1.6kg greater at 6m ($p=0.006$), 1.2kg greater at 18m ($p=0.07$) and 1.7 kg at 36m ($p=0.02$).

Five studies were conducted in women only[38], and all detected significant evidence of an effect at 12 months (ranging from a mean difference of -2.42 kg in Fitzgibbon 2010 to -8.20 in Foster-Schubert

[37] See Figure 2, Diabetes Prevention Program Working Group. 2009. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. Lancet, 374, (9702) 1677-1686.

2012). Two studies were conducted in males only; Morgan 2011 detected a small but significant effect at 12 months (mean difference -2.10, 95% CI -4.46 to 0.26), and Patrick 2011 did not detect evidence of an effect (mean difference -0.70, 95% CI -1.96 to +0.56).

In summary, there is modest evidence that men achieve slightly more weight loss on BWLPs than do women, but there is no evidence that one programme type suits one gender more than another.

Ethnicity

Stevens 1993 restricted analyses to white participants only (79% of the entire study population) and found that the results "remained essentially unchanged" from those done in conducted in all participants, suggesting that ethnicity did not have a significant effect on weight loss. On the other hand, Stevens 2001 detected significant differences between white and black intervention participants at 18 months (white people lost 1.8kg more than black people at both time points, p=0.01 and p=0.03). However, this difference did not persist at 36 months (P>0.2).

Fitzgibbon 2010 was conducted exclusively in African-American women, and detected evidence of an effect at 12 months (mean difference -2.42 kg, 95% CI -4.09 to -0.75). No other studies reported results based on ethnicity.

In summary, there is scant data on ethnicity but one study suggests that European Americans lose more weight than African Americans on the same programme. There is no evidence that one type of BWLP suits one ethnic group more than another.

Adverse events

Reporting of adverse events was sparse and inconsistent in included studies: only nine of the 30 included studies included any mention of adverse events.

Mensink 2003 reported only that no serious adverse events were observed. Similarly, Jebb 2011 and Eriksson 2009 reported only that no adverse events attributable to trial participation occurred.

In Appel 2011, one adverse event that may have been related to study treatment occurred in the in-person intervention arm: a participant was assaulted whilst exercising, resulting in musculoskeletal injuries. The authors also report number of hospitalizations, which were similar in each study arm: 15 in the call-centre directed arm, 18 in the in-person arm, and 15 in the control group. No deaths or serious hypoglycaemias were reported in any group during the study.

Bertz 2012 was conducted in women postpartum, and measured the effects of the intervention on breastfeeding and infant weight. The authors found that the intervention had no effect on infant weight but that at 12 months, there was a significant effect of diet on introducing non breastfeeding (all women from the diet and diet + exercise group were not breastfeeding, whereas two women from the control group and exercise only group were still breastfeeding with complementary foods). All women who gave up breastfeeding did so voluntarily.

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[38] Bertz 2012, Fitzgibbon 2010, Foster-Schubert 2012, Kuller 2012, Silva 2010

At three year follow up in the DPP study, the only significant difference in adverse events reported was that there were fewer GI symptoms/events in the intervention than in the control group (12.9 per 100 in-person years versus 30.7). The authors report similar incidences of musculoskeletal events and hospitalizations in both arms. The death rate was lower in the intervention arm at three years: there were 0.10 deaths per 100 person years in intervention group, compared to 0.16 in control group.

Rejeski 2011 recruited only participants aged 60 to 79 years with self-reported mobility limitations. The authors report adverse events (total number in each arm and broken down by system) and serious adverse events definitely or possibly related to study treatment. There were no significant differences in the incidence of adverse events by study arm, though there was a higher incidence of adverse and serious adverse events in the BWMP intervention arm than there was in the control arm. The authors note that most adverse events in the BWMP intervention arm were transient musculoskeletal complaints, and only two of the serious adverse events were considered definitely related to study treatment. A further four serious adverse events in the BWMP intervention arm were considered possibly related to treatment.

Ross 2012 detected more musculoskeletal injuries during exercise in the control group than in the intervention group (311 as opposed to 300, total participant numbers 241 and 249, respectively). The authors found no differences in other non-study related adverse events.

Similar to Rejeski 2011, Villareal 2011 was conducted in an older population (65 years or older) with mild to moderate frailty. One participant in the intervention group fell during exercise training, but no other study related adverse events were reported.

In summary, BWMPs appear to cause few adverse events and no serious ones have been detected. The adverse events likely to be due to participation appear due to taking exercise.

Cost effectiveness

A separate piece of work has been commissioned by NICE to address cost effectiveness models for weight loss interventions. Therefore, in this review we present only cost and cost effectiveness data relating to our included studies.

Five of the included studies provided data on cost per participant, listed in Table 4. Three of these also provided further discussion and/or analysis of cost effectiveness; relevant findings from these three studies are summarized narratively below.

Table 4. Costs of interventions (where more than one intervention arm in a study, costs are listed on additional rows)

Study ID	Cost per participant (or other data if cost per participant not available)	
	Intervention	Control (categories 1-4)
DPP 2002	(10 year costs) USD 4601 or USD 3023 if completed as groups and no individual sessions	(10 year costs) USD 769
Hersey 2012 (RCT 2)	RCT 2 (interactive website): USD 160	USD $145
Hersey 2012 (RCT 3)	RCT 3 (interactive website plus phone/e-mail): USD 390	USD $145
Heshka 2003	Not stated, but authors report that during the study the retail value of one voucher (for a Weight Watchers session) was 9 USD. This would result in a maximum of 936 USD per participant (max session number 104).	Not stated
Jebb 2011	Cost per participant not provided. Cost per kilogram of weight loss: UK: USD 90 Germany: USD 180 Australia: USD 122	Cost per participant not provided. Cost per kilogram of weight loss: UK: USD 151 Germany: USD 133 Australia: USD 138
Jolly 2011 (general practice)	Provider cost: 55 GBP Total cost[39]: 76.87 GBP	Not stated
Jolly 2011 (NHS Size Down)	Provider cost: 70 GBP Total cost: 91.87 GBP	Not stated
Jolly 2011 (pharmacy)	Provider cost: 90.43 GBP Total cost: 112.30 GBP	Not stated
Jolly 2011 (Rosemary Conley)	Provider cost: 55 GBP Total cost: 76.87 GBP	Not stated
Jolly 2011 (Slimming World)	Provider cost: 49.50 GBP Total cost: 71.37 GBP	Not stated
Jolly 2011 (Weight Watchers)	Provider cost: 55 GBP Total cost: 76.87 GBP Using a number of assumptions, authors approximate cost of 77 GBP per life year saved.	Not stated

DPP

The DPP randomised participants to intensive BWMP or control condition. The cost-effectiveness analysis examined costs and benefits over 10 years, using a 3% discount rate.[40]

As seen in Table 3, the cumulative, undiscounted per capita direct medical cost of the DPP lifestyle intervention was USD 4601, which was greater than metformin (USD 2300) or placebo (treated as the control arm for our purposes, USD 769). However, the cumulative direct medical costs of care outside of the programme were the lowest in the lifestyle group (USD 24563 compared to USD

[39] For each arm, cost per participant recruited includes: £10 for call centre; £3.54 for practices to run a search of their lists and for GPs to screen the lists for ineligible participants; £8.33 for invitation letters sent by practices (£1 per letter, with 12% response rate).

[40] Diabetes Prevention Program Research Group. 2012. The 10-year cost-effectiveness of lifestyle intervention or metformin for diabetes prevention: an intent-to-treat analysis of the DPP/DPPOS. Diabetes Care, 35, (4) 723-730.

27468 in placebo), and the cumulative QALYs accrued over ten years were greater for lifestyle than for placebo (6.81 versus 6.67). When including only direct medical costs in their base-case analysis (a health system perspective), the authors computed a cost per QALY over placebo as USD 6651. Incorporating a modified societal perspective and direct nonmedical costs, the cost per QALY over placebo increased to USD 11274. In both cases, if the programme was completed as a group intervention it was found to be cost-saving. The paper concludes that over the course of ten years, from a payer perspective, the DPP programme was cost-effective.

A three-year cost-effectiveness analysis found higher costs per QALY than in the 10 year analysis, as the costs of the lifestyle intervention decreased in years 4 through 10 and as many of the benefits of the lifestyle treatment occurred after three years of follow-up.[41] Readers should note that this study was based in a population at elevated risk for developing type 2 diabetes, a condition with high immediate healthcare costs, and cost-effectiveness calculations would be different in the general population of overweight and obese adults.

Hersey 2012

Hersey 2012 included two multicomponent BWMPs, one delivered exclusively over the internet (RCT2), and one delivered by internet and telephone and email support (RCT3), and one control group given information only on a website. Hersey estimated the cost per participant to be USD 160 in RCT 2 (interactive website), USD 390 in RCT 3 (interactive website + phone/e-mail support), and USD 145 in the control group (static website only). The authors also calculated the amount required to produce one percent weight loss when compared to a 'do nothing' alternative: USD 30 to 40 in RCT2 and in the control group and USD 70 in RCT 3.

The authors estimated the cost/QALY over 19 years by modelling the health consequences of various BMIs, discounting health costs incurred at 3%. Compared to a 'do nothing' approach, gaining one discounted QALY was estimated to cost USD 900 to 1000 in the control group and in RCT 2, and USD 19000 in RCT 3. Using results from DPP to estimate a trend in long-term weight loss maintenance, the authors estimated a total potential savings of approximately 500 USD per participant in RCT 2 and the control group over 20 years, with a cost recovery period of three years, and savings of approximately USD 750 in RCT 3, with a cost recovery period of approximately 6 years.

Jebb 2011

Jebb 2011 randomised participants to a commercial programme or control group given a leaflet only but with usual GP care. A within-trial cost-effectiveness analysis used data from Jebb 2011, comparing standard care (defined as weight loss advice from primary care professional, advised minimum of 6 visits over 12 months) with referral to the commercial programme with the time horizon of one year.[42] The authors calculated cost per kilogram of weight loss by country (Australia,

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[41] Herman WH, Brandle M, Zhang P, et al; Diabetes Prevention Program Research Group. 2003. Within-trial cost-effectiveness of lifestyle intervention or metformin for the primary prevention of type 2 diabetes. Diabetes Care, 26, 2518–2523.

[42] Fuller, N. R., et al. 2012. A within-trial cost-effectiveness analysis of primary care referral to a commercial provider for weight loss treatment, relative to usual care – an international randomised controlled trial. International Journal of Obesity, 1-7.

Germany, and the UK) and incremental cost effectiveness ratios (ICER) using a health sector and societal approach, over the course of one year. Using both approaches, the intervention was found to be cost effective over one year in all three countries: from the health-sector perspective, ICER for the intervention relative to standard care was USD 18,266 in Australia, USD 12,100 in the UK and USD 40,933 in Germany, and from a societal perspective corresponding ICER values were USD 31,663, USD 24,996, and USD 51,571, respectively. Costs per kilogram of weight lost are reported in Table 3.

Evidence statements

Notes:

- Unless stated otherwise, control includes arms with no contact through to arms with multiple weight related contacts delivered by a generalist with no specialist training in weight management, and pooled mean differences given are for weight loss at 12 to 18 months. All data are from randomized controlled trials. Quality scores for individual studies are represented as ++, +, or -.
- Evidence from subgroup analyses has not been translated into evidence statements, as analysis of programme components is covered more robustly in review 1b.

Please see the final agreed evidence statements for this guideline which are contained in a separate document on the NICE website. The final statements reflect conclusions drawn from reviews 1a, 1b, 1c and 2 (as appropriate)

Evidence statement 1.0 Applicability of available data

There is a large body of evidence comparing BWMPs to control that was judged to be of high quality and applicable to the UK. The evidence reviewed supported and extended the conclusions drawn by Loveman et al 2011, i.e. that BWMPs can be effective and cost effective. Of the 30 RCTs identified, 18 were judged to be applicable to the UK population and to be of high external validity. The remaining 12 RCTs identified were judged to be of moderate external validity due to some concern that the intervention may not be widely applicable or that the population or the study was highly selective and may not be representative. Of the RCTs identified, 15 were conducted in the USA, three were conducted in the UK, two each were conducted in Netherlands and Sweden, and one each were conducted in Australia, Belgium, Canada, Finland, New Zealand, Portugal, and Switzerland. The remaining study was a multicentre study conducted in the UK, Germany, and Australia.

Evidence statement 1.1 Mid-term weight loss in behavioural weight management programs (BWMP).

Strong evidence from a meta-analysis indicates that behavioural weight management programmes (BWMPs) can lead to greater weight-loss over a 12 to 18 month period than control arms (pooled mean difference -2.59 kg, 95% CI -2.78 to -2.41). The substantial between study heterogeneity indicates that the effectiveness of these programmes varies. The meta-analysis was based on 29 randomised controlled trials (RCTs), with 7,540 BWMP participants and 5,913 controls in the following countries: 14 US studies (12 ++[1], two +[2]), three UK (one ++ [3], two +[4]), two Netherlands (two +[5]), two Sweden (two ++[6]), one Canadian (++[7]), one Australian (++[8]), one New Zealand (+[9]), one Finland (++[10]), one Switzerland (-[11]), one Portugal (++[12]), one Belgium (+[13]) and one multi-country (UK, Germany, Australia) study (+[14]).

[1]Appel 2011, DPP, Fitzgibbon 2010, Foster-Schubert 2012, Heshka 2006, Kuller 2012, Patrick 2011, Rock 2010, Stevens 1993, Stevens 2001, Villareal 2011, Wadden 2011
[2]Hersey 2012, Rejeski 2011
[3]Nanchalal 2012
[4]Jolly 2011, Penn 2009
[5]Mensink 2003, Vermunt 2011
[6]Bertz 2012, Eriksson 2009
[7]Ross 2012
[8]Morgan 2011
[9]Dale 2008
[10]Lindstrom 2003
[11]Munsch 2003
[12]Silva 2010
[13]Vissers 2010
[14]Jebb 2011

Evidence statement 1.2 Long term weight-loss in behavioural weight management programs (BWMP).

Strong evidence from a meta-analysis indicates that BWMPs can lead to greater weight-loss over 18 to 24 months (pooled mean difference -1.54 kg, 95% CI -1.79 to -1.30) and at 36 months (pooled mean difference -2.21 kg, 95% CI -2.66 to -1.75) than control arms. The substantial between study heterogeneity indicates that the effectiveness of these programmes varies. The meta-analysis for 18 to 24 month differences was based on 15 RCTs in the following countries: ten USA (8++,2+)[1, 2], two Netherlands (+),[3] one New Zealand (+),[4] one UK (+),[5] one Canada (++).[6] The meta-analysis for 36 months differences was based on four studies in the following countries two USA (two ++)[7], one Finland (++)[8], one UK (+).[9]

[1] Appel 2011, Fitzgibbon 2010, Heshka 2006, Kuller 2012, Rock 2010, Stevens 1993, Stevens 2001, Wadden 2011
[2] Hersey 2012, Rejeski 2011
[3] Mensink 2003, Vermunt 2011
[4] Dale 2008
[5] Penn 2009
[6] Ross 2012
[7] Kuller 2012, Stevens 2001
[8] Lindstrom 2003
[9] Penn 2009

Evidence statement 1.3 Weight loss in programmes currently available in the UK

There is strong evidence that BWMPs currently available in the UK can lead to greater weight-loss over a 12-18 month period than usual care control arms. There is moderate evidence to suggest commercial BWMP's are associated with greater weight-loss than BWMPs delivered in primary care but this should be interpreted with caution due to the limited number of studies and programmes

included. The analysis of UK available programmes included four studies with commercial BWMPs in the following countries, two USA (two ++)[1], one UK (+)[2], one multi-country (+)[3]; and six studies with BWMPs delivered in primary care in the following countries, two UK (one ++[4], one +[5]), one Switzerland (-[6]), one Canada (++[7]), one Netherlands (+[8]), one USA (++[9]).

[1] Heshka 2006, Rock 2010
[2] Jolly 2011
[3]Jebb 2011
[4]Nanchahal 2011
[5]Jolly 2011
[6]Munsch 2003
[7]Ross 2012
[8]Vermunt 2011
[9]Wadden 2011

Evidence statement 1.4 Effectiveness for different population groups: gender.

There was inconsistent evidence that men achieve slightly more weight loss than women on BWMPs. Three of five studies that reported on weight loss split by gender found that weight loss was significantly greater in men than in women at 12 months or longer. Four studies were based in the USA (three ++[1], one +[2]) and one was based in the UK (+)[3]. There is no evidence that one type of BWMP suits one gender more than another.

[1] Heshka 2006, Stevens 1993, Stevens 2001
[2] Jeffery 1995
[3]Jolly 2011

Evidence statement 1.5 Effectiveness for different population groups: age.

There was moderate evidence that BWMPs are effective in all age groups but that older participants (> 60) lose more weight than younger participants from two studies that reported results by age group. Both were conducted in the USA (both ++)[1]. There is no evidence that one type of BWMP suits one age group more than another.

[1]DPP, Stevens 2001

Evidence statement 1.6 Effectiveness for different population groups: ethnicity.

There is inconsistent evidence that European Americans lose more weight than African Americans on the same BWMP. Of the two studies that reported results by ethnicity, one found no difference between African Americans and European Americans and one found that European Americans lost more weight than African Americans at 18 months but not at 36 months. Both studies were

conducted in the USA (both ++)[1], and both tested the same intervention. There is no evidence that one type of BWMP suits one ethnic group more than another.

[1]Stevens 1993, Stevens 2001

Evidence statement 1.7 Effectiveness for different population groups: other categories.

There is no evidence as to whether the effectiveness of BWMPs varies based on the sexual orientation, disability, religion, place of residence, occupation, education, socioeconomic position or social capital of participants. No studies reported results using these demographics.

Evidence statement 1.8 Diet and physical activity outcomes.

There is moderate evidence that BWMPs influence diet and physical activity outcomes at 12 to 18 months. Relatively few studies reported on dietary or physical activity outcomes, and in those that did, reporting was variable. Selective reporting is a risk and hence results should be interpreted with caution. In the 11 studies that reported dietary data, eight studies found energy intake (EI) to be significantly lower in BWMPs (in four cases, differences were statistically significant) and eight studies reported greater improvements in BWMP groups for other dietary behaviours. In the 16 studies that reported physical activity, 14 reported improvements in physical activity with 11 observing significantly greater improvement in physical activity in BWMPs. Evidence on dietary outcomes is based on 11 studies in the following countries, five USA (four ++[1], one +[2]) two Netherlands (two +)[3], one Sweden (++) [4], one New Zealand (+)[5], one multi country (+)[6], and one Finland (++)[7]. Evidence on physical activity outcomes is based on 16 studies in the following countries, eight USA (six ++[8], one +[9]), two UK (two +[10]), two Sweden (two ++[11]), one Netherlands (+[12]), one New Zealand (+[13]), one Finland (++[14]), one Canada (++[15]), one Portugal (++[16]).

[1] DPP, Fitzgibbon 2010, Foster-Schubert 2012, Kuller 2012
[2]Jeffery 1995
[3] Mensink 2003, Vermunt 2011
[4] Bertz 2012
[5] Dale 2008
[6] Jebb 2011
[7] Lindstrom 2003
[8] DPP, Fitzgibbon 2010, Foster-Schubert 2012, Kuller 2012, Patrick 2011, Stevens 1993
[9] Rejeski 2011
[10] Jolly 2011, Penn 2009
[11] Bertz 2012, Eriksson 2009
[12] Vermunt 2011
[14] Lindstrom 2003
[15] Ross 2012
[16] Jebb 2011

Evidence statement 1.9 Adverse events.

There was moderate evidence that BWMPs cause few adverse events and no serious adverse events. A minority of studies reported on adverse events. In those that did, the adverse events likely to be due to participation occurred during exercise and were primarily musculoskeletal events that were not serious. Reporting varied within trials and the majority of studies did not report on adverse events. This evidence is based on nine studies in the following countries: three USA (two ++[1], one +[2]), two Sweden (both ++)[3], one Canada (++)[4], one Netherlands (+)[5], and one based in the UK, Germany and Australia (+)[6].

[1] Appel 2011, DPP
[2] Rejeski 2011
[3] Bertz 2012, Eriksson 2009
[4] Ross 2012
[5] Mensink 2003
[6] Jebb 2011

Evidence statement 1.10 Cost effectiveness.

There was weak evidence that BWMPs are cost effective. Only three of the 30 included studies reported cost-effectiveness analyses. These concluded that interventions were cost effective, but there is variability between costs of individual interventions and between the methods of analysis used. Of the three studies, one was based in the UK, Germany and Australia (+)[1] and two were based in the USA (one ++[2], one +[3]).

[1] Jebb 2011
[2] DPP
[3] Hersey 2012

Discussion

We reviewed the effectiveness of 44 different multicomponent BWMPs reported in 30 different studies which were compared against control conditions where there was no or minimal weight loss assistance. In almost all studies the population mean showed a decrease in weight in the control conditions: participants in the control conditions being about 1kg lighter 12 months later, though this varied slightly between studies. Weight loss was seen in all intervention programmes too, but in almost all cases, the BWMPs produced several kilograms greater weight loss than the control conditions at 12 to 18 months, showing evidence of effectiveness. Although we conducted meta-analyses this was a way of quantifying heterogeneity of programme effects, which was, predictably, very great. The meta-analyses therefore provide strong evidence of effectiveness of many programmes, but the summary mean is not a reliable measure of the size of the effect, which varies between programmes. On average, though, the programmes studied produced 2-3kg more weight loss than achieved by the control groups. We explored whether the differences in effectiveness varied primarily as a result of *how* the programmes were delivered, though in one case we examined programme content. The variables relating to delivery were mode of delivery, length, intensity, and whether or not face-to-face contact occurred. There was some evidence that programmes that were six months or longer, and that involved face-to-face contact, supervised exercise, set energy goals (e.g. calorie counting), and provided group and individual sessions tended to produce greater weight loss than other interventions. The evidence suggests that the greater weight loss from following a programme compared to trying to lose weight without assistance is maintained for as long as participants have been followed; certainly for 36 months, and the graphs suggest for longer. However, the difference between intervention and control appears to decrease with length of follow-up. All these interventions were judged applicable in the UK. Of the currently available UK interventions, Jenny Craig and Weight Watchers show evidence of substantial greater weight loss at 12 months than achieved by control groups. Generalists (GPs, health trainers, nurses) given minimal extra training showed evidence of effectiveness but the effect was very small, with less than 800g difference between the mean of a population given no or minimal assistance and those given a weight loss programme by generalists. There is insufficient evidence to be sure about whether Rosemary Conley or Slimming World are effective, though the confidence intervals imply the effect may be similar to Weight Watchers. There was no evidence that BWMPs produce common or serious adverse effects. There was some evidence that these programmes are cost-effective, though data are scant.

It is worth noting how the evidence from Loveman compares with this review. Loveman included three studies that met our inclusion criteria, that is compared multicomponent BWMPs to control conditions and found similar evidence that interventions work, but was unable to determine which interventions and why. The Loveman review did not investigate how the features we discuss above contribute to effectiveness.

The strength of this review relates to the comprehensive search, which included detailed database searches and searches based on the reference lists of other reviews. We also used explicit inclusion and exclusion criteria, with similarly rigorous criteria for appraising the studies. In particular,

compared with Loveman and other reviews, we extracted weight loss data using a common approach, which removes one potential source of heterogeneity between studies. The meta-analysis provided a comprehensive description of the study outcomes which we explored in several subgroup analyses.

The validity of our conclusions rests upon the validity of the studies themselves. On the whole, studies were at low risk of selection bias from inadequate randomisation procedures and at low risk of observation bias from poor follow-up rates. One issue that we did not report on was blinding. It is difficult to produce a programme that looks and feels like a BWMP but which can be known in advance to be totally ineffective i.e. a placebo. In any case, participants stop attending programmes that are not working for them so blinding of participants to allocation is to all intents and purposes impossible. The prime outcome of our review was weight, which is objective, and not susceptible to bias in its assessment, whether or not assessors were blind to allocation. Again, blinding of assessors is often practically impossible because participants naturally give away their allocation and perception of how well it has worked at follow-up as part of the normal chatter that inevitably occurs. We therefore judge that bias has a small or non-existent impact on the results of the review.

The data indicate that many but not all BWMPs that have been tested are effective. Although there was some evidence that differences in intensity, programme length, and face-to-face contact explain the differences, there were substantial differences between studies in each subgroup. This means that it may be that subgroup differences are explained by factors other than the subgrouping itself. With so many subgroup analyses, some are likely to suggest differences between subgroups by chance alone and as a result we have interpreted the evidence cautiously, despite very high p values for some differences between some subgroups. Nevertheless, the subgroup differences that do emerge fit with a common-sense model of how programme effectiveness might be improved, for example that longer programmes appear more effective than shorter ones. However, we will investigate these subgroup differences in Review 1b more thoroughly, because we will use studies that have randomised participants to different programmes, for example longer or shorter programmes. Such evidence is not clouded by other differences between groups.

The pooled data indicate that differences in the mode of delivery, intensity, or length of programme do not fully explain differences in effectiveness. This is unsurprising. It is likely that differences in what was delivered, the content of the intervention, is likely to be an important driver of effectiveness. There was some evidence of this in that programmes with a specific energy prescription seemed to cause greater weight loss than programmes without. In Review 1b we will investigate how other components of the interventions tested drive the effectiveness seen, and this is the major outstanding question.

While the search was comprehensive it is important to consider those studies excluded. The scope of this work as defined by NICE was to follow the approach of Loveman and to consider only programmes in which participants were not following a weight loss programme as treatment for a disease that might be ameliorated by weight loss. This excluded, for example, the Look AHEAD study, a very large randomised trial of a multicomponent BWMP for people with diabetes; a weight loss programme for women after a diagnosis of breast cancer; as well as several other studies. Most of the trials included in this review would have included such participants, but in these

particular trials all participants had to meet this criterion and the programmes were usually presented as a treatment for the underlying condition. We therefore could not examine whether weight loss programmes for people with a pre-existing condition are effective in ameliorating that condition.

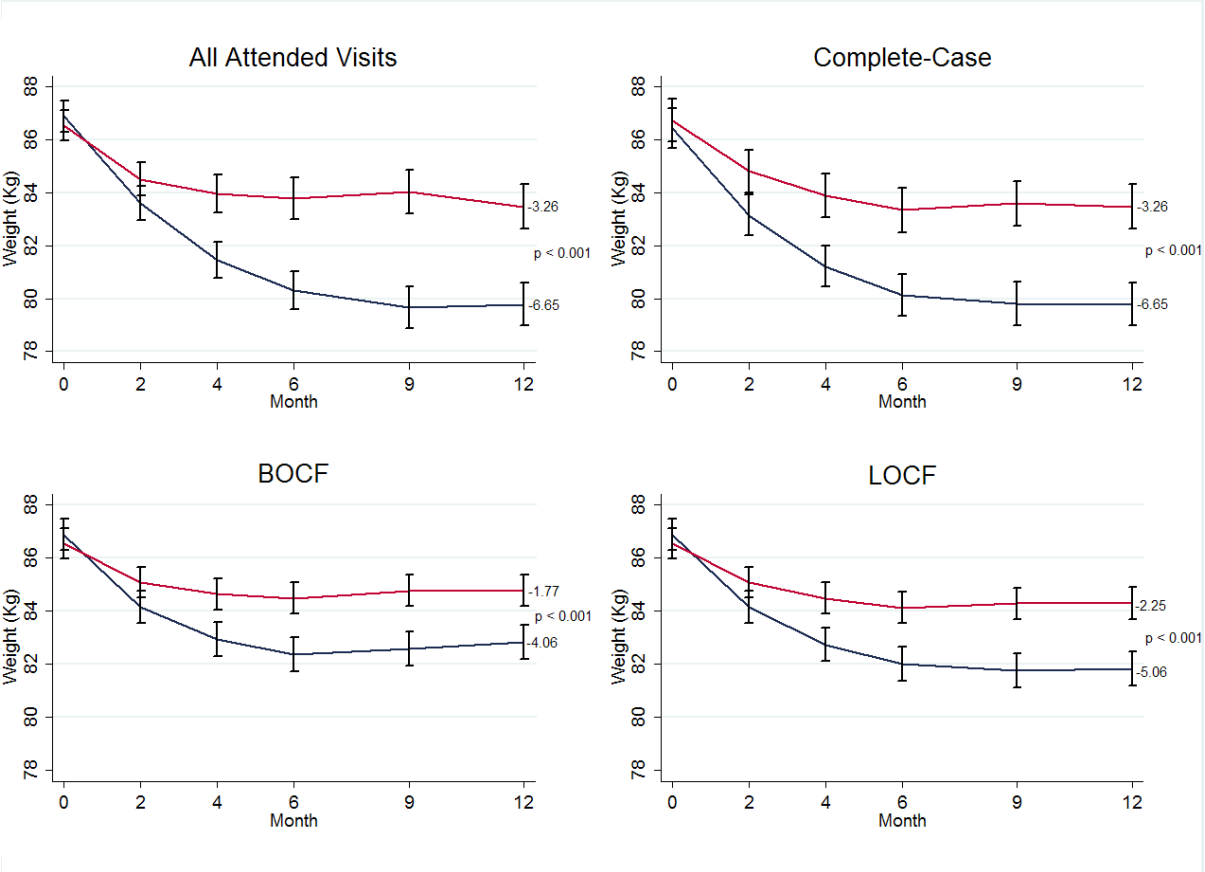
Loveman's inclusion/exclusion criteria were tight and, had we followed Loveman's criteria we would have excluded several trials that tested commercial programmes. This is because such trial reports described the intervention by brand name and did not describe the detail of the intervention sufficiently to meet the inclusion criteria i.e. details about the diet and physical activity recommendations. We modified the inclusion criteria to include such programmes where the detail were available elsewhere and therefore included these and other trials using the same approach. However, some trials were still excluded because they did not describe the intervention in insufficient detail to meet the inclusion criteria and these may have been relevant and tested useful programmes. These studies are listed under insufficient intervention details. Many of these studies described the behavioural interventions, but did not give sufficient details of the diet and physical activity recommendations. The reports often implied that these were standard and followed national recommendations and, perhaps as a consequence, did not describe the details of the energy prescription, much as was the case with the Weight Watcher studies. In keeping with the scope and protocol agreed with NICE, these studies were excluded. Exclusion of studies where programme descriptions were obtained from commercial bodies (for example, Heshka 2006 and Jebb 2011) would not have materially changed our findings. We do not believe that excluding other studies where the details of the diet and physical activity for weight loss are 'standard' would lead to bias, but this is impossible to test empirically. These strict inclusion criteria have limited somewhat the availability of evidence in the review.

In summary, many different multicomponent BWMPs are effective. Longer programmes that set energy prescription targets, and that involve face-to-face contact, possibly in a mixture of groups and individual settings, appear more effective.

Appendices

Appendix 1. Understanding how weight loss data are presented

Most reviews, including Loveman, take the data on weight loss as presented in the report. However, reports vary in how weight loss is reported and this can have very marked effects on the weight loss figures. For example, below we show four commonly used ways of presenting data from the trial of a commercial programme conducted by Jebb and reported in the Lancet. The absolute weight loss varies markedly between systems of presenting data and, most importantly of all, the difference in weight loss between arms varies from 2.29kg to 3.39kg depending on the method used. This means that one method of analysis can create a 48% increase in the effectiveness and cost effectiveness of treatments. Combining results from studies that used one method of analysis versus another method of analysis could lead to incorrect conclusions. As touched on above, we therefore sought to improve on Loveman by using a standardised method of presenting weight loss data.



The difference between these curves is due to the method of treating data from participants who are not followed up. It is common in behavioural trials of all kinds, not just weight loss studies, that loss to follow up is much more common than in standard trials of medication, for example. A review

estimated that loss to follow up in the medium term varied between 15 to 90%.[43] There is evidence that people who are not doing well on a programme drop out of the programme and are much less likely to return for follow up to demonstrate that they have not lost weight or perhaps even put on weight. In this way, data from completers, people who attend follow-up, is biased towards an optimistic view of weight loss. To deal with this, various systems of imputation have been employed. The simplest is baseline observation carried forward (BOCF), which imputes that anyone who did not attend follow up weighed the same at follow up as at the beginning i.e. zero kg weight lost. Last observation carried forward (LOCF) imputes the last weight achieved. However, this may be optimistic because some people do well in a programme and their last weight in the programme is usually lower than their weight at follow-up. The most technically complex method is multiple imputation, which assumes that the weight of people who are missing is typical of the people who were followed up, but that the imputation for each individual is based on their characteristics, such as age, gender, social class, starting weight, and so on. However, it cannot deal with the issue that people who do not lose weight or put it back on may decide not to turn up for follow-up. There are no data that show which method of imputation gives the most accurate estimate of the effects of these interventions on population weight change. However, all methods other than BOCF assume that loss to follow up is random and unrelated to whether or not a person lost weight or not. We feel this assumption is unlikely to hold and we preferred to use BOCF methods in this review as the prime method of analysis.

That said, it is very unlikely that any single programme will suit every potential participant who tries it. Programmes may be successful with those who like them and completer data, data from people who attend follow up, which is often very similar to people who complete the programme as the example above shows, can tell us about what happens to people who stick with a programme. We therefore report such data as secondary in this review.

[43] Moroshko, I., Brennan, L., and O'Brien, P. 2011. Predictors of dropout in weight loss interventions: a systematic review of the literature. Obesity Reviews, 12, 912-934.

Appendix 2. Review protocol: Managing overweight and obese adults: update review (covering review 1a and review 1b)[44]

NICE Reference	CPHE-URWMS-EV03-2012
Long title	The clinical effectiveness of long-term weight management schemes for adults: a systematic review
Project lead	Paul Aveyard (paul.aveyard@phc.ox.ac.uk)
Project manager	Jamie Hartmann-Boyce (Jamie.hartmann-boyce@phc.ox.ac.uk)
CPHE Technical Lead	Adrienne Cullum
CPHE Associate Director	Jane Huntley

Review team

This project will be conducted by a team of researchers from different institutions. The team members, and their roles on the review, will be:

Paul Aveyard, Professor of Behavioural Medicine, Department of Primary Care Health Sciences, University of Oxford	Lead systematic reviewer. Making key methodological choices within the systematic review. Chair meetings of the review team. Overall responsibility for delivery to NICE, ensuring report meets agreed protocol, discussing and agreeing with NICE any divergences from protocol. Writing and editing drafts and final report. Acting as third reviewer in cases of controversy.
Jamie Hartmann-Boyce, Research Associate, Department of Primary Care Health Sciences, University of Oxford	Systematic reviewer. Project managing the delivery of the various parts of the project. Working with NICE on search methods. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.
David Johns, Investigator Scientist, MRC Human Nutrition Research	Systematic reviewer. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.
Rafael Perera, Director Statistics Group, Department of Primary Health Care Sciences, University of	Statistics advice.

[44] The protocol is recorded here exactly as it was agreed with NICE. Since the protocol was signed off, NICE and the review team agreed to split review 1 into two parts, as described in the introduction and methods section of this review.

Oxford	
Igho Onakpoya, Researcher in Pharmacovigilance, Department of Primary Health Care Sciences, University of Oxford	Systematic reviewer. Assisting with data extraction.

Note: The search will be run by Daniel Tuvey at NICE, with input from Jamie Hartmann-Boyce.

Advisory team

In addition to the core project team, we have a team of advisors who the core team will call upon the on matters relating directly to their areas of expertise, as identified below.

Carolyn Summerbell, Professor of Human Nutrition and Principal of John Snow College, Durham University	Advice on matters relating to systematic review methodology
Jane Ogden, Professor in Health Psychology, Department of Psychology, University of Surrey	Guidance on psychological theories and patients views and perceptions regarding weight loss programmes
Susan Jebb, Head of Department, Diet and Population Health, MRC Human Nutrition Research	Advice in relation to dietary prescriptions
Dawn Phillips, Public Health Portfolio Lead for Adult Obesity and Physical Activity, County Durham	Guidance on clinical aspects
Igho Onakpoya, Researcher in Pharmacovigilance, Department of Primary Care Health Sciences, University of Oxford	Advice on systematic review methodology

Key deliverables and dates

Deliverable	**Date**	**Comments back from NICE CPHE by:**
1st Draft review protocol	19 October 2012	26 October 2012
Revised review protocol	30 October 2012	2 November 2012
Signing-off of review protocol	7 November 2012	
Signing-off of search strategy	5 November 2012	
Interim progress meeting/ teleconference (1) –	21 November	
Interim progress meeting/ teleconference (2) –	19 December 2012	
Draft report submitted to NICE	18 January 2013	25 January 2013
Amended report submitted to NICE	11 February 2013	

Slides for PDG meeting submitted to NICE	19 February 2013	
Review presented to PDG	26 February 2013	
Final review submitted	13 March 2013	

Context

This Review Protocol is for Review 1, with the first draft submitted by the agreed delivery date of 18 January 2013, and the final review to be submitted by 13 March 2013. A separate but related evidence review (Review 2) is covered in a separate protocol. As this is an update of an existing review (Loveman et al 2011[45]), the scope is unlikely to change beyond what is agreed here.

Purpose of this document

This document describes the aims, scope and intended methods of the update review which will be produced to support the development of NICE Public Health Guidance on lifestyle weight management programmes for overweight and obese adults.

Unless otherwise stated in this Review Protocol, this review, and its report will be conducted according to the rigorous methods described in the Cochrane Handbook, the York Centre for Reviews and Dissemination Handbook, and the 2nd Edition of the *Methods for the development of NICE public health guidance* (2009). As this is an update review it will follow as closely as possible the scope and format of the original review (Loveman 2011) to enable direct comparison between the two, and the use of the two reviews in conjunction with one another. Where there is a discrepancy between Loveman's reporting methods and those suggested by the above listed handbooks, CPHE will be consulted.

Clarification of scope

This review aims to inform readers about the relative importance of the components included in multi-component lifestyle interventions for the treatment of obesity. This review will therefore cover only those interventions that include both a diet and exercise component, and will exclude referral to individual clinicians, management of associated conditions, surgery, and pharmacological treatments. The review will be restricted to interventions that are judged to be feasible for implementation in the UK.

For the remainder of the document, multi-component lifestyle weight management programs (LWMPs) will be defined as those which focus on reducing energy intake, increasing physical activity and changing behaviour. These may include weight management programmes, courses or clubs:

- specifically designed for adults who are obese or overweight
- that accept adults through self-referral or referral from a health practitioner

[45] Loveman E, Frampton GK, Shepher J, Picot J, Cooper K, Bryant J, et al. The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review. *Health Technology Assessment* 2011;15(2).

- provided by the public, private or voluntary sector
- based in the community, workplaces, primary care or online.

Review questions

The primary question in this review is similar to that of Loveman 2011, though this update will not focus on cost-effectiveness. The primary question is therefore:

- How effective and cost-effective are multi-component lifestyle weight management programmes for adults?

We will also attempt to answer secondary questions relating to these programmes. Should data be available, we will attempt to answer:

- How does effectiveness vary for different population groups (for example, men, black and minority ethnic or low-income groups)?
- How does effectiveness and cost effectiveness vary based on the components of the individual programmes (including behavioural or psychological components)?
- Are there any adverse or unintended effects associated with the use of LWMPs?

Factors which influence the effectiveness, implementation or sustainability of initiatives may be either positive ('facilitators') or negative ('barriers'), and will also be explored when assessing the included studies. However, detailed questions about key components of LWMPs, their implementation, user experience, and facilitators and barriers (overall and for specific population groups) will be addressed separately in review 2. Review 1 will focus only on the effectiveness of the LWMPs.

Outcomes

We will extract and report data on the following outcomes:

- Quantitative changes in anthropometric measures – weight, BMI, waist circumference, etc
- Intermediate measures of diet and physical activity
- Process measures such as participant satisfaction with weight management services, adherence to the intervention and attendance at sessions
- Economic outcomes (narrative only)
- Adverse effects

Inclusion criteria

For the clinical effectiveness review, we propose to follow similar criteria for including and excluding studies as used in the Loveman 2011 report, with two key changes: we will not include LWMPs that involve medications for obesity of any type, unless their use is not part of the LWMP and is comparable in both intervention and control groups; and we will include studies with 12 month follow-up or longer (Loveman required a minimum of 18 months follow-up, we will examine those

studies excluded from Loveman on the basis of too short a follow-up period.. The revised inclusion criteria are listed below.

Population

- Adults (≥ 18 years) classified as overweight or obese, i.e. people with a BMI of ≥ 25 kg/m2 and ≥ 30 kg/m2, respectively.
- Studies in children, pregnant women, and people with eating disorders were not included, nor were studies specifically in people with a pre-existing medical condition such as diabetes, heart failure, uncontrolled hypertension or angina.

Intervention

- Structured, sustained multi-component weight management programmes (i.e. the intervention had to be a combination of diet and physical activity with a behaviour change strategy to influence lifestyle).
- Components of the programme had to be clearly specified (i.e. details provided of the diet, behavioural definition, and exercise components; see below).
- Programmes that included a long-term follow-up of more than 12 months.
- The programme was delivered by the health sector, in the community or commercially.
- Multi-component programmes that involved the use of any surgery or medication, over-the-counter or otherwise, are excluded.
- Interventions incorporating other lifestyle changes such as efforts at smoking cessation or reduction of alcohol intake were not included.

Comparators

- Normal practice (as defined by the study).
- Single-component weight management strategies.
- Other structured multi-component weight management programmes.

Outcomes

- Studies were required to include a measure of weight loss.

Types of studies

- RCTs only.
- Studies published as abstracts or conference presentations were only included if sufficient details were presented to allow an appraisal of the methodology and the assessment of results to be undertaken.
- Case series, case studies, cohort studies, narrative reviews, feasibility studies, editorials and opinions were not included.
- Systematic reviews were used as a source of references.

Location

- Undertaken in any setting (i.e. community, commercial, primary care, online).

- Studies conducted in OECD countries will be considered for inclusion.[46] In the instance that a study has been conducted in an OECD country but the reviewers and advisory panel judge that the intervention would not be feasible for implementation in the UK, the reviewers will consult with CPHE regarding its inclusion.
- Studies conducted in non OECD countries will be excluded.

Cost effectiveness

As per Loveman 2011, references identified by the search strategy for the systematic review of cost-effectiveness will be considered for inclusion only if:

- They report both health service costs and effectiveness of multicomponent adult weight management programmes

OR

- Present a systematic review of such evaluations

Unlike Loveman, initially, only UK cost effectiveness studies will be included in the search, but if this results in too few studies being included, we will consult NICE to agree on a wider search being undertaken (likely all English language OECD countries).

Specification of components of intervention

Loveman et al required that, in order for a study to be included, at least two items under each of the below components (diet, exercise, and behaviour modification) had to be specified.

Diet

- type of diet
- calories
- proportion of diet (e.g. proportion of diet made up of fats, protein, carbohydrate)
- monitoring

Exercise

- mode
- type
- frequency/length sessions
- delivered by
- level of supervision
- monitoring

Behaviour modification

- mode
- type
- content
- frequency/length sessions

[46] The original scope specified studies in the UK only. The extension to OECD countries has been agreed with NICE with the understanding that the completion of the review by stated dates is the key priority, and that the revised scope can be limited to UK only countries if the schedule so requires.

- delivered by.

Where studies are multicomponent but the study report does not meet the above criteria, we will follow the below approach:

- If the study identifies that the intervention is a defined weight loss programme (commercial or otherwise), we will search online for details of the weight loss programme and use these to classify the study components. Where insufficient details are available online, we will contact the programme directly, specifying that a response will be needed by 10 December 2012.
- If the study is not of an identifiable and defined weight loss programme, we will email study authors with a template email asking them to provide any details they have on the above elements, specifying that a response will be needed by 10 December 2012.
- Where authors do not respond by the deadline specified, provide insufficient information, or where we cannot find a current e-mail address, the study will be excluded, with the reason for exclusion clearly identified (for example, "unclear detail on physical activity component").

Search methods

This is an update of an existing review and as such the existing search strategy as published in Loveman 2011 will be used. The literature search will be run by NICE with input from one reviewer (Jamie Hartmann-Boyce). Searches will be fully documented and references will be stored in a Reference Manager database.

The detailed search strategy will be agreed separately between reviewers and the CPHE's information specialist (see schedule). Any adaptations to the Loveman 2011 strategy will be confirmed with NICE and are likely to be related to increasing the specificity of the search, given the time constraints involved.

Study selection at search stage

- Studies indexed since date of last Loveman search (December 2009)
- Studies conducted in OECD countries.

In addition to running the updated searches specified above, we are aware that Loveman has excluded some diabetes prevention studies which meet the above inclusion criteria (ie lifestyle interventions for overweight and obese adults, pre-existing clinical condition not a prerequisite for study enrollment). After discussion with NICE, we have agreed to include these studies. These have not been explicitly excluded from Loveman so there is no means of gathering a quick list of these studies. Instead, to ensure we have not missed major trials in this area published prior to the period of our updated search, we will use published reviews of diabetes prevention trials to identify relevant studies.

Study selection process

Assessment for inclusion will be undertaken initially at title and/or abstract level (to identify potential papers/reports for inclusion) by a single reviewer (and a sample checked by a

second reviewer), and then by examination of full papers. A third reviewer will be used to help adjudicate inclusion decisions in cases of disagreement. Where the research methods used or type of initiative evaluated are not clear from the abstract, assessment will be based upon a reading of the full paper.

Quality assessment and data extraction

For the review of clinical effectiveness, we will critically appraise the literature for inclusion using a checklist based on the York CRD approach and as described in the CPHE manual.[18] However, we will modify this slightly for behavioural intervention trials and will not evaluate included studies on the basis of blinding. We will present the appraisal in tables and summarise the findings in text as described in the CPHE manual.

Data extraction will be conducted using a pre-specified data extraction form, which will be piloted by two reviewers before its use. Data extraction and quality assessment will be done independently by two reviewers, who will then compare data extraction forms. Any discrepancies will be resolved by discussion or, where needed, by referral to a third reviewer.

If deemed to be helpful for the write-up, we will reference data extracted as part of the Loveman 2011 review, but in narrative elements of the write-up we will use the data extracted by the Loveman et al rather than re-extracting these data ourselves (full, completed data extraction forms are published in the appendices of Loveman). If we conduct meta-analyses or meta-regression (see next section), we will re-extract key outcomes from the included studies in Loveman to ensure we are using the same approach to data across all studies included in the analysis.

For the review of cost-effectiveness, we will critically appraise the literature using Lovemans' *Critical appraisal checklist of economic evaluation* (table 23, page 53). Elements of this table refer to applicability to the UK; if as discussed above we do not include cost-effectiveness literature from outside the UK, we will remove these items from the checklist. All other items will remain the same.

Data synthesis and presentation, including evidence statements

We will synthesise the data in narrative form, as Loveman et al did. However, we will consider whether meta-analysis and meta-regression could be undertaken and use the baseline observation carried forward approach with standard errors calculated as described recently.[47] This is likely to be an exploratory technique rather than a definitive guide to a single underlying effect size, and such analyses will only be conducted if appropriate data is available and if time allows.

If data and time allow, we will run a meta-regression on variables of LWMPs. Meta-regression will allow us to explore whether outcomes are associated with the various characteristics of the interventions and this will prove especially useful when it comes to giving guidance on Review 2

[47] Kaiser KA, Affuso O, Beasley TM, Allison DB. Getting carried away: a note showing baseline observation carried forward (BOCF) results can be calculated from published complete-cases results. Int J Obes 2012; 36(6):886-889.

questions. Regardless of whether a meta-regression is performed, we will categorise studies based on the following elements (taken from Jolly et al[48]):

- Professional background of therapies
- Training of therapist
- Assessment of therapist's competence
- Fidelity checking of intervention
- Group or individual
- Duration of sessions, frequency, programme length and setting
- Content of sessions
- Weight loss goal
- Relative emphasis on diet and exercise
- Intervention theoretical background
- Predominant behavioural change techniques used

Behavioural change techniques will be assessed through the use of a pre-defined taxonomy, included as an element of the data extraction process. Each included study will be assessed against a checklist of the taxonomy, with a dichotomous yes/no option for the reviewer to indicate if the intervention included that behavioural element. The description will be obtained through the study report, and hence it should be noted that the application of the taxonomy will be limited by the depth of description provided in the report. We will use the 40-item refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours (the CALORE taxonomy) as defined by Michie et al.[49]

Where possible, we will draw weight curves for each study, mapping weight change during intervention and weight change after intervention end and seek to summarise these as appropriate.

We will group studies by the nature of the comparison, including the nature of the control group. We will note whether the control group received an active treatment that might be expected to lower weight gain or not and try to account for this in the analysis. We will also describe the nature of the intervention e.g. the energy prescription/deficit given, the intensity of the physical activity prescription, the length of the programme, and any ongoing support offered. If possible, we will calculate the energy expenditure prescription in METs so that it will be possible to compare energy restriction with increased energy burning.

Data synthesis and presentation, including evidence statements, will be conducted according to the procedures outlined in the 2nd Edition of *Methods for development of NICE public health guidance 2009* where appropriate.

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[48] Jolly K, Lewis A, Beach J, Denley J, Adab P, Deeks JJ et al. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. BMJ 2011; 343.

[49] Susan Michie, Stefanie Ashford, Falko F. Sniehotta, Stephan U. Dombrowski, Alex Bishop & David P. French (2011): A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy,
Psychology & Health, 26:11, 1479-1498

Key choices in how to synthesise the included evidence, or in how to develop evidence statements for this review, will be discussed with the relevant analysts at CPHE.

Appendix 3. Search methods

Database: OVID Embase 1980 to 2012 Week 45 **(searched 14 November 2012)**		
Notes: Some minor adjustments were made to the strategy to remove non Emtree terms. The original Emtree term "obesity" was amended to only include types of obesity specific to the review. The population filter was amended to mirror the Medline approach. As the Embase strategy was returning over 11,000 records a decision was made to replace the original study type filter with an RCT filter from CENTRAL and a systematic review filter from SIGN.		
1	morbid obesity/ or abdominal obesity/ or diabetic obesity/ or metabolic syndrome X/	50823
2	weight gain/	54597
3	(overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.	45217
4	(weight adj1 gain*).ti,ab.	49225
5	obes*.ti,ab.	194648
6	or/1-5	296936
7	(modific* or therap* or intervention* or strateg* or program* or management or scheme* or group* or pathway*).ti,ab.	6569873
8	(weight adj1 los*).ti,ab.	66404
9	(weight adj1 reduc*).ti,ab.	11320
10	weight reduction/	78847
11	7 and (8 or 9 or 10)	56167
12	obesity/dm, pc, th	22053
13	Obesity, Morbid/dm, pc, th	753
14	7 and (12 or 13)	12352
15	Diet Therapy/	42853
16	low calory diet/	6886
17	low fat diet/	5897
18	diet restriction/	53105

19	caloric restriction/	9194
20	Dietetics/ or Dietetics Education/	4600
21	(diet or diets or dieting).ti,ab.	255420
22	(low calorie or hypocaloric or calorie control*).ti,ab.	4097
23	(health* adj1 eating).ti,ab.	3335
24	(diet* adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	19207
25	(nutrition adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	6630
26	(Weight Watchers or weightwatchers).ti,ab.	104
27	(slimming world or slimmingworld).ti,ab.	20
28	(lighterlife or “lighter life”).ti,ab.	34
29	or/15-28	350921
30	7 and 29	173997
31	exp exercise/	180427
32	exp kinesiotherapy/	41449
33	(exercise and (therapy or therapies or activity or activities or class* or program* or group* or session* or scheme*)).ti,ab.	108245
34	(Gym and (trainer* or therap* or activit* or class* or program* or group* or session* or scheme* or club*)).ti,ab.	438
35	(walk* or step* or jog* or run*).ti,ab.	653482
36	(aerobic* or physical therap* or physical activit*).ti,ab.	132930
37	(fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.	796
38	(reduc* adj2 sedentary behavio?r).ti,ab.	99
39	(dance and (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.	1506
40	personal trainer*.ti,ab.	74

41	(gym or gyms or gymnasium).ti,ab.	1181
42	or/31-41	961241
43	7 and (31 or 32 or 35 or 36)	397874
44	33 or 34 or 37 or 38 or 39 or 40 or 41 or 43	445895
45	cognitive therapy/	28701
46	Counseling/ or nutritional counseling/ or patient counseling/ or patient guidance/	63945
47	behavior therapy/	35278
48	cognitive behavio?r* therapy.ti,ab.	9041
49	behavio?ral intervention*.ti,ab.	5565
50	(change* adj2 lifestyle*).ti,ab.	6970
51	(changing adj2 lifestyle*).ti,ab.	354
52	(lifestyle adj2 modif*).ti,ab.	4841
53	Hypnosis/	12732
54	hypnosis.ti,ab.	6915
55	(counseling or counselling).ti,ab.	66527
56	or/45-55	177061
57	11 or 14	62764
58	Antiobesity Agent/	2901
59	(sibutramine or orlistat or rimonabant).mp.	9656
60	exp bariatric surgery/	12687
61	exp obesity/su	11117
62	or/58-61	28158
63	(editorial or letter or conference*).pt.	2811641
64	(random* or factorial* or crossover* or cross over* or cross-over* or placebo*).ti,ab.	874840
65	(doubl* adj blind*).ti,ab.	132052

66	(singl* adj blind*).ti,ab.	12761
67	(assign* or allocat* or volunteer*).ti,ab.	437126
68	crossover procedure/	35492
69	double blind procedure/	111739
70	randomized controlled trial/	332167
71	single blind procedure/	16616
72	or/64-71	1253479
73	exp Meta Analysis/	66989
74	((meta adj analy$) or metaanalys$).tw.	62086
75	(systematic adj (review$1 or overview$1)).tw.	47901
76	or/73-75	123424
77	(cancerlit or cochrane or embase or (psychlit or psyclit) or (cinahl or cinhal) or science citation index or bids).ab.	40909
78	(reference lists or bibliograph$ or hand-search$ or manual search$ or relevant journals).ab.	25642
79	data extraction.ab.	10543
80	selection criteria.ab.	19211
81	or/79-80	28399
82	review.pt.	1890142
83	81 and 82	17033
84	(letter or editorial).pt.	1212487
85	72 or 76 or 77 or 78 or 83	1346632
86	85 not 84	1328966
87	6 and 86 and 57	7718
88	6 and 29 and 86	11537
89	6 and 30 and 86	8837

90	6 and 42 and 86	7414
91	6 and 44 and 86	6281
92	6 and 56 and 86	2652
93	88 and 90 and 92	749
94	88 and 90	3190
95	88 and 92	1181
96	90 and 92	1241
97	94 or 95 or 96	4114
98	89 and 91	2832
99	89 and 92	1124
100	91 and 92	1188
101	98 or 99 or 100	3698
102	93 or 97 or 101	4114
103	102 not 62	3704
104	limit 103 to (human and english language)	3056
105	limit 104 to embase	2340
106	(editorial or letter or conference*).pt.	2811641
107	105 not 106	1904
108	limit 107 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)	270
109	107 not 108	1634
110	**limit 109 to dd=20090509-20121109**	**596**

Database: CDSR, DARE and CENTRAL via Wiley (searched 07 November 2012)
Strategy used:
#1 (obes* or overweight or "over weight" or weight gain) and (diet* and exercis* and

behav*):ti,ab,kw 386

#2 (surg* or sibutramine or orlistat or rimonabant):ti,ab,kw 75969

#3 #1 not #2 373

#4 #3 from 2009 to 2012 130

Database: Ovid MEDLINE(R) 1946 to November Week 1 2012 (searched 05 November 2012) **(searched 07 November 2012)**

Strategy used:

1	Obesity/ or Obesity, Morbid/ or Obesity, Abdominal/	123238
2	exp weight gain/	20568
3	Overweight/	9128
4	(overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.	31841
5	(weight adj1 gain*).ti,ab.	39248
6	obes*.ti,ab.	141694
7	or/1-6	222143
8	(modific* or therap* or intervention* or strateg* or program* or management or scheme* or group* or pathway*).ti,ab.	5144033
9	(weight adj1 los*).ti,ab.	48349
10	(weight adj1 reduc*).ti,ab.	8480
11	exp weight loss/	25371
12	8 and (9 or 10 or 11)	33193
13	Obesity/dh, pc, th	24748
14	Obesity, Morbid/pc, dh, th	853
15	8 and (13 or 14)	13379
16	Diet Therapy/	9220

17	Diet, Fat-Restricted/	2540
18	Diet, Reducing/	9012
19	Dietetics/ed, mt	1404
20	(diet or diets or dieting).ti,ab.	211027
21	(low calorie or hypocaloric or calorie control*).ti,ab.	3114
22	(health* adj1 eating).ti,ab.	2466
23	(diet* adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	14494
24	(nutrition adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	5223
25	(Weight Watchers or weightwatchers).ti,ab.	68
26	(slimming world or slimmingworld).ti,ab.	6
27	(lighterlife or "lighter life").ti,ab.	2
28	or/16-27	234902
29	8 and 28	113479
30	exp exercise/	99163
31	exercise therapy/	23599
32	(exercise and (therapy or therapies or activity or activities or class* or program* or group* or session* or scheme*)).ti,ab.	82464
33	(Gym and (trainer* or therap* or activit* or class* or program* or group* or session* or scheme* or club*)).ti,ab.	266
34	(walk* or step* or jog* or run*).ti,ab.	508441
35	(aerobic* or physical therap* or physical activit*).ti,ab.	103199
36	(fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.	639
37	(reduc* adj2 sedentary behavio?r).ti,ab.	76
38	(dance and (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.	923

39	personal trainer*.ti,ab.	50
40	(gym or gyms or gymnasium*).ti,ab.	507
41	or/30-40	709062
42	8 and (30 or 31 or 34 or 35)	278037
43	32 or 33 or 36 or 37 or 38 or 39 or 40 or 42	326663
44	cognitive therapy/	13691
45	Counseling/	26315
46	behavior therapy/	22689
47	cognitive therapy/	13691
48	behavio?ral intervention*.ti,ab.	4133
49	(change* adj2 lifestyle*).ti,ab.	4694
50	(changing adj2 lifestyle*).ti,ab.	240
51	(lifestyle adj2 modif*).ti,ab.	3195
52	Hypnosis/	7959
53	Counseling/	26315
54	(counseling or counselling).ti,ab.	51271
55	or/44-54	115644
56	Randomised Controlled Trials as Topic/	0
57	randomised controlled trial.pt.	0
58	controlled clinical trial.pt.	85628
59	Controlled Clinical Trial/	85628
60	placebos/	31541
61	random allocation/	76495
62	Double-Blind Method/	118292
63	Single-Blind Method/	17027

64	(random* adj2 allocat*).tw.	18103
65	placebo*.tw.	140863
66	((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).tw.	115919
67	Research Design/	68479
68	((random* or control*) adj5 (trial* or stud*)).tw.	455808
69	Clinical Trials as Topic/	163570
70	randomly.ab.	174754
71	(randomised or randomized).ab.	292746
72	Evaluation studies as topic/	120236
73	comparative study/	1618176
74	(matched communities or matched populations).mp.	132
75	(control* adj (trial* or stud* or evaluation*)).mp.	640997
76	(comparison group* or control* group*).mp.	254374
77	Matched-Pair Analysis/	3898
78	matched pair*.ti,ab.	4979
79	Meta-Analysis/	37655
80	meta analy*.ti,ab.	43508
81	"Outcome Assessment (Health Care)"/	44209
82	outcome stud*.ti,ab.	5005
83	intervention studies/	5681
84	follow up studies/	462711
85	(systematic* adj (review* or methodolog* or research* or search*)).ti,ab.	40921
86	((hand or manual or computer or electronic or database) and search*).ti,ab.	40251
87	(hand adj search*).ti,ab.	3143
88	(medline or embase or Cochrane or cinahl or psychlit or psychinfo or scisearch or	61108

	pubmed).ab.	
89	Health technology assessment*.ab,in.	1691
90	(pooled adj analys*).ti,ab.	3102
91	(electronic* adj search*).ti,ab.	2095
92	(synthes* adj5 (literature* or research* or studies or data)).ti,ab.	24187
93	or/56-92	3191920
94	12 or 15	40783
95	7 and 93 and 94	10271
96	7 and 28 and 93	13362
97	7 and 29 and 93	9256
98	7 and 41 and 93	9019
99	7 and 43 and 93	7094
100	7 and 55 and 93	2796
101	96 or 98 or 100	20374
102	97 or 99 or 100	14867
103	96 and 98 and 100	698
104	96 and 98	3100
105	96 and 100	1157
106	98 and 100	1244
107	104 or 105 or 106	4105
108	97 and 99	2682
109	97 and 100	1084
110	99 and 100	1189
111	108 or 109 or 110	3603
112	103 or 107 or 111	4105

113	Anti-Obesity Agents/	2817
114	(sibutramine or orlistat or rimonabant).ti,ab,nm.	3908
115	exp Bariatric Surgery/	12408
116	exp obesity/su	9025
117	113 or 114 or 115 or 116	20186
118	112 not 117	3781
119	limit 118 to (english language and humans)	3393
120	limit 119 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)")	1006
121	119 not 120	2387
122	(editorial or comment or letter).pt.	1164724
123	121 not 122	2370
124	limit 123 to ed=20091208-20120530	539
125	**limit 123 to ed=20091208-20121031**	**646**

Database: Medline in Process (OVID) (searched 07 November 2012)

Strategy used:

Same strategy as used for Medline

Database: Science Citation Index via Web of Science (searched 06 November 2012)

Strategy used:

# 22	**406**	#21 OR #20 OR #19 OR #17 *Databases=SCI-EXPANDED Timespan=2009-05-07 - 2012-11-08* *Lemmatization=On*

# 21	7	#18 AND #12 AND #1 *Databases=SCI-EXPANDED Timespan=2009-05-07 - 2012-11-08* *Lemmatization=On*
# 20	7	#18 AND #15 AND #1 *Databases=SCI-EXPANDED Timespan=2009-05-07 - 2012-11-08* *Lemmatization=On*
# 19	35	#18 AND #9 *Databases=SCI-EXPANDED Timespan=2009-05-07 - 2012-11-08* *Lemmatization=On*
# 18	91,187	TS=((systematic review* or meta analy*)) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 17	1,116	#16 OR #14 OR #11 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 16	287	#15 AND #13 AND #1 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 15	456	TS=(((weight reduc*) SAME (diet and exercise and behav*))) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*

# 14	**314**	#13 AND #12 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 13	**7,516,452**	TS=((trial* or study or studies)) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 12	**423**	TS=(((weight management or weight maintenance) SAME (diet and exercise and behav*))) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 11	**958**	#10 AND #9 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 10	**1,805,930**	TS=(((random* or placebo or control* or blind*) SAME (trial* or study or studies))) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 9	**1,935**	#8 OR #6 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 8	**1,187**	#7 AND #1 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*

# 7	2,384	TS=((diet* and exercis* and behav*)) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 6	1,603	#5 AND #1 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 5	2,954	#4 AND #3 AND #2 *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 4	112,662	TS=(((exercis* or physical therap*) SAME (scheme* or therapy or therapies or interven* or strateg* or program* or management or maintenance or modif* or reduc*))) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 3	464,820	TS=(((lifestyle or behav*) SAME (scheme* or therapy or therapies or interven* or strateg* or program* or management or maintenance or modif* or reduc*))) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 2	103,956	TS=(((diet) SAME (scheme* or therapy or therapies or interven* or strateg* or program* or management or maintenance or modif* or reduc*))) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*
# 1	224,203	TS=((obes* or overweight or "over weight" or weight gain*)) *Databases=SCI-EXPANDED Timespan=All Years* *Lemmatization=On*

Database: Conference Proceedings Citation Index via Web of Science (searched 09 November 2012)

Strategy used:

Same strategy as used for Science Citation Index

Database: BIOSIS via Web of Science (searched 09 November 2012)

Strategy used:

Same strategy as used for Science Citation Index

Database: PsycINFO 2002 to November Week 1 2012 (searched 08 November 2012)

Strategy used:

1	(obes* or overweight or "over weight" or "weight gain").ti,ab.	18733
2	Obesity/	9152
3	Overweight/	1892
4	2 or 3	9781
5	1 or 4	19007
6	(diet* and exercis* and behav*).ti,ab.	943
7	Diets/	4524
8	Exercise/ or Aerobic Exercise/ or Weightlifting/ or Yoga/ or (Physical Activity/ or Exercise/)	13843
9	Behavior/	7653
10	Behavior Change/	4262
11	Behavior Modification/	1504

12	Behavior Therapy/	2607
13	Biofeedback Training/	151
14	Classroom Behavior Modification/	274
15	Contingency Management/	638
16	"Fading (Conditioning)"/	27
17	Omission Training/	18
18	Overcorrection/	5
19	Self Management/	2009
20	Time Out/	49
21	Aversion Therapy/	18
22	Conversion Therapy/	42
23	Exposure Therapy/	951
24	Implosive Therapy/	11
25	Reciprocal Inhibition Therapy/	13
26	"Response Cost"/	46
27	Systematic Desensitization Therapy/	96
28	Behaviorism/	638
29	or/9-28	20413
30	Cognitive Behavior Therapy/	8961
31	29 or 30	28709
32	7 and 8 and 31	70
33	5 and 32	25
34	1 and 6	317
35	33 or 34	327
36	(multicomponent or "multi component").ti,ab.	1072

37	5 and 36	57
38	(("weight maintenance" or maintenance) adj3 weight loss*).ti,ab.	232
39	5 and 38	196
40	(program* or strateg* or intervention* or scheme* or pathway*).ti,ab.	343262
41	39 and 40	139
42	Clinical Trials/	6040
43	Placebo/	2102
44	Random Sampling/	289
45	or/42-44	7908
46	((random* adj5 trial*) or (placebo adj5 trial*) or (controlled adj5 trial*)).ti,ab.	24489
47	41 and (45 or 46)	26
48	35 or 37 or 47	407
49	**limit 48 to yr="2009 -Current"**	**187**

Database: CRD (searched 07 November 2012). Only the HTA database results were exported. DARE was searched via Wiley

Strategy used:

1	((obes* OR overweight OR "over weight" OR "weight gain"))	1334
2	MeSH DESCRIPTOR Obesity EXPLODE ALL TREES IN HTA	137
3	MeSH DESCRIPTOR Obesity, Morbid EXPLODE ALL TREES IN HTA	60
4	#1 OR #2 OR #3	1335
5	(("weight management" OR "weight maintenance"))	91

6	#4 AND #5	85
7	((surgery OR surgical OR hypertension OR diabetes OR sibutramine OR orlistat OR rimonabant))	14669
8	#6 NOT #7	42
9	((child* OR adolesc* OR teenage* OR youth*))	8414
10	#6 NOT #9	64
11	#8 AND #10	28
12	(#11) FROM 2009 TO 2012	18
13	(#12) IN HTA FROM 2009 TO 2012	2

Database: CRD (searched 07 November 2012) Only the HTA database results were exported. DARE was searched via Wiley

Strategy used:

1	((obes* OR overweight OR "over weight" OR "weight gain"))	1339
2	MeSH DESCRIPTOR Obesity EXPLODE ALL TREES	537
3	MeSH DESCRIPTOR Obesity, morbid EXPLODE ALL TREES	128
4	#1 OR #2 OR #3	1344
5	diet* AND exercis* AND behav*	210
6	diet* AND physical AND behav*	200
7	MeSH DESCRIPTOR diet therapy EXPLODE ALL TREES	151

8	MeSH DESCRIPTOR exercise EXPLODE ALL TREES	631
9	MeSH DESCRIPTOR behavior therapy EXPLODE ALL TREES	849
10	MeSH DESCRIPTOR cognitive therapy EXPLODE ALL TREES	507
11	#9 OR #10	849
12	#7 AND #8 AND #11	12
13	#5 OR #6 OR #12	289
14	#4 AND #13	165
15	((surgery OR surgical OR hypertension OR diabetes OR sibutramine OR orlistat OR rimonabant))	14700
16	#14 NOT #15	81
17	((child* OR adolesc* OR teenage* OR youth*))	8424
18	#16 NOT #17	31

Database: Ovid MEDLINE(R) 1946 to November Week 1 2012 **(searched 28 October 2012)**

Strategy used:

1	("weight management" or "weight loss" or "weight maintenance" or "weight reduction").ti.	9414
2	program*.ti.	122232
3	1 and 2	670
4	(Long term or follow up).ti,ab.	884349

5	3 and 4	196
6	**limit 5 to ed=20090415-20121028**	**73**

Database: Embase 1980 to 2012 Week 45 **(searched 28 October 2012)**

Strategy used:

1	(modific* or therap* or intervention* or strateg* or program* or management or scheme* or group* or pathway*).ti,ab.	6574753
2	("weight management" or "weight loss" or "weight maintenance" or "weight reduction").ti.	12544
3	1 and 2	7218
4	(Long term or follow up).ti,ab.	1167826
5	3 and 4	1762
6	Antiobesity Agent/	2904
7	(sibutramine or orlistat or rimonabant).mp.	9748
8	exp bariatric surgery/	12702
9	exp obesity/su	11111
10	or/6-9	28263
11	5 not 10	1368
12	limit 11 to (human and english language and (adult <18 to 64 years> or aged <65+ years>))	702
13	limit 12 to dd=20090416-20121109	258
14	**limit 13 to embase**	**192**

Appendix 4. Excluded studies

Insufficient intervention detail (authors contacted and no response, or could not contact author, or author replied but still did not meet inclusion criteria)

Driehuis, F., Barte, J.C., Ter Bogt, N.C., Beltman, F.W., Smit, A.J., van der Meer, K., & Bemelmans, W.J. 2012. Maintenance of lifestyle changes: 3-year results of the Groningen Overweight and Lifestyle study. *Patient Education & Counseling*, 88, (2) 249-255

McDermott, S., Whitner, W., Thomas-Koger, M., Mann, J.R., Clarkson, J., Barnes, T.L., Bao, H., & Meriwether, R.A. 2012. An efficacy trial of 'Steps to Your Health', a health promotion programme for adults with intellectual disability. *Health Education Journal.71 (3) (pp 278-290), 2012.Date of Publication: May 2012.* (3) 278-290

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Appendix 5. Evidence tables

Unless otherwise specified, all values given are as mean (SD). Weight and weight change values are given in kg, all BMIs are kg/m^2, and all waist circumference measurements are cm.

Control group coding based on following scale (also reported in methods):

1. No intervention at all or leaflet/s only[50]
2. Discussion/advice/counselling in one-off session +/-leaflet
3. Seeing someone more than once for discussion of something other than weight loss.
4. Seeing someone more than once for weight management, person untrained +/- leaflets
5. Behavioural weight loss programme comprising one of either diet or physical activity plus behavioural programme. 5 also includes seeing a health professional with special training on more than one occasion, such as a dietitian, who, because of their training will naturally create a weight loss programme with (in this case) dietary and behavioural elements (unless explicitly stated that they did not create a weight loss programme, in which case coded as 4). 5 also included seeing a professional with no basic training in weight loss management but who has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.
6. Behavioural weight loss programme comprising diet and physical activity plus behavioural programme. 6 also includes seeing a professional has no basic training in weight loss management but has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.

Internal validity (study quality) scores

Studies were rated ++ if all or most of checklist criteria were fulfilled and conclusions were judged very unlikely to alter; + if some criteria were fulfilled and conclusions were unlikely to alter; and - if few or no criteria were fulfilled and conclusions were likely or very likely to alter.

External validity

As for internal validity, studies were rated ++, + or –. This was based on:

- If the participants were representative of the general population of people who are overweight (in part through assessing the number of those screened who were enrolled, where this information was provided)
- If the intervention required no extraordinary efforts to implement broadly in the UK

[50] Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Appel et al **Year:** 2011 **Citation:** Appel, L.J., Clark, J.M., Yeh, H.C., Wang, N.Y., Coughlin, J.W., Daumit, G., et al. 2011. Comparative effectiveness of weight-loss interventions in clinical practice. *New England Journal of Medicine*, 365, (21) 1959-1968. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** + (requirement of computer literacy and regular access to computer)	**Source population/s:** USA; *Across whole study:* 64% F, mean age 54 years, 44% minority population, 59% college graduate. *For each arm* (mean, SD): baseline weight (kg): in-person directed (IPD) 105.0 (20.7), call centre directed (CCD) 102.1 (13.9), control 104.4 (18.6); baseline BMI: IPD 36.8 (5.2), CCD 36.0 (4.7), control 36.8 (5.1); baseline weight circumference (cm): IPD 118 (14), CCD 118 (13), control 118 (14). **Eligible population:** Recruited through primary care practices – physician referral, brochures and targeted mailings **Selected population:** Obese (BMI ≥ 30), at least 21 years old, one or more cardiovascular risk factors (hypertension, hypercholesterolemia, diabetes mellitus). Regular access to a computer, basic computer skills. **Excluded population/s:** Recently lost 5% or more of body weight, taking medications that affect weight. 43% of those screened were enrolled. **Setting:** Telephone, web and face-to-face intervention. Setting for counselling not specified.	**Method of allocation**: Web based randomization and allocation **Intervention (1) description**: *In-person directed (IPD)*: • Reduced energy diet (DASH) (calorie intake dependent on weight, 1200-2200 kcal/day) • Recommended moderate intensity physical activity, 180 minutes/week, >10 minutes/session • Group and individual delivery, phone, web, in-person • Delivered by weight loss coaches trained before intervention and quarterly thereafter • 61 sessions of 20-90 minutes over 24 months • PCPs play supportive role **Intervention (2) description**: *Call centre directed (CCD):* As per intervention 1, except: • 33 sessions of 20 minutes over 24 months • Delivered via phone and web only • Individual counselling via weight loss coaches and HealthWays call centre **Control description:** (2) Usual care: Met with weight loss coach at randomization. Received brochures and list of recommended web sites promoting weight loss. **Sample sizes (baseline):** Total n = 415 In person = 138 Call centre = 139 Control = 138 **At 12 months** Total n = 355 In person = 123 Call centre = 124 Control = 108 **At 24 months** Total n = 401 In person = 133 Call centre = 139 Control = 129 **Baseline comparisons**: Groups similar at study outset	**Published data only** **Outcome calculation method:** When necessary, reviewers calculated SD from SE provided **Follow up periods:** 6, 12 and 24 months	**BOCF weight change**: 12m IPD -4.8 (7.6), CCD -5.1 (7.6), control -0.9 (4.6). At 24m, IPD -4.9 (9.1), CCD -4.5 (8.3), control -0.8 (7.7). **Complete case weight change:** 12m IPD -5.4 (7.8), CCD -5.7 (7.8), control -1.1 (5.2). At 24m, IPD -5.1 (9.2), CCD -4.5 (8.3), control -0.8 (8.0). **Secondary outcomes:** waist circumference at 12m NR, complete case change in BMI (mean, SD) at 12m: IPD -1.8 (2.2), CCD -1.9 (2.2), control -0.4 (2.1) *Adverse effects:* One AE in IPD arm possibly related to study treatment – assault whilst exercising resulting in musculoskeletal injuries. No difference in total number of hospitalizations between arms (18 IPD, 15 CCD, 15 control). **Attrition details:** 86% followed up at 12m, IPD 89%, CCD 89%, control 78%. Reasons for attrition NR.	**Source of funding:** National Heart, Lung and Blood institute, Baltimore Diabetes research and Training Center, National Center for Research Resources **Other notes:** See also: Jerome, G. J., Yeh, H-C., Dalcin, A., Reynolds, J., Gauvey-Kern, M. E., Charleston, J., Durkin, N., and Appel, L. J. 2009. Treatment of obesity in primary care practice: The Practice based Opportunities for Weight Reduction (POWER) trial at Johns Hopkins. *Obesity and Weight Management*, 5, (5) 216-221.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Bertz et al **Year:** 2012 **Citation:** Bertz, F.f.b.g.s., Brekke, H.K., Ellegard, L., Rasmussen, K.M., Wennergren, M., & Winkvist, A. 2012. Diet and exercise weight-loss trial in lactating overweight and obese women. *American Journal of Clinical Nutrition*, 96, (4) 698-705 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Sweden *Across whole study:* 100% female, mean age 32, ethnicity NR, 74% >3 years education post high school *For each arm* (mean, SD): baseline weight (kg): Diet (D) 85.4 (10.0), Exercise (E) 88.3 (11.7), D+E 83.8 (7.3), Control 85.5 (10.3); baseline BMI: D 30.0 (2.6), E 30.4 (3.1), D+E 29.2 (2.2), Control 30.2 (3.4); baseline weight circumference NR. **Eligible population:** Recruited via antenatal clinics, of 76 women screened 5 (7%) excluded and 3 (4%) withdrew prior to randomization **Selected population:** Self-reported pre-pregnancy BMI 25-35, 8-12wk post partum at study entry, non-smoking, singleton term delivery, intention to breastfeed for 6m, no illness in mother or infant, 20% of infant energy intake as complementary foods, birth weight of infant .2500 g, **Excluded population/s:** Not explicitly stated, but serious illness or anything that ruled out physical activity implied **Setting:** Face-to-face in research clinic and at participant's homes, plus text messaging	**Method of allocation**: Random number table, allocation method not reported but described as 'concealed' **Intervention description**: • Energy restriction (deficit of 500 kcal/day) • Brisk walking (moderate intensity), supervised twice, and recommended 4 days a week, with length of each session incremental to 45 mins • Individual in person sessions • Delivered by dietitians and registered physical therapists • 2 sessions (2.5 hours at baseline, 2 hours at 6 weeks) • Participants instructed to text in weight and number of walks to study staff weekly over 12 weeks **Diet only control:** As per intervention, but shorter sessions (1.5 hours at baseline, 1 hour at 6 weeks), no physical activity instruction or contact with physical therapist, not instructed to text in number of walks **Exercise only control:** As per intervention, but only 2 sessions (1.5 hours at baseline, 1 hour at 6 weeks), no energy restriction or contact with dietitian, not instructed to text in weight **No intervention control:** Usual care (1) **Sample sizes (baseline):** Total n = 68 Intervention n = 16 Diet only = 17 Exercise only = 18 Usual care control n= 17 **12 months:** Total n = 57 Intervention n = 16 Diet only = 13 Exercise only = 15 Usual care control n= 13 **Baseline comparisons**: Groups similar at study outset	**Published or unpublished** Published data only **Outcome calculation method** Standard methods for calculation used **Follow up periods:** 12 weeks and 12 months	**BOCF weight change**: At 12m intervention (D+E): -7.3 (6.3); D only -7.8 (6.7); E only -2.3 (5.5); Usual care control -0.7 (5.7) **Complete case weight change:** At 12m intervention (D+E) -7.3 (6.3); D only -10.2 (5.7); E only -2.7 (5.9); Usual care control -0.9 (6.6) **Secondary outcomes:** Complete case change in BMI (mean, SD): Intervention (D+E): --2.6 (2.2); D only -3.6 (2.0); E only -0.9 (2.0); Usual care control -0.3 (2.4). Waist circumference NR *Adverse effects:* Effects on breastfeeding and infant weight reported. At 1 year, significant main effect of D on introducing non breastfeeding (p=.030). In no cases did women give up breastfeeding involuntarily. No differences in infant weight. **Attrition details:** 92% followed up at 12 months, intervention 100%, D 76%, E 83%, control 76%. 4 missing (6%); 2 medical reasons (3%).	**Source of funding:** Swedish Research Council, Swedish Council for Working Life and Social Research

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Dale et al **Year:** 2008 **Citation:** Dale, K.S., Mann, J.I., McAuley, K.A., Williams, S.M., & Farmer, V.L. 2009. Sustainability of lifestyle changes following an intensive lifestyle intervention in insulin resistant adults: Follow-up at 2-years. Asia Pacific Journal of Clinical Nutrition, 18, (1) 114-120 **Aim of study:** Diabetes prevention (increase insulin sensitivity) **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** New Zealand *Across whole study:* 67% female, mean age 46, 0% ethnic minority, SES data NR *For each arm*: baseline weight modest intervention (MI) 95.1 (12.2), intensive intervention (II) 91.1 (16.2), control 102.8 (15.4); baseline BMI MI 33.9 (4.4), II 32.5 (5.2), control 36.5 (4.3); baseline weight circumference MI 106.1 (9.8), II 100.9 (12.1), control 113.7 (9.7) **Eligible population:** Local advertisements **Selected population:** Being overweight/obese not an inclusion criteria (but baseline figures suggest vast majority would have fell into this category). 25 to 70 years old, able and willing to take part in dietary and exercise program, fasting glucose <6.1mmol/l, insulin sensitivity index <4.2 G mU^{-1} $*l^{-1}$ **Excluded population/s:** Diabetes or major medical condition, psychiatric illness, drug or alcohol dependence, on warfarin or oral steroids, on meds for <6m, likely to alter meds during intervention period 440 responded to advertisements, 79 enrolled (18%) **Setting:** In person, setting not specified. Phone discussion if missed face-to-face check in.	**Method of allocation**: NR **Intervention 1 description**: Intensive arm (II) • Macronutrient balance with some energy restriction, diets individually prescribed to lead to gradual and sustained weight reduction • Recommended and supervised physical activity, 30 minutes 5 days a week (at least 1x week supervised), at 80-90% of age predicted maximum heart rate • Mainly individual, some group exercise sessions, mostly in person but with phone catch ups if session missed • Delivered by dietitians, exercise consultants and researchers • 36 sessions over 4 months (18 diet, 18 exercise), length not specified • Free gym passes and some food provided **Intervention 2 description:** Modest arm (MI) • As per intervention 1, but macronutrient proportions of diet differ (more energy from fat allowed) and no specified heart rate targets for physical activity **Control description:** (4) usual care – at 8 and 12 months, "some advice" regarding lifestyle changes **Sample sizes (baseline):** Total n = 79 II n = 25 MI n = 31 Control n = 23 **At 12 months:** Total n = 70 MI+II n = 50 (not broken down, assumed MI 27, II 23) Control n= 20 **At 24 months:** Total n = 63 MI+II n = 43 (not broken down, assumed MI 23, II 20) Control n= 20 **Baseline comparisons**: At baseline, higher BMI, weight and waist circumference in control group.	**Published data only** **Outcome calculation method** Reviewers calculated weight change from weight data given at each time point. Reviewers interpreted results reported in paper (table 1) as complete case data, though unclear from information reported. Number of participants followed up in each intervention group not clear at 12 or 24 months, only combined n for two intervention groups available. Reviewers assumed equal loss to follow-up between intervention arms. BMI and waist circumference data only available for control and combined intervention, baseline data only represents those with 2 year follow-up **Follow up periods:** 4, 8, 12 and 24 months	**BOCF weight change**: 12 months MI -2.0 (6.6), II -2.5 (7.5), control -6.1 (6.0). At 24 months, MI -2.2 (5.7), II -2.1 (6.9), control -3.7 (5.5). **Complete case weight change (presumed):** 12 months MI -2.3 (7.0), II -2.7 (7.8), control -7.0 (5.9). At 24 months, MI -3.0 (6.5), II -2.6 (7.7), control -4.3 (5.7). **Secondary outcomes:** At 24 months, complete case change in waist circumference MI+II -1 (5.7), control -2 (3.3); complete case BMI change MI+II -0.7 (2.2), control -0.8 (1.9). *Adverse effects:* NR **Attrition details:** 87% followed up at 12 months (87% MI, 92% II, 87% control). Reasons for attrition NR.	**Source of funding:** Health Research Council, Otago University, Otago Diabetes Research Trust, NZ **Other notes:** *Quality score downgraded because randomization and allocation procedures not described **External validity score downgraded as, of those who initially responded to advertisements, 18% enrolled *See also:* McAuley, K.A. et al. 2002. Intensive lifestyle changes are necessary to improve insulin sensitivity. Diabetes Care, 25, (3) 445-452.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Diabetes Prevention Program Research Group (DPP) **Year:** 2002 **Citation:** Diabetes Prevention Program Research Group. 2002. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. NEJM, 346, (6) 393-403. **Aim of study:** Diabetes prevention **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA; *Across whole study:* Female: 68% Age: 51y Ethnicity: 54% White Education: Some college and above: 74% Family income: Median $35-50,000 /y *For each arm* (mean, SD): Weight (kg) Intervention: 94.1 (20.8) Control: 94.3 (20.2) BMI (kg/m^2) Intervention: 33.9 (6.8) Control: 34.2 (6.7) Waist circumference (cm) Intervention: 105.1 (14.8) Control: 105.2 (14.3) **Eligible population:** Participants recruited by a variety of methods including mass media, mail and telephone contacts. Also by work site and other screenings **Selected population:** 1) Age ≥25y 2) BMI ≥ 24kg/m2 (≥22kg/m2 in Asians) 3) Fasting plasma glucose concentration 5.3 to 6.9 mmol/l 4) OGTT : 7.8 to 11.0 mmol/l **Excluded population/s:** Participants with diabetes, and those taking medicines known to alter glucose tolerance. Recent MI or presence of illnesses that could seriously reduce their life expectancy or their ability to participate. **Setting:** In person	**Method of allocation**: Randomization and allocation methods **Intervention description**: • Lifestyle • Reduction in dietary fat intake to <25% of energy • Energy goal is added, if weight loss does not occur with fat restriction only – 1200 kcal/ day (33g fat) if initial weight 120-170lbs, – 1500 kcal/day (42g fat) if initial weight 175-215lbs, – 1800 kcal/day (50g fat) if initial weight 220-245lbs and – 2000 kcal/day (55g fat) if initial weight >250lbs. • Minimum 3 physical activity sessions weekly • Total of 150 minutes of moderate intensity exercise (e.g. brisk walking) per week with target to burn 700kcal/week • Voluntary activity sessions were organised in the community twice a week e.g. group walks, group aerobic classes • Individual sessions in person and by telephone • Delivered by lifestyle coaches who were dietitans or others with masters degree in exercise physiology, behavioural psychology or health education. • All lifestyle coaches received 2 day national training sessions and ongoing support • 16 core sessions lasting 30-60 minutes delivered in 24 weeks then unspecified but a minmimum of one session of 15-45 minutes every two months. • After 4 years, participants were invited to	**Published or unpublished** 12 month data from U.S. Preventive Services Task Force as only displayed graphically in published data. **Outcome calculation method** Complete case data not available. Authors report ITT analysis. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs given using baseline n. **Follow up periods:** 0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9 and 10	**BOCF weight change**: 12 months Intervention: -6.5 (6.6) Control: -0.4 (6.4) **ITT weight change:** 12 months Intervention: -6.8 (6.6) Control: -0.4 (6.6) 4 years *(Standard errors not available)*: Intervention: -3.5 (NR) Control: -0.2 (NR) **Secondary outcomes:** Waist circumference: NR BMI: NR *Adverse effects:* at 3 years Gastrointestinal symptoms (events/100 person years) Intervention: 12.9 Control: 30.7 Musculoskeletal symptoms (events/100 person years) Intervention: 24.1 Control:21.1 No deaths or hospitalisation due to the intervention **Attrition details:** **12 months** Total: 95% follow up **4 years** Total: 98% follow up	**Source of funding:** National Institute of Diabetes and Digestive Kidney Disease (NIDDK) **Other notes:** **DPPOS:** After 4 years, participants were invited to take part in DPPOS, an observational follow up study. In this phase all participants had the option to complete the 16 core DPP sessions and/or booster sessions. **Economic data** **Intervention:** 10-year study cost of $4,601 or $3,023 if completed as groups and not individual sessions 10-year cost outside of DPP : $24,563 Health system: Cost per QALY over placebo = $6,651 (undiscounted) if completed all as a group intervention then becomes cost-saving Societal perspective: Cost per QALY over placebo = $11,274 if completed as a group then cost saving **Control:** 10-year cost of study cost $769

		take part in DPPOS, an observational follow up study. In this phase all participants had the option to complete the 16 core DPP sessions and/or booster sessions – no scheduling or time scale reported. **Control description:** Usual care (4). This was a placebo control group with written lifestyle advice provided at baseline and alongside an annual individual session. **Sample sizes (baseline):** Total n = 3234 Intervention n = 1079 Control n= 1082 (Group with metformin n = 1073) **At 12 months (or closest point):** Total n = 3074 Intervention n = 1027 Control n= 1029 (Group with metformin n = 1018) **At longest 4 years:** Total n = 3182 Intervention n = 1066 Control n=1059 (Group with metformin = 1057) Groups similar at study outset			10-year cost outside of DPP : $27,463 **Additional references:** Report: Screening for the Management of Obesity in adults U.S. Preventive Services Task Force.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Eriksson et al **Year:** 2009 **Citation:** Eriksson, M.K., Franks, P.W., & Eliasson, M. 2009. A 3-Year Randomized Trial of Lifestyle Intervention for Cardiovascular Risk Reduction in the Primary Care Setting: The Swedish Bjorknas Study. Plos One, 4, (4) e5195 **Aim of study:** cardiovascular disease prevention **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Sweden *Across whole study:* percentage female: 57%, weighted mean age:54 years, ethnicity NR but likely to be all ethnic Swedish, SES data NR *For each arm* (mean, SD): baseline weight: Intervention 87.0 (16.4)kg and Control 84.5 (19.8), baseline BMI: Intervention 30.1 (5.3) Control 29.4 (5.1), baseline waist circumference Intervention: 104 (13) Control 100 (16) **Eligible population:** computerised search and mailed invitation **Selected population:** aged 18–65 years with a clinically documented diagnosis of hypertension, dyslipidemia, type 2 diabetes, obesity or any combinations thereof were identified from computerised case records. (ie obesity not entrance criteria, but ~90% obese at study entry) **Excluded population/s:** coronary heart disease, stroke, transient ischemic attack, severe hypertension, dementia or severe psychiatric morbidity 82% of those screened were enrolled **Setting:** in person primary care and sports facilities	**Method of allocation**: independent statistician generated the allocation sequence and randomisation numbers were kept in sealed, opaque envelopes. **Intervention (1) description**: • Reduced energy low fat diet, no target calories • Recommended and supervised daily physical activity, supervised 3 times per week. Supervised exercise lasted for 45 minutes increasing to 1 hour. • Group in-person • Delivered by physiotherapist or assistant and dietitian • 8 sessions with a dietitian who dealt only with diet and 45 sessions with a physiotherapist who dealt with diet and exercise over 3 years (53 total). • Focus on exercise over diet **Control description:** (2) One off education session by doctor, physiotherapist, and dietitian **Sample sizes (baseline):** Total n =151 Intervention n =75 Control n=76 **At 12 months (or closest point):** Total n =123 Intervention n =60 Control n=63	**Published data only** **Outcome calculation method:** standard **Follow up periods:** 12 months. 6 months and 36 months reported but data not extractable	**BOCF weight change**: At 12m, intervention -1.2 (2.6)kg Control, -0.6 (2.7) kg **Complete case weight change:** At 12m, intervention -1.5 (2.8), control: -0.7 (2.9) **Secondary outcomes:** At 12m, complete case change in waist circumference: Intervention -2.0 (2.8) Control: -0.2 (2.5) BMI: Intervention: -0.5 (1.0) Control: -0.2 (1.1) *Adverse effects:* no AEs attributed to intervention in either arm **Attrition details:** Total n =123 (81%) Intervention n =60 (80%) Control n=63 (83%) Reasons for loss: Intervention: 3 (4%) unavoidable; 12 (16%) missing; 0 medical. Control: Intervention: 3 (4%) unavoidable; 10 (13%) missing; 0 medical.	**Source of funding:** Swedish local health board **Other notes:** Data on 6 months and 36 months are available but incompletely reported making use in a meta-analysis difficult *See also:*Eriksson K. M., Westborg, C-J., Eliasson, M. C. E. 2006. A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors: The Bjorknas study. Scandinavian Journal of Public Health, 34, 453-461.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Fitzgibbon et al **Year:** 2010 **Citation:** Fitzgibbon, M.L., Stolley, M.R., Schiffer, L., Sharp, L.K., Singh, V., & Dyer, A. 2010. Obesity reduction black intervention trial (ORBIT): 18-month results. Obesity, 18, (12) 2317-2325 **Aim of study:** Weight loss in African American women **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA; *Across whole study:* All female, mean age 46, 100% minority group (all self-identified African American), 44% college graduate. *For each arm* (mean, SD): baseline weight (kg) intervention 103.9 (15.7), control 105.9 (17.4); baseline BMI intervention 38.7 (5.5), control 39.8 (5.8), weight circumference NR. **Eligible population:** University staff and students, recruited via mass e-mail and face-to-face recruitment within 2 mile radius of campus **Selected population:** Self-identified African American women aged 30-65, BMI 30-50, able to participate in 30 minutes of physical activity and attend classes at scheduled times. **Excluded population/s:** Pregnant, nursing, or planning a pregnancy, planning to move during course of study, consumes more than 2 alcoholic drinks/day on daily basis, treated for cancer in last 5 years (except for skin cancer other than melanoma), unable to exercise because of medical condition, taking weight loss medications prescribed by doctor or currently participating in weight loss program. 31% of those screened were enrolled **Setting:** face-to-face on university campus and telephone	**Method of allocation**: Centralized randomization and allocation, generated by program written by data analyst **Intervention description**: • Reduced energy and reduced fat diet (reduction based on individual, formula not provided) • Recommended and supervised moderate to high intensity physical activity, incremental to 30-40 minutes 3-4x week, plus goal of >10,000 steps/day. • Group and individual, in person and phone • Delivered by trained interventionists (details NR) and black peer mentors • 134 sessions of 60-90 minutes over 18 months • Intervention elements designed to take into account barriers specific to population (African-American women) **Control description:** (3) General health intervention – regular newsletters covering general health information, phone call from staff member every month relating to newsletter information **Sample sizes (baseline):** Total n = 213 Intervention n = 107 Control n= 106 **At 18 months:** Total n = 190 Intervention n = 93 Control n= 97 **Baseline comparisons**: Groups similar at study outset besides percentage of calories from alcohol, which authors state is "almost certainly not biologically meaningful"	**Published information only** **Outcome calculation method** Standard methods used **Follow up periods:** 6 and 18 months. Change data also provided from 6 to 18 months.	**BOCF weight change**: at 18 months: intervention -1.96 (6.95), control 0.46 (5.41) **Complete case weight change:** at 18 months: intervention -2.26 (7.42), control 0.51 (5.69) **Secondary outcomes:** waist circumference NR, complete case change in BMI at 18 months intervention -0.86 (2.79), control 0.22 (2.07) *Adverse effects:* NR **Attrition details:** 89% followed up at 18 months, 87% intervention, 92% control. 1 unavoidable (dead); 15% missing; 2% medical.	**Source of funding:** National Cancer Institute **Other notes:** External validity score downgraded as only 31% of those screened were subsequently enrolled *For protocol, see*: Fitzgibbon, M. L., Stolley, M., Schiffer, L., Sharp, L., Singh, V., Van Horn L., Dyer, A. 2008. Obesity reduction black intervention trial (ORBIT): Design and baseline characteristics. Journal of Women's Health, 17, (7), 1099-1110. *For 6m results, see*: Stolley, M.R., Fitzgibbon, M.L., Schiffer, L., Sharp, L.K., Singh, V., Horn, L., & Dyer, A. 2009. Obesity reduction black intervention trial (ORBIT): six-month results. Obesity, 17, (1) 100-106

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Foster-Schubert et al **Year:** 2012 **Citation:** Foster-Schubert, K.E., Alfano, C.M., Duggan, C.R., Xiao, L.R., Campbell, K.L., Kong, A., Bain, C.E., Wang, C.Y., Blackburn, G.L., & McTiernan, A. 2012. Effect of Diet and Exercise, Alone or Combined, on Weight and Body Composition in Overweight-to-Obese Postmenopausal Women. Obesity, 20, (8) 1628-1638 **Aim of study:** Weight loss in post-menopausal women **Study design:** RCT, factorial design **Quality score:** ++ **External validity score:** + (limited population)	**Source population/s:** USA; *Across whole study:* 100% female, mean age 58, 15% minority groups, 66% college graduate *For each arm* (mean, SD): baseline weight (kg) diet and exercise (D+E) 82.5 (10.8), diet only (D) 84.0 (11.8), exercise only (E) 83.7 (12.3), usual care 84.2 (12.5); baseline BMI D+E 31.0 (4.3), D 31.0 (3.9), E 30.7 (3.7), usual care 30.7 (3.9); baseline weight circumference (cm) D+E 93.7 (9.9), D 94.6 (10.2), E 95.1 (10.1), usual care 94.3 (11.3) **Eligible population:** Targeted mass mailing campaigns, media publicity and community outreach in greater Seattle, WA area. **Selected population:** Females aged 50-75, BMI ≥25, or ≥23 for Asian-American women, exercising <100 min/week at moderate intensity or greater, post menopausal, able to attend sessions, normal exercise tolerance test **Excluded population/s:** Diagnosed diabetes, use of hormone replacement therapy within prior 3 months, history of breast cancer or other serious medical conditions, alcohol intake in excess of 2 drinks/day, current smoker, contraindication to participating in diet/exercise program, current or planned participation in other weight loss program, use of weight loss medications. 6% of those screened were randomized. **Setting:** Face-to-face, phone and e-mail. "Study facility," location NR.	**Method of allocation**: Computer generated randomization list, central computerised allocation. **Intervention description (D+E)**: • Reduced energy and low fat (1200-2000 kcal/day based on baseline weight) • Recommended and supervised moderate to high intensity physical activity, 45 minutes 5 days/wk • Group and individual, in person, via phone, and via email • Dietitian with training in behaviour modification and exercise physiologist • 194 sessions, length not specified, over 12 months (156 supervised exercise + minimum of 38 diet) **Control descriptions:** Three control arms: • Usual care (1): no contact. • Diet only (D) (5): diet elements as above • Exercise only (E) (5): exercise elements as above **Sample sizes (baseline):** Total n = 439 Intervention (D+E) n = 117 D n = 118 E n = 117 Usual care n = 87 **At 12 months:** Total n = 399 Intervention (D+E) n = 108 D n = 105 E n = 106 Usual care n = 80 **Baseline comparisons**: Groups similar at study outset	**Published data only** **Outcome calculation method** Complete case data not available, all data presented as BOCF and not as change data. Reviewers calculated BOCF change data using baseline values and BOCF mean weight, BMI, and waist circumference provided by authors at 12m follow-up. **Follow up periods:** 12 months	**BOCF weight change**: At 12m D+E -8.9 (5.5), D -7.1 (6.3), E -2.0 (6.1), usual care -0.7 (4.6) **Complete case weight change:** NR **Secondary outcomes:** Complete case change in waist circumference and BMI NR. At 12m, BOCF BMI change D+E -7 (5.5), D -2.6 (2.2), E -0.8 (1.8), usual care -0.2 (1.5); waist circumference change (cm) D+E -7.0 (5.5), D -4.4 (5.5), E -2.0 (4.9), usual care 1.4 (4.3) *Adverse effects:* NR **Attrition details:** 91% followed up at 12m overall: 92% D+E, 89% D only, 91% E only, 92% usual care. 2 unavoidable losses (<1%); 8% missing; 1% medical reason.	**Source of funding:** National Cancer Institute and National Center for Research Resources **Other notes:** External validity downgraded on basis of high percentage excluded from source population (6% of those screened were randomized) *See also:* Imayama, I., et al. 2011. Dietary weight loss and exercise interventions effects on quality of life in overweight/obese postmenopausal women: a randomized controlled trial. International Journal of Behavioral Nutrition & Physical Activity, 8, 118 Imayama, I., et al. 2012. Effects of a caloric restriction weight loss diet and exercise on inflammatory biomarkers in overweight/obese postmenopausal women: a randomized controlled trial. Cancer Research, 72, (9) 2314-2326 Mason, C., et al. 2011. Dietary weight loss and exercise effects on insulin resistance in postmenopausal women. American Journal of Preventive Medicine, 41, (4) 366-375

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Hersey et al **Year:** 2012 **Citation:** Hersey, J.C., Khavjou, O., Strange, L.B., Atkinson, R.L., Blair, S.N., Campbell, S., Hobbs, C.L., Kelly, B., Fitzgerald, T.M., Kish-Doto, J., Koch, M.A., Munoz, B., Peele, E., Stockdale, J., Augustine, C., Mitchell, G., Arday, D., Kugler, J., Dorn, P., Ellzy, J., Julian, R., Grissom, J., & Britt, M. 2012. The efficacy and cost-effectiveness of a community weight management intervention: a randomized controlled trial of the health weight management demonstration. Preventive Medicine, 54, (1) 42-49 **Aim of study:** Weight loss **Study design:** **Quality score:** -* **External validity score:** ++	**Source population/s:** USA; *Across whole study:* Female: 74% Age: 40y Non-White: 16.4 Education: NR SES: NR BMI (kg) *(not reported for each arm)* : 33.6 *For each arm* (mean, SD): Weight (kg) Intervention1: 100.6 (18.8) Intervention2: 101.1 (19.1) Control: 99.9 (17.7) Waist circumference: NR **Eligible population:** Population approached for recruitment/recruitment methods **Selected population:** Participants were recruited through direct mail (80.5%) and community outreach (19.5%). Participants were non active duty personnel beneficiaries. **Excluded population/s:** Participants who were pregnant, had eating disorders or active cancer 10% of participants eligible were excluded before randomisation **Setting:** Telephone and Web	**Method of allocation**: NR **Intervention 1 description**: • RCT2 • No specific type of diet, but general advice encouraged reduction in calories, saturated fats, and reduction of salty, sugared rich but low nutrient density snacks ("junk foods") and increases in consumption of F&V's, low-fat proteins, low-fat dairy, and whole grains • An increase in moderate and vigorous physical activity was recommended • Individual internet intervention • Computerised weekly feedback on diet and exercise • Frequency was dependent on participants providing diet and exercise records **Intervention 2 description:** • RCT3 • Same diet and physical activity recommendations as Intervention (1) • Individual intervention • Delivered by health lifestyle coaches with at least an undergraduate degree and who had 2 weeks training with a psychologist • Alternating Telephone and Email support (15-20minutes) every 2 weeks for 18 months (39 sessions) **Control description:** Usual care (2): provided with a booklet about encouraging exercise and weight loss and also access to the basic (non-interactive) internet component. (Study label: RCT1) **Sample sizes (baseline):**	**Published or unpublished** Published data with an additional description of the intervention from the author **Outcome calculation method** Standard **Follow up periods:** 6, 12 and 15-18 months	**BOCF weight change**: 12 months Intervention 1: -1.9 (5.8) Intervention2: -1.8 (5.9) Control: -1.2 (4.2) 15-18 months: Intervention 1: -1.0 (4.9) Intervention2: -1.5 (5.6) Control: -1.0 (4.0) **Complete case weight change:** 12 months Intervention 1: -6.0 (8.9) Intervention 2: -5.4 (9.3) Control: : -1.2 (4.2) 15-18 months Intervention 1: -3.5 (8.8) Intervention2: -5.2 (9.4) Control: -3.8 (7.3) **Secondary outcomes:** Waist circumference: NR BMI: NR **Attrition details:** 12 months: Total : 31% follow up Intervention 1: 32% follow up Intervention 2: 33% follow up Control: 28% follow up	**Source of funding:** Department of Defence **Other notes:** *Quality score downgraded as randomisation procedures not described and follow up <50% at 12 months **Economic data** Cost per participant Intervention 1: $160 Intervention 2: $390 Control: $145 Cost per 1% weight-loss Intervention1: $40 Intervention2:$70 Control: $30

		Total n = 1755 Intervention1 n = 579 Intervention2 n = 578 Control n= 598 **At 12 months (or closest point):** Total n = 542 Intervention 1 n = 186 Intervention2 n = 188 Control n= 168 **At longest follow-up (as per results column):** **15-18 months** Total n = 486 Intervention 1 = 163 Intervention 2 = 168 Control n= 155 **Baseline comparisons** Groups similar at study outset		15-18 months: Total: 28% follow up Intervention 1: 28% follow up Intervention 2: 29% follow up Control: 26% follow up Reasons 12 months Medical: 3% Unavoidable: 5% 15-18 months Medical: 3% Unavoidable: 6%	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Heshka et al. **Year:** 2003 **Citation:** Heshka, S., Anderson, J.W., Atkinson, R.L., Greenway, F.L., Hill, J.O., Phinney, S.D., Kolotkin, R.L., Miller-Kovach, K., Pi-Sunyer, F.X. 2003. Weight loss with self-help compared with a structured commercial program: a randomized trial. JAMA, 289, (14) 1792-1798 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA; *Across whole study:* Female: 82% Age: 45y Ethnicity: NR SES or Education: NR *For each arm*: Weight (kg) Intervention: 94.2 (13.1) Control: 93.1 (14.4) BMI (kg/m^2) Intervention: 33.8 (3.4) Control: 33.6 (3.7) Waist circumference (cm) Intervention: 101 (12) Control: 99 (12) **Eligible population:** Recruited by existing clinic records or by advertising a long-term non-medication weight loss study for moderately overweight persons **Selected population:** 1) Age 18-65 2) BMI 27-40 **Excluded population/s:** Fasting glucose >140 mg/dL (7.8 mmol/L) Triglycerides > 1000 mg/dL (11.3 mmol/L) Liver function test results more than 2 times the upper normal limit Serum creatinine >1.4 mg/dL (124 umol/L) Also, those using systemic or inhaled corticosteroids or lithium; having history of alcohol abuse within past year; history or presence of significant psychiatric disorder or other condition that would interfere with participation Those who had initiated new drug	**Method of allocation**: Random number table with randomisation envelope prepared by data co-ordinator **Intervention description**: • Commercial programme: Weight watchers • Free vouchers for Weight watchers • Energy restricted balanced diet using a points system • The ProPoints plan is a programme designed to deliver an individual energy deficit that leads to a healthy and sustainable rate of weight loss of up to 2lbs a week. • Minimum physical activity recommendation is 30 minutes of moderate intensity aerobic activity on 5 or more days a week with 2+ resistance exercise sessions a week. For weight loss and weight maintenance, the aim was to earn 2-4 ProPoints and 4-6 ProPoints, respectively. This equates to 1hr daily. • In person, group sessions with additional web, mobile and paper based resources • Delivered by trained peers who receive on-going training and assessment. • Weekly sessions of 60 minutes for 24 months. **Control description:** Usual care (4). Participants had a 20minute consultation with a dietitian and received publically available	**Published or unpublished** Published information supplemented by the provision of raw data and author information on the programme details. **Outcome calculation method** Data presented as LOCF but BOCF and complete case weight change was calculated from raw data by the reviewers. **Follow up periods:** 3, 6, 12, 18 and 24 months	**BOCF weight change**: 12 months Intervention: -4.1 (6.5) Control: -1.1 (5.4) 24 months Intervention: -2.1 (6.1) Control: 0.0 (6.1) **Complete case weight change:** 12 months Intervention: -4.9 (6.8) Control: -1.3 (5.9) 24 months Intervention: -3.0 (7.1) Control: -0.1 (7.1) **Secondary outcomes:** LOCF waist circumference change *(Complete case data NR)* 12 months Intervention: -4.9 (10.6), Control: -1.9 (10.4). 24 months Intervention: -2.6 (8.6) Control: -0.2 (8.8) LOCF BMI change *(Complete case data NR)* 12 months Intervention: -1.9 (2.7) Control: -0.6 (2.6) 24 months Intervention: -1.2 (2.4) Control: -0.1 (2.5) *Adverse effects:* NR **Attrition details:** 80% followed up at 12 months, no difference between arms. Reasons for attrition NR. At 24 months, authors report 2 excluded because of lymphoma, group assignment unclear, and 2 excluded from intervention for using WL meds. No other reasons provided.	**Source of funding:** Weight Watchers International **Other notes:** Vouchers were $9 per session

	therapy in past 30 days, were already participating in WL program or who tool prescription weight loss or investigational medications within 90 days of randomisation were excluded **Setting:** In person at non-clinical community centres	information. The dietitian provided basic information and did not use their training to personalise or help set individual goals. **Sample sizes (baseline):** Total n = 433 Intervention n = 221 Control n= 212 **At 12 months:** Total n = 346 Intervention n = 176 Control n= 170 **At 24 months:** Total n = 309 Intervention n = 150 Control n= 159 Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Jebb et al **Year:** 2011 **Citation:** Jebb, S.A., Ahern, A.L., Olson, A.D., Aston, L.M., Holzapfel, C., Stoll, J., Amann-Gassner, U., Simpson, A.E., Fuller, N.R., Pearson, S., Lau, N.S., Mander, A.P., Hauner, H., & Caterson, I.D. 2011. Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. Lancet, 378, (9801) 1485-1492 **Aim of study:** Weight loss **Study design:** **Quality score:** + (<50% follow up at 12m) **External validity score:** ++	**Source population/s:** United Kingdom, Germany and Australia *Across whole study:* Female 87%; Age: 47y; Ethnicity and SES data: NR Baseline weight: intervention 86.9 (11.6), control: 86.5 (11.5) BMI: intervention 31.5 (2.6), control 31.3 (2.6) Waist circumference (cm): intervention 100 (9.2), control: 99.9 (9.3) **Eligible population:** Obese adults recruited from primary care practices **Selected population:** 1) ≥ 18 years 2) BMI 27-35 kg/m^2 3) One risk factor for obesity related disease **Excluded population/s:** Weight loss of 5kg or more in last 3 months; history of clinically disordered eating; orthopaedic limitations; untreated thyroid disease; medication that effects weight-loss; GI disorders, previous surgery for WL, major surgery in previous 3m, HbA1C 9% or more, heart problems in previous 3m, uncontrolled hypertension, new rx for chronic disorder in previous 3m or change in dose in previous 1m, history or presence of cancer **Setting:** In person	**Method of allocation**: Computer generated randomisation and allocation **Intervention (1) description**: • Weight Watchers • Energy restricted balanced diet using a points system • The ProPoints plan is a programme designed to deliver an individual energy deficit that leads to a healthy and sustainable rate of weight loss of up to 2lbs a week. • Minimum physical activity recommendation is 30 minutes of moderate intensity aerobic activity on 5 or more days a week with 2+ resistance exercise sessions a week. For weight loss and weight maintenance, the aim was to earn 2-4 ProPoints and 4-6 ProPoints, respectively. This equates to 1hr daily. • In person, group sessions with additional web, mobile and paper based resources • Delivered by trained peers who receive on-going training and assessment. • Weekly sessions of 60 minutes for 12 months. **Control description:** Nurse practitioner (4) **Sample sizes:** Total n = 772 Intervention n = 377 Control n= 395 **At 12 months** Total n = 444 Intervention n= 230 Control n = 214 Groups similar at study outset	**Published data only** **Outcome calculation methods** BOCF reported in paper. Reviewer calculated SD from SE given where possible. **Follow up periods:** 2, 4, 6, 9 and 12 months	**BOCF weight change**: At 12m intervention -4.06 (6.02), control -1.77 (3.78) **Complete case weight change** At 12m intervention -6.65 (0.43) Control: -3.26 (0.33) **Secondary outcomes:** BOCF Waist circumference (SE) 12 months Intervention: -4.05 (0.35) Control: -2.34 (0.26) *Adverse effects*: No adverse events attributable to trial participation **Attrition details:** **12 months** Total: 58% Follow up **Intervention:** Total: 61% follow up Medical: 3% Missing: 34% Unavoidable: 2% **Control:** Total: 54% follow up Medical: 2% Missing: 41% Unavoidable: 3%	**Source of funding:** Weight Watchers International (through grant to UK MRC) **Cost effectiveness summary:** In the UK, the cost per kilogram of weight loss was GBP 55 for the intervention and 92 GBP for the control group. Cost in other countries also available. See Fuller, N. R. et al. 2012. A within-trial cost-effectiveness analysis of primary care referral to a commercial provider for weight loss treatment, relative to standard care- an international randomised contolled trial. International Journal of Obesity. 1-7. *See also:* Eberhard, M. I. et al. 2011. Greater improvements in diet quality in participants randomised to a commercial weight loss programme compared with standard care delivered in GP practices. Proceedings of the Nutrition Scoeity, 70, (OCE4) E252.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Jeffery and Wing **Year:** 1995 **Citation:** Jeffery, R.W., and Wing, R. W. 1995. Long-term effects of interventions for weight loss using food provision and monetary incentives. Journal of Consulting and Clinical Psychology, 63, (5) 793-796. **Aim of study:** weight loss **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** USA *Across whole study:* 50% female, mean age 37, 8% ethnic minority, 50% college education. *For each arm*: Baseline weight: intervention 1 89.4, intervention 2 88.1, intervention 3 92.3, intervention 4 91.1, control 88.2. Baseline BMI: intervention 1 30.9, intervention 2 30.8, intervention 3 31.1, intervention 4 31.1, control 31.1 . Baseline weight circumference NR **Eligible population:** Newspaper and radio advertisements and mailed invitations in two US cities **Selected population:** 14-32 kg above insurance industry standards for height and weight (Metropolitan Life Insurance Company, 1983), 25-45 years old, non-smokers, moderate drinkers or non-drinkers, not on any special diet, not taking prescription medications, free of serious medical problems **Excluded population/s:** NR Percentage screened who were enrolled NR **Setting:** In person	**Method of allocation**: NR **Intervention 1 description**: • Standard behavioural therapy (SBT) • Reduced energy diet, 1000 or 1500 kcal/day based on initial body weight • Recommended moderate intensity physical activity (walking or biking) 5 days a week, weekly goal of building up to burning 1000 kcal/week via exercise. • Group in-person • Led by trained interventionists with advanced degrees in nutrition or behavioural sciences • 33 sessions over 18 months, length not specified **Intervention 2 description:** SBT + food. As per SBT above, plus provided with food each week for 18 months (premeasured and prepackaged dinners and breakfasts for 5 days/week) **Intervention 3 description:** SBT + incentives. As per SBT above, plus incentive program – each participant could earn financial rewards up to $25/week for achieving and maintaining weight loss **Intervention 4 description:** SBT + incentives + food. As per interventions 2 and 3. **Control description:** (1) no intervention **Sample sizes (baseline):** Total n = 202 Intervention 1 n = 40 Intervention 2 n = 40 Intervention 3 n = 41 Intervention 4 n = 41 Control n= 40 **At 12 months:** Total n = 176. Breakdown by group NR **At 30 months:** Total at least 153, breakdown by group NR Groups similar at study outset	**Published data only** **Outcome calculation method** Limited data available, study not included in meta analysis or weight curves. SDs not available except for at 30 months. Weight change data extrapolated from graph. BOCF calculations not available as number followed-up at each time point not provided by arm. Unclear if 30 month data is complete case, ITT, or other. BMI change calculated based on mean BMIs given. At 12 months, BMI data reported in control group not consistent with weight change data reported. **Follow up periods:** 6, 12, 18, 30 months	**BOCF weight change**: Unable to calculate **Complete case weight change:** At 12 months: intervention 1 -4.5, intervention 2 -9.0, intervention 3 -5.5, intervention 4 -9.0, control -0.2 At 30 months (unclear if data is complete case): intervention 1 -1.4 (7.2), intervention 2 -2.2 (6.6), intervention 3 -1.6 (5.5), intervention 4 -1.6 (6.3), control +0.6 (5.3) **Secondary outcomes:** Complete case BMI change at 12 months: intervention 1 -1.95, intervention 2 -3.20, intervention 3 -1.85, intervention 4 -2.97, control -0.5 Waist circumference NR *Adverse effects:* NR **Attrition details:** 87% completed 12 month follow-up, no differences between treatment groups	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** Loveman 2011 included study. *Quality score downgraded as no information on randomization or allocation provided **External validity score downgraded as unclear percentage screen who enrolled and no numbers on who was followed up within groups See also Jeffrew, R.W., Wing, R.R., et al. 1993. Strengthening behavioural interventions for weight loss: a randomized trial of food provision and monetary incentives

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Jolly et al **Year:** 2011 **Citation:** Jolly, K., Daley, A., Adab, P., Lewis, A., Denley, J., Beach, J., & Aveyard, P. 2010. A randomised controlled trial to compare a range of commercial or primary care led weight reduction programmes with a minimal intervention control for weight loss in obesity: the Lighten Up trial. Bmc Public Health, 10, 439 **Aim of study:** weight loss **Study design:** 8 arm RCT (choice arm excluded from review) **Quality score:** + **External validity score:** ++	**Source population/s:** UK Percentage female: 71%, Mean age: 49 years, Percentage in all minority groups: 6%, SES: IMD score- participants more deprived than country average Baseline weight: Weight Watchers: 93 (14) Slimming World: 94 (13) Rosemary Conley: 94 (14) Size Down: 95 (18) GP: 92 (15) Pharmacist: 93 (14) Control: 93 (15) Baseline BMI Weight Watchers: 34.0 (3.9) Slimming World: 33.8 (3.8) Rosemary Conley: 33.4 (3.5) Size Down: 33.8 (3.9) GP: 33.1 (3.5) Pharmacist: 33.4 (3.5) Control: 33.9 (4.4) Baseline weight circumference: NR **Eligible population:** Practices wrote to patients >18 with a raised BMI (dependent upon ethnic group and comorbidities) and invited them to join the study. **Selected population:** Everyone who responded who did not have a comorbidity **Excluded population/s:** Unable to understand English,	**Method of allocation**: Sequence prepared by statistician using block randomisation and concealment through envelopes **Intervention 1 description**: • Weight Watchers (WW) • Low fat diet, set based upon height and weight but aiming for 500Kcal deficit • Recommended physical activity, no specific target • Group in-person • Delivered by lay person who successfully lost weight with WW and then trained • 12 weekly hour long sessions **Intervention 2 description:** • Slimming World (SW) • Low fat low energy density diet, includes free foods, eaten without restriction, and allowances for other types of food. No energy restriction as such • Recommended physical activity, building to 10x15 minutes of moderate activity or 5x30 minutes weekly • Group in-person • Delivered by lay person who successfully lost weight with SW and then trained • 12 weekly hour long sessions **Intervention 3 description:** • Rosemary Conley (RC) • Reduced energy low fat diet, low GI diet with energy goals of week 1&2: 1200kcal, Week 3&4: 1400kcal, Week 5 onwards: personal energy allowance based on age, gender and current weight • Recommended physical activity and one 45-minute dance-based exercise session per week • Group in-person • Delivered by lay person who successfully lost weight with RC and then trained • 12 weekly hour long sessions **Intervention 4 description:**	**Published or unpublished** Published only **Outcome calculation method** Standard **Follow up periods:** 3 and 12 months	**BOCF weight change**: 12 months WW -3.5 (6.9) SW -1.9 (5.1) RC -2.1 (6.4) SD -2.5 (5.9) GP -0.8 (5.1) Pharmacist -0.7 (4.5) Control -1.1 (5.1) **Complete case weight change:** 12 months WW -4.4 (7.7) SW -3.1 (6.4) RC -3.3 (7.8) SD -3.7 (7.0) GP -1.3 (6.4) Control -1.7 (6.6) **Secondary outcomes:** Waist circumference: NR Change in BMI WW -1.8 (3.2) SW -1.4 (2.6) RC -1.3 (4.2) SD -1.2 (2.7) GP -0.7 (2.4) Pharmacist -0.7 (2.6) Control -0.8 (2.6) Adverse effects: NR though all participants had the opportunity to given feedback. **Attrition details:** Reasons for loss to follow up not reported	**Source of funding:** Local health service **Other notes:** Lost a + on quality because >20% difference between arms in loss to follow up at 12m

	pregnant, so ill that weight loss inappropriate e.g. terminal illness Percentage screened who were enrolled NR **Setting:** In person programmes delivered in community settings, pharmacies, or GP surgeries depending on programme.	• Size Down (NHS group-based weight loss programme) • Reduced energy low fat diet based on Eatwell plate aiming to lose about 0.15kg/week • Recommended physical activity, no specific target • Group in-person • Lay people taken NVQ Level 3- 25 hours of training from dietitians plus assessment to pass • 8 sessions of 2 hours over 12 wks **Intervention 5 description:** • GP and pharmacist based care differed only in the background of the therapist • Reduced energy low fat diet based on Eatwell plate aiming to lose about 0.5-1kg/week • Recommended physical activity incremental to 30 mins of moderate activity/week 3-6 METS • Individual in-person • GP mainly given by nurses. GPs, nurses and pharmacists all had 2-day training to deliver course • 12 sessions of approx 20 mins over 12 weeks **Control description:** (1) Offered 12 free entries to local sports centre **Sample sizes (baseline):** Total n = 100 for all groups except GP and pharmacist, which was 70 each **At 12 months (or closest point):** Total n = 430 (67%); WW n =78 (78%); SW n=62 (62%); RC n=68 (68%); SD n=66 (66%); GP n=46 (66%) Pharmacist n=40 (57%); Control n=70 (70%) Groups similar at study outset.			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Kuller et al **Year:** 2012 **Citation:** Kuller, L.H., Pettee Gabriel, K.K., Kinzel, L.S., Underwood, D.A., Conroy, M.B., Chang, Y., Mackey, R.H., Edmundowicz, D., Tyrrell, K.S., Buhari, A.M., & Kriska, A.M. 2012. The Women on the Move Through Activity and Nutrition (WOMAN) study: final 48-month results. Obesity, 20, (3) 636-643 **Aim of study:** Modify lipoproteins, weight loss and exercise in postmenopausal women (originally designed to slow progression of subclinical atherosclerosis among women on hormone therapy) **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA *Across whole study:* 100% female, mean age 57, 12% minority group, 80% had 0-4 years college, 79% employed for wages *For each arm*: baseline weight (kg) intervention 105.5 (11.1), control 106.3 (11.4); baseline BMI intervention 30.6 (3.8), control 30.9 (3.8); baseline weight circumference NR **Eligible population:** Direct mailings to selected zip codes **Selected population:** Postmenopausal women, 52-62 years old, BMI 35-39.9, waist circumference >80cm, BP <140/90, LDL cholesterol 100-1600mg%, Beck Depression Inventory score <20, successful completion of 400 meter corridor walk test. Originally also required to be on hormone therapy for at least 2 years. **Excluded population/s:** History of CVD, diagnosis of psychotic disorder, use of cholesterol-lowering medication, diagnosis of diabetes or use of diabetes medication. 52% of those screened were randomized. **Setting:** face-to-face, location not specified	**Method of allocation**: Randomization sequence designed by independent statistician, allocation via sealed, numbered envelopes opened sequentially **Intervention description**: • Energy and fat reduction (1300 kcal/day if baseline weight < 175 lb, if >175 lb 1500 kcal/day) • Recommended moderate intensity physical activity incremental to 240 minutes/week. • Group face-to-face • Delivered by qualified nutritionists, behavioural psychologists, and exercise physiologists • 64 sessions over 36 months, length not specified • Intervention was originally intended to last 48 months but study was cut short **Control description:** Health education group (3): met 6x in year one and 'several times' over following years to discuss women's health **Sample sizes (baseline):** Total n = 508 Intervention n = 253 Control n= 255 **At 18 months:** Total n = 421 Intervention n = 208 Control n= 213 **At 48 months:** Total n = 446 Intervention n = 216 Control n= 230 Groups similar at study outset	**Published data only** **Outcome calculation method** Standard methods used **Follow up periods:** 6, 18, 30, 48 months	**BOCF weight change**: at 18m intervention -6.4 (7.1), control -1.3 (5.1); at 48m intervention -2.9 (6.7), control -0.2 (5.3) **Complete case weight change:** at 18m intervention -7.8 (7.1), control -1.6 (5.5); at 48m intervention -3.4 (7.2), control -0.2 (5.6) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 83% followed up at 18m overall: 82% intervention, 84% control. Reasons for attrition NR.	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** This was originally a trial exclusively in women with HRT. However, when risks discovered, turned into study in general population. *See also:* *Design:* Kuller, L. H., et al. 2007. The clinical trial of Women On the Move through Activity and Nutrition (WOMAN) study. Contemporary Clinical Trials 28, 370-381. *For results at 18m:* Kuller, L. H., et al. 2006. Lifestyle intervention and coronary heart disease risk factor changes over 18 months in postmenopausal women: the Women On the Move through Activity and Nutrition (WOMAN Study) clinical trial. Journal of Women's Health, 15, (8) 962-974. *Other outcomes:* Gabriel, K.K., et al. 2011. The impact of weight and fat mass loss and increased physical activity on physical function in overweight, postmenopausal women: results from the Women on the Move Through Activity and Nutrition study. Menopause, 18, (7) 759-765

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Lindstrom et al **Year:** 2003 **Citation:** Lindstrom, J., et al. Finnish Diabetes prevention Study Group. 2003. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. Diabetes Care, 26, 3230-3236. **Aim of study:** Diabetes prevention **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Finland *Across whole study:* Female 67%, mean age 55, Ethnicity NR, SES: years of education 0-9 : 40%, 10-12 : 27%, >=13 : 33% *For each arm* (mean, SD): Weight Intervention: 86.7kg (14.0) Control: 85.5kg (14.4) BMI Intervention: 31.4 (4.5) Control: 31.1 (4.5) Weight circumference Intervention: 102.0 (11.0) Control: 100.5 (10.9) **Eligible population:** High-risk groups such as first-degree relatives of type 2 diabetes patients **Selected population:** 1) Age 40–64y 2) BMI >25 kg/m2 3) Impaired glucose tolerance **Excluded population/s:** Diabetes, unlikely to survive 6 years due to disease, psychological or physical characteristics that mean that intervention or study follow up impractical. Percentage screened but not enrolled: NR **Setting:** In person & phone	**Method of randomization and allocation concealment** A randomization list was used. The nurses scheduling visits were blinded to randomisation. Study staff were not blinded. **Intervention description**: • Lifestyle Intervention • Low fat diet (<30% kcal from fat) • Recommended moderate intensity exercise every day for 30 minutes • Individual with voluntary group sessions • Delivered by dietitian/nutritionist and physician • 7 compulsory sessions in year one then every 3 months indefinitely. Plus voluntary sessions. **Control description:** Usual Care (2) – General information about lifestyle was provided at baseline in an individual or group session lasting 30-60minutes. Written material was also provided at baseline. **Sample sizes:** Total n = 522 Intervention n = 265 Control n = 257 **12 months** Total n = 506 Intervention n = 256 Control n = 250 **3 years** Total n = 434 Intervention n = 231 Control n = 203 Groups similar at study outset	**Published or unpublished** Published **Outcome calculation method** Standard **Follow up periods:** 1y, 3y	**BOCF weight change** **12 months** Intervention: -4.3 (5.0) Control: -1.0 (3.7) **3 years** Intervention: -3.5 (5.6) Control: -0.7 (4.8) **Complete case weight change** **12 months** Intervention: -4.5 (5.0) Control: -1.0 (3.7) **3 years** Intervention: -3.5 (5.1) Control: -0.9 (5.4) **Secondary outcomes:** **12 months** *Waist circumference change* Intervention: - 4 (5) Control - 1 (5) *BMI change* Intervention: -1.6 (1.8) Control: - 0.4 (1.3) Adverse events NR **Attrition details:** **12 months** 97% followed-up overall. Intervention = 97% follow up Control n = 97% follow up Reasons for attrition: NR	**Source of funding:** Finish academy, ministry of education; Novo nordisk foundation; Yrjo Jahnsson Foundation; Juho Vainio Foundation; and Finish diabetes research foundation **Other notes:** The study was prematurely terminated in March 2000 by an independent end point committee, since the incidence of diabetes in the intervention group was highly significantly lower than in the control group *See also:* Tuomilehto J, Lindström J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P, Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M: Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med344:1343–1350, 2001

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Mensink et al. **Year:** 2003 **Citation:** Mensink M., Blaak E. E., Corpeleijn, E., Saris W. H., de Bruin T. W., Feskens, E. J. 2003. Lifestyle interventions according to general recommendations improves glucose tolerance. Obesity Research, 11, (12) 1588-1596 **Aim of study:** Improved glucose tolerance in subjects with high risk for developing type 2 diabetes **Study design:** RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** Netherlands. *Across whole study:* 43% female, mean age 57, ethnicity and SES data NR *For each arm*: baseline weight intervention 86 (14.1), control 83.7 (11.5), baseline BMI intervention 29.8 (3.7), control 29.3 (3.1), baseline weight circumference intervention 102.4 (11.1), control 102.3 (8.4) ** **Eligible population:** Selected from existing cohort in Maastricht area **Selected population:** Aged >40, family history of diabetes or BMI ≥25, mean 2 hour glucose concentration of two OGTTs between 7.8 and 12.5, with fasting glucose concentration <7.8 mM **Excluded population/s:** Previously diagnosed diabetes (other than gestational), medication known to interfere with glucose tolerance, participation in regular vigorous exercise or intensive weight reduction programme in year prior to study start, any chronic disease that 'hampered participation' in lifestyle intervention, improbability of 5-yr survival Percentage screened who were enrolled NR **Setting:** face-to-face, setting NR	**Method of allocation**: Randomization and allocation methods **Intervention (1) description**: • Fat and carbohydrate restriction based on Dutch Nutrition Council guidelines. If participants did not lose 5-7% weight by year 2, given 'mild' energy restriction diet. • Recommended and supervised, moderate intensity physical activity for 30 minutes 5 days a week • Individual in person counselling, supervised exercise in group form • Trained dietitian and exercise trainers • 8 behavioural sessions over 2 years, length not specified. 208 supervised physical activity sessions of 30 minutes each over 2 years. **Control description:** Oral and written information (2): at baseline, oral and written information on diet, weight loss, and physical activity. **Sample sizes (baseline):** Total n = 114 Intervention n = 55 Control n = 59 **At 12 months:** Total n = 88 Intervention n = 40 Control n = 48 **At 24 months:** Total n = 88 Intervention n = 40 Control n = 48 **Baseline comparisons**: Groups similar at study outset	**Published information only** **Outcome calculation method** Reviewer calculated SD from SE provided **Follow up periods:** 12 and 24 months	**BOCF weight change**: 12 months intervention -2.25 (3.51), control -0.2 (3.1); 24 months intervention -1.8 (3.9), control -0.1 (3.2) **Complete case weight change:** 12 months intervention -3.1 (3.8), control -0.2 (3.5); 24 months intervention -2.4 (4.4), control -0.1 (3.5) **Secondary outcomes:** At 12 months, complete case change in waist circumference (cm) intervention -3.8 (3.8), control -1.2 (4.2), at 24 months intervention -1.9 (4.4), control -0.6 (4.2). Complete case change in BMI at 12 months intervention -1.1 (1.3), control -0.1 (1.4); at 24 months intervention -0.8 (1.3), control 0.00 (1.4) *Adverse effects:* Authors state no serious adverse effects were observed. No other details reported. **Attrition details:** 77% followed up at 12 months overall: 73% intervention, 81% control. 18% missing; 4% medical.	**Source of funding:** Diabetes Research Foundation and Netherlands Organization for Scientific Research **Other notes:** *Quality score downgraded by one as allocation methods unclear, unlikely to affect results but it is a possibility **Being overweight/ obese was not an inclusion criteria, but included as 93% intervention and 91% control BMI >25. *See also:* Mensink, M., et al. 2003. Study on lifestyle-intervention and impaired glucose tolerance Maastricht (SLIM): design and screening results. Diabetes Research and Clinical Practice, 61, (1) 49-58

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Morgan et al. **Year:** 2011 **Citation:** Morgan, P.J., Lubans, D.R., Collins, C.E., Warren, J.M., & Callister, R. 2011. 12-month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men. Obesity, 19, (1) 142-151 **Aim of study:** Weight loss in men **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** Australia *Across whole study:* 0% female, mean age 36, ethnicity NR, 52% in high or highest SES bracket (7-10 on scale of 1-10) *For each arm*: baseline weight (kg) intervention 99.1 (12.2), control 99.2 (13.7); baseline BMI intervention 30.6 (2.7), control 30.5 (3.0), baseline weight circumference (cm) intervention 102.8 (6.8), control 103.4 (8.3) **Eligible population:** university staff and students recruited through university notice boards and website **Selected population:** male university staff and students, BMI 25-37, aged 18-60 years **Excluded population/s:** history of major medical problems (eg heart disease) in past 5 years, diabetes, orthopaedic, or joint problems that would be a barrier to physical activity, recent weight loss of ≥4.5 kg, taking medications that might affect body weight. Access to a computer with email and Internet facilities. 48% screened subsequently enrolled **Setting:** group and online, setting for group session NR	**Method of allocation**: Computer-based random allocation sequence, randomization completed by research assistant not involved in project and allocation sequence was 'concealed.' **Intervention description**: • Reduced energy diet, deficit of at least 480 kcal/day less than personal daily energy expenditure (calculated using Harris Benedict equation and personalized activity factor) • Recommended moderate to high intensity physical activity for 30 minutes a day • 1 session face-to-face group, remaining contacts individual e-mail • Male researcher, training not specified • 8 sessions over 3 months. First session 75 minutes, all other contacts e-mail-based. • Free access to Calorie King website **Control description:** Information session (2): identical information session to that in intervention, without online component description, plus program booklet **Sample sizes (baseline):** Total n = 65 Intervention n = 34 Control n = 31 **At 12 months:** Total n = 46 Intervention n = 26 Control n = 20 **Baseline comparisons**: Groups similar at study outset	**Published and unpublished data** Further detail on intervention components provided via email from author **Outcome calculation method** Authors report ITT analysis only, including all randomized participants (using linear mixed models, results adjusted for effects of significant covariates). Reviewers used ITT in place of complete case data to calculate BOCF using standard methods. Reviewers calculated SDs from 95% CIs provided, using t values to derive denominators due to small sample sizes. **Follow up periods:** 3, 6 and 12 months	**BOCF weight change**: (kg) at 12 months intervention -4.1 (5.4), control -2.0 (4.3) ***ITT analysis (not complete case) weight change:*** (kg) at 12 months intervention -5.3 (5.6), control -3.1 (5.0) **Secondary outcomes:** *ITT analysis (not complete case)* change in waist circumference (cm) intervention -5.8 (5.3), control -3.8 (4.8); change in BMI intervention -1.7 (1.7), control -0.9 (1.6) *Adverse effects:* NR **Attrition details:** 71% followed up at 12m overall: 76% intervention, 65% control. 3% unavoidable, 26% missing.	**Source of funding:** University of Newcastle Strategic Pilot grant and The Men's Health Golf Day **Other notes:** Additional intervention detail provided by authors. *External validity score downgraded due to requirement of access to a computer with e-mail and internet facilities. 48% of those screened were enrolled. *See also:* Morgan, P.J., et al. 2010. The SHED-IT community trial study protocol: a randomised controlled trial of weight loss programs for overweight and obese men. Bmc Public Health, 10, 701 Morgan, P.J., et al. 2009. The SHED-IT randomized controlled trial: evaluation of an Internet-based weight-loss program for men. Obesity, 17, (11) 2025-2032

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Munsch et al **Year:** 2003 **Citation:** Munsch S, Biedert E et al. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. *Swiss Med Wkly* 2003;133: 148-154. **Aim of study:** Weight loss **Study design:** **Quality score:** -* **External validity score:** ++	**Source population/s:** Switzerland *Across whole study:* Female: 75% Age: 46y Ethnicity: NR SES/Education: NR *For each arm* (mean, SD): Weight (kg) Intervention 1: 96.8 (17.1) Intervention 2: 106.8 (26.1) Control: 86.3 (6.4) BMI (kg/m^2) Intervention 1: 36.2 (6.5) Intervention 2: 38.5 (7.5) Control: 32.6 (1.8) Waist circumference (cm): NR **Eligible population:** Patients were recruited from a clinical centre, GP practices and via a newspaper advert **Selected population:** 1) BMI >30kg/m^2 2) GP physical exam **Excluded population/s:** Severe mental disorders, insulin-dependent diabetes, hypothyroidism, terminal diseases **Setting:** In person at GP or health clinic	**Method of allocation**: NR **Intervention (1) description**: • GP BASEL • Balanced diet with fat intake target of 20g per day. • 15 mins of exercise daily with examples swimming, walking and incorporation into daily life. • Group • Delivered by a General Practitioner who was trained by a psychologist and dietitian in two 4 hour sessions. • 16 weekly sessions of 90 minutes over 16 weeks **Intervention 2 description:** • Clinic BASEL • Balanced diet with fat intake target of 20g per day. • 15 mins of exercise daily with examples swimming, walking and incorporation into daily life. • Group • Delivered by a clinic tutor who was trained by a psychologist and dietitian in two 4 hour sessions. • 16 weekly sessions of 90 minutes for **Control description:** Usual care (4): received non-specific comments about general measures to lose weight from GP. Authors write "No specific technique, tools or written material was used." **Sample sizes (baseline):** Total n = 122 Intervention 1 n = 53 Intervention2 n= 52 Control n= 17 **At 12 months:** Total n = 65 Intervention 1 n = 41 Intervention 2 n = 16 Control n= 8 **Baseline comparisons**: Groups similar at study outset	**Published or unpublished** Published data was supplemented with intervention details provided by the authors **Outcome calculation method** Complete cases converted to BOCF **Follow up periods:** 16 weeks and 12 months	**BOCF weight change (kg)**: 12 months Intervention 1: -3.6 (7.9) Intervention2: -0.9 (6.9) Control : -0.2 (2.7) **Complete case weight change:** Intervention 1: -4.7 (8.7) Intervention 2: -2.9 (12.5) Control: -0.4 (4.0) **Secondary outcomes: 12 months** **BMI change:** Intervention1: -1.8 (3.3) Intervention 2: -0.9 (3.6) Control: -0.2 (1.2) **Waist circumference:** NR *Adverse effects:* NR **Attrition details:** No breakdown	**Source of funding:** Unrestricted grant from Knoll AG, Liestal, Switzerland **Other notes:** *Quality score downgraded as randomisation process not defined; Groups were not similar at outset; and imbalance in dropouts between arms not accounted for. Quality of life variables available

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes

Authors: Nanchahal et al **Year:** 2012 **Citation:** Nanchahal K, Power T, Holdsworth E, et al. A pragmatic randomised controlled trial in primary care of the Camden weight loss (CAMWEL) programme. BMJ Open 2012;2:e000793 **Aim of study:** Weight-loss **Study design:** **Quality score:** ++ **External validity score:** ++	**Source population/s:** UK *Across whole study:* Female: 72%; Age: 49y Minority: 29%; Education: 12% had no qualification *For each arm* (mean, SD): Weight: Intervention 91 (18); Control 94 (18) BMI: Intervention 33.0 (5.4); Control: 33.9 (5.6) Waist circumference: Intervention 106 (13); Control 108 (13) **Eligible population:** Population recruited by letter (and some text messages) from GP and personal referral from GP in consultations **Selected population:** Age 18 years and above, BMI >25 kg/m^2, attending a participating practice and willing to attend visits with a CAMWEL advisor over 12 months. **Excluded population/s:** Pregnancy or lactation, diagnosis of renal failure, use of a pacemaker, recent diagnosis of cancer or participation in another weight management study. **Setting:** In person at primary care centre	**Method of allocation**: Computer generated randomisation **Intervention description**: • Calorie reduced diet based on the Eatwell plate. Calorie goal set to achieve 1kg/week weight-loss. • Recommended exercise focussing on walking with exercise diaries provided. • Individual, in person delivery • Delivered by health trainers who are lay people trained in behaviour change counselling. • The advisors received initial training over 2 days and further meetings with the research team every 3 to 4 months. • 14, 30 minute sessions in total over 36 weeks. Sessions were every fortnight for the first 12 weeks, every 3 weeks for 12 weeks and finally monthly for the next 12 weeks **Control description:** Usual care (1) group who received a British Health Foundation booklet at baseline **Sample sizes (baseline):** Total n = 381 Intervention n = 191 Control n= 190 **At 12 months:** Total n = 117 Intervention n = 103 Control n= 114 Groups similar at study outset	**Published or unpublished** Published data only **Outcome calculation method** Standard BOCF calculation **Follow up periods:** 6,12 months	**BOCF weight change**: Intervention: -1.3 (4.3) Control: -1.0 (4.5) **Complete case weight change:** Intervention:-2.4 (5.6 Control: -1.3 (5.1) **Secondary outcomes:** Waist circumference (cm) Intervention: -3.37 (8) Control: -1.49 (6) BMI (kg/m^2) Intervention: -0.8 (2.0) Control: -0.5 (1.9) *Adverse effects:* NR **Attrition details:** Total: Intervention Unavoidable 3% Missing 42% Medical 1% Control Unavoidable 1% Avoidable 39%	**Source of funding:** Camden PCT

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Patrick **Year:** 2011 **Citation:** Patrick, K., Calfas, K.J., Norman, G.J., Rosenberg, D., Zabinski, M.F., Sallis, J.F., Rock, C.L., & Dillon, L.W. 2011. Outcomes of a 12-month web-based intervention for overweight and obese men. Annals of Behavioral Medicine, 42, (3) 391-401 **Aim of study:** Weight Loss **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* 0% female Age 44y 29% minority group SES data: College graduate and above 63.1% *For each arm* (mean, SD): Weight (kg) Intervention: 104.7 (15.3) Control: 104.6 (15.3) BMI (kg/m^2) Intervention: 34.2 (4.2) Control: 34.3 (4.0) Waist circumference (cm) Intervention: 113.7 (11) Control: 112.9 (11.1) **Eligible population:** Printed advertisements to local newspapers, radio advertisements and a TV news story featuring our study, and flyers **Selected population:** 1) Age 25-55y 2) BMI $\geq$25kg/m^2 **Excluded population/s:** NR **Setting:** Web based	**Method of allocation**: Fixed allocation and randomization by computer **Intervention (1) description**: • Balanced diet with emphasis on increasing fruit and vegetable intake (5-9 servings); 3+ servings of whole grains; and <20g saturated fat. • Recommendation of 10,000 steps on 5 days per week and strength training on 2 days per week. • Group based web sessions with option of individual email support • Delivered by a dietitian, exercise trainer and psychologist • Weekly sessions for 12 months (52 sessions) **Control description:** (1) Access to alternate website with general health information, authors state not likely to lead to changes in diet or physical activity **Sample sizes (baseline):** Total n = 441 Intervention n = 224 Control n= 217 **At 12 months:** Total n = 309 Intervention n = 154 Control n= 155 **Baseline comparisons**: Difference in age with control group younger (44.9 (7.8) v 42.8 (8.0)). No other differences.	**Published data only** **Outcome calculation method** Authors report BOCF calculations only. Complete case data not available **Follow up periods:** 12 months	**BOCF weight change**: 12 months Intervention: -0.9 (7.7) Control: -0.2 (5.7) *Complete case weight change data NR.* **Secondary outcomes:** 12 months, *BOCF only, complete case data NR.* BOCF BMI change Intervention = -0.4 (2.1) Control = -0.1 (1.5) BOCF waist circumference change Intervention = -1.6 (5.6) Control = -1.3 (4.3) **Adverse events :** NR **Attrition details:** **12 months** 70% Follow up total, 69% intervention, 71% control. Reasons for attrition: intervention Unavoidable: 2% Missing: 30%; control Unavoidable: 1% Missing: 29%	**Source of funding:** NIH/NCI **Other notes:** *External validity score downgraded as only 44% of those contacted enrolled in the study

Study details	Population and setting	Intervention and comparators	Outcomes and	Results	Notes

			methods of analysis		
Authors: Penn et al **Year:** 2009 **Citation:** Penn, L., White, M., Oldroyd, J., Walker, M., Alberti, K.G., & Mathers, J.C. 2009. Prevention of type 2 diabetes in adults with impaired glucose tolerance: the European Diabetes Prevention RCT in Newcastle upon Tyne, UK. Bmc Public Health, 9, 342 **Aim of study:** diabetes prevention, **Study design:** 2-arm RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** UK percentage female: 60% mean age: 57 years percentage in all minority groups: NR SES: Manual workers 48% Baseline weight: Intervention:93 (16) Control: 91 (13) Baseline BMI Intervention: 34.1 (5.5) Control 33.5 (4.6) Baseline waist circumference Intervention: 105 (11) Control: 104 (9) **Eligible population:** Population approached for recruitment/recruitment methods: GPs wrote to people over 40 years with a BMI>25 and this population were tested twice for impaired glucose tolerance **Selected population:** Inclusion criteria: IGT, >40 years, BMI>25 **Excluded population/s:** illness that would make PA impossible, on a special diet for medical reasons 96% of all volunteers who met inclusion criteria were enrolled but many people were not screened for IGT **Setting:** Mode of delivery: in person, in hospital intervention.	**Method of allocation**: Randomization stratified by age, sex, and 2-hour plasma glucose level. Allocation concealment not described though likely **Intervention description**: • Low fat weight loss diet, no specific target • Recommended accumulation of 30 minutes of PA moderate intensity 3-6 METS/day • Mainly individual with few group cook and eat sessions. • Delivered by dietitian and physiotherapist • 30 minutes/session with physio and dietitian combined. Seen baseline, 2 weeks, then monthly until 3 months then every 3 months i.e. 8x30 mins to 12 months and 20 sessions total • Based on motivational interviewing **Control description:** (2) single session of advice from dietitian and physio (we assume) and leaflets **Sample sizes (baseline):** Total n =102 Intervention n=51 Control n=51 **At 12 months (or closest point):** Total n =82 (80%) Intervention n = 39 (76%) Control n= 43 (84%) **At longest follow-up (as per results column):** 48 months (60 months also reported but follow up incomplete) Total n = 56 (55%) Intervention n = 28 (55%) Control n= 28 (55%) Groups similar at study outset	**Published and unpublished data** Authors sent unpublished data on weight **Outcome calculation method** Standard from completer data **Follow up periods:** 12, 24, 36, 48 and 60 months. Very small numbers followed up in time for 60 month follow-up (as dependent on time of study enrolment), hence data at 48 months used as longest follow-up.	**BOCF weight change**: At 12 months Intervention: -2.0 (4.1) Control: +0.1 (3.1) At 48 months Intervention: -1.3 (4.6) Control: -1.0 (4.7) **Complete case weight change:** At 12 months Intervention: -2.4 (4.4) Control: 0.1 (3.5) At 48 months Intervention: -2.3 (6.1) Control: - 1.8 (6.3) **Secondary outcomes:** Waist circumference: NR Change in BMI: NR Adverse effects: NR **Attrition details:** At 12 months Intervention: unavoidable 2 (4%), avoidable 9 (18%), medical 0 Control unavoidable 4 (8%), avoidable 4 (8%), medical 0 At 48 months Intervention: unavoidable 5 (10%), avoidable 20 (40%), medical 5 (10%) Control unavoidable 5 (12%), avoidable 17 (24%), medical 7 (14%)	**Source of funding:** Wellcome Trust (medical charity) **Other notes:** *Downgraded because no clear evidence of allocation concealment Unpublished data from authors contributes to this.
Study details	**Population and setting**	**Intervention and comparators**	**Outcomes and**	**Results**	**Notes**

			methods of analysis		
Authors: Rejeski et al. **Year:** 2011 **Citation:** Rejeski, W.J., Brubaker, P.H., Goff, D.C., Jr., Bearon, L.B., McClelland, J.W., Perri, M.G., & Ambrosius, W.T. 2011. Translating weight loss and physical activity programs into the community to preserve mobility in older, obese adults in poor cardiovascular health. Archives of Internal Medicine, 171, (10) 880-886 **Aim of study:** Determine effects of physical activity and weight loss intervention on mobility in overweight or obese adults **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** USA *Across whole study:* 67% female, mean age 67, 15% minority group, 50% had at least 4 years of college education *For each arm*: baseline weight intervention 92.8 (16.1), physical activity only (PA) 91.7 (13.1), control 91.2 (15.1); baseline BMI intervention 33.1 (4.1), PA 32.8 (3.9), control 32.6 (3.5); baseline weight circumference NR **Eligible population:** Newspaper advertisements and direct mailings in local area **Selected population:** Ambulatory, community-dwelling, older adults 60-79 years old. Less than 60 mins/wk moderate PA. BMI >28 and <40. Evidence of cardiovascular disease or diagnosis of the metabolic syndrome. Self-reported mobility limitation. **Excluded population/s:** Bipolar or schizophrenia, unstable angina, symptomatic congestive heart failure, exercise induced complex ventricular arrhythmias, resting BP >160/100, diagnosis of systemic diseases that preclude safely participating in intervention, fasting blood glucose >140mg/dl, type 1 DM, type 2 DM with insulin therapy, active treatment for cancer, clinically significant visual or	**Method of allocation**: Randomization and allocation methods NR, permuted block randomization used. **Intervention (1) description**: • Reduced energy diet (1200-1500 kcal/day if baseline weight <113.4kg, 1500-1800 kcal/day if ≥113.4 kg) • Recommended and supervised, moderate intensity physical activity, at least 5 days/week, 30-45 minutes per session. • Group and individual, in person and via telephone • "Professional interventionists" (degree in health sciences, trained by study investigators) and Cooperative Extension Agents (Family and Consumer Science educators, field faculty from university, degrees in home economics and/or nutrition education) • 48 sessions of 10-90 minutes over 18 months • Months 1-6 most intensive, months 7-18 'maintenance' but weight loss continued unless BMI <20 **Control description:** Two control arms: 1. Physical activity only (PA) (5): as above, but no Cooperative Extension Agents, no diet component 2. Successful aging education control arm (3): 18 sessions over 18 months covering general topics related to aging and health. Physical activity and nutrition for aging addressed, but not focus. **Sample sizes (baseline):** Total n = 288 Intervention n = 98 Physical activity n = 97 Control n= 93 **At 18 months:** Total n = 261	**Published data only** **Outcome calculation method** Authors do not provide weight change data, reviewer calculated based on complete case compared with baseline, but not a true cohort due to dropouts. N in each arm unclear for weight at follow-up points, reviewer used N of those who completed 400 metre walk test. BOCF calculated from these figures. **Follow up periods:** 6, 12 and 18 months, though weight data not provided at 12 months.	**BOCF weight change**: at 18 months intervention -6.3 (7.7), PA -0.7 (6.3), control -0.8 (7.2) **Complete case weight change:** at 18 months intervention -7.1 (7.8), PA -0.8 (6.9), control -0.9 (7.7) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* Serious adverse effects possibly or definitely related to study treatment: intervention 6, PA 3, control 0. More AEs in total in intervention and PA arms than in control (35, 34 and 18, respectively). **Attrition details:** 86% followed up at 18 months (for walk test) overall: 96% intervention, 86% physical activity, 90% control. 1% unavoidable; 11% missing; 1% medical (unable to complete walk test).	**Source of funding:** National Heart, Lung and Blood Institute; National Institutes for Aging; General Clinical Research Center **Other notes:** *Quality score downgraded as randomization and allocation concealment methods not detailed, and as authors measured, but did not report, weight at 12 months ** External validity score downgraded as less than half of those screened were enrolled (44%), suggesting limited external validity of selected population

	hearing impairment, dementia, delirium, impaired cognitive function, participation in another medical intervention study, more than 21 alcoholic drinks/wk, inability to walk unassisted, inability to speak or read English. 44% of those screened were enrolled. **Setting:** face-to-face and phone, setting for face-to-face not specified	Intervention n = 94 Physical activity n = 83 Control n= 84 **Baseline comparisons**: Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Rock et al. **Year:** 2010 **Citation:** Rock, C.L., Flatt, S.W., Sherwood, N.E., Karanja, N., Pakiz, B., & Thomson, C.A. 2010. Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial. JAMA, 304, (16) 1803-1810 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA *Across whole study:* 100% female, mean age 44, 26% minority group, 45% college graduate or higher *For each arm*: baseline weight (kg) centre-based (CB) 92.2, telephone-based (TB) 92.9 (11.8), control 91.0 (10.5); baseline BMI CB 33.8 (3.6), TB 33.8 (3.3), control 34.0 (3.2); baseline weight circumference (cm) CB 108.9 (8.9), TB 108.5 (10.1), control 108.3 (9.1) **Eligible population:** List serves and flyers distributed at universities and health maintenance organization (HMO) **Selected population:** Women 18 years or older, BMI 25-40, minimum 15kg over ideal weight as defined by 1983 Metropolitan Life Insurance Tables **Excluded population/s:** Pregnant or breastfeeding or planning to become pregnant in next 2 years, eating disorders, food allergies or intolerances, current active involvement in another diet intervention study or organized weight loss program, history or presence of significant psychiatric disorder or any	**Method of allocation**: Randomization sequence generated by study statistician, centralized web-based allocation **Intervention 1 description (CB)**: • Jenny Craig, centre-based • Low fat and reduced energy (1200-2000 kcal/day, aiming for deficit of 500-1000 kcal/day). Includes free, pre-packaged meals. • Recommended physical activity, intensity not specified, 5 or more days a week for 30 minutes a session. CDs and DVDs provided for physical activity support • Individual, in person, with follow-up via phone, email, and website message board • Delivered by trained lay person (certified Jenny Craig Trainer) • 104 sessions ("brief," length NR), plus follow-up by phone, email, and message board (frequency NR), over 24 months **Intervention 2 description (TB):** • Jenny Craig, telephone-based • As per CB, but no in person interaction – telephone, email and website message board only **Control description:** Repeated weight loss contact (4): consultation with research staff dietetics professional plus written information at baseline and 6 months, plus monthly check-ins by email or phone. **Sample sizes (baseline):** Total n = 442 CB n = 167 (originally 169, 2 excluded	**Published data only** Data from website used for additional information on intervention (see See www.jennycraig.com/how-it-works/science-weight-loss/) **Outcome calculation method** Reviewer calculated SD from 95% CI given for anthropometric data. Authors report ITT analysis using BOCF but slight discrepancies (SD only) with reviewers BOCF calculations based on complete case data. Reviewers BOCF calculations presented here. **Follow up periods:** 6, 12 and 24 months	**BOCF weight change**: at 12 months CB -10.1 (7.3), TB -8.5 (8.0), control -2.5 (6.2); at 24 months CB -7.4 (8.4), TB -6.3 (9.3), control -1.9 (7.2) **Complete case weight change:** at 12 months CB -10.6 (7.1), TB -8.9 (8.0), control -2.7 (6.4); at 24 months CB -8.2 (8.5), TB -6.7 (9.5), control -2.1 (7.5) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 94% followed up at 12 months overall: 95% CB, 96% TB, 91% control. Over course of study (not broken down by follow-up point) at 24 months: 0% unavoidable; 5% missing; 2% medical.	**Source of funding:** Jenny Craig Inc **Other notes:** Additional information on intervention extracted from Jenny Craig website.

	other condition that would interfere with participation 78% of those screened were enrolled **Setting:** CB face-to-face, phone, email, website. TB phone, email, website. Setting "conveniently located" centres, further details NR.	post randomization) TB n = 164 Control n = 111 (originally 113, 2 excluded post randomization) **At 12 months:** Total n = 417 CB n = 159 TB n = 157 Control n = 101 **At 24 months:** Total n = 442 CB n = 151 TB n = 153 Control n = 103 **Baseline comparisons**: Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Ross et al **Year:** 2012 **Citation:** Ross, R., Lam, M., Blair, S.N., Church, T.S., Godwin, M., Hotz, S.B., Johnson, A., Katzmarzyk, P.T., Levesque, L., & MacDonald, S. 2012. Trial of prevention and reduction of obesity through active living in clinical settings: a randomized controlled trial. Archives of Internal Medicine, 172, (5) 414-424 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Canada *Across whole study:* Female 71% Age 52 Ethnicity and SES data NR *For each arm*: Weight Intervention: 91 (14) Control: 89 (14) BMI Intervention: 32.6 (4.1) Control: 32.0 (4.2) Waist circumference Intervention: 107 (11) Control: 106 (11) **Eligible population:** Population approached for recruitment/recruitment methods **Selected population:** 1) Age 25-75y 2) BMI 25-39.9 3) Waist circumference >102cm in men or >88cm in women 4) Sedentary (planned activity for purpose of health <=1d/wk); 5) Weight stable (w/in 2kg) for 6m before study start **Excluded population/s:** Significant cardiovascular disease; insulin dependent DM, pregnancy or intention to be pregnant in next 2years, physical impairment, plan to move from area, participating	**Method of allocation**: Computer generated randomisation **Intervention description**: • Mediterranean diet – increase in whole grains, fruits, veg, legumes, nuts, seeds, health fats and low fat dairy products • Recommended moderate exercise for 45-60min daily • Individual, in person sessions • Delivered by Health educators with a degree in kinesiology and training in behavioural counselling. • 33 sessions over a 24 month intervention. Eight sessions in the first 6 weeks. Every fortnight until 6 months then monthly till 24 months. **Control description:** (2) usual care – general advice from physicians on merits of physical activity as strategy for obesity reduction **Sample sizes:** Total n = 490 Intervention n = 249 Control n= 241 **12 months** Total n = 415 Intervention n = 207 Control n = 208 **24 months** Total n = 396 Intervention n = 190 Control n = 206 Groups similar at study outset	**Published data only** **Outcome calculation method** Complete case data not available. Authors report ITT analysis using linear mixed models with multiple covariates to impute missing values. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs given using baseline n. **Follow up periods:** All follow up periods	**BOCF weight change**: 12 months Intervention: -2.0 (4.4) Control: -0.8 (5.8) 24 months Intervention: -0.9 (5.5) Control: -0.5 (5.7) **Multiple imputation weight change** *(Complete case not available)***:** **12 months** Intervention: -2.4 (4.7) Control: -0.9 (6.2) **24 months** Intervention: -1.2 (6.3) Control: -0.6 (6.2) **Secondary outcomes:** **12 months** *(Using multiple imputation data, complete case not available)***:** Waist circumference change Intervention: -2.5 (6.3), Control: -0.9 (6.2) BMI Change Intervention: -0.84 (2.1), Control: -0.27 (2.0) *Adverse events:* Intervention:300 musculoskeletal injuries during exercise Control: 311 musculoskeletal injuries during exercise No differences in other	**Source of funding:** Canadian Institute of Health *See also:* Ross, R., Blair, S.N., Godwin, M., Hotz, S., Katzmarzyk, P.T., Lam, M., Lévesque, L., & MacDonald, S. 2009. Prevention and Reduction of Obesity through Active Living (PROACTIVE): rationale, design and methods. British Journal of Sports Medicine, 43, (1) 57-63

	in another research study, clinically judged unsuitable for participation or adherence 19% of those screened were excluded or withdrew before randomisation **Setting:** In person			non-study related adverse events reported. **Attrition details:** 12 months 84% followed up overall, Intervention 83%, control 86% **Reasons for attrition at 24 months** Intervention Missing: 28% Medical: 3% Unavoidable: 0.5% Control Missing: 14% Medical: 2% Unavoidable: 1%	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Silva et al. **Year:** 2010 **Citation:** Silva, M.N., Vieira, P.N., Coutinho, S.R., Minderico, C.S., Matos, M.G., Sardinha, L.B., & Teixeira, P.J. 2010. Using self-determination theory to promote physical activity and weight control: a randomized controlled trial in women. Journal of Behavioral Medicine, 33, (2) 110-122 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** Portugal *Across whole study:* 100% female, mean age 38, ethnicity NR, 67% had education beyond high school *For each arm*: baseline weight (kg) intervention 82.1 (11.9), control 81.5 (12.1); baseline BMI intervention 31.7 (4.24), control 31.3 (4.0); baseline weight circumference NR **Eligible population:** Respondents to newspapers, flyers and TV advertisements **Selected population:** Premenopausal women, 25-50 years old, not pregnant, BMI 25-40, willing to attend weekly meetings for 1 year and be tested regularly, willing not to participate in any other weight loss programme during first year of study **Excluded population/s:** "Major illnesses," taking meds that affect weight (or having done so in past yearr) 25% of those screened were enrolled **Setting:** Face-to-face, setting NR	**Method of allocation**: Random number generator used, allocation concealment methods NR. **Intervention (1) description**: • Reduced energy diet (reduction of daily caloric intake 300-400 kcal/day) • Recommended and supervised physical activity, intensity NR, daily, length NR • Group in-person • Dietitians, nutritionists, psychologists, exercise physiologists, all PhD or MS level • 30 sessions of 120 minutes over 12 months **Control description:** General health education programme (3): 29 face-to-face sessions in thematic courses, including healthy nutrition, but weight loss not focus **Sample sizes (baseline):** Total n = 239 Intervention n = 123 Control n = 116 **At 12 months:** Total n = 201 Intervention n = 112 Control n = 89 **Baseline comparisons**: Groups similar at study outset	**Published and unpublished data** Complete case weight data at 4 and 12 months provided by author via e-mail **Outcome calculation method** 19 participants who were enrolled were subsequently excluded from all analyses for violating study protocol; authors report that participants had a similar age and BMI to those of the whole same. Otherwise, standard methods used. **Follow up periods:** 4 and 12 months available, plus percentage weight loss at 3 years.	**BOCF weight change**: at 12 months intervention -5.49 (5.13), control -1.07 (3.69) **Complete case weight change:** at 12 months intervention -6.03 (5.06), control -1.4 (4.2) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 84% followed up at 12m overall: 91% intervention, 77% control. 12% missing, 1% unavoidable (note, numbers reported in paper do not quite add up).	**Source of funding:** Portuguese Science and Technology Foundation, Calouste Gulbenkian Foundation, The Oeiras City Council, Nestlé Portugal, and IBESA Portugal **Other notes:** Additional weight data provided by author via e-mail *External validity downgraded as 25% of those screened enrolled, suggests population may not be representative of source population. *See also:* Silva, M. N., et al. 2008. A randomized controlled trial to evaluate self-determination theory for exercise adherence and weight control: rationale and intervention description. BMC Public Health, 8, 234. Silva, M. N., et al. 2011. Exercise autonomous motivation predicts 3-yr weight loss in women. Medicine & Science in Sports and Exercise, 43, (4) 728-737. Teixeira, P.J., et al. 2010. Mediators of weight loss and weight loss maintenance in middle-aged women. [References]. Obesity, 18, (4) 725-735

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Stevens et al. **Year:** 1993 **Citation:** Stevens, V. J., Corrigan, S. A., Obarzanek, E., Bernauer, E., Cook, N. R., Hebert, P., Mattfeldt-Beman, M., Oberman, A., Sugars, C., Dalcin, A. T., Whelton, P. K. 1993. Weight loss intervention in Phase 1 of the trials of hypertension prevention. Archives of Internal Medicine, 153, 849-858 **Aim of study:** Lowering diastolic blood pressure in those whose blood pressure was initially in the high normal range **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* 79% female, mean age 43, 21% ethnic minority, 47% college graduates, 91% full time employed *For each arm*: baseline weight (kg) intervention 90.2 (13.3), control 89.3 (13.0); baseline BMI intervention 29.5 (2.9), control 29.5 (2.8); waist circumference NR **Eligible population:** NR **Selected population:** 30-54 years old, BMI 26.1-36.1 for men, 24.3-36.1 for women, diastolic blood pressure 80-89 mmHg (average over 3 visits 1 to 3 wks apart), compliance (ability to complete and return 24 hour urine collection and food frequency questionnaire) **Excluded population/s:** History of cardiovascular disease, diabetes mellitus, gastrointestinal disease, chronic renal failure, malignant neoplasm, current pregnancy or intent to become pregnant during study, recent history of psychiatric disorders, unwillingness to accept	**Method of allocation**: Sequence generation NR. Centralized allocation by telephone; if not possible, sealed opaque envelopes. **Intervention description**: • Reduced energy diet calculated individually with goal of achieving weight loss not to exceed 0.9 kg/wk, not to fall below 1200 kcal/day • Recommended and supervised moderate intensity physical activity at 40-55% heart rate reserve, incremental to 4-5 days/ week, 30-45 minutes/session • Group and individual, in-person but with phone and e-mail if in-person appointment missed • Registered dietitian, exercise physiologist, psychologist • 45 sessions (90 minutes group, individual length NR) over 18 months • Occasionally friends and family invited to group sessions. Participants offered informal weigh ins between sessions, in addition to 45 scheduled. **Control description:** Usual care (1): details NR **Sample sizes (baseline):** Total n = 564 Intervention n = 308 Control n = 256 **At 12 months (those who completed blood pressure test):**	**Published data only** **Outcome calculation method** Limited weight data presented (means for men and women separately but no combined means and no SDs reported). Means and SDs given calculated by reviewers, assuming that the p value at 12 and 18 m was the same as that calculated at the first follow-up visit ($7*10^{-21}$). Control values extrapolated from graph. N at follow-up derived from blood pressure results tables. **Follow up periods:** 6, 12, 18 months	**BOCF weight change**: at 12 months intervention -4.5 (6.3), control 0 (5.6); at 18 months intervention -3.7 (5.0), control 0 (4.3); at 18 months intervention -3.7 (5.0), control 0 (4.3) **Complete case weight change:** at 12 months intervention -4.8 (6.4), control 0 (5.8); at 18 months intervention -3.85 (5.0), control 0 (4.5) ; at 18 months intervention -3.7 (5.0), control 0 (4.3); at 18 months intervention -3.85 (5.0), control 0 (4.5) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 93% followed up at 12 months overall: 93% intervention, 93% control. Reasons for attrition NR.	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** Included study from Loveman 2010. This is a subset of data (2 arms reported here, out of 10 arms total in the study). Other arms not relevant to weight loss and not valid comparators. *Downgraded as number screened enrolled not reported. *See also:* Satterfield, S., et al. Trials of Hypertension Prevention: Phase 1 design. Annals of Epidemiology, 1, (5) 455-471 The Trials of Hypertension Prevention Collaborative Research Group. The effects of nonpharmacologic interventions on blood

	randomization into any study group, serious physical handicap, current alcohol intake >21 drinks/wk, current use of meds that could interfere with study intervention (diuretics, beta-blockers, anticoagulants), serum cholesterol >=260 mg/dL, serum creatinine >=1.7mg/dL for men or 1.5mg/dL for women, casual serum glucose >=200 mg/dL, unexplained hyperkalemia, hypercalcemia. Percentage screened who were enrolled NR **Setting:** Face-to-face at 'clinical centres', phone and email if face-to-face not possible	Total n = 524 Intervention n = 287 Control n = 237 **At 18 months (those who completed blood pressure test):** Total n = 531 Intervention n = 295 Control n = 236 **Baseline comparisons**: More men in intervention group (72.7% versus 62.9%), no other significant between-group differences.			pressure of persons with high normal levels: Results of the Trials of Hypertension Prevention, Phase I. JAMA, 267, (9) 1213-1220

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Stevens et al **Year:** 2001 **Citation:** Stevens, V.J., Obarzanek, E., Cook, N. R., Lee, I-M., Appel, L. J., West, D. S., et al. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. 2001. Long-term weight loss and changes in blood pressure: Results of the trials of hypertension prevention, phase II. Annals of Internal Medicine, 134, (1) 1-11 **Aim of study:** Test efficacy of lifestyle interventions for reducing blood pressure over 3-4 years **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* 34% female, mean age 43, 21% minority group, 51% college graduate *For each arm*: baseline weight (kg) intervention 91.5 (12.1), control 90.7 (11.3), baseline BMI intervention 31.0 (3.3), control 30.9 (3.2), baseline waist circumference NR **Eligible population:** NR, varied by recruiting centre **Selected population:** Age 30 to 54 years, BMI 26.1-37.4 for men and 24.4 -37.4 women. Diastolic blood pressure 83-89, systolic blood pressure <140, compliance (completion and return of 24 hour and 8 hour urine collections and 3 day food record) **Excluded population/s:** Hypertension, current (w/in past 2 months) use of antihypertensives, history of cardiovascular disease, diabetes mellitus, malignancy (other than nonmelanoma skin cancer) during past 5 years, other serious life-threatening conditions that require medication, renal deficiency, current alcohol intake > 21 drinks/week, current pregnancy or intent to become pregnant.	**Method of allocation**: Method of sequence generation NR. Centralized allocation via telephone to central randomizing centre or via sealed opaque envelopes. **Intervention description**: • Reduced energy diet (individually determined to produce moderate weight loss no more than 2lbs/week, men not to consume ≤1500 kcal/day, women not ≤1200 kcal/day) • Recommended and supervised moderate intensity physical activity at 40-55% heart rate reserve, incremental to 4-5 days/ week, 30-45 minutes/session • Group and individual, primarily in person but some contact via phone, fax, and post • Registered dietitians, psychologists, MA level counsellors • 41-47 structured sessions total (90 minutes in first phase, then length NR) over 36 months, plus participant initiated contacts • Occasionally friends and family invited to group sessions. Participants waited 1- 4 months between randomization and first group meeting, contacted monthly by interventionist during this time **Control description:** Usual care (1): details NR **Sample sizes (baseline):** Total n = 1191 Intervention n = 595 Control n= 596	**Published or unpublished** Published data only **Outcome calculation method** Baseline weight and BMI reported by gender, reviewers computed averages to derive combined mean and SD at baseline. Follow-up results reported with 95% CI, reviewer calculated SD. **Follow up periods:** 6, 12, 18 and 36 months. 12 month weight data not reported except in graph.	**BOCF weight change**: at 18 months intervention -1.8 (5.8), control 0.6 (6.9); at 36 months intervention -0.2 (5.8), control 1.7 (5.2). **Complete case weight change:** at 18 months intervention -2.0 (6.0), control 0.7 (7.2); at 36 months intervention -0.2 (6.0), control 1.8 (5.4) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 92% followed up at 18 months overall: 92% intervention, 92% control. Reasons for attrition NR.	**Source of funding:** National Heart, Lung, and Blood Institute, National Institutes of Health **Other notes:** Included study from Loveman 2011. Four armed study, two arms not reported here (reduced sodium and reduced sodium + weight loss). *External validity score downgraded due to representativeness of population – only 13% of screened population were randomized *See also*: Hebert, P.R., Bolt, R.J., Borhani, N.O., Cook, N.R., Cohen, J.D, Cutler, J.A., Hollis, J.F., et al. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. 1995. Design of a multcentre trial to evaluate long-term life-style intervention in adults with high-normal blood pressure levels: Trials of hypertension prevention (Phase II). Annals of Epidemiology, 5, (2) 130-139

	13% of those screened were enrolled (in study overall, including all 4 arms) **Setting:** Mostly in-person, plus participant initiated via phone, mail, and fax. Setting NR.	**At 18 months:** Total n = 1096 Intervention n = 545 Control n = 551 **At 36 months:** Total n = 1101 Intervention n = 547 Control n = 554 **Baseline comparisons**: Groups similar at study outset			Hollis J.F., Satterfield S., Smith F., Fouad M., Allender P.S., Borhani N., et al. Recruitment for phase II of the Trials of Hypertension Prevention. Effective strategies and predictors of randomization. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. Annals of Epidemiology, 5, 140-8.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Vermunt et al **Year:** 2011 **Citation:** Vermunt, P.W., Milder, I.E., Wielaard, F., de Vries, J.H., van Oers, H.A., & Westert, G.P. 2011. Lifestyle counseling for type 2 diabetes risk reduction in Dutch primary care: results of the APHRODITE study after 0.5 and 1.5 years. Diabetes Care, 34, (9) 1919-1925 **Aim of study:** Diabetes prevention **Study design:** 2 arm RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** Netherlands Percentage female ~60% Mean age: 58 years Percentage in all minority groups: NR SES data: 50% of low education Baseline weight (kg), Intervention: 89 Control: 88 Baseline BMI, Intervention: 29.0 (4.4) Control: 28.5 (4.1) Baseline waist circumference (cm) Intervention: 100 (12) Control: 99 (11) **Eligible population:** Primary care random sample of patients fitting criteria written to and asked to complete FINDRISC score for predicting diabetes. Invited for OGT and then entered into study if risk score >=13 (out of 26 and not having frank diabetes **Selected population:** Inclusion criteria. FINDRISC>13 **Excluded population/s:** Known diabetes, terminal disease or physical or mental disabilities making active participation in the study impossible. **Percentage screened who were enrolled** 96% of all eligible volunteers **Setting:** In person primary care	**Method of allocation**: Alternate allocation, non-random though list randomly ordered **Intervention description**: • Name of programme: Aphrodite • Low fat, reduced energy, high fibre diet aiming for 5% weight loss • Recommended 30 mins of moderate-high (3-6 METS) intensity physical activity for 5 days per week • Individual in-person • Nurse practitioner was main therapist had 5 evening sessions of training, also saw dietitian and GP who had 2 hours of training as well as physiotherapist • 17 sessions over 3 years, length not specified (7 with nurse, 4 with dietitian, 5 with GP, 1 with physiotherapist) **Control description:** (2) Single session of advice from GP about health benefits of healthy diet and exercise **Sample sizes (baseline):** Total n = 925 Intervention n = Calculated number at baseline is 479 but baseline data on 393 presented Control n= Calculated number at baseline is 444 but baseline data on 371 is presented **At 18 months (closest point to 12 months):** Total n = 764 (83%) Intervention n = 393 (82%) Control n= 371 (84%) **At longest follow-up (as per results column):** N/A **Baseline comparisons**: Groups pretty similar but significant difference in baseline weight adds to suspicion of biased allocation	**Published or unpublished** Published **Outcome calculation method** Based on change in BMI. This study did not report weight loss only BMI change but not mean height. We therefore assumed the males and females were the mean height of the Dutch population. Mean baseline weights are calculated on this basis. 18% of participants were of healthy weight but were excluded from the analysis of weight loss. **Follow up periods:** 6 and 18 months	**BOCF weight change:** (18 months) Intervention: -0.5 (4.7) Control: -0.3 (4.9) **Complete case weight change:** (18 months) Intervention: -0.6 (5.2) Control: -0.3 (4.9) **Secondary outcomes:** Waist circumference: Intervention: -0.4 (6.5) Control: +0.3 (5.6) Change in BMI: Intervention: -0.2 (1.7) Control: -0.1 (1.6) Adverse effects*:* *NR*. **Attrition details:** Overall percentage followed up at 12m: 83% Intervention loss to follow up: Avoidable: 10% Unavoidable:0% Medical:7% Control loss to follow up: Avoidable:8% Unavoidable:0% Medical:7%	**Source of funding:** Netherlands R&D government funding **Other notes:** *Quality score downgraded because allocation to intervention and control was alternate and known to GP prior to enrolment. If alternate allocation was used it is impossible to have this much imbalance in number in each arm, suggesting biased allocation.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Villareal **Year:** 2011 **Citation:** Villareal, D.T., Chode, S., Parimi, N., Sinacore, D.R., Hilton, T., Armamento-Villareal, R., Napoli, N., Qualls, C., & Shah, K. 2011. Weight loss, exercise, or both and physical function in obese older adults. New England Journal of Medicine, 364, (13) 1218-1229 **Aim of study:** Weight-loss and improvement in physical function **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA *Across whole study:* Female: 63% Age: 70y Ethnicity: NR College degree and above: 70% *For each arm* (mean, SD): Weight (kg) Intervention: 99.1 (16.8) Control 1: 104.1 (15.3) Control 2: 99.2 (17.4) Control 3: 101 (16.3) BMI (kg/m^2) Intervention 37.2 (5.4) Control 1: 37.2 (4.5) Control 2: 36.9 (5.4) Control 3: 37.3 (4.7) Waist circumference: NR **Eligible population:** Media advertisements **Selected population:** 1) Age 65 years or older 2) BMI 30 or more 3) Sedentary lifestyle 4) Stable body weight for 12 months 5) Stable medications for 6 months 6) Mild to moderate frailty **Excluded population/s:** Persons who had severe	**Method of allocation**: Random permutations procedure. **Intervention description**: • Diet and Exercise • Energy restriction of 500-750kcal per day (determined by REE x 1.7) • Supervised activity sessions (3/wk) of 90 mins including moderate to high intensity exercise (gradual increase to 70-80% of peak HR) • Both exercise and diet were delivered in, in person group sessions. • Delivered by a dietitian and physical therapist • 208 sessions over 12 months, length not specified. (Weekly sessions with a dietitian over 1y and 3 exercise sessions a week for a 1y). • Participants aimed to lose 10% of their baseline weight by 6 months and maintain during the next 6 months. **Control 1**: (5) (diet) Participants completed only the diet portion of Intervention 1. **Control 2:** (5) (exercise) Participants completed only the exercise portion of Intervention 1. **Control 3:** (4) Usual care Participants were provided general information about a healthy diet during monthly visits with the staff. **Sample sizes (baseline):** Total n = 107 Intervention n = 28 Control 1 n= 26	**Published or unpublished** Published **Outcome calculation method** Authors report LOCF analysis only, including all randomized participants. Reviewers used LOCF in place of complete case data. Reviewers calculated BOCF based on LOCF data provided, therefore some margin of error possible. **Follow up periods:** 6 and 12 months	**BOCF weight change** 12 months Intervention: -7.7 (4.5) Control 1: -8.6 (6.0) Control 2: -0.4 (3.3) Control 3: 0.1 (3.1) **LOCF weight change**: 12 months Intervention: -8.6 (3.8) Control 1: -9.7 (5.4) Control 2: -0.5 (3.6) Control 3: 0.1 (3.5) **Secondary outcomes:** Waist circumference and BMI change NR. *Adverse effects:* One participant in the intervention group fell during exercise training **Attrition details:** **12 months** **Total:** 87% follow up. **Intervention** Missing: 3.5% Medical: 7% **Control 1** Missing: 12% **Control 2** Missing: 12% Medical: 4% **Control 3** Missing: 3.7% Medical: 11%	**Source of funding:** National Institutes of Health

	cardiopulmonary disease; musculoskeletal or neuromuscular impairments that preclude exercise; visual, hearing, or cognitive impairments; or a history of cancer, as well as persons who were receiving drugs that affect bone health and metabolism or who were current smokers. 54% of those screened were excluded **Setting:** In person	Control 2 n =26 Control 3 n = 27 **At 12 months:** Total n = 93 (87%) Intervention n = 25 Control 1 n= 23 Control 2 n = 22 Control 3 n = 22 **Baseline comparisons**: Groups similar at study outset			

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Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Vissers **Year:** 2010 **Citation:** Vissers, D., Verrijken, A., Mertens, I., Van, G.C., Van de Sompel, A., Truijen, S., & Van, G.L. 2010. Effect of long-term whole body vibration training on visceral adipose tissue: a preliminary report. Obesity Facts, 3, (2) 93-100 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** Belgium *Across whole study:* Gender: NR; Age: 45y Education: NR; SES: NR *For each arm* (mean, SD): Weight Control: 88.6 (15.9) Diet: 92.1 (11.1) Fitness: 94.5 (11.7) Vibration: 95.2 (17.8) BMI Control: 30.8 (3.4) Diet: 32.9 (3.1) Fitness: 33.1 (3.4) Vibration: 31.9 (4.7) Waist circumference Control: 99.7 (11.1) Diet: 102.3 (7.9) Fitness: 103.5 (9.4) Vibration: 100.0 (13.5) **Eligible population:** Obese adults approached via media advertising and outpatient clinic **Selected population:** NR **Excluded population/s:** Diabetes, pregnancy, treatment with tricyclic antidepressants, joint replacement orthopaedic surgery, use of weight loss drugs, endocrine conditions causing weight change, BMI >40 kg/m2, weight loss > 5% of body weight within 6 weeks prior to start of the study.	**Method of allocation**: Unclear **Intervention (1) description:** Fitness • Hypocaloric diet calculated on an individual level using: (RMRx1.3) – 600kcal/d • Aerobic interval training + general muscle strengthening exercise • Individual, in person sessions • Dietitian & Physiotherapist • 12 sessions over 12 months as: 0-3 months: every fortnight; 3-6 months: 1x month; 6-12 months: 3 more visits • In addition exercise sessions: 0-3 Months: 2 supervised and one home/week; 3-6 months: 1 supervised session and 2 home/week; 6-12 months: advised to maintain an active lifestyle **Intervention (2) description:** Vibration • Diet as per intervention 1 • Whole body vibration – exercises chosen to train all major muscle groups with machine frequency increasing from 30 to 35 and finally 40Hz. • Individual, in person sessions • Dietitian & Physiotherapist • 12 sessions over 12 months, schedule as intervention 1 • In addition exercise sessions: 0-3 Months: Static exercises on whole body vibration platform; 3-6 months: Dynamic exercises; 6-12 months: advised to maintain an active lifestyle **Control (1) description:** Single component (5). Diet (as per diet component of intervention 1, without fitness and exercise elements) **Control (2) description:** No contact (1) **Sample sizes:** Total n = 79 Intervention 1 n = 20 Intervention 2 n = 18 Control 1 n= 20 Control 2 n= 21 **12 months** Total n = 61 Intervention 1 n = 19	**Published data only** **Outcome calculation method:** standard **Follow up periods:** 3, 6, 12 months	**BOCF weight change**: 12 months Intervention 1: -6.3 (6.4) Intervention 2: -7.2 (6.9) Control 1:-2.6 (4.2) Control 2: 1.1 (3.4) **Complete case weight change:** 12 months Intervention 1: -6.6 (6.4) Intervention 2: -9.9 (6.2) Control 1: -4.3 (4.8) Control 2: 1.3 (3.7) **Secondary outcomes:** 12 months complete case BMI change: Intervention 1: -2.3 (2.1) Intervention 2: -3.4 (2.0) Control 1: -1.5 (1.7) Control 2: 0.4 (1.4) 12 months complete case waist circumference change: Intervention 1: -6.9 (7.4) Intervention 2: -9.5 (6.3) Control 1: -3.5 (3.8) Control 2: 0.5 (4.0) **Attrition details:** **12 months** Total: 77.2% Follow up **Intervention 1:** Medical 5% **Intervention 2:** Missing 22%; Medical 6% **Control 1:** Missing 35%; Medical 5% **Control 2:** Unavoidable 10%; Missing 5%; Medical 5%	**Source of funding:** Doctorate grant, University College of Antwerp **Other notes:** *Quality score downgraded by one as randomization and allocation procedures NR

	Setting: In person	Intervention 2 n = 13 **Baseline comparisons**: Groups similar at study outset. Some differences in VO2 max with higher values in Intervention 2.			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Wadden **Year:** 2011 **Citation:** Wadden, T. A., Volger, S., Sarwer, D. B., Vetter, M. L., Tsai, A. G., Berkowitz, R. I., Kumanyika, S., Schmitz, K. H., Diewald, L. K., Barg, R., Chittams, J., Moore, R. H. 2011. NEJM, 365, 1969-79. **Aim of study:** Weight loss **Study design:** **Quality score:** ++ **External validity score:** +	**Source population/s:** USA *Across whole study:* Female: 80% Age: 52y Ethnicity NR Education: 39% University or higher *For each arm:* Weight Intervention: 106 (17) Control: 111 (20) BMI Intervention: 38.5 (4.6) Control: 39.0 (4.8) Waist circumference Intervention: 117.1 (11.9) Control: 119.8 (13.9) **Eligible population:** Referral from Primary Care Provider and self-referral through clinic ads **Selected population:** 1) Age: 21y+ 2) BMI 30-50 3) Weight <400lbs 4) 2+ criteria for metabolic syndrome **Excluded population/s:** - Medical condition that may hinder weight measurement - Prior or planned bariatric surgery - Blood pressure > 160/100 - Chronic use of medications that affect body weight - Unintentional weight loss in last 6 months (≥ 5% of body weight)	**Method of allocation**: Computerised randomisation and allocation **Intervention description**: • Brief lifestyle intervention • Energy restriction: If weight <113.4, 1200-1500 kcal/day; and If 113.4kg or more, 1500-1800 per day • Recommended moderate intensity physical activity for minimum 30 minutes, 6 days/week • Individual in person and some telephone conversations • Delivered by a lifestyle coach • 25 (plus 8 visits with PCPs as per control) sessions over 24 months **Control description:** (4) GP care - same goals as intervention, and given pedometer, calorie counting book and handouts. Quarterly PCP visits during 24m to address coexisting illnesses. At each visit, PCP spent 5-7min reviewing weight change and discussing info in handouts. **Sample sizes:** Total n = 261 Intervention n = 131 Control n= 130 **12 months** Total n = 221 Intervention n = 109 Control n = 112 **24 months** Total n = 222 Intervention n = 112 Control n = 110 Groups similar at study outset	**Published data only** **Method of analysis:** Complete case data not available. Authors report ITT analysis using linear mixed models with multiple covariates to impute missing values. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs given using baseline n. **Follow up periods:** 6, 12, 18, 24 months	**BOCF weight change**: 12 months Intervention: -2.8 (6.4) Control: -2.0 (6.4) 24 months Intervention: -2.4 (7.4) Control: -1.5 (7.4) **Multiple imputation weight change:** *(Complete case data NR)* 12 months Intervention: -3.4 (6.9) Control: -2.3 (6.8) 24 months Intervention: -2.9 (8.0) Control: -1.7 (8.0) **Secondary outcomes:** 12 months, multiple imputation *(Complete case data NR)* BMI Change Intervention: -1.3 (2.3) Control: -0.8 (2.3) 24 months Intervention: -0.9 (2.3) Control: -0.6 (2.3) Waist circumference NR *Adverse events:* NR **Attrition details:** 85% followed up at 12m overall, 83% intervention, 86% control At 24 months, reasons for attrition: Missing	**Source of funding:** National Heart Lung and Blood Institute **Other notes:** *External validity score downgraded as 60% excluded from 1196 that were screened Third study arm not included as included option to use drugs

	- Intentional weight loss in last 6 months (≥ 5% of body weight) - Pregnant or nursing within past 6 months - Plans to relocate from the area within 2 years - Another member of household is a study participant or staff in the trial - Consumes > 14 alcoholic drinks per week - Current use of illicit substances - Psychiatric hospitalization in last year - Psychiatric condition likely to impair adherence to treatment (e.g., schizophrenia) 60.2% of those screened were excluded before randomisation **Setting:** In person and telephone			Intervention 28%, Control 31%; medical Intervention 0.8%	

Appendix 6. Summary of judgements from quality checklists

Green cells indicate a positive judgement and red cells indicate a negative judgement. Reasons for negative judgements are recorded in comments. Criteria regarding intention to treat analyses and treatment of missing data are not reported here as these would not affect the quality of the findings in our review (because we used the same methods for each study).

Study ID	Was the method used to generate random allocations adequate?	Was the allocation adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were there any unexpected imbalances in dropouts between groups?	If so, were they explained or adjusted for?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Comments
Appel 2011	Y	Y	Y	N	n/a	N	
Bertz 2012	Y	U	Y	Y	Y	N	
Dale 2008	U	U	N	N	n/a	N	Higher BMI, weight and waist circumference in control group
DPP	Y	Y	Y	N	n/a	N	
Eriksson 2009	Y	Y	N	N	n/a	Y	BMI slightly higher in intervention group but unlikely to affect results. 6 and 36m weight measured but not reported
Fitzgibbon 2010	Y	Y	Y	N	n/a	N	
Foster-Schubert 2012	Y	Y	Y	N	n/a	N	
Hersey 2012	U	U	Y	N	n/a	N	
Heshka 2006	Y	Y	Y	N	n/a	N	
Jebb 2011	Y	Y	Y	N	n/a	N	
Jeffery 1995	U	U	U	U	U	N	
Jolly 2011	Y	Y	Y	N	n/a	N	Differences in rates of starting intervention and attendance, but this is inherent in the programme and not unexpected (therefore does not need to be adjusted for). Differences in rates of follow up.
Kuller 2012	Y	Y	Y	N	n/a	N	
Lindstrom 2003	Y	Y	Y	N	n/a	N	
Mensink 2003	Y	N	Y	N	n/a	N	
Morgan 2011	y	Y	Y	N	n/a	N	

Munsch 2003	N	N	N	Y	N	N	Those recruited from GP randomised within two GP groups. Those recruited in clinic stayed in clinic. Those recruited via newspaper unclear. BMI higher in clinic intervention than GP control. Dropout at end of treatment slightly higher in clinic BASEL group but much higher in this group by follow up.
Nanchahal 2011	Y	Y	Y	N	n/a	Y	Psychological variables measured but not reported
Patrick 2011	Y	Y	Y	N	n/a	N	
Penn 2009	Y	U	Y	N	n/a	Y	Authors measured waist circumference and weight annually and did not report it as the differences were not significant
Rejeski 2011	U	U	Y	N	n/a	Y	Authors do not report weight at 12 months although the article suggests this would have been measured.
Rock 2010	Y	Y	Y	N	n/a	N	
Ross 2012	Y	U	Y	N	n/a	N	Allocation method not specified but conducted by data manager
Silva 2010	Y	N	Y	N	n/a	Y	Data on BMI and weight change missing at some follow-up points
Stevens 1993	U	Y	Y	N	n/a	N	
Stevens 2001	U	Y	Y	N	n/a	Y	BMI not included at 6,18,36 months
Vermunt 2011	N	N	Y	N	n/a	Y	Weight data missing at a number of time points
Villareal 2011	Y	U	Y	N	n/a	N	
Vissers 2010	U	U	Y	Y	N	N	Uneven dropouts between arms
Wadden 2011	Y	Y	Y	N	n/a	N	