Contents

Appendix 13

Children

1 Evidence tables

1.1 Comparison of guidelines included in the syntheses

COMPARISON OF SCOPE AND CONTENT	
Objectives and scope	
AAP (2003)	• To propose strategies to foster prevention and early identification of overweight and obesity in children
AHA (2005) **New**	• To examine the patho-physiology and epidemiology of overweight in children and adolescents • To present updated information on the adverse outcomes associated with childhood overweight and discuss approaches for the prevention and treatment of overweight in young individuals
RNAO (2005)	• To provide best practice guidelines focused on the primary prevention of obesity in children from birth to age 18 years • To provide direction for nurses who work with children and families across diverse practice settings and at population, family, and/or individual levels **Note**: Treatment of obesity is not within the scope of this guideline.
SIGN (2003)	• To provide recommendations based on current evidence for best practice in the management of obesity in children and young people, up to the age of 18 years • To review the definition of childhood obesity and information on prevalence of childhood obesity in the UK and recent trends in the prevalence of obesity • To identify the immediate consequences of obesity in childhood and possible consequences in adulthood • To identify subgroups of children at high risk for developing obesity • To review preventive interventions for childhood obesity • To discuss the treatment of childhood obesity and the goals of therapy, particularly management in the community and management beyond primary care, including advice on healthy eating • To make recommendations for research for systematic evaluation of childhood obesity **Note**: Appraising the role of screening for obesity in children was not

	within the remit of this guideline.
SINGAPORE MOH (2004)	• To assist health care professionals who have a role in managing overweight or obese patients • To provide current evidence-based clinical practice recommendations on various aspects of obesity management found across various medical disciplines • To provide a framework to assist doctors in the management of overweight and obesity without restricting the physician's individual judgment • To provide a review of the various medical, surgical, and ancillary intervention modalities in the management of obesity • To aid primary care physicians in basic management of obesity and subsequent referrals to specialists for more resistant cases
USPSTF (2005) **New**	• To summarise the US Preventive Services Task Force (USPSTF) recommendations on screening for overweight in children and adolescents and the supporting scientific evidence
Target population	
AAP (2003)	• USA • Children
AHA (2005) **New**	• USA • Infants, children and adolescents in the general population *(prevention)* • Overweight or obese children and adolescents with or without co morbidities *(prevention and treatment)*
RNAO (2005)	• Canada • Children from birth to age 18 years
SIGN (2003)	• Scotland • Children and young people up to the age of 18 years who are suspected of being obese
SINGAPORE MOH (2004)	• Singapore • Children and adolescents who are obese or overweight, or who are at risk of obesity **Note**: The guideline also targets adults who are obese or overweight or who are at risk for obesity. This target group is addressed in a

	companion synthesis.
USPSTF (2005) **New**	• USA • Asymptomatic children and adolescents (aged 6 to 19 years) seen in primary care
Intended users	
AAP (2003)	Healthcare Providers; Physicians
AHA (2005) **New**	Healthcare Providers; Physicians
RNAO (2005)	Advanced Practice Nurses; Nurses
SIGN (2003)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physician Assistants; Physicians; Psychologists/Non-physician Behavioural Health Clinicians
SINGAPORE MOH (2004)	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Nurses; Physician Assistants; Psychologists/Non-physician Behavioural Health Clinicians; Public Health Departments; Respiratory Care Practitioners
USPSTF (2005) **New**	Advanced Practice Nurses; Allied Health Personnel; Dietitians; Healthcare Providers; Health Plans; Managed Care Organisations; Nurses; Physician Assistants; Physicians
Interventions and practices considered	
AAP (2003)	**Assessment** 1. Body mass index (BMI) percentile (for age and sex) 2. Routine assessment of eating and PA patterns for early recognition 3. Assessment of risk factors (including genetic, biological, psychological, socio-economic and environmental factors) **Prevention** 1. Promoting healthy eating patterns and breastfeeding, encouraging PA, and limiting television and video time 2. Parent and caregiver involvement 3. Recognising and monitoring changes in obesity-associated risk factors for adult chronic disease

	Note: Physician advocacy interventions directed at parents, teachers, and policy makers/legislators, etc., are also provided.
AHA (2005) **New**	**Assessment** 1. Evaluation of growth, including height, weight, and BMI percentile for age and sex 2. Medical evaluation for co morbidities, including medical history, blood pressure, physical assessment for orthopaedic abnormalities, laboratory studies, as indicated, and echocardiography **Prevention** *Population-specific approaches* 1. Breastfeeding (infants) 2. Establishing behaviour targets (toddlers) • increased consumption of fruits and vegetables • increased consumption of fibre-containing grain products • switching from full-fat to 1% or fat-free dairy products after 2 years of age • preparing and eating family meals at home • increasing daily physical activity (PA) • limiting sedentary time 3. Theory-based interventions including classroom curricula, physical education curricula, changes in school meals, vending machines, cafeterias and after-school programmes (school-age children and adolescents) 4. Implementation of tailored strategies that are well matched to the social and cultural contexts of children in ethnic minority populations *Setting-specific approaches* 1. Targeting institutions that provide access to groups of children (e.g. schools, Head Start programmes, healthcare settings, homes, community and government programmes) 2. Community-wide approaches including coordinated interventions in multiple settings 3. Providing social and physical environments where healthful choices are available **Treatment** 1. Age-specific dietary modification 2. PA (30–60 min of regular exercise daily) 3. Pharmacological treatment 4. Surgical treatment (reserved for full-grown adolescents with the

	severest obesity-related morbidity)
RNAO (2005)	**Assessment** 1. Lifestyle history, including discussing/documenting dietary and PA patterns, and identifying individual and family risk factors for childhood obesity 2. Monitoring growth, including accurate height and weight measurement 3. Calculating and plotting BMI percentile, and monitoring for changes over time **Prevention** 1. Promotion of healthy eating and PA at population, community, family, and individual levels 2. Support of exclusive breastfeeding until 6 months of age 3. Referral to allied healthcare professionals as needed **Note**: Other interventions and practices addressed in the guideline but not considered here include recommendations for nursing academic and continuing education programmes, research studies and implementation planning.
SIGN (2003)	**Assessment and preventive counselling** 1. BMI percentile (for age and sex) 2. Recognition of risk factors for obesity, including parental obesity 3. School, family, and societal interventions for obesity prevention **Treatment/management** 1. Healthier eating 2. Increased habitual PA (e.g. brisk walking) to a minimum of 30 min/day 3. Reduction in physical inactivity (e.g. watching television and playing computer games) to <2 hours/day or 14 hours/week 4. Weight maintenance 5. Referral to hospital or community paediatric consultants 6. Modest weight loss of no more than 0.5 kg/month* *For obese children >7 years old who can demonstrate prolonged weight maintenance and who are cared for by secondary services
SINGAPORE MOH (2004)	**Assessment** 1. Full clinical evaluation including BMI percentile (for age and

	sex) 2. Consideration of predisposing risk factors and secondary causes of obesity **Management of obesity in children and adolescents** 1. Nutritionally balanced diet designed to meet growth requirement 2. Age-appropriate PA 3. Weight loss programmes that include BT (BT) 4. Family involvement in weight loss efforts 5. Bariatric surgery (only in high-risk adolescents) **Note**: Interventions for assessment and management of overweight and obesity in adults are also considered in this guideline. These interventions are addressed in another synthesis.
USPSTF (2005) **New**	Routine screening for overweight in children and adolescents using BMI percentile (not specifically recommended). The evidence for effectiveness of behavioural, pharmacological and surgical interventions is discussed.

1.2 Measures other than BMI

Detailed evidence tables not included, as narrative describes the studies in appropriate detail.

1.3 Measures and morbidity in ethnic populations[1]

Detailed evidence tables not included, as narrative describes the studies in appropriate detail.

1.4 Lifestyle interventions

1.4.1 Interventions emphasising a combination of diet and/or physical activity and behavioural modification component

Epstein 1995 (in Cochrane) RCT [946]	
Aim	To assess the effects of increasing PA vs. decreasing sedentary behaviours.
Country and setting	USA. Setting unclear. Probably outpatient clinic at University medical school.
Participants	Sixty-one families, with children ranging from 8 to 12 years. Weight entry criteria between 20 and 100% overweight. Neither parent greater than 100% overweight, one parent willing to attend treatment meetings, no family member on an alternative weight-control programme, no child or parent having current psychiatric

[1] Evidence tables only done for UK studies.

	problems, and no medical conditions preventing exercise. Mean weight on entry: 51.8% overweight for height.
Recruitment	Radio announcements, television commercials, posters, and referred by physicians and nurses.
Intervention	Groups: 1) focus on a reduction in sedentary behaviours (sedentary); 2) focus on an increase in PA (exercise); and 3) focus on a reduction in sedentary behaviours and an increase in PA (combined). Diet: the traffic light diet[2] was prescribed to the subjects. Activity: subjects in the exercise group were reinforced for increasing PA, and subjects in the combined group were reinforced for both decreasing their sedentary activity and increasing their PA. Sedentary behaviour was to involve a decrease from a goal of 35 hours or less per week of the targeted sedentary activities at level 1 to 15 hours or less per week at level 5, decreasing in 5 hour increments across the five levels. PA goals involved an increase from a goal of 30 points per week at level 1 to a goal at level 5 of 150 points per week, with level goals increasing in 30-point increments. Behavioural principles: subjects received a personalised system of instruction, self-monitoring, stimulus control and reinforcement.
Delivery of intervention	Not clear.
Control	Three treatment groups.
Length of follow-up	1 year.
Results (4 month treatment and 1 year follow)	Three comparisons: for the first comparison (decreased sedentary behaviours group vs. increased exercise and decreased sedentary behaviours [combined] group), the decreased sedentary behaviours group had a greater decrease in percentage overweight than did the combined group (–18.7 [sedentary] vs. –10.3% [combined]). Post hoc tests showed significant differences ($p < 0.05$) in percentage overweight for children in the sedentary group vs. children in the combined group at 1 year. For the second comparison (decreased sedentary behaviours group vs. the increased exercise group), the decreased sedentary behaviours group had a greater reduction in percentage overweight than did the exercise group (–18.7 [sedentary] vs. –8.7% [exercise]).

[2] The majority of the studies from Epstein et al (which are extensively used as evidence throughout interventions to treat childhood obesity) are based on the traffic light diet. This is a energy-based food-exchange system. Foods are divided into five groups (fruits and vegetables, grains, proteins, dairy and other foods) and the foods in each group are colour coded according to nutrient density: green for 'go', yellow for 'eat with care' and red for 'stop'. Green foods are foods containing <20 kcal (84 kJ) per serving, yellow foods are the staple of the diet and provide most of the basic nutrition, and red foods are those foods high in fat and simple carbohydrates. All sweets and sugared beverages are classified as red foods. Families are then instructed to 'count calories' and cannot have more than four red foods per week.

	The difference in percentage overweight between the groups was statistically significant. For the third comparison (increased exercise group vs. the combined group), after 1 year, percentage overweight had decreased in both groups (–10.3 [combined], –8.7 [increased exercise]).
Other outcomes	Child fitness improved significantly over time ($p = 0.011$), with no differential changes by group ($p > 0.05$). Fitness increased from baseline to both 4 and 12 months. Significant treatment effect was observed for child preference of high intensity activities ($p = 0.02$), with children in the sedentary group increasing preferences more than children in the exercise group ($p = 0.004$). Child energy intake estimated from habit books was significantly different across the groups after 4 months of treatment ($p < 0.001$), with significantly greater intake per day ($p < 0.001$) for the exercise vs. combined or sedentary groups.
Dropout rates	9.8%
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only data from those who completed treatment. Unclear.
Quality and comments	Dropouts 9.8%. Blinding unclear. Random allocation not described.

1

Epstein 1985a (in Cochrane) RCT [925]	
Aim	To assess the effectiveness of lifestyle exercise vs. programmed aerobic exercise and low-intensity callisthenics for the long-term treatment of childhood obesity.
Country and setting	USA. Unclear nature of setting.
Participants	Obese parents and children from 41 families were selected for participation in the study. Entry requirements included: 1) child between the ages of 8 and 12 years; 2) child and at least one participating parent >20% over ideal weight for height; 3) parent and child showing no problems that would interfere with regular exercise.
Recruitment	Unclear.
Intervention (8-week treatment followed by 10-month maintenance and 12- and 24-months follow-up)	Three groups: aerobic exercise group ($n = 13$); lifestyle exercise group ($n = 12$); and the callisthenics group ($n = 10$). The aerobic exercise consisted of a walk, run, bicycle or swim programme, based on family's preference, three times per week beginning at 1 mile (1.6 km) of walking or running, 2 miles (3.2 km) of bicycling or 0.25 mile (0.4 km) of swimming, and advancing in regular intervals up to 3 miles

	(4.8 km) of running or walking, 6 miles (9.7 km) of bicycling, or 0.75 miles (1.2 km) of swimming. All participants were trained to exercise at 60–70% of their age-adjusted maximal heart rate. The lifestyle exercise was designed to be isoenergetic to the aerobic exercise, allowing participants to choose from a range of exercises, although they were not instructed to exercise at any specific intensity. As for example, while the aerobic subjects would run for 1 mile (1.6 km) in the evening at aerobic intensity, the lifestyle subjects could walk 0.5 miles (0.8 km) back and forth from school. For the callisthenics programme, participants performed 6 to 12 callisthenics per week. The expenditure for the six most intense exercises done at the maximal number of repetitions was approximately one-third the expenditure for the first level of aerobic or lifestyle exercise. Participants were instructed with four behavioural components: self-monitoring, modelling, contingency contracting and parent management, and given the traffic light diet[3], a 1200 kcal (5.20 MJ) diet that provides a colour-coded food reference guide that includes energy content per serving.
Delivery of intervention	Unclear.
Control	Not reported.
Length of follow-up	Up to 24 months.
Results	For the first comparison (the aerobic exercise group vs. the lifestyle exercise group), statistically significant decreases in percentage overweight were observed for both groups during the year of the treatment, (at 6 and 12 months). Despite this, in the following year of observation, children in the lifestyle group maintained their weight change, while children in the aerobic exercise group gained significant amounts of weight: aerobic exercise group percentage overweight 47.8 (SD 15.2) at baseline, 31.5 (SD 15.4) at 12 months 41.0 (SD 17.5) at 24 months; lifestyle exercise group percentage overweight 48.3 (SD 17.2) at baseline, to 32.2 (SD 21.3) at 12 months, 30.3 (SD 24.3) at 24 months. After 24 months the lifestyle exercise group had significantly lower ($p < 0.05$) percentage overweight than the aerobic group. For the second comparison (aerobic exercise vs. the callisthenics group) significant decreases in percentage overweight from baseline were observed for both groups during the year of treatment (at 2, 6 and 12 months). During the following year of observation, children in both groups gained significant amounts of weight: aerobic exercise group percentage overweight 47.8 (SD 15.2) at baseline, 31.5 (SD 15.4) at 12 months, 41.0 (SD 17.5) at 24 months; callisthenics group percentage overweight 48.0 (SD 23.2) at

[3] See Glossary

	baseline, 30.5 (SD 26.0) at 12 months and 40.8 (SD 27.0) at 24 months. After 6 and 24 months the difference in percentage overweight between the aerobic group and the callisthenics group was not significant. In third comparison (lifestyle exercise vs. the callisthenics group), significant decreases in percentage overweight from baseline were observed for both groups during the year of treatment (at 2, 6 and 12 months): lifestyle exercise group percentage overweight 48.3 (SD 17.2) at baseline, 32.2 (SD 21.3) at 12 months, and 30.3 (SD 24.3) at 24 months; callisthenics group percentage overweight 48.0 (SD 23.2) at baseline, 30.5 (SD 26.0) at 12 months and 40.8 (SD 27.0) at 24 months. After 24 months the difference in percentage overweight between the lifestyle exercise group (large reduction in sedentary behaviours) and the callisthenics group was significant ($p < 0.05$). At 24 months, the lifestyle group had maintained relative weight changes while the callisthenics group had returned to baseline levels.
Other outcomes	No significant improvements in fitness were observed for children after 2 months. After 6 months children in the lifestyle group showed significant ($p < 0.05$) improvement in fitness from pre to 6 months, but they returned to baseline levels of fitness at 1 year. Children in the aerobic exercise group were the only subjects to show significant ($p < 0.05$) effects at 1 year. No changes in fitness were observed for children in the callisthenics group. Children showed significantly improved eating behaviour ($p < 0.001$) from pre to 6 months and 1 year, with no differences across groups. The relationship between parent and child relative weight changes increased across time, with $p < 0.10$ from 0–6 months, $p < 0.01$ from months 6 to 12, and $p < 0.01$from months 12 to 36.
Dropout rates	14.6%
Treatment of dropouts (return to baseline, or last measurement?)	Only data for those who finished treatment and follow-up.
Quality and comments	Dropout rate 14.6%. Blinding unclear. Random allocation not described. Absence of adherence data beyond the initial 8 weeks.

1

Epstein 2000 (in Cochrane) RCT [898]	
Aim	To compare the influence of targeting decreases in sedentary behaviour vs. increases in PA in the treatment of obesity in children.
Country and	USA. Childhood obesity research clinic.

setting	
Participants	Ninety obese 8–12-year-old children and their parents were recruited in two cohorts that began 1 year apart. Children had to be between 20 and 100% overweight, neither parents more than 100% overweight, one parent willing to attend treatment meetings, no parent or child with current psychiatric problems, and no dietary or exercise restrictions on the participating parent or child.
Recruitment	Through physician referrals, posters, and newspaper and television advertisements.
Intervention	Families were randomised to four groups that varied the targeted behaviours (sedentary behaviours vs. PA. Low and high doses for the decrease sedentary or increase PA groups were 10 or 20 hours/week of targeted sedentary behaviours, or the equivalent energy expenditure of 16.1 or 32.2 km/week, respectively. The 6-month treatment included 16 weekly meetings, followed by two biweekly and two monthly meetings. Families were followed up. Families received parent and child workbooks, which included introduction to weight control and self-monitoring, the traffic light diet, the specific activity programme, behaviour change techniques, and maintenance of behaviour change. At treatment meetings, families met with an individual therapist for 15 to 30 min, and they attended separate 30 min parent and child group meetings. Parents and children were taught positive reinforcement techniques including praise for targeted behaviours and reciprocal contracts in which parents and children set goals and reinforcers to be provided by the parent based on meeting the goal. Participants assigned to the increase PA group were reinforced for increasing PAs in addition to those enrolled at the beginning of the programme. Participants assigned to the decrease sedentary activity group were reinforced for reducing sedentary behaviours. Not all sedentary activities were targeted, allowing participants to substitute non-targeted sedentary activities for targeted ones.
Delivery of intervention	Individual therapists.
Control	Not reported.
Length of follow-up	2 years.
Results (6-month treatment and 2-year follow-up)	Three comparisons were made. The first was decreasing sedentary behaviours vs. increasing PA. Results showed that targeting decreased sedentary behaviour or increased PA was associated with significant decreases in percentage overweight, body fat and improved aerobic fitness. In the low dose increased PA group (n = 18), the percentage overweight decrease from baseline was –25.6 (SD 8.1) at 6 months and –12.4 (SD 13.3) at 24 months. In the high dose increased PA group (n = 19) the values were –26.4

	(SD 10.5) at 6 months and –13.2 (SD 16.4) at 24 months. In the decreased sedentary behaviour group the differences in percentage overweight from baseline were –22.4 (SD 12.6) (low dose, $n = 19$), –27.4 (SD 10.7) (high dose, $n = 20$) at 6 months and –11.6 (SD 21.9) (low dose), –14.3 (SD 16.9) (high dose) at 24 months. Both the decreased sedentary behaviour groups and the increased PA groups showed similar decreases in percentage overweight but the differences were not statistically significant. The second comparison was high vs. low doses of increased PA. Both groups showed significant decreases in percentage overweight from baseline to 6 and 24 months but the differences between the high and low dose increased PA groups were not statistically significant. The last comparison was high vs. low doses of reducing sedentary behaviours. Results were similar to increasing PA.
Other outcomes	Physical work capacity improved significantly, with increases of 33% ($p < 0.001$) from baseline to 6 months, and an increase of 55% from 6 months to 24 months ($p < 0.001$). A significant increase in percentage of time being active was observed from baseline to 2 years ($p < 0.05$). Targeted sedentary behaviours showed a significant decrease from baseline at 6 ($p < 0.001$) and 24 ($p < 0.05$) months
Dropout rates	15.5%
Treatment of dropouts (return to baseline, or last measurement?)	Analyses were conducted based on the subjects who attended the follow-up measurements, as well as intention to treat (ITT) analyses.
Quality and comments	Dropouts 15.5%. Blinding unclear. Random allocation stratified by gender and degree of child and parent obesity. Financial deposit of US$75 returned dependent on completion of intervention and families paid US$50 for attending the 24-month follow-up.

1

Epstein 1985b (in Cochrane) RCT [927]	
Aim	To evaluate the effects of adding exercise to diet for weight control in obese children.
Country and setting	USA.
Participants	Girls between the ages of 8 and 12 years. Inclusion criteria were: 1) child with at least 20% over her ideal weight for height and age; 2) absence of medical problems that would contraindicate weight loss, exercise or fitness testing; and 3) at least one parent willing to participate in the programme.
Recruitment	By physician and school nurse referral and in response to media coverage.

Intervention (8-week treatment followed by 10-month maintenance and 12-months follow-up)	Twenty obese girls distributed in two groups: diet and exercise (group 1) and diet (group 2). All families were provided with an intensive 8-week treatment programme followed by ten monthly maintenance sessions. Parents and children met separately for treatment sessions. Children in group 1 met for their exercise programme an additional three mornings per week during the initial 6 weeks of treatment. The two groups were given the same information on diet, nutrition and behaviour management techniques. For the diet, the traffic light diet was used, with a maximum of 1200 kcal (5.02 MJ) and a minimum of 900 kcal (3.77 MJ). Regarding PA, children in group 1 received an aerobic exercise programme designed to increase energy expenditure, During the first 6 weeks children met three mornings per week for sessions that included 10 min of stationary aerobic exercise, warm-up games and a 3 mile (4.8 km) walk or run. During the maintenance phase, parents were instructed to walk 3 miles (4.8 km) with their children three times per week. Both groups received behavioural methods such as: self-monitoring, praise and modelling, therapist contact, contracting and measurement.
Delivery of intervention	Therapists.
Control	Not reported.
Length of follow-up	Up to 12 months.
Results	Statistically significant decreases from baseline weight, and in percentage overweight, were observed for both groups during the year of treatment. Percentage overweight in the diet plus exercise group decreased from 48.0 (SD 23.2) at baseline to 20.5 (SD 22.6) at 6 months and after 12 months was 22.6 (SD 29.3). In the diet only group, percentage overweight was 48.1(SD 17.6) at baseline, 29.3 (SD 22.3) at 6 months and 29.4 (SD 22.5) at 12 months. The differences in percentage overweight between the groups were statistically significant ($p < 0.05$) at 6 months but not at 12 months.
Other outcomes	Fitness showed improvements for children in group 1 from 0 to 2 months ($p < 0.05$), improvement maintained at 6 months ($p < 0.05$) and further improvement from 6 to 12 months. Children in group 2 showed no significant changes from baseline levels. The groups differed significantly ($p < 0.01$) in fitness at 1 year. The Leisure Time Activity Survey showed significant differences only for the medium activity level from baseline to 6 months ($p < 0.01$), which included the exercise prescribed for the walking programme. The levels for children in the exercise group went from 45 (SD 29.9) to 145.5 (59.6), whilst those for children in the no-exercise group were 47.4 (36.0) at

	baseline and 58.0 (32.9) at 6 months.
Dropout rates	17%
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Dropout rate 17%. Blinding unclear. Random allocation stratified by age, percentage overweight and physical work capacity. Each family deposited US$80 before treatment; one US$20 cheque was returned for each of the following: 1) attending a minimum of three-quarters of the weekly treatment meetings; 2) the child's attendance at two all-day assessment sessions; 3) parent and child's attendance at the 6 months assessment; and 4) parent and child's attendance at the 1 year assessment.

1

Amador 1990 RCT [937]	
Aim	To examine the benefits of a non-restrictive diet for preservation of growth and maturation rates during the treatment of obese children at early stages of their puberty.
Country and setting	Cuba. Outpatient service at the Paediatric Hospital of La Havana.
Participants	Ninety-four obese children aged 10.6 to 12.9 years with no evidence of endocrine or metabolic disease which could lead to overweight; no slimming treatment at least 6 months before the study; not receiving drugs which could affect energy metabolism or lipolysis–lipogenesis mechanisms; triceps and subscapular skinfold thicknesses above the 90th percentile; relative fat weight >25% in males and >30% in females; and stage of sexual development genitals 2 in males or breast 2 in females.
Recruitment	Not reported.
Intervention	Groups were created: the experimental group (EG; non-restricted) and the control (CG; restriction to 30% of energy requirements). Energy intake in the diet was the only difference between the two groups: 0.25 MJ/kg of expected body weight for height in EG, 0.17 MJ/kg in CG. Energy restriction was maintained up to 6 months, when a reduction in body fat reached about 20%. From 6 to 12 months both groups received a non-restrictive diet. A programme of PA comprising jogging, walking and running with progressive loads was created. A programme of nutritional education, including individual and group activities, was created: children and parents were invited in order to change attitude and habits of the child and their family regarding food consumption and PA.

Delivery of intervention	Paediatricians, psychologists, psychiatrists, nutritionists, dietitians, anthropometrists and phys**iotherapist**
Control	Restriction to 30% of energy requirements
Length of follow-up	Up to 12 months
Results	Body weight decreased 7.55 ± 2.76 kg ($p < 0.01$) at 6 months and 5.54 ± 2.54 kg ($p < 0.00$) at 12 months for the control group. In the experimental group, body weight decreased 4.51± 2.72 kg at 6 months ($p < 0.01$) and 2.19 ± 3.14 kg ($p < 0.01$) at 12 months.
Other outcomes	No other outcomes were reported.
Dropout rates	17%
Treatment of dropouts (return to baseline, or last measurement?)	Only data from subjects who completed follow-up.
Quality and comments	No details of randomisation. No blinding.

1

Nova 2001 CCT [902]	
Aim	To compare two types of intervention intended to reduce weight in obese children that can be carried out in the family paediatrician's (FP) office.
Country and setting	Italy. FP's office.
Participants	Children with excess weight ≥20% of ideal body weight (IBW), aged 3–12 years, who attended the FP during the period from 15 November 1997 to 31 March 1998.
Recruitment	From the FP's office.
Intervention	A total of 18 from the 139 FPs from different regions in Italy who were contacted, agreed to participate and were randomised into two groups. FPs would then obtain information about the amount of PA; time spent watching television or using the computer, outdoor games, consumption of snacks during the day, and scholastic results. In group A ($n = 114$), the given leaflets contained only general information regarding obesity and associated risks, general advice on healthy eating and an invitation to practice some PA. In group B ($n = 72$), a specific diet (approximately 1400 kcal [5.86 MJ]), detailed guidelines regarding PA and active parental commitment, and an alimentary diary with instructions for use were supplied to the children and their families. The FP then reviewed the diary with the child and parents in order to reinforce the family's compliance in regard to changes in eating behaviour.

Delivery of intervention	FP.
Control	Two treatment groups.
Length of follow-up	12 months.
Results	Compared with baseline, percentage overweight decreased in both group A (–2.9 ± 8.5, –2.9 ± 10.8 at 6 and 12 months respectively) and group B (–8.8 ± 6.6, –8.5 ± 9.7 at 6 and 12 months respectively). Results were statistically significant for both groups. The reduction in percentage overweight was significantly greater in children whose parents had a good level of commitment compared with parents with a sufficient or poor level of commitment ($p = 0.005$ for group A and $p = 0.02$ for group B).
Other outcomes	Not reported.
Dropout rates	Average of 30% at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed.
Quality and comments	No details of randomisation. No blinding occurred. Methodological flaws.

1

Figueroa-Colon 1993 CCT [928]	
Aim	To examine whether a protein-sparing modified fast (PSMF) diet and a hypoenergetic balanced diet are safe and effective for children in an outpatient weight reduction programme.
Country and setting	USA. Outpatient weight reduction programme.
Participants	Nineteen children with weight for height >40% above the mean weight for age, sex, and height using standards from the national centre for health statistics. All children weighed between 45 and 131% more than the IBW for their height. All in good health, not taking any medication and from a middle socio-economic class.
Recruitment	By referral by either a physician or a parent.
Intervention	First group: ten children, assigned to a high-protein, low-carbohydrate (CHO), low-energy diet or PSMF. Second group: nine children, assigned to a hypoenergetic balanced diet. After the first 10 weeks, patients from both groups were placed on a 4200 kJ balanced diet; energy intake was increased in 3 months to 5040 kJ and maintained for 1 year. Group 1 were placed on a PSMF diet, consisting of 1.5–2 g of high-biological quality protein/kg IBW per day up to 100 g. Total dietary

	fat intake was low and ranged from 27 to 36 g/day. Moreover, children were given multivitamin and mineral daily supplements. group 2 were prescribed a hypoenergetic balanced diet (3360 to 4200 kJ). Children in this group did not receive vitamin and mineral supplements and were instructed to maintain a reasonable intake of milk and vegetables. Children reported any side effects and their degree on a checklist provided by the examiner. Children received information about lifestyle change related to activity. The amount of daily activity was regulated using Cooper's aerobic point system. Aerobic activity was conducted for 20 min/day. One parent or guardian was asked to participate in all sessions. The behavioural component included self-monitoring of food intake and PA, as well as discussions and applications of behavioural change techniques. The change techniques included stimulus control, cue elimination, behaviour chains and preplanning, cognitive restructuring, and exploring alternatives to overeating.
Delivery of intervention	Nutritionist is only mentioned deliverer.
Control	Two treatment groups.
Length of follow-up	Up to 14.5 months.
Results	Children on the PSMF diet had a significantly higher weight loss (–11.2 ± 4.4 kg) at 10 weeks then the hypoenergetic balanced group (–5.1± 4.1 kg; $p < 0.01$). At 6 months the PSMF group had lost –11.2 vs. –5.8 kg for the hypoenergetic balanced group. Differences between baseline and 6-month values were not statistically different for dietary groups. Nevertheless, the PSMF showed a significant change in the percentage overweight compared with the hypoenergetic group (–32.2 ± 13.4 vs. –17.5 ± 15.2; $p < 0.05$) and change in BMI (–5.6 ± 2.5 vs. –3.0 ± 2.6 kg/m^2; $p < 0.05$). The mean weight at 14.5 months for both dietary groups had returned to baseline levels. The decrease in the percentage of overweight (–23.3 ± 19.2) in the PSMF group at 14.5 months compared with baseline was statistically different
Other outcomes	Changes in systolic and diastolic blood pressures did not reach statistical significance. No additional mineral supplements were required for children on PSMF. When groups were combined, the initial serum cholesterol value (4.47 ± 0.79 mmol/l) decreased significantly at 10 weeks (3.74 ± 0.84 mmol/l), while the decrease in triacyglycerol levels (1.25 ± 0.57 vs. 0.98 ± 0.47 mmol/l) did not reach statistical significance.

Reported harms	Almost half the children in both dietary groups experienced decreased appetite. Hunger, fatigue, weakness, and muscle cramps were more common in the hypoenergetic balanced group. Bad breath was more common in the PSMF group (11%) than in the HCB group (3%) during the first 10 weeks. 5% of the PSMF group also reported diarrhoea/vomiting, whilst 19% of the HCB reported headaches and abdominal pain.
Dropout rates	No dropouts.
Treatment of dropouts (return to baseline, or last measurement?)	Data from all subjects.
Quality and comments	Authors report that randomisation was performed, although it is not clear. Group leaders were not blinded.

1

Epstein 1984[4] and 1989 RCT [929]	
Aim	To assess the effects of weight change on serum lipid changes.
Country and setting	USA. Unclear but appears to be specialist programme.
Participants	Children between 8 and 12 years old; at least one child and one natural parent who were >20% over ideal weight for age, sex, and height; child's triceps skinfold thicknesses greater than the 95th percentile for age and sex; and no history of psychiatric contact for the children.
Recruitment	Subjects were recruited by newspaper advertisements, fliers distributed by schools and physician referrals.
Intervention	Subjects were assigned to one of three treatment groups: 1) diet (n = 18); 2) diet plus lifestyle and exercise (n = 19); and 3) no treatment-control group (n = 19). The two treatment groups entered a 15-session programme. The first eight sessions were conducted weekly, with the other seven sessions spread out over the next 20 weeks with three biweekly meetings and the other four meetings at monthly intervals, where information on diet, exercise, stimulus control, reinforcement, modelling, and contingency contracting was presented to parents and their children. Each of the 15 sessions involved reviewing a short module given to participants the previous week and discussing the application of the technique or information described. Families were seen in groups, with parents and children separated. At each treatment meeting, trained therapists individually reviewed parent and child habit

[4] Although this study is earlier than the 1985 cut-off, we decided to include it as it has a follow-up of 5 years (Epstein 1989).

	books, assessing progress in eating and exercise habit changes, implementation of the point economy and use of social reinforcers. Parents were encouraged to provide earned incentives, to spend some time each day reviewing child habit books, and to use praise for motivation. Parents were provided social reinforcement from the therapists for their own habit changes and for correct implementation of the child programme. Subjects were prescribed the traffic light diet, and those in the diet-plus-exercise group were given a lifestyle change exercise programme that required increasing voluntary energy expenditure above normal through a series of gradual steps, from 1400 kcal [5.86 MJ] at week 1 to 2800 kcal [11.72 MJ] by week 12.
Delivery of intervention	Trained therapists.
Control	No treatment control.
Length of follow-up	Up to 5 years.
Results	From baseline to 6 months, significant improvements in weight ($p < 0.001$) and percentage overweight ($p < 0.001$) were reported in the treated vs. the control group. Treated groups had decreased in weight 3.6 kg and in percentage overweight of 17.4, while the control group gained 5.2 kg. Over the 5 years, significant increases in weight ($p < 0.001$) were reported, but no differences in the percentage overweight compared to baseline values.
Other outcomes	Fitness improved significantly ($p = 0.002$) about 33 percentile points for the treated children and remained unchanged for the control group. Significant group effects in changes in serum cholesterol ($p = 0.03$), were reported with decreases of 0.27 mmol/l for the treated children and an increase of 0.09 mmol/l for controls. There was a significant difference in HDL-cholesterol levels over the 6 months of the study ($p = 0.007$), with greater increases in the treated children (+0.20 mmol/l) than in the control children (+0.06 mmol/l). Serum triacyglycerol levels decreased significantly over 6 months ($p = 0.01$) with greater decreases in the treated groups (–0.55 mmol/l) than in the control children (–0.12 mmol/l). At 5 years the HDL-cholesterol level was significantly improved compared with baseline levels ($p = 0.003$).
Dropout rates	20% at 5 years.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be with data from only those who completed the study.

Quality and comments	The two treatment groups were combined for purposes of evaluating the effects of weight change on serum lipid change, as no significant differences were found in the two treatment groups.

1

Eliakim 2002 CCT [525]	
Aim	To assess the effects of a weight management programme on body weight, BMI and fitness in obese children and adolescents.
Country and setting	Israel. Obesity treatment programme at the Child Health and Sports Centre, Meir general Hospital, Tel Aviv University.
Participants	Children aged 6 to 16 years.
Recruitment	Not specified.
Intervention	Participants visited the dietitian once per month. In children aged 6–8 years, only parents were invited for the first two meetings and then children joined thereafter. Each family was instructed to come to the first meeting with a 24-h dietary record. The first appointment was dedicated to learning about the reasons for childhood obesity, receiving information about food choices, dietary and cooking habits, understanding the motivation for weight loss, as well as trying to enrol the entire family. The subsequent appointments were devoted to nutritional education. Subjects were prescribed with a balanced hypoenergetic diet, consisting of 1200–200 kcal [5.02–0.84 MJ] depending on the age and weight of the child, or of an energy deficit of about 30% of the reported intake. All subjects participated in a twice-weekly training programme (1 hour). The intervention was designed to copy the type and intensity of exercise that elementary and high school children normally perform. The physicians who worked in the programme participated regularly in the training sessions for encouragement. To promote personal responsibility, subjects were instructed to add and extra 30–45 min of walking. Subjects were also encouraged throughout the programme by physicians, nutritionist and coaches to reduce inactivity (as for example television viewing, video games, use of stairs instead of lifts, play outside instead of inside).
Delivery of intervention	Physicians and dietitians of the child health and sports centre. Also professional youth coaches.
Control	Group of 25 obese children and adolescent who were followed in the obesity clinic and were unable to participate in the dietary and exercise programme due to other obligations and transportation. These were referred every 3 months to an outpatient nutritional consultation and were instructed to perform PA three times per week on their own.
Length of follow-up	Up to 6 months.

Results	The decrease in body weight (from 55.8 ± 1.2 kg to 54.9 kg) and BMI (from 26.1 ± 0.3 to 25.4 ± 0.3kg/m^2) was statistically significant. Changes in body weight and BMI following the 3-month programme were not significantly affected by gender, pubertal status, degree of obesity or by parental overweight. In the control group there was a significant increase in body weight and BMI. None of the control groups lost weight. At 6 months the decrease in body weight and BMI was significantly greater compared with those who discontinued the programme after 3 months (body weight –0.58 ± 0.18 vs. –1.25 ± 0.36 kg in 3 months and 6 months subjects respectively ($p < 0.05$); BMI –0.53 ± 0.09 vs. –0.95 ± 0.16 kg/m^2 in 3 and 6 months respectively ($p < 0.01$). During the second 3 months of the programme, participants without parental overweight had significantly favourable BMI changes compared to subjects who had both obese parents.
Other outcomes	Endurance time increased significantly in both groups, but the increase in the intervention participants was significantly greater (from 629 ± 24 to 793 ± 24 s and from 560 ± 55 to 586 ± 42 s in the intervention and control subjects, respectively; $p < 0.0005$).
Dropout rates	13%
Treatment of dropouts (return to baseline, or last measurement?)	Only those who completed both the 3-month and 6-month programme.
Quality and comments	

1

Sothern 2000 CCT [930]	
Aim	To assess the safety, feasibility and efficacy of a resistance training programme preadolescent obese children.
Country and setting	USA. Weight management programme at the Children's Hospital of New Orleans.
Participants	Nineteen preadolescent obese children, aged 7 to 12 years of age, and 48 control subjects (with a baseline age of <12 years). Subjects were not enrolled if weight was <120% of IBW and if there was evidence of cardiovascular disease, diabetes or other chronic systemic diseases. The subjects in the control group received the intervention approximately 1.5 years before the subjects in the treatment group.
Recruitment	Not reported.
Intervention	Treatment and control subjects participated in a 10-week intensive period, and at the very beginning, treatment subjects were given handbooks that explained all aspects of the acute weight loss the

	handbooks were colour-coded according to the initial severity of obesity. The colour-coding was used as positive reinforcement as subjects dropped from one obesity classification level into less severe category. During the acute 10-week phase, both groups attended a weekly 2-hour weight reduction clinic, they were instructed concerning the PSMF diet, nutrition and a moderate-intensity progressive exercise programme; walking programme (control) and behaviour modification. During the 10-week weight loss phase, dietary adherence was monitored through self-reported urine ketone records. Exercise: The treatment subjects were given a home-based exercise programme that included and instructional video. Subjects and family members participated in 30 to 45 min of moderate intensity (45–55% VO_{2max}) exercise during weekly intervention meetings. MPEP included aerobic, muscular flexibility, and muscular strength exercises. The resistance-training programme, was a balanced routine of 6 to 12 different exercises designed for obese youth. Severely obese children initially performed six different strength exercises per session. Two to three additional exercises were added to each phase of the programme as the subjects progressed from one phase to another.
Delivery of intervention	Exercise professional.
Control	Control subjects were instructed to walk three times per week for 60 min at an intensity of approximately 65 to 70% VO_{2max} or 75 to 80% of maximum heart rate.
Length of follow-up	1 year.
Results	For the treatment group, weight changed from 65.3 ± 21.0 to 56.7 ± 18.2 kg at 10 weeks ($p < 0.0003$) and the controls changed from 61.95 ± 20.3 to 54.3 ± 19.9 kg at 10 weeks ($p < 0.0001$). BMI in the treatment group changed from 28.6 ± 6.3 kg/m^2 to 24.4 ± 6.2 kg/m^2 at 10 weeks ($p < 0.0001$) and for the control group, results were 30.8 ± 5.8 kg/m^2 at baseline and 26.6 ± 5.8 kg/m^2 at 10 weeks ($p < 0.0001$). The decrease in total body weight over the 1-year period in both groups was significant ($p < 0.0003$). Post hoc contrasts in the treatment subjects showed that the baseline weight was significantly higher than the weight at 10 weeks and at 1-year follow-up ($p < 0.001$). In both treatment and control subjects, the decrease in BMI over the 1-year period was significant ($p < 0.0001$). Post hoc contrasts showed that the baseline BMI was significantly higher than the BMI at 10 weeks and at 1-year follow-up ($p < 0.0001$). Nevertheless, the difference in BMI between that at 10 weeks and at the 1-year follow-up points in both groups was not significant.

	Post hoc contrasts showed that the baseline %IBW was significantly higher than the %IBW at 10 weeks and at 1-year follow-up ($p < 0.001$) (treatment) and ($p < 0.0001$) (control).
Other outcomes	No other outcomes were reported.
Dropout rates	21.1% for the treatment group and 64.6% for the controls.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only data from those who finished the programme.
Quality and comments	No randomisation, blinding or concealment was made. Weight and BMI values at 1 year were not given. Only statistical significance.

1

Flodmark 1993 (in Cochrane) RCT [931]	
Aim	To examine the differences between conventional behavioural treatment, conventional treatment combined with family therapy and no treatment.
Country and setting	Sweden. Screened in schools and attended sessions with paediatrician.
Participants	Ninety-four obese children. Mean age range 10–11 years. 48% male. BMI >23.0 kg/m^2. Treatment groups mean BMI on entry 22.0 kg/m^2. Control group mean BMI on entry 25.1 kg/m^2.
Recruitment	Unclear.
Intervention	Two treatment intervention groups: 1) conventional treatment ($n = 19$) which consisted of dietary counselling by a dietitian and regular visits to an experienced paediatrician The prescribed diet contained 1500 to 1700 kcal [6.28–7.12 MJ] and the families were also advised to reduce their fat intake by 30%; 2) family therapy ($n = 24$), which received the same dietary counselling and medical check-ups by another paediatrician, and also the paediatrician and psychologist offered six family therapy sessions over 1 year. During therapy, the therapists tried to reinforce the resources of the family and to create an optimal emotional climate for helping the obese child. The therapist supported the family's own belief systems in different ways with a view to encourage mutual respect and a confident environment. There was also a control group ($n = 50$).
Delivery of intervention/control	Dietitian and paediatrician.
Dropout rates	21% for the conventional treatment group at 1 year. 37.3% for the family therapy group at 1 year. No details for control group.

Control	No intervention.
Length of follow-up	1 year.
Results (14–18 months intervention and 1 year follow-up)	For the family therapy and conventional treatment group vs. the conventional treatment group, BMI increased from 24.7 (SD 0.36) to 25.8 (SD 0.73) kg/m^2 in the first group, and increased from 25.5 (SD 0.53) to 27.1 (SD 0.88) kg/m^2 in the second group. For the conventional treatment group vs. untreated control group, BMI increased from 25.5 (SD 0.5) to 27.1 (SD 0.9) kg/m^2 for the first group and from 25.1 (SD 0.4) to 27.9 kg/m^2 for the control. For the family and conventional treatment group vs. the untreated control group, BMI changed from 24.7 (SD 0.4) to 25.8 (SD 0.7) kg/m^2 for the first group and from 25.1 (SD 0.4) to 27.9 (SD 0.6) kg/m^2 for the control.
Other outcomes	Physical fitness improved significantly in the family therapy group at 1-year follow-up. No untreated control group was available for comparison of physical fitness data.
Treatment of dropouts (return to baseline, or last measurement?)	All available data, except for the pilot case was included in the analysis. ITTperformed.
Quality and comments	Dropouts 7%. Blinding unclear. No description of the randomisation.

1

Mellin 1987 (in Cochrane) RCT [932]	
Aim	To evaluate the effectiveness of the SHAPEDOWN programme, an adolescent obesity intervention that includes a range of cognitive, behavioural and affective techniques over 15 months.
Country and setting	USA. University research centre.
Participants	Sixty-six obese adolescents, aged 12 to 18 (mean 15.6) years. No details of weight entry criteria. Weight on entry: 78 kg and 33% overweight for age, sex and height.
Recruitment	Group leaders recruited participants through announcements in local papers and notices to physicians and school personnel.
Intervention	The test participants paid intervention fees for 14 × 90 min sessions using the materials of the SHAPEDOWN programme plus two parent sessions. The programme included a range of cognitive, behavioural, affective and interactional techniques adapted to the needs of adolescents. It encourages adolescents to make continuous, sustainable, small modifications in diet, exercise, relationships, lifestyle, communications and attitudes. Very-low-energy or restrictive diets were avoided in the programme. The control group participants did not receive any treatment and did not pay any fees.
Delivery of	Four volunteered nutritionists. Three of them were registered

intervention/control	dietitians; three had Masters degrees; and all were women. None had conducted adolescent obesity group interventions previously or had clinical experience with obese adolescents.
Dropout rates	16% (although details are unclear).
Control	No treatment.
Length of follow-up	12 months.
Results (3-months intervention and 12-months follow-up)	In the SHAPEDOWN group, mean weight decreased from 79.2 kg at baseline to 77.8 kg at 6 months, In the control group, mean weight was decreased from 77.0 kg at baseline to 75.9 kg at 6 months.
Other outcomes	Participants of the SHAPEDOWN showed improvements in weight-related behaviour, depression and knowledge of weight management concepts at post-treatment and at 12-months follow-up compared with the control group. At 3 and 15 months, the test group showed significant improvement in weight-related behaviour ($p < 0.005$, $p < 0.05$), self-esteem ($p < 0.005$, $p < 0.001$) and weight management knowledge ($p < 0.001$, $p < 0.001$), and less depression ($p < 0.005$, $p < 0.005$), whilst the control group only improved in self-esteem.
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed.
Quality and comments	No blinding was performed and no detailed description of the methodology was given.

1

Israel 1990 CCT [933]	
Aim	To compare the parental involvement in two different roles in a behavioural weight loss programme for children.
Country and setting	USA. Unclear setting.
Participants	Forty children ranging from 9 years, 5 months to 13 years, 4 months with at least one parent. Children had to: be at least 20% above ideal weight for height, age, and gender; obtain a medical release; have no involvement in other weight or psychological treatment(s); have at least one parent who agreed to attend all treatment and measurement sessions. Helper group $n = 28$, weight loss group $n = 12$.
Recruitment	Through referrals from local medical personnel, school health personnel, and notices through local school systems.
Intervention	Separate child and parent groups involved member from four to eight families for eight weekly 90-min sessions, which was the intensive phase of treatment. Extended treatment consisted of six additional sessions over the next 18 weeks, with increasing

	time intervals between sessions.. The treatment was a behavioural programme based on four-prong CAIR (cues, activity, intake and reward) approach. The parents were required to select one of two roles at week 4 of treatment. Parents could choose to engage in their own weight loss effort (WL), which was a weight reduction programme that paralleled that of their child. These parents monitored behaviours and engaged in behaviour change efforts in the four CAIR areas. Weekly habit records included items such as staying below prescribed energy limit, meeting a PA goal and eating in only one place. Optionally, parents could engage to target those behaviours that would directly help their child's weight loss effort (Helper [H] condition) and not engage in their own weight-loss effort. Weekly habit records in this condition included items such as helping their child fill out eating records, keeping high-energy foods out of sight, and making low-energy snacks available. To summarise, in the WL condition, parental involvement was programmed by targeting the parents own weight loss behaviours, whilst in the other condition (H) behaviours directed at assisting the child's weight loss efforts were targeted. Parents in the H were not involved in their own weight loss efforts, and parents in the WL condition did not monitor their helping behaviour explicitly.
Delivery of intervention/control	Not clear.
Dropout rates	Helper group 14.3% at follow-up. Weight loss group 8.3% at follow-up.
Control	Comparison of two treatment groups.
Length of follow-up	1 year.
Results (26 weeks treatment and 1 year follow-up)	During the treatment period, percentage overweight in the H group changed from 42. 2 ± 16.4 at week 1 to 32.5 ± 19.0 at week 26, whilst the WL group went from 51.9 ± 17.2 at week 1 to 40.8 ± 17.8 at week 26. During follow-up the H group changed from 42.8 ± 17.4 at week 1 to 38.4 ± 24.7 at year 1, while the WL group changed from 51.8 ± 18.0 to 47.7 ± 24.8.
Other outcomes	No other outcomes were reported.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from subjects who completed both treatment and follow-up.
Quality and comments	No details of randomisation. No blinding or concealment methods were reported.

1

Epstein 1986 and 1987 (in Mclean review) RCT [934] [935]	
Aim	To assess the effect of parent weight and parent control vs.

	child self-control on weight loss of obese preadolescent children.
Country and setting	USA. Unclear setting
Participants	Forty-nine families with 8- to 12-year-old children between 20 and 80% over their IBW; having triceps skinfold thickness values greater than the 85th percentile; and with no psychiatric contact or learning disability; 24 children had at least one obese parent, and 17 had parents who were not currently obese.
Recruitment	Unclear.
Intervention	Two treatment groups: parent control and child control. These two treatments involved eight weekly treatment meetings with ten monthly meetings where parents and children were seen separately over a period of 1 year. Both children and parents were prescribed a 1200 kcal (5.02 MJ) diet and a lifestyle exercise programme. Non-obese parents were prescribed an energy level to maintain their weight, and were given the same exercise programme. In both groups, determination of when goals were met and awarding of points were made initially by therapists, with parents being trained to take over contingency control.
Delivery of intervention/control	Therapists.
Dropout rates	20% at 5 years.
Control	Not reported.
Length of follow-up	Up to 36 months.
Results (26 weeks intervention and 6 months, 1, 3 and 5 years follow-up)	Significant ($p < 0.01$) decreases were reported from baseline to 6 months for children of both non-obese (–17.2%) and obese (–14.3%). At year 1, children of non-obese parents were significantly lighter ($p < 0.01$) than baseline (–16.3%) and lighter ($p < 0.01$) than children of obese parents (–7.7%). At year 3, neither group was significantly different from baseline for children of non-obese and obese parents. The *p* value was not reported (Epstein, 1986) The proportion of children who were non-obese at 5 years was higher for children with non-obese parents than for children with obese parents, although these differences were not significant ($p > 0.05$). Obese parents had a greater percentage overweight then the non-obese parents at baseline, although changes for obese and non-obese parents from baseline to 6 months (–10.4, –7.5) and 12 months (–8.3, –5.0) were similar. At 36 months, parents in both groups were equally above baseline (+1.42, 0.74). At 60 months, parents in both groups were equally above baseline relative weight (+5.0, +5.7). No relationship between initial child percentage overweight and relative weight change were

	observed from baseline to 6, 12, 26, or 60 months. Significant correlations between parent and child were reported at 6 months and 3 years ($p < 0.01$), but not at 1 or 5 years ($p > 0.05$) (Epstein 1987).
Other outcomes	Children with non-obese parents were more compliant than those with obese parents for energy limit ($p = 0.01$), exercise goal ($p = 0.02$) and recording completely ($p = 0.03$). Obese children with non-obese parents had better eating behaviour across all measurements ($p < 0.01$). Planned comparisons showed that the rate of improvement in eating behaviour from 0 to 6 months was greater ($p < 0.05$) for children of non-obese than of obese parents.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed follow-up.
Quality and comments	Unclear blinding and concealment. Randomisation method not described.

1

2 ### 1.4.2 Interventions emphasising diet and physical activity

Schwingshandl 1999 (in Cochrane) RCT [912]	
Aim	To evaluate the effect of a standardised training programme focusing on maintenance of fat-free mass during weight reduction by energy reduction in obese children.
Country and setting	Austria. Not clear nature of setting but appears to be obesity research clinic.
Participants	Children were randomised to two groups: Group A (physical training programme and dietary advice): six boys and eight girls; mean age 11.0 (SD 2.5) years; mean standard deviation score for BMI 5.58 (2.46). Group B (dietary advice alone): seven boys and nine girls; mean age 12.2 (2.7) years; mean BMI 5.33 (1.79) kg/m^2.
Recruitment	Unclear.
Intervention (12-week treatment and 1-year follow-up)	The dietary intervention included general dietary advice given by group teaching that comprised: energy requirements; relation of the different nutrients in a balanced diet (20%/30%/50%) of total energy ***[specify protein, fat, CHO?]***); and the importance of fibre, vitamins, minerals and fluids. Energy intake was reduced to 4180 kJ/day; children >14 years old were restricted to 5016 kJ/day (girls) and 5852 kJ/day (boys). At each visit (at baseline; after 4, 8 and 12 weeks; and after 6 and 12 months) each participant received re-education on an individual basis. Training sessions were performed twice weekly in a public gym, with a duration of approximately 60–70 min each session. The volume increased after 2 weeks, working up to as many as three to

	four sets for each exercise. In group A, participants received standardised dietary advice for weight reduction by a dietitian at baseline and after 4, 8 and 12 weeks of the study, and participated in a training programme twice weekly. In group B, participants had the dietary intervention only.
Delivery of intervention	Dietary advice given by a dietitian.
Control	Not reported
Length of follow-up	1 year.
Results	The main outcome of this study was fat-free mass. This was estimated from the resistance index, obtained by bioelectrical impedance analysis at baseline and at 12 weeks. After 12 weeks the children given physical training and dietary advice (Group A) had significantly greater mean change in fat free mass (2.7 [SD 3.7] kg) than that of the children given dietary advice alone (Group B) (0.4 [SD 1.7] kg)
Other outcomes	No other outcomes were reported.
Dropout rates	33%
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Dropouts 33%. Blinding unclear. Random allocation not described. Although follow-up at 6 and 12 months is discussed in the paper only 12-week fat free mass data were reported and no further information was available from the authors.

1

Woo 2004 RCT [139]	
Aim	To evaluate the effects of dietary and exercise interventions on vascular dysfunction in obese children.
Country and setting	Hong Kong. Unclear, but appears to be research clinic at university.
Participants	Eight-two overweight or obese children (BMI ≥21 kg/m^2). Children had to have no known medical illness and no alternative cause for their obesity, no family history of premature cardiovascular disease, be taking no regular medications or vitamin supplementation, and have resting brachial artery diameter >2.5 mm. Children with a history of diabetes, renal disease, cardiovascular disease or those whose sexual maturity status was more advanced than Tanner stage 2 were excluded.
Recruitment	Invitations to participate were sent to apparently obese children 9–12 years of age by school teachers in 13 local primary schools

Intervention	The children were prescribed with a 900 to 1200 kcal (3.77 to 5.02 MJ) hypoenergetic diet, which varied according to the children's ages and eating habits. The diet was low in fat (20–25% of energy), high in complex CHO (50–60% of energy), and sufficient in protein (25–30% of energy). The exercise intervention was carried out in the hospital and supervised by the same physiotherapist team, and was circuit style. Each child had to go through nine stations in each session, twice per week for 6 weeks and then once weekly for 1 year. Each training session lasted 75 min, including 10 min of warm up, 30 min of resistance training, 10 min of aerobic exercise, 10 min of agility training, 5 min of cool-down, and short periods between stations.
Delivery of intervention	Dietitian and trained physiotherapists.
Control	Not reported.
Length of follow-up	1 year.
Results (6 week intervention and 1 year follow-up).	After 6 weeks, waist-to-hip ratio decreased significantly in both groups, although there was no significant change in weight, BMI, body fat content or fat free mass. At 1 year, there were significant changes in body fat content from baseline in the combined group but not in the diet only group. No change in weight was reported, although BMI showed no significant changes in either group.
Other outcomes	At 1 year, a significant decrease was seen in total cholesterol from baseline in the diet group, but not in the combined group. LDL-cholesterol improved significantly from baseline in both groups, with improved HDL levels in the combined group only. Fasting glucose ($p < 0.002$) reduced slightly in the exercise group only. An improvement in endothelium-dependent dilation (EDD) but not nitroglycerin-induced dilation of brachial artery was visible in both groups after 6 weeks, although more evident after diet plus exercise than diet alone ($p = 0.01$).
Dropout rates	After 6 weeks, 22 of the 41 children assigned to the diet plus exercise agreed to continue the weekly exercise programme, and the other 19 children stopped regular supervised exercise but continued two monthly diet monitoring programme, as the original 41 diet-only children.
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	After 6 weeks, 22 of the 41 children assigned to the diet plus exercise agreed to continue the weekly exercise programme, and the other 19 children stopped regular supervised exercise but continued

	2-monthly diet-monitoring programme, as the original 41 diet-only children. Compliance with the intervention in both groups was promoted with an incentive award of a sporty-look souvenir watch on completion. Unclear blinding of children. Dietitian blinded to the exercise programme allocation.

1

Rolland-Cachera 2004 RCT [192]	
Aim	To compare the influence of weight-reducing diets containing different amounts of protein and CHO on body composition in obese adolescents and to examine dietary and PA behaviours during follow-up.
Country and setting	France. Specialised centre for obesity treatment.
Participants	One hundred and twenty-one obese children with a BMI exceeding the 97th centile of the French reference values, age between 11 and 16 years, and no pathologies contributing to obesity and no use of regular medication.
Recruitment	By referral from their general practitioner.
Intervention	The subjects lived for one school year in a medical centre specialised in the treatment of obese children. During treatment parameters were recorded on four occasions: at inclusion (P1), 2 weeks following inclusion (P2), when the body weight goal determined by the physician was achieved (P3) and at the end of the stabilisation phase (P4). During follow-up, nutritional intakes and PA were recorded at home 1 year (P5) and 2 years (P6) after treatment. The treatment encompassed diet, physical exercise and psychological support. Subjects were allocated either to a PROT + diet (19% of energy as protein and 50% of energy as CHO; protein content was 85 g/day; meat, fish or eggs were served twice per day) or to a PROT– diet (15% of energy as protein and 54% of energy as CHO; protein content was 65 g/day when total energy was 1750 kcal (7.33 MJ); and meat, fish or eggs were only consumed once per day). Fat content was identical in both diets (31% of energy). Energy intake was restricted to 1750 kcal (7.33 MJ)/day until reaching the body weight goal (P1–P3). After this, daily energy intake was increased progressively, in 1-week steps until about 2200 kcal (9.21 MJ) (on average depending on age and sex). The maintenance diet was then followed for 4 weeks (P3–P4). Both children and parents were advised to maintain the same level of energy and nutrient intake after leaving the centre (P4–P6). PA consisted of 7 hours/week of vigorous sports and 7 hours/week of outdoor activities (such as playing or walking). The children were not able to watch television in the centre, but could spend time

	reading, acting, singing, talking or strolling in the centre.
Delivery of intervention	Physician is only the professional reported.
Control	Not reported.
Length of follow-up	2 years.
Results (9 month intervention and 2 years follow-up).	BMI values changed from 36.1 (SD 4.6) kg/m^2 at baseline to 24.2 (SD 2.6) kg/m^2 at the end of treatment (P4) for the PROT– group. In the PROT+ group, BMI changed from 36.4 (SD 5.4) kg/m^2 at baseline to 24.0 (SD 2.5) kg/m^2 at the end of treatment. After treatment, mean BMI *z*-scores increased until P6. No significant difference in BMI *z*-scores from P1 to P6 was recorded between the two dietary groups. Height increased over the 9-month period, while all other measurements (except the subscapular/triceps skinfold thickness and the waist-to-hip ratio) significantly decreased.
Other outcomes	No difference in urinary growth hormone/creatinine ratio was observed between dietary groups at P1. Between P1 and P2 urinary growth hormone significantly increased in PROT– group ($p = 0.02$), whereas no significant change occurred in PROT+ group ($p = 0.92$). Between the first and second year, energy intake increased by 171 kcal (716 kJ). PA decreased and time watching television increased. No difference was observed between PROT– and PROT+.
Dropout rates	18% of children dropped out until the end of the treatment, and 40% until the end of the follow-up.
Treatment of dropouts (return to baseline, or last measurement?)	Only for those who completed the treatment and follow-up.
Quality and comments	Study supported by Lesieur and Nestle France companies. 18% of children dropped out until the end of the treatment, and 40% until the end of the follow-up. Random allocation not described.

1

Reybrouck 1990 CCT [936]	
Aim	To compare the effectiveness of combining a low-energy diet and exercise against diet only.
Country and setting	Belgium. Outpatient paediatric clinic.
Participants	Fifteen girls and 10 boys, aged 3.9 to 16.4 years. Endocrine disorders were excluded in all patients.

Recruitment	No reported.
Intervention	Group 1 consisted of eleven patients treated by a low-energy diet of 800 to 1000 kcal (3.35 to 4.19 MJ)/day, which was carefully explained by a dietitian. Group 2 included 14 patients who in addition to keeping the same low-energy diet were instructed to perform daily PA programme. The total duration of the exercise programme was adjusted to the actual body weight of the patient in order to consume about 250 kcal (1.05 MJ) per exercise session. The children could choose their favourite exercise from a list of equienergetic PAs. Consent was obtained from parents. The parents were encouraged to accompany their children when performing their exercises, in order to improve compliance.
Delivery of intervention	Dietitian, paediatrician and physical therapist.
Control	Two treatment groups.
Length of follow-up	8 months.
Results	After 4 months of treatment, the mean decrease in overweight was significantly ($p < 0.05$) greater for the children treated with diet and exercise therapy (–25.5 ± 13.5%) than in those treated with diet only (–15.8 ± 10.5%). In the combined treatment group, the decrease in percentage overweight after 4 months correlated significantly ($p < 0.05$) with the initial value of percentage overweight. No significant correlation ($p > 0.25$) was found between both variables for the patients of the other group. From 4 to 8 months, the mean decrease of the percentage overweight was much smaller and similar in both groups: –4.1 ± 5.6 for the children treated with diet and exercise and –3.5 ± 3.4 for the children treated with diet only.
Other outcomes	No other outcomes reported.
Dropout rates	48% at 8 months.
Treatment of dropouts (return to baseline, or last measurement?)	Only for those who completed 4- and 8-months follow-up.
Quality and comments	Follow-up at 8 months was available for only four children of the diet group and eight in the diet/exercise group. Very small study. High dropout rate at 8 months.

1

1.4.3 Interventions emphasising diet only

Spieth 2000 Cohort study [938]	
Aim	To examine the effects of a low-glycaemic-index (GI) diet compared with a standard reduced-fat diet in the management of paediatric obesity.
Country and setting	USA. Optimal Weight Life programme at Children's Hospital, Boston, MA. Academic medical centre.
Participants	One hundred and ninety patients. Mean age and BMI were 10.6 (SD 4.0) years and 32.5 (SD 7.3) kg/m^2 for the low-GI group and 10.2 (SD 3.1) years and 34.5 (SD 7.2) kg/m^2 for the reduced-fat group. Patients with Cushing syndrome, hypothyroidism, hypothalamic disease, diabetes mellitus or an obesity-associated genetic syndrome, or those concurrently following a very-low-energy diet. Cohort had 107 patients.
Recruitment	Unclear.
Intervention	All patients received a comprehensive medical evaluation, dietary counselling and lifestyle counselling. Counselling sessions included the child and at least one parent. Specific goals were individualised, taking into account the patients developmental level and readiness to change. In addition, problem-focused BT was provided, where a specific nutritional of PA goal was identified as a primary treatment target. Subsequently, a behavioural programme was then created, by applying positive reinforcement for meeting the specified goal. One group was given a standard balanced, hypoenergetic reduced-fat diet. Intake of high-fat, high-sugar and energy-dense foods was limited and intake of grain products, vegetables and fruits increased. Energy restriction was about 250 to 500 kcal (1.05 to 2.09 MJ)/day compared with usual energy intake. Specific macronutrient goals were 55–60% of energy from CHO, 15–20% of energy from protein and 25–30% of energy from fat. The other group was given a low-GI diet, designed to achieve the lowest glycaemic response possible while providing adequate dietary CHO. This diet differed from the standard diet not only in the gI of the CHO content, but also in the macronutrient ratio. A low-GI pyramid was used as a teaching tool. This pyramid placed vegetables, legumes and fruits at the base, lean proteins and dairy products on the second level, wholegrain products on the third level, and refined grain products, potatoes and concentrated sugars at the top. Specific macronutrient goals were 45–50% of energy from CHO, 20–25% of energy from protein and 30–35% of energy from fat.
Delivery of intervention	Subspecialty-trained paediatrician, dietitian, paediatric nurse practitioner and programme psychologist.
Control	Unclear if standard diet was control.
Length of follow-	4.3 months.

up	
Results	The low-GI had a significantly larger decrease in BMI than the standard diet ($p < 0.02$ for each comparison). Compared with the standard diet, a greater percentage of patients in the low-GI group experienced a decrease in BMI of at least –3 kg/m^2 ($p = 0.03$). The overall mean change in BMI for the low-GI group was –1.53 kg/m^2, compared with –0.06 kg/m^2 for the standard diet ($p < 0.001$). This difference remained statistically significant after adjusting for age, sex, ethnicity, length of follow-up, baseline BMI and behavioural therapy referral. Similar results were achieved in subjects that did not receive behavioural treatment: –1.47 kg/m^2 for low-GI diet ($n = 31$) and –0.20 kg/m^2 for the standard diet ($n = 28$) ($p < 0.001$). For white subjects the results were: –1.73 kg/m^2 for the low-GI diet ($n = 54$) and –0.29 kg/m^2 for the standard diet ($n = 23$) ($p < 0.01$).
Other outcomes	No other outcomes were reported.
Dropout rates	56.3%
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Eighty-three subjects were excluded for lack of follow-up and/or incomplete data. No randomisation. Short follow-up. The macronutrient composition of the low-GI diet differed from that of the reduced-fat diet. Retrospective cohort study.

1.4.4 Interventions comparing problem-solving with usual care or behaviour therapy

Graves 1988 (in Cochrane) RCT [973]	
Aim	To determine whether the inclusion of parental problem-solving training in a family-based BT programme would help weight loss in children.
Country and setting	USA. University outpatient weight reduction programme
Participants	Forty obese children and their parents. Age range 6 to 12 (mean 9.3) years. At least 20% overweight for age, sex and height. Mean weight on entry 124.5 lb (56.5 kg).
Recruitment	Through media announcement.
Intervention (including details of the BT)	The behavioural group was trained in behavioural weight loss methods (training in self-monitoring, diet information, exercise information, stimulus control strategies, family support, cognitive restructuring, peer relations and

	maintenance strategies). The problem-solving group was under the same BT plus problem-solving exercises aimed at problems associated with children's weight control. The instruction-only group were presented with the same diet and exercise information as the problem-solving group and were asked to exercise for 15 min during treatment sessions. Three comparisons were performed: problem-solving group plus BT vs. instruction-only group; problem-solving group vs. BT group only; and BT vs. the instruction only group.
Delivery of intervention/control	Unclear.
Dropout rates	23%
Control	Unclear if the instruction-only is the control group.
Length of follow-up	6 months.
Results (8 weeks intervention and 3 and 6 months follow-up)	Children in the problem-solving plus BT group (53.0% baseline) had a percentage overweight of 28.6 at 6 months, and the instruction only group (baseline 51.8) had presented at 42.3 at 6 months. In the second comparison, the percentage overweight in the problem-solving group decreased from 53.0 to 28.6 at 6 months, whereas in the BT-only group the percentage overweight decreased from 56.3 (SD 36.2) to 47.7 (SD 35.7) at post-treatment and 46.1 (SD 39.1) at 6 months. In the third comparison, the percentage overweight in the BT group decreased from 56.3 (SD 36.2) to 47.7 (SD 35.7) at post-treatment and 46.1 (SD 39.1) at 6 months. For the instruction group the percentage overweight at pre-treatment was 51.8 (SD 22.0), decreasing to 47.1 (SD 23.5) at post-treatment and 42.3 (SD 18.6) at 6 months.
Other outcomes	Post hoc analyses showed the parents in the problem-solving group increased their problem-solving ability from pre-treatment to post-treatment, whereas behavioural and instruction-only parents did not. Significant changes from pre-treatment to the 3- and 6-month follow-up sessions existed for parents in the problem-solving group only. Children in both the problem-solving and behavioural groups increased their consumption of green food and decreased their consumption of red foods significantly more than instruction only children.
Treatment of dropouts (return to baseline, or last measurement)	Data only from those who finished trial.
Quality and comments	Dropouts 22.5%. Blinding was unclear.

1

Epstein 2000 (in Cochrane) RCT [832]	
Aim	To determine whether problem-solving taught to child and parent increases treatment effectiveness of standard family-based treatment.
Country and setting	USA. Appears to be a University outpatient obesity treatment programme.
Participants	Sixty-seven families, Age mean 10.3 (SD 1.1) years. 48% male. 20% overweight, mean weight on entry 59.8 (SD 53.1) kg.
Recruitment	From referrals from physicians and previous participants and in response to newspaper and poster advertising.
Intervention	Three groups: problem-solving taught to parent and child; problem-solving taught to child; and standard family-based treatment. Didactic training in problem-solving was provided in group formats for parents and/or children. Parents and children in problem-solving groups were provided problem-solving worksheets and problem-solving homework. Families in the non-problem-solving groups were provided similar homework assignments not based on problem-solving. All parents and children were given workbooks with information on the traffic light diet, a 1200 kcal (5.02 MJ) diet that provides a colour-coded food reference guide that includes energy content per serving; PA: walk, run, bicycle or swim programme, three times per week beginning at 1 mile (1.61 km) of walking or running, 2 miles (3.22 km) of bicycling or 0.25 miles (0.40 km) of swimming, and advancing in regular intervals up to 3 miles (4.83 km) of running or walking, 6 miles (9.66 km) of bicycling, or 0.75 miles (1.21 km) of swimming. All participants were trained to exercise at 60–70% of their age-adjusted maximal heart rate; and behaviour change techniques (self-monitoring, positive reinforcement, stimulus control and preplanning). The 6-month treatment programme comprised 16 weekly meetings followed by two-monthly meetings. At treatment meetings, family members were weighed, met with and individual therapist for 15–30 min, and attended separate 30-min group meetings (one for parents and one for children).
Delivery of intervention/control	Unclear.
Dropout rates	7.5%
Control	Unclear if standard family based treatment is control.
Length of follow-up	24 months.
Results (6 months intervention	In the parent and child group, weight decreased from 64.2 (SD 13.2) kg at baseline to 57.4 (SD 11.8) kg, compared with

and 12 and 24 months follow-up)	a reduction from 57 (SD 11.4) kg at baseline to 50.8 kg in the control group at 6 months. In the child alone group, mean weight decreased from 58.2 kg at baseline to 51.2 kg. At 12 months the mean weight was 63 (SD 12.6) kg for the parent and child group; 55.8 (SD 13.4) kg for the child alone group; and 55.7 (SD 11.4) kg in the control group. No reduction in weight was observed for the problem-solving group vs. problem-solving with family.
Other outcomes	Significant improvement in Symptom Checklist-90 (SCL-90; based on the global Severity Index [GSI]) were observed at 6 months ($p < 0.005$) with a loss of improvement from 6 to 24 months ($p < 0.003$). A significant reduction in the percentage of parents with clinically significant GSI distress scores was observed from 18% at baseline to 4% at 6 months. Improvements in problem-solving for both parents and children was reported for the problem-solving group vs. problem-solving with family
Treatment of dropouts (return to baseline, or last measurement)	Appears to be data from those who finished trial.
Quality and comments	Dropouts 7.5%. Blinding was unclear. Attrition was 11% and 15% at 12 and 24 months. Details of initial randomisation were not provided.

1.4.5 Interventions where the main focus was behavioural treatment in comparison with no treatment or usual care

Epstein 1985 (in Cochrane) RCT [940]	
Aim	To determine the effectiveness of BT with emphasis on parent management.
Country and setting	USA. University outpatient weight control programme
Participants	Twenty-four obese girls aged 5–8 years old. girls had to be 20–80% overweight, and no history of psychiatric disorder or medical condition contraindicating weight loss or exercise. Mothers were required to participate and to attend all treatment meetings.
Recruitment	By school nurse and physician referrals, and in response to media coverage.
Intervention (Including details of BT)	Comparison between a BT programme with parent management orientation, and a control group with equal education and attention, but with no behavioural component. Both groups undertook the traffic light diet. Children under the age of 7 years were given an upper limit of 1000 kcal

	(4.19 MJ)/day. While parents and children >7 years were given an upper limit of 1200 kcal (4.02 MJ)/day. Minimum of 900 kcal (3.77 MJ/day) was given to all participants. The behavioural group received training in self-monitoring, praise and modelling, and also contracts for the participants to encourage health habits changes that were in line with the programme objectives. Both groups received the same amount of therapist contact time during treatment.
Delivery of intervention/control	Therapist.
Dropout rates	20.8%
Control	The control group provided equal education and attention, although did not have a behavioural orientation.
Length of intervention	12-month treatment programme, no follow-up
Results (12-months intervention)	BMI decreased from 22.8 (SD 2.6) kg/m^2 at baseline to 19.1 (SD 2.8) kg/m^2 after 12 months in the behavioural group, and from 22.7 (SD 3.0) to 21.4 (SD 3.3) kg/m^2 in the control group.
Other outcomes	Significant interactions of treatment × time were observed for children eating behaviours ($p < 0.001$), but not for their mothers. Post hoc examination of treatment means suggests that the treated children had improved eating habits compared with the control.
Treatment of dropouts (return to baseline, or last measurement?)	Data only for those who completed treatment.
Quality and comments	Dropouts 20.8%. Blinding was unclear. Randomisation was not described.

1

Senediak 1985 (in Cochrane) RCT [939]	
Aim	To examine whether frequency has repercussions on the effectiveness of the BT.
Country and setting	Australia. Appears to be University outpatient weight control programme
Participants	Forty-five overweight children. Age range 72 to 150 (mean 123.61) months. 66% male. Weight entry criteria: >20% overweight for height, age and sex. Mean weight on entry 37.22%.
Recruitment	After responding to newspaper and radio advertisements and publicity issued to medical practitioners, community health centres and parents' organisations in the Sydney metropolitan area.
Intervention	Four groups: 1) rapid behavioural group ($n = 12$), where sessions were carried out on a group basis with five or six

	parent–child pairs. The eight sessions were conducted twice weekly for 4 weeks, with follow-up evaluations taking place at 11 and 21 weeks after treatment each session lasted 90 min and was focused on a range of dietary, nutritional and environmental approaches; 2) gradual behavioural procedure (n = 12), included eight treatment sessions that were spaced over a period of 15 weeks, having sessions 1 to 4 on weekly basis, sessions 5 to 6 on a fortnight basis, and sessions 7 to 8 after a 3-week interval. This group only received an 11-week after follow-up; 3) non-specific control condition (n = 11), where treatment and follow-up were scheduled in the same way as the rapid group, with the same kind of therapists, although no information concerning the energy values of food or exercise activities were provided; 4) and a waiting list control group (n = 10), that were informed that because of the great response to the programme, there would be a delay in the star of their treatment. Assessments were performed at weeks 1 and 4.
Delivery of intervention/control	Two therapists were involved: qualified clinical psychologist and a Master's student in clinical psychology.
Dropout rates	31%
Control	Two control groups, as described above.
Length of follow-up	Regarding follow-up, groups 1 and 3 received 21 weeks, group 2 received 10 weeks and no follow-up for group 4.
Results	Percentage overweight in the rapid behavioural group decreased from 32.9 (SD 13.98) at baseline to 19.9 (SD 14.2) after 6 months. For the gradual behavioural group, percentage overweight decreased from 35.9 (SD 12.2) at baseline to 16.6 (SD 11.5) at 6 months. In the non-specific control group, mean percentage overweight decreased from 36.7 (SD 5.5) to 30.80 (SD 10.4) at 6 months. No significant differences were found between the rapid and gradual groups over 6 months. No valid data was available for the comparison between treatment and no treatment groups, as the waiting list control group was only monitored for 4 weeks.
Other outcomes	There was a significant reduction of daily energy intake at post-treatment for the two combined groups (week 4 for the rapid group and week 15 for the gradual group) ($p < 0.01$).
Treatment of dropouts (return to baseline, or last measurement?)	Only data from subjects present at the two assessment occasions.
Quality and comments	Dropouts 31%. Double blinding. No description of the randomisation.

1

Saelens 2002 RCT [628]	
Aim	To evaluate the short-term follow-up efficacy of a behavioural

	weight control programme.
Country and setting	USA paediatric primary care clinics.
Participants	Participants were on average 14.2 (SD 1.2) years old with a BMI of 30.7 (SD 3.1) kg/m^2, 59.1% were male and self-identified as 70.5% White, 15.9% Hispanic, 4.5% African American, 2.3% Asian and 6.8% multi-ethnic.
Recruitment	Waiting room flyers and by encouraging paediatricians in the clinics to elicit discussion on possible study participation with eligible adolescents.
Intervention	n = 23 participants for the Healthy Habits (HH) group, which consisted of a multi-component behavioural intervention, that included computer interaction and physician counselling in the paediatric primary care clinic, followed by 4 months of telephone and mail-based behavioural counselling; and n = 21 participants for the Typical Care (TC) group, that received single session physician counselling (included encouragement of adolescent's motivation for weight related behaviour change, provision of information about short- and long-term health consequences of high weight status and benefits of better weight control, recommendations for healthy eating, review PA recommendations for adolescents, and encourage consistency and persistence with health behaviour changes).
Delivery of intervention/control	Paediatrician and counsellors.
Dropout rates	15.9%
Control	Two treatment groups.
Length of follow-up	4 months.
Results	BMI for the HH changed from 31.0 (SD 3.5) kg/m^2 at baseline to 30.9 (SD 3.8) kg/m^2 at post-treatment to 31.1 (SD 4.5) kg/m^2 at follow-up. For the TC, BMI changed from 30.7 (SD 3.1) to 31.8 (SD 3.4) to 32.1 (SD 3.8) kg/m^2. Weight values for the HH group changed from 85.5 (SD 13.9) kg at baseline to 86.1 (SD 14.0) kg at post-treatment and 87.5 (SD 16.0) kg at follow-up. For the TC, weight changed from 80.5 (SD 13.5) to 84.1 (SD 13.8) and 85.8 (SD 14.6) kg.
Other outcomes	There were no significant changes by condition from baseline to post-treatment for total energy or dietary fat intake, PA, sedentary behaviour, or problematic eating and weight-related behaviour or beliefs.
Treatment of dropouts (return to baseline, or last measurement?)	Conservative ITT analysis on the primary outcome conducted by replacing missing values of HH adolescents at post-treatment and follow-up with the mean change of the TC condition from the baseline to post-treatment and post-treatment to follow-up, respectively.

Quality and comments	Blinding of providers, unclear if children blinded. Adequate description of randomisation process.

1.4.6 Interventions comparing behavioural treatment at varying degrees of family involvement

Golan 1998 (in Cochrane) and Golan 2004 RCT [941] [45]	
Aim	To examine the effectiveness of BT when responsibility of the parents vs. responsibility of the child.
Country and setting	Israel. University Research Centre (outpatient).
Participants	Sixty obese children. Mean age range from 6 to 11 (mean 9.2, SD 1.0) years. 38% male. Inclusion criteria: 20% or above overweight for age, height and sex. Weight on entry: 39% overweight.
Recruitment	From the public school system of the middle class town of Rchovot.
Intervention	One treatment intervention group: family based approach. In this group only parents participated in the sessions. The parents were subdivided into two groups that attended 14 1-hour sessions conducted by a clinical dietitian. The first four sessions were held weekly, the next three biweekly, and the last six, once very 6 weeks. Parents were taught to change the family sedentary lifestyle, provide a prudent diet, decrease the family's exposure to food stimuli, apply behavioural modifications and practice relevant parenting skills.
Delivery of intervention	Clinical dietitian.
Dropout rates	16.6%
Control	Conventional child approach, where only children participated. A 6.3 MJ/day diet was prescribed to each child. Children were also divided to two groups to attend 30 1-hour sessions conducted by a clinical dietitian. They were taught how to follow a prudent diet, restrict energy intake, increase exercise, control food stimuli, techniques in self-monitoring, practice problem-solving and cognitive restructuring.
Length of follow-up	1 and 7 years.
Results (1-year follow-up, second study follow-up was at 7-years.	There were significant reductions in degree of overweight and mean weight, although the decreases were greater in the family-based intervention (14.6 vs. 8.4%, $p < 0.05$). After 7 years, the children in the parent-only group achieved a significantly higher reduction in percentage overweight compared with the children in the child-only group (14.6 vs. 8.43%; $p < 0.03$). Both groups demonstrated substantial weight loss, although the mean reduction in overweight was 29% in children

	in the parent-only group and 20.2% in those of the child-only group ($p < 0.05$).
Other outcomes	Stimulus exposure: There was a significant difference between groups in the overall reduction of food stimuli in the home ($p < 0.05$) and in the reduction of snacks, sweets and cakes ($p < 0.001$, $p < 0.05$, $p < 0.05$, respectively). Children's behaviour to food stimuli: At termination of the programme, a significant increase in the children's asking permission on both counts was noted only in the experimental group ($p < 0.001$) for taking and ($p < 0.01$) for buying. Eating style: The overall reduction in prevalence of poor eating habits was significantly greater in the experimental group. Moreover, the reduction in eating outside the dinning room was significant only in the experimental intervention ($p < 0.001$). Finally, a significant reduction in the rate of eating, after the intervention, was only observed in the experimental group ($p < 0.05$) and a significant reduction in the request for second helpings at mealtimes ($p < 0.05$).
Treatment of dropouts (return to baseline, or last measurement)	Unclear.
Quality and comments	Dropouts 16.6%. Blinding unclear. No description of the randomisation.

1

Israel 1985 (in Cochrane) RCT [944]	
Aim	To compare BT with a parental responsibility orientation vs. BT with a conventional parent/child behavioural weight reduction programme.
Country and setting	USA. Outpatient weight reduction programme.
Participants	Thirty-three overweight children (30 families, where 24 were treatment and six control). Age range from 8 to 12 years (mean 11 years 4 months). 30% male. Weight inclusion criteria: 20% overweight for height. Mean weight on baseline not stated.
Recruitment	Through letters to paediatricians and school nurses and advertisements in a local newspaper.
Intervention	Two treatment groups: Weight reduction only group ($n = 12$), where parents and children undertook a multi-component behavioural weight reduction programme on a nine weekly 90-min session basis, and a parent training group ($n = 12$), where parents attended the same weight reduction programme (same frequency) and also 2-hour long sessions where they received behavioural child management skills.
Delivery of	Therapists: Advanced graduate student in clinical psychology. Two

intervention	other graduate student co-therapists assisted in conducting meetings and made between-session phone calls to assist parents with homework assignments,, provide motivational input, and individualise the treatment. Each children's group was led by two undergraduate students who were trained and supervised by the parents' group leader.
Dropout rates	Only values reported relate to family dropouts. Thirty families at the start of the programme, and 20 at the end.
Control	Waiting list control group ($n = 9$).
Length of follow-up	1 year.
Results (9 weeks intervention and 1 year follow-up)	When comparing the weight reduction group vs. waiting list control group, the latter group showed an increase in weight. In the weight reduction group the percentage overweight of the children decreased from 46.8 (SD 15.6) at the first week to 33.6 (SD 17.0) at the end of the treatment period, and was 45.5 (SD 21.2) at 1 year. For the parent training group vs. the weight reduction only group, the first group went from 50.6 (SD 17.5)% at baseline to 43.4 (SD 21.6)% at the end of the treatment, and to 40.4(SD 32.9) % at 1 year. The second group went from 46.8% overweight (SD 15.6) at baseline to 33.6 (SD 17.0)% at post-treatment, and to 45.5 (SD 21.2)% at 1 year. For the parent training group vs. control group, the first group lost weight, going from 50.6 (SD 17.5)% at baseline to 43.4 (SD 21.6)% at post-treatment and to 40.4 (SD 32.9)% at 1 year. The control group gained weight, although comparable follow-up values are not quoted for this group.
Other outcomes	Scores on the EHC decreased over the follow-up for both treatment conditions ($p < 0.001$), with no differences between the PT and WRO groups. The difference between EHC scores at 1-year follow-up of children who achieved non-obese status vs. those who were successful during treatment but did not achieve non-obese status during the follow-up period was significant ($p < 0.05$).
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only data from completers.
Quality and comments	Dropouts 39%. No blinding for children and providers, unclear for the outcome assessors. Randomly assigned to conditions from stratified blocks based on child % overweight and age. Attrition rates for children are unclear.

1

Wadden 1990 (in Cochrane) RCT [942]	
Aim	To compare BT with a parental responsibility orientation vs. BT with a conventional parent/child behavioural weight reduction

	programme.
Country and setting	USA. Outpatient weight control programme
Participants	Thirty-six black female adolescents. Age range from 12 to 16 (mean 13.8) years. Weight inclusion criteria: above 10 kg overweight for age, sex and height. Weight on baseline: 95.1 kg (mean).
Recruitment	By advertisements in community newspapers; school nurses in district 1 of the Philadelphian school system; and by attending physicians and residents at the Children's Hospital of Philadelphia.
Intervention	Behavioural weight control programme with three groups: 1) child alone (n = 19); 2) mother–child together (n = 14); and 3) mother–child separately. Sixteen weekly 1-hour treatment sessions based on the weight reduction and pride (WRAP) programme. The programme instructed children to: record their food and energy intake; consume low-fat well-balanced meals of 1000 to 1500 kcal (4.19 to 6.28 MJ)/day; understand macronutrients, vitamins, and minerals; limit their consumption of high-energy snacks and fast foods; limit times and places of eating; slowing their rate of eating; modifying self-defeating thoughts concerning weight and food; and increasing their PA by walking and other lifestyle behaviours. Sessions also included homework assignment and a quiz.
Delivery of intervention	Investigator, two clinical psychologists, a nutritionist and therapists.
Dropout rates	Paper reports 22% although 31/47 completed, which equals 34%.
Control	Not reported.
Length of follow-up	6 months.
Results (16 weeks intervention and 6 months follow-up)	For the mother and child group vs. child alone group, at post-treatment children in the second group had lost 1.6 kg weight, children in the mother and child in the same session group had lost 3.7 kg and children in the mother and child in different sessions group had lost 3.1 kg. For mother and child treated in the same session vs. mother and child treated in separate but concurrent sessions, the mother and child together group had lost 3.7 kg and children in the group that treated mother and child in different sessions had lost 3.1 kg. None of the results were statistically significant.
Other outcomes	Total cholesterol concentration decreased significantly during treatment from 178.8 to 164.2 mg/dl ($p < 0.01$). HDL-cholesterol decreased from 47.5 to 44.7 mg/dl ($p < 0.06$). Subjects with higher initial values of total cholesterol, LDL-cholesterol and HDL-cholesterol tended to show larger end of treatment reductions. Subjects scores on the Pier–Harris scale increased significantly ($p < 0.05$) during treatment from 57.6 to 59.9 suggesting enhanced self-esteem. Scores on the Child Depression Inventory decreased significantly ($p < 0.01$) from 9.7 to 6.8, which shows reductions in

	feelings of depression. Changes on these two measures did not correlate significantly with changes in weight or fat percentage.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed the programme.
Quality and comments	Dropouts: paper reports 22% although 31/47 completed, which equals 34%. Blinding unclear. Randomisation not described

1

Israel 1994 (in Cochrane) RCT [943]	
Aim	To compare behavioural treatment with focus on child responsibility vs. focus on parent responsibility.
Country and setting	USA. Appears to be outpatient childhood obesity treatment programme
Participants	Twenty obese children aged 8 to 13 (mean 10) years and parents. Weight inclusion criteria: above 20% overweight for weight, height and sex. Mean weight on baseline: 47% overweight for age, height and sex. No details given of male percentage.
Recruitment	Through newspaper articles, letters to paediatricians, and letters to school nurses.
Intervention	Two treatment groups: standard treatment condition (ST) (n = 18), which consisted of a multi-component behavioural intervention where parents were given primary responsibility for following programme prescription; and enhanced child involvement (Early Child Development) (n = 16), which provided the same basic intervention but with greater emphasis on, and training in, child self-regulation. Children in the enhanced treatment group received comprehensive training in self-management skills and the children were assigned homework exercises to practice the new skills. Parents also rewarded their children for engaging in self-management skills. Parents met separately for eight × 90 min sessions followed by nine biweekly sessions for a total of 26 weeks. Treatment involved discussions and homework assignments.
Delivery of intervention/control	Unclear.
Dropout rates	41% at follow-up.
Control	Not reported.
Length of follow-up	1 and 3 years.
Results (26 weeks intervention	Percentage overweight in the standard treatment group was 45.9 (SD 17.1) at baseline, 33.4 (SD 17.0) at the end of the 6-

and 1 and 3 years follow-up)	month treatment period, 45.2 (SD 23.9) at 1-year follow-up and 52.3 (SD 24.4) after 3 years. In the enhanced child involvement group, percentage overweight was 48.1 (SD 18.3) at baseline, 32.6 (SD 17.4) at 6 months, 42.3 (SD 22.5) at 1 year and 43.3 (21.2) after 3 years. The results clearly show a trend of weight reduction during treatment, and of weight gain during follow-up.
Other outcomes	Children adopted a significantly more internal locus of control (LOCSC) from week 1 to week 26.Likewise, an analysis of the Eating and Activity Self-Control Scale (EASC) indicated an increase in children's self-control and parental control regarding weight-related behaviours ($p < 0.001$) and ($p < 0.05$), respectively. Parental judgements from the Self-Control Rating Scale (SCRS) also indicated significantly more self-controlled behaviours at week 26 than at week 1 ($p < 0.05$).
Treatment of dropouts (return to baseline, or last measurement?)	Unclear.
Quality and comments	Dropouts: 41% at follow-up. Unclear blinding. Randomisation method not described.

1

Wrotniak 2004 Secondary data analysis of three RCTs [971]	
Aim	To determine whether parent-standardised body mass index (BMI *z*-score) change predicts child BMI *z*-score change.
Country and setting	USA. University paediatric obesity research clinic
Participants	One participating parent and one 8–12-year-old child from each of 142 families were recruited for one of three family-based weight control programmes. Inclusion criteria were: children with greater than the 85th BMI percentile and participating parents greater that the 70th BMI percentile who were willing to attend treatment meetings.
Recruitment	Not reported.
Intervention	Participating parents were asked to change their eating and activity patterns and home environment. If the parents were not overweight, they were asked to eat more fruits and vegetables and low-fat dairy products and be more physically active, so all parents could make positive health changes, even if they were not obese. All families were provided with an educational programme based on the traffic light diet and a PA programme. Families were also taught how to rearrange their environment to support eating-related behaviour change, by making unhealthy choices more difficult to access or by making healthy choices more appealing. Families were taught how to limit the amount of red

	foods in the house and to increase the amount of green foods. Behaviour change was accomplished by the use of contracts negotiated between the parent and child and by social reinforcement.
Delivery of intervention/control	Unclear.
Dropout rates	Not applicable.
Control	Not reported.
Length of follow-up	24 months.
Results	Children of the parents in the greatest BMI *z*-score change quartile had greater reductions in weight for height and in percentage overweight (weight –7.2 kg; percentage overweight –27.6) after 6 months compared with children of the parents in the other three categories (weight –4.0 kg; percentage overweight –20.9). After 2 years, children of the parents in the greatest BMI *z*-score change quartile gained less weight for height and had greater percentage overweight changes (–16.8%) compared with children in the lowest tree parent BMI *z*-score change quartiles. Parent BMI *z*-score change significantly predicted child BMI *z*-score change from 0–6 months ($p < 0.001$) and from 0–24 months ($p < 0.009$). Parents in the highest quartile of BMI *z*-score change had children with significantly greater BMI *z*-score change than that of children with parents in the other quartiles.
Other outcomes	No other outcomes were reported.
Treatment of dropouts (return to baseline, or last measurement?)	Only families with complete parent and child data at all time points were included for analyses.
Quality and comments	No details of randomisation given. Unclear if blinded. Participants included in this report are from three studies that differed in their goals and study hypotheses (Epstein 2000a,b, 2004), which are included in this review.

1

Epstein 1981 and 1987 (in Mclean review) RCT [947] [946]	
Aim	To assess the importance of targeting the child or parent and child in a family based obesity programme with high-risk, preadolescent obese children.
Country and setting	USA. Outpatient university research centre
Participants	Seventy-six families met the inclusion criteria of: 1) at least one child and one parent between 115 and 180% of the ideal weight for height and age; 2) having triceps skinfold thickness values >95% of children their age; 3) height not below the 25th percentile for children their age; 4) no psychiatric contact; 5) both parents at home; 6) target parent

	willing to participate in the weight loss programme, and 7) ability to attend at least 12/14 treatment sessions.
Recruitment	Through newspapers advertisements, fliers distributed at schools, and physicians.
Intervention	Three treatment groups: Parent/child target (group 1), child target (group 2) and non-specific target (group 3). The three groups were given identical information on diet (each group undertook the 'traffic light diet', in which each family was provided with a colour-coded food reference guide that included caloric content per serving. Participants were taught how to keep a diet diary and to chart daily weights, energy intake, and number of red foods eaten, for a 1200 or 1500 kcal (5.02 or 6.28 MJ) limit, exercise (each group received information on aerobic exercise, stretching and spot reducing) and behavioural procedures (such as contracting, self-monitoring, social reinforcement and prompts, therapist contact, and contingency management). Each of the groups was provided with a 14 session treatment programme, which included eight weekly sessions and six sessions distributed over the next 6 months, which were held 2.5, 3, 4, 5, 6.5 and 8 months after the beginning of the treatment. At the 5-year measurement, both parents and children completed a retrospective questionnaire to assess the use of the behaviour change techniques taught during the programme.
Delivery of intervention/control	Therapists.
Dropout rates	Unclear.
Control	Unclear if non-specific group is control.
Length of follow-up	Up to 13 months after the termination of the treatment, or 21 months after the beginning.
Results (8 months treatment and 21 and 60 (Epstein 1987) months follow-up)	All groups changed in percentage overweight. A significant decrease ($p < 0.01$) was observed from 0 to 2 months, with a further decrease from 2 to 8 months ($p < 0.01$). Adults also showed significant percentage overweigh changes. Parents in group 1 lost more weight than parents in groups 2 and 3 ($p < 0.01$) at 8 months. At the end of the treatment, a significantly greater ($p < 0.05$) proportion of group 2 children compared with group 3 were non-obese. At 21 months, a greater proportion of non-obese (non-significant) from group 1 than in groups 2 and 3. 32% of the adults were non-obese at the end of treatment, with only 19% non-obese at follow-up. The proportion of non-obese parents was less in group 3 at 8 and 21 months, although non-significant. At 5 years significant univariate changes were shown for

	percentage overweight ($p = 0.001$) but not for weight or height. The percentage overweight in children in the parent-plus-child group decreased (–12.7%), whereas that of children in the other two groups increased (4.3 and 8.2%, respectively). At 5 years the percentage of children in the parent plus child, child alone and non-specific groups who were not obese were 33, 19 and 4.5% ($p = 0.048$), respectively (Epstein 1987).
Other outcomes	The consumption of red, yellow and green foods at the start and end of treatment was compared. The results showed significant pre-post ($p < 0.001$); food group ($p < 0.001$); pre-post × food group ($p < 0.001$); and treatment × pre-post × food group ($p < 0.05$) effects. Significant increased ($p < 0.0001$) in height of 22.8 cm and significant decreases ($p < 0.0001$) in height percentile from the 72nd to the 60th percentile were observed. No differences were observed between groups in height change, and subsequent height analyses are based on the total sample.
Treatment of dropouts (return to baseline, or last measurement?)	Results for each analysis were based only on families who attended at least the last weekly treatment meeting, the 6.5- or 8-months treatment meeting, and the 13-month follow-up.
Quality and comments	Dropouts: unclear. Unclear blinding and concealment. Stratified random assignment.

1

Epstein 1990 [970]	
Aim	To examine the effects of behavioural family-based treatment on percentage overweight and growth over 10 years in obese 6 to 12-year-old children.
Country and Setting	USA. University research centre.
Recruitment	Not clear.
Participants	Seventy-six families with children aged 6 to 12 years were eligible for randomisation after which one child was removed from the sample due to unreported psychiatric problems. Inclusion criteria was as follow: greater than 20% over ideal weight for age, height, and sex, triceps skinfold thickness greater than 95th percentile for children their age, no history of psychiatric contact for children; both parents living at home, at least one obese parent, and a parent willing to attend treatment meetings with their child.
Intervention	Participants were randomised to one of three groups: child and parent target (group 1), child target (group 2), or non-specific target (group 3). All families were provided with eight weekly treatment meetings and six additional meetings distributed during the next 6 months.

	They were then seen at 21-, 60- and 120-month follow-up Participants were given the traffic light diet, and all subjects were given information on aerobic exercise, stretching, and spot reducing and were instructed to begin an aerobic exercise programme according to Cooper. A range of behavioural procedures were used across the three groups to differentially reinforce families for behaviour change and weight loss: contracting; self-monitoring; and social reinforcement and modelling.
Control	Three treatment groups.
Length of follow-up	10 years
Results	At the 5-year follow-up, data was available on 67 of the 75 eligible families. At 10 years, one death occured, and data were collected from 61 of 66 families. Significant percentage overweight differences ($p < 0.05$) were shown at both 5 and 10 years between children in groups 1 and with children in group 2 midway between the other groups. Children in group 1 showed a decrease from baseline in percentage overweight after 5 and 10 years, whilst children in groups 2 and 3 showed an increase in percentage overweight from baseline to 5 and 10 years. Differential weight gain across the three groups was observed so that after 10 years children in group 3 had gained 12.6 kg more (+46.6 kg) than children in group 2 (+34.0 kg) while children in group 2 had gained 9.1 kg more than children in group 1. Children in groups 2 and 3 were significantly heavier ($p < 0.05$) than children in group 1. No significant differences across groups were shown in percentage overweight changes for parents at 10 years. There was little relationship between long-term child and parent changes in percentage overweight.
Dropouts	19% at 10 years.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those that completed follow-ups.
Quality and comments	No details of randomisation. No blinding or concealment methods mentioned.

1

1.4.7 Interventions focusing on cognitive behaviour therapy

Duffy 1993 (in Cochrane) RCT [974]	
Aim	To examine the effectiveness of cognitive self-management training as an adjunct to the behavioural management of childhood obesity.
Country and setting	Australia. Not clear but probably clinic.
Participants	Age range (mean) 7–13 years (118.71 months, SD 20.16). % Male: 21%. Weight inclusion criteria: 15% overweight for age, height and sex. Weight on entry (mean): 48.6% overweight for age, height and sex (SD 22.12).
Recruitment	Through articles in local and State newspapers.
Intervention	8-week 90-min cognitive behaviour therapy (CBT) sessions with the intervention group (n = 9) receiving additional cognitive self-management sessions and the control group (BT + **APC**, n = 8) receiving relaxation training. Children were encouraged to do aerobic exercise and avoid 'red light foods'. Food intake was recorded for 7 days. A behavioural contract approach was used in which parents paid a redeemable US$30.
Delivery of intervention/control	Unclear.
Dropout rates	37%
Control	As described above.
Length of follow-up	6 months.
Results (8 weeks intervention and 6 months follow-up)	Percentage overweight decreased in the relaxation control group from 46.3 (SD 19.3) at pre-treatment to 37.0 (SD 18.3) at post-treatment, 38.2 (SD 20.7) at 3-month follow-up and 37.1 (SD 21.7) at 6-month follow-up. In the CBT group percentage overweight decreased from 46.0 (SD 18.6) to 37.6 (SD 19.6) at post-treatment, 39.1 (SD 19.3) at 3-month follow-up and 37.0 (SD 24.6) at 6-month follow-up.
Other outcomes	No other outcomes were reported.
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed the treatment and follow-up.
Quality and comments	Dropouts 37%. Unclear how many children were randomised to each treatment group. No children and provider blinding, unclear blinding of the outcome assessor. Randomisation method not described.

Warschburger 2001 (in Cochrane) RCT [975]	
Aim	To compare the effectiveness of CBT with relaxation therapy.

Country and setting	Germany. Rehabilitation hospital.
Participants	*n* = 197. Age range 9 to 19 (mean 13.8, SD 1.1) years in experimental group, mean 13.1 (SD 1.1) in the control group. % Male: No details. Weight inclusion criteria: above 20% overweight for height and weight on baseline (mean): % overweight experimental group 63.8 ± 25.4, control group 64.6 ± 23.7.
Recruitment	Unclear.
Intervention	Two groups: 1) Experimental group (CBT)[5] which participated in 'obesity training' that included specific skills to facilitate behaviour change and also behaviour management skills to encourage habit change. Self-monitoring, contract-management, stimulus control, modelling, eating management and reinforcement principles were applied; 2) comparison group which undertook the same diet and exercise programmes but received muscle-relaxation training instead of the psychological intervention component.
Delivery of intervention/control	Unclear.
Dropout rates	No details given.
Control	Comparison group.
Length of follow-up	6 and 12 months.
Results (6 weeks intervention and 6 and 12 months follow-up)	The mean percentage overweight in the experimental group was 62.8 (SD 25.1) at admission; 47.4 (SD 22.9) at discharge at 6 weeks; 46.4 (SD 23.3) 6 months later; and 48.5 (SD 28.1) 1 year later. The mean percentage overweight in the comparison group was 62.5 (SD 23.5) at admission; 48.6 (SD 23.1) at discharge; 45.4 (SD 21.9) 6 months later and 46.8 (SD 27.0) 1 year later. The mean BMI (kg/m^2) in the experimental group was 31.1 (SD 5.0) at admission; 28.6 (SD 5.3) at discharge; 29.2 (SD 4.7) 6 months later; and 30.4 (SD 5.7) 1 year later. The mean BMI in the comparison group was 31.7 (SD 4.6) at admission; 28.8 (SD 4.4) at discharge; 29.0 (SD 5.5) 6 months later and 30.1 (SD 5.9) 1 year later.
Other outcomes	Pre- vs. post-tests showed significant improvements in self-reported eating behaviours for the experimental group compared with the control group ($p < 0.05$). No age or sex differences were found. Both groups showed improvements in their quality of life over time ($p < 0.01$); neither the group nor the interaction effect occurred. During the first 6 months self-reported quality of life increased slightly but not significantly more in the

[5] Details of this CBT programme are in Warschburger 1999 study (German language).

	experimental group than in the control group ($p = 0.08$).
Reported harms	High degree of stress-induced eating behaviours and a high level of anxiety in the muscle relation group.
Treatment of dropouts (return to baseline, or last measurement?)	Data from completers.
Quality and comments	Dropouts: no details given. Unclear blinding. Randomisation method not described.

1

Braet 1997, 2000 CCT [976] [804]	
Aim	To assess the additional benefits of introducing a 'healthy eating' lifestyle programme instead of a strict diet prescription, in combination with the principles of CBT.
Country and setting	Belgium. Outpatient and inpatient.
Participants	Obese children ($n = 259$). All White and of normal intelligence. The children were between 7 and 16 years of age and were at least 20% overweight. Overweight ranged from 20 to 100%. All socio-economic classes were represented equally. Subjects were free of other medical problems such as diabetes, or did not suffer from any syndromic obesity.
Recruitment	From media advertisements and physician referral.
Intervention	Self-instructions, self-observation, self-evaluation and self-reward techniques were introduced in each session. Modelling, behaviour rehearsal and homework were used to train self-regulation skills. Problem-solving skills were taught in different high-risk eating situations. Contracts were established including what a child would receive if it followed the programme. Parents were asked to praise their children for good performance. Children were taught about the benefits of exercise and energy expenditure. Exercises were promoted with a frequency of 30 min each day in combination with lifestyle changes such as taking the stairs, walking instead of going by car, helping in the garden or cleaning the house. Moderate intensity in order to keep the exercises up for 30 min, and children were not instructed to exercise at a particular intensity. Changes in eating habits were proposed in small steps, and children were given the chance to make their own choices. They were instructed on how to eat in a healthy way many times a day including many vegetables. 'Counting calories' was not permitted. Subjects were assigned to four different treatment groups: group; individual, advice; and camp. Summer camp: 18 subjects in one camp, organised three times. They received healthy food (1500 kcal [6.28 MJ]/day) and daily lifestyle exercises. The outpatient

programme (group or individual) consisted of an intensive part for the child only, including seven sessions of 90 min (twice per month) and seven family follow-up sessions (once per month). There were no differences between the programme of the group and the individual training. For some families, the treatment was not feasible because of other family plans, so children could be assigned to and advice in one session group.

In all treatment conditions children received the same package of information. Parents were given a treatment manual for parents of obese children and the child had his own workbook.

Delivery of intervention/control: Unclear.

Dropout rates: 19.9% at 4.6 years, which accounted for 27 children.

Control: Fifty-four non-clinical obese children with no treatment.

Length of follow-up: At year 1 and 4.6 years.

Results

	During treatment	**After treatment**	**1-year follow-up**
Condition			
Group	3.31	8.44	13.08
Individual	5.72	8.34	9.84
Advice	–	–	6.84
Camp	8.22	15.59	14.67
Control	–	–	–2.52

The above table summarises the results for mean weight loss (%) for all the condition and control groups. All results were significant ($p < 0.001$).

At 4.6 years follow-up, mean % overweight were as follows: group ($n = 19$) 34 (SD 19); individual $n = 13$ (39) (SD 24); summer camp ($n = 30$) 45 (SD 21); and advice ($n = 47$) 45 (SD 30). In total the children had a mean percentage overweight of 42%.

Paired *t* tests revealed significant time effects in four different treatment groups at 4.6 years follow-up: treatment in group ($p < 0.001$); individual treatment ($p < 0.05$); summer camp ($p < 0.001$); and advice group ($p < 0.001$). No significant results were found in comparing the 1-year follow-up with the 4.6-year follow-up.

Other outcomes[6]: In a pilot study, the authors contend that they noticed that eating patterns changed during the treatment.

[6] Details of these outcomes are in the Harms section.

	Paired *t* test on the subscales of the Dutch Eating Disorder Questionnaire (DEBQ) revealed a significant reduction in external eating ($p < 0.001$), a significant increase in restrained eating ($p < 0.001$), and no difference between pre-testing and the 4.6-year follow-up for emotional eating. Mean score on the drive for thinness (DT) subscale of the EDI was 5.6 (SD 5); for the body dissatisfaction (BD) subscale the mean score for the total sample was 13.2 (SD 7) and for the bulimia (B) subscale the mean score was 1.2 (SD 3).
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who completed treatment and follow-up.
Quality and comments	The percentage overweight of the non-clinical control group was lower than in the subjects in the other conditions, although this was taken into account in the analysis. Overall methodologically limited study, with no randomisation.

1
2

Braet 2003 [801]	
Aim	To assess the effect of an inpatient multi-component treatment programme for obese children and adolescents on their weight and psychological well-being
Country and setting	Belgium. Inpatients treatment centre.
Participants	Seventy-six children and adolescents were referred to the centre. Median age in both groups was 13 (range 10–17) years. At baseline median BMI of the study group was 33 (range 22–46) kg/m^2 and the control group 33 (range 24–51) kg/m^2. Children with Prader–Willi syndrome were not recruited.
Recruitment	By referral from physicians for inpatient treatment due to obesity.
Intervention	Every fifth children on the alphabetical list of patients starting treatment in September 1996, 1997 and 1998 was included in this study, resulting in a sample of 38 patients, or 20% of the total group treated. The diet consisted of 30% energy as fat, 15% energy as protein, and 55% energy as CHO, consisting of servings of fruits, three servings of vegetables, 100 g of meat or 150 g of fish, semi-skimmed milk and low-fat cheese, and high fibre staples. It provided between 1500 and 1800 kcal (6.28 and 7.54 MJ)/day. All children received an adapted individual PA training programme for 4 hours/week. Before and after school, the children were encouraged to exercise for 10 hour/week or even more if they wanted.

	Children also received a 12-week CBT programme in small groups, followed by personalised problem-solving-based booster sessions every week. To change their lifestyles, the children were taught self-regulation skills, such as self-observation, self-instruction, self-evaluation and self-reward. A problem-solving approach was introduced to teach the children how to cope with different high-risk situations, and were trained to cope with different stressful situations, such as feeling hungry. Interaction with parents was limited, and children saw the parents every 2 weeks. They received leaflets on how to prepare healthy food and how to (re)organise their shopping habits. Children stayed in the centre for one school year (10 months), and twice per month the children returned home for the weekend. The other two weekends and half of the school-holidays they stayed in the centre.
Delivery of intervention/control	Standardised treatment was developed and supervised by two behaviour therapists and two medical doctors. It was carried out with the help of one dietitian, one psychologist, one social worker, one medical doctor, one physiotherapist and six group leaders.
Dropout rates	Seven children left the programme during the study. At 6 months, data for three children could not be collected, and at 14 months one additional child could not be traced.
Control	For each 38 children, a case-control (based on age and gender) was selected from the waiting list of the centre.
Length of follow-up	14 months.
Results	During treatment, the children in the study group showed a decrease in the median adjusted BMI of –48 (range –4 to –102)%. Median weight loss was –19 (range +2 to –41) kg. At 6 months after finishing the treatment, the median adjusted BMI was 135 (range 105–192)% and at 14 months, it was 143 (range 104–198)%. This was a result of an increase in the adjusted BMI at 6 months follow-up of +6 (range –19 to –37)% and at 14 months follow-up an additional increase of +4 (range –30 to +41)%. At the 14-month follow-up, 13/27 children showed an increase in their overweight of <10% or continued to lose weight compared with their post-treatment weight and 14/27 children had an increase of >10% overweight (up to +41%).
Other outcomes[7]	Eating behaviours showed no increase in eating psychopathology during the 10-month treatment. On the subscales of the EDI, a significant reduction on the drive for thinness subscale was reported ($p < 0.001$) and no change was reported on the bulimia subscale. The scores on the emotional eating and restrained eating showed an insignificant trend, whilst

[7] Details of these outcomes are in the Harms section.

	the scores on the subscale 'external eating' declined significantly, $p < 0.001$. On the Self Perception Profile for Children (SPPC), the scores on three subscales increased significantly during the 10-months treatment: physical appearance, $p < 0.001$; athletic competence, $p < 0.05$; and social competence, $p < 0.05$. On the subscales academic competence, behavioural conduct and global self-worth, no significant trends were found.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only from those who completed the study.
Quality and comments	The therapists were blinded for the study. Not randomised study. Overall poor quality study.

1.4.8 Interventions comparing reinforcement or stimulus control of sedentary behaviours

Epstein 2004 RCT [20]	
Aim	The main goal of the study was to assess whether different methods of reducing targeted sedentary behaviours are associated with differences in the pattern of change in sedentary and active behaviours and in percentage overweight change.
Country and setting	USA. Unclear setting.
Participants	Seventy-two families with 8–12-year-old children with the following inclusion criteria: child being over the 85th BMI percentile, one parent willing to attend treatment meetings, no family members participating in another weight control programme, no child or parent with current psychiatric problems or dietary or exercise restrictions, and child able to read the manuals and complete the self-monitoring of food and activity.
Recruitment	Through physician referral, brochures, fliers, and newspaper advertisements.
Intervention	Families were randomised into one of two treatment groups: reinforced reduced sedentary behaviour or stimulus control of sedentary behaviours. The treatment programme included 16 weekly meetings, followed by two biweekly meetings and two monthly meetings during the 6-month intensive treatment. Families received parent an child family-based weight control workbooks, which included four main sections: 1) introduction to weight control and self-monitoring; 2) the traffic light diet; 3) behaviour change techniques; and 4) maintenance of behaviour change. Families in both groups were taught to praise children for meeting goals specific to their group, and children were also

	provided a contract reinforcement system to motivate children for behaviour change. Preplanning was taught to facilitate eating and exercise control when difficult eating and activity situations could be anticipated, such as parties, holiday gatherings, and school or work functions. All subjects were instructed to reduce hours of targeted sedentary activity to ≤15 per week. Children in the reinforcement group were provided points for reducing their sedentary behaviours to no more than 15 hours/week. The reinforcement group had shaping steps of 25, 20 and 15 hours/week to reduce their sedentary time and were rewarded for meeting their goals. goals were set on the basis of the children's baseline values. Praise and contract goals specific to decreasing targeted sedentary behaviours were used in this group. Children in the stimulus control group were positively reinforced for recording their sedentary behaviours but not for behaviour change. They were also instructed to change their environment to prevent them from engaging in the targeted behaviours and to establish rules regarding the sedentary behaviours. They also received instructions to help sedentary behaviour change, which involved posting signs indicating the sedentary limit and unplugging targeted sedentary activities such as television or computers. In the reinforced reduction group positive reinforcement was contingent on reducing targeted sedentary behaviours, whilst in the stimulus control group positive reinforcement was contingent on recording targeted sedentary behaviours.
Delivery of intervention/control	Therapist.
Dropout rates	8%
Control	Only two treatment groups reported.
Length of follow-up	12 months.
Results (6 month treatment and 12 months follow-up)	There were significant changes in BMI *z*-score, with significant treatment effects observed at both 6 months ($p < 0.001$) and 12 months ($p < 0.001$), but there were no significant differences in the rate of change between groups. BMI *z*-score values for the stimulus control group were 3.3 ± 1.0, 2.3 ± 1.0, and 2.4 ± 1.0, at 0, 6, and 12 months, respectively, whilst the values for the reinforced reduction group at the same time were 3.2 ± 1.0, 2.2 ± 1.1 and 2.6 ± 1.0. Analysis of changes in BMI *z*-score over time as a function of substituters and non-substituters showed significant differences in the rate of change between the two groups ($p < 0.01$), with those who substituted showing greater change at 6 months (BMI *z*-score –1.21 vs. –0.76) ($p < 0.02$) and 12 months (BMI *z*-score –1.05 vs. –0.51) ($p < 0.02$).

	Those who showed complementary relationships between high-energy-density foods and changes in sedentary behaviours also showed stronger BMI *z*-score changes over time ($p < 0.03$), with those who complemented showing greater change at 6 months (BMI *z*-score –1.17 vs. –0.69) ($p < 0.02$), but not at 12 months (BMI *z*-score –0.93 vs. –0.51) ($p = 3.24$).
Other outcomes	Significant decreases in high energy-density (red) foods (–2.6 ± 2.2 servings were observed from 0–6 months ($p < 0.001$), and also significant increases servings of fruits and vegetables (0.6 ± 2.3) ($p < 0.05$). There was also a significant decrease (–2.2 ± 7.4) in percentage of time in targeted sedentary behaviours ($p < 0.05$). There was an effect of substituting PA for targeted sedentary behaviours on targeted sedentary behaviours ($p < 0.001$), with greater decreases at 6 months for those who substituted. greater increases in moderate to vigorous PA were observed at 6 months for those who substituted vs. those who did not substitute ($p < 0.001$). Greater increases in activity level for those who substituted were also observed ($p < 0.001$).
Treatment of dropouts (return to baseline, or last measurement?)	Only complete data from subjects was included for analyses.
Quality and comments	No details of randomisation were given. Subjects were blinded.

1

Epstein 1994 (in Cochrane) RCT [977]	
Aim	To compare mastery criteria and contingent reinforcement with BT.
Participants	*n* = 44 randomised, 39 completed. Age range (mean): 8–12 (10.2 ± 1.1) years. % Male: 26. Weight inclusion criteria: between 20 and 100% overweight for height. Weight on baseline (mean): 59.6% ± 22.0% over the 50th percentile for BMI.
Intervention	Comparison of two behavioural treatments groups: the experimental group (*n* = 17) was targeted and reinforced for mastery of diet, exercise, weight loss and parenting skills; and the control group (*n* = 22) was taught behaviour change strategies and provided non-contingent reinforcement at a pace linked to that of the experimental group. Treatment was given over 26 weekly meetings and 6-monthly meetings.
Control	As described above.
Length of follow-up	2 years.
Results (26 weeks intervention and 6 monthly follow-ups	Mean percentage overweight decreased in the experimental group from 60.6 (SD 25.3) at baseline to 30.5 at 6 months and 34.1 at 1 year. In the control group mean percentage overweight decreased from 58.8 (SD 19.6) at baseline to 38.8 at 6 months and then

up to 2 years)	increased to 42.1 at 1 year.
Other outcomes	Significant changes in red foods per week ($p < 0.05$), days with complete recording ($p < 0.001$), and days within the energy range ($p < 0.025$). No significant differences were observed for graphing weight, child meetings per week, or meeting the exercise goal ($p = 0.12$). Parents showed a significant improvement in knowledge of behavioural principles across time ($p < 0.001$), with equivalent improvements across experimental and control groups.
Quality and comments	Dropouts 11%. Blinding was unclear. Details of randomisation were not provided.

1.5 Pharmacological interventions

1.5.1 Orlistat

Weight loss

Chanoine 2005 RCT	
Aim	To determine the efficacy and safety of orlistat in the weight management of adolescents
Participants	Adolescents (aged 12–16 years) who were overweight (BMI ≥2 kg/m^2 above 95th centile). Total $n = 533$ (357 female, 176 male). Mean age: 13.6 (SD 1.3) years; orlistat ($n = 352$) 13.5 (SD 1.2) years; control ($n = 181$) Mean age 13.6 (SD 1.2) Mean BMI (kg/m^2): 35.7 (SD 4.2) control; 35.4 (SD 4.1) placebo.
Intervention	Diet: Maintained on a nutritionally balanced, hypoenergetic diet designed to produce an initial weight loss of 0.5 to 1.0 kg/week. The energy distribution of the diet was 30% of energy as fat (10% saturated, 10% monounsaturated and 10% polyunsaturated; 70 g/d maximum), 50% as CHO and 20% as protein. Maximum intakes of cholesterol and calcium were 300 mg/d and 1300 mg/d, respectively. Daily energy intake was adjusted during the double-blind treatment period if the participant reached a BMI of 22 kg/m^2 or if the participant was losing weight too rapidly (>1 kg/week). At each study visit, the dietitian spoke with the patient about compliance with diet. Participants in both treatment groups received a commercially available daily multivitamin supplement throughout the study. Activity: Guidelines were provided to encourage regular PA and reduce sedentary behaviour. Strength, flexibility and aerobic activities were included as part of the exercise plan wherever possible. A behavioural psychologist spoke about compliance with the exercise programme at each study visit. Behaviour modification: All centres had behavioural modification programmes in place, but used a study-specific manual as a guideline.

	generally involved recording food intake and activity; limiting high-energy and high-fat foods in the household; restricting food intake to the dining area at meal times; eating slowly; avoiding snacking; encouraging participants to understand their cues for overeating; and substituting new behaviours for overeating. Staff supported and reinforced behavioural modification techniques regularly. Drug: Orlistat 120 mg three times per day.
Control	As above except: Drug: Placebo three times per day.
Length of follow-up	54 weeks (including 2-week pre-treatment phase).
Results	Compared with baseline, both groups lost weight during the first 4 weeks of the study, although participants receiving orlistat lost more weight. Starting at week 4, participants treated with orlistat continued to lose weight steadily to a maximum weight loss at week 12. In contrast, placebo-treated participants' weight was stable during weeks 4 through 12. Subsequently, both groups regained weight, but the effect attributable to the drug (i.e. the between-group difference in body weight) after 6 months was sustained. Significant differences were seen between the orlistat and placebo groups at 12 months for weight change (+0.53 vs. +3.14 kg, $p < 0.001$) and BMI (–0.55 vs. +0.31 kg/m^2, $p = 0.001$). At 12 months, 26.5% of the orlistat group compared with 15.7% of the placebo group lost 5% or more of initial BMI ($p = 0.005$). At 12 months, 13.3% of the orlistat group compared with 4.5% of the placebo group lost 10% or more of initial BMI ($p = 0.002$).
Quality and comments	Blinded assessment not reported explicitly, but described as 'triple blind'. Modified ITT analysis done. Good concealment of allocation (central computerised allocation).
Sponsor details	Hoffman-La Roche.

1

McDuffie 2004	**Before and after study**
Aim	To study the safety, tolerability and potential efficacy of orlistat in adolescents with obesity and its co-morbid conditions.
Participants	Adolescents (aged 12–17 years) who were obese (BMI >95th centile for age, race, sex). Total $n = 20$: ten female, ten male. Mean age 14.6 (SD 2.0) years. Mean BMI 44.1 (SD 12.6) kg/m^2.
Intervention	Diet: 500 (2.09 MJ) kcal deficit/day diet with ≤30% of energy from fat. given multivitamin supplement. Activity: Encouraging 30 min of daily aerobic exercise and inclusion of lifestyle exercise whenever possible, monitored by pedometer readings; and on-site PAs and education led by a recreation therapist for 15–30 min

	of each weekly meeting. Behaviour modification: Goals of the programme were to reinforce dietary principles, encourage PA, discourage inactivity, and provide psychosocial support. The programme used three avenues to achieve these goals: nutrition education, an exercise programme and behaviour modification skills training. Nutrition education review used a game format for 15–30 min during each weekly meeting and homework assignments supplied in a programme manual provided to each subject. The behaviour modification programme concentrated on stimulus control and eating management skills. Compliance was gauged through self-monitoring of medication taken, food eaten, activity performed, amount of inactive time spent and pedometer readings, recorded in a progress book reviewed by the group leaders each week. Points toward winning prizes were awarded each week contingent on a minimum 0.5 lb (0.23 kg) weight loss and a completed progress book. Drug: Orlistat 120 mg three times per day with meals.
Control	No control group – results compared with before treatment.
Length of follow-up	6 months.
Results	At 3 months, mean weight change was –4.4 (SD 4.6) kg ($p < 0.001$), or –3.8 (SD 4.1)% of initial body weight. Mean BMI change was –1.9 (SD 2.5), $p < 0.0002$. At 6 months, mean weight change was –5.4 (SD) ($p < 0.02$) kg, or –3.5 (SD 6.0)% of initial body weight. Mean BMI change was –2.0 ($p = 0.001$) kg/m^2. At 6 months, 30% had lost 5% or more of initial weight and 15% had lost 10% or more. An analysis of the ten African American compared with White participants found that African Americans showed significantly less improvement in weight ($p < 0.05$) and BMI ($p < 0.01$).
Quality and comments	ITT done. Not RCT.
Sponsor details	NICHD grant and National Centre on Minority Health and Health Disparities

1

Norgren 2003 Before and after study	
Aim	To investigate orlistat treatment in obese pre-pubertal children with regard to tolerance, safety and psychological well-being.
Participants	Pre-pubertal children (aged 7–12 years) who were overweight (BMI >4 SDs above normal). Total n =11: seven female, four male. Mean age 10.7 (range 8.3–12.3) years. BMI standard deviation score range of 5.3 to 9.2.
Intervention	Diet: Given detailed information on sources of fat and recommended intake of dietary fat.

	Drug: Orlistat 120 mg with each eating/meal about three times per day (occasionally four times per day).
Control	No control group.
Length of follow-up	12 weeks.
Results	Over the 12 weeks preceding treatment, the children were not subjected to any form of intervention and exhibited a median weight change of +2.6 (range 0.9–6.4) kg, $p = 0.003$. All participants completed the 12-week treatment, resulting in a median weight change of –4.0 (range –12.7 to +2.5) kg, $p = 0.016$. Median BMI changed from 33.3 (range 27.6–37.5) to 31.4 (range 24.4–34.2) kg/m^2, $p = 0.008$.
Quality and comments	Not RCT.
Sponsor details	Swedish Medical Foundation and Swedish Medical Research Council.

1

Ozkan 2004 Quasi-RCT	
Aim	To investigate the efficacy and tolerability of orlistat in adolescents who were obese.
Participants	Adolescents (aged 10–16 years) who were obese (weight for height index >140%). Total $n = 42$: 20 female, ten male (completers only). Mean age 12.9 (SD 2.4) years orlistat ($n = 15$), 12.5 (SD 2.2) control ($n = 15$). Median BMI (kg/m^2) 32.5 orlistat, 31.2 control. Results for completers only. Not sure if age at beginning or end of study.
Intervention	Diet: 20% reduction in daily energy intake. Activity: At least 30 min moderate exercise per day. Drug: Orlistat 120 mg three times per day.
Control	As above except: Drug: No placebo offered.
Length of follow-up	Mean duration of follow-up (months): 11.7 (SD 3.7) orlistat, 10.2 (SD 3.7) control (not significant).
Results	Compared with initial body weight, the orlistat group showed a mean weight change of–6.27 (SD 5.4) kg, while the control group showed a mean weight change of +4.16 (SD 6.45) kg, $p < 0.001$. Compared with initial BMI, the orlistat group showed a mean change of –4.09 (SD 2.9) kg/m^2, while the control group showed a mean change of +0.11 (2.49) kg/m^2, $p < 0.001$. Compared with initial body weight, the orlistat group showed a mean weight change of –7.65 (SD 6.5)%, while the control group showed a mean weight change of +5.70 (SD 8.30)%, $p < 0.001$.
Quality and	Significantly higher BMI in the orlistat group at beginning of study

comments	(p = 0.018). Not placebo controlled. Quasi-randomised (alternation). Concealment of allocation and outcome assessment assessed as addressed. Blinding and ITT not reported.
Sponsor details	Turkish Academy of Sciences.

1

Zhi 2003 RCT	
Aim	To assess whether orlistat has an effect on the physiologic balance of minerals (calcium, phosphorus, magnesium, iron, zinc, copper).
Participants	Adolescents (aged 12–16 years) who were obese (BMI ≥85th centile adjusted for age and gender). Total n = 32: 19 female, 13 male. Mean age (years): 14 (SD 1) orlistat (n = 16), 14 (SD 1) placebo (n = 16). Mean BMI (kg/m^2): 34 (SD 6) orlistat, 34 (SD 8) placebo.
Intervention	Diet: Approximately 18% and 28–40% lower than average energy intake for female and male participants responses. Approximately 30% of energy from fat. Drug: Orlistat 120 mg three times per day
Control	As above except: Drug: Placebo three times per day.
Length of follow-up	21 days.
Results	At 3 weeks, mean weight change from initial body weight was –7.0% for the orlistat group and –7.8% for the placebo group.
Quality and comments	Aim was not weight loss. Randomisation, blinding and ITT not reported. Concealment of allocation and baseline comparison assessed as poor.
Sponsor details	Hoffman-La Roche.

2 **Other outcomes**

Chanoine 2005 RCT	
Results	No significant differences were found between the two groups with regard to changes in lipid or glucose levels. Participants treated with orlistat experienced significantly greater decreases from baseline to end-point in both waist circumference (–2.67 vs. –0.89 cm, p = 0.01) and hip circumference (–1.52 vs. –0.10 cm, p = 0.01) than participants receiving placebo. At 12 months, diastolic blood pressure decreased in participants treated with orlistat and increased in placebo recipients (–0.51 vs. +1.30 mmHg, p = 0.04). There was no statistically significant change in systolic blood pressure, lipid, triacylglycerol or fasting plasma glucose levels. In general, levels of vitamins A, D and E and beta-carotene were within the

	normal range and increased in both groups during treatment. The levels of oestradiol among girls decreased from baseline in the orlistat group compared with a slight increase in the placebo group (–7.5 vs. +0.7 pg/ml; $p = 0.05$) at study end. There was no significant difference in height gain between groups. Participants in both groups experienced normal sexual maturation, as shown by changes in Tanner stage over the 52 weeks of the study. In the subgroup of participants undergoing dual-energy X-ray absorptiometry (DEXA) evaluation, bone mineral content (+182 g in the orlistat group and +177 g in the placebo group) and bone mineral density (+0.04 g/cm^2 in both groups) increased similarly in the two treatment groups independently of sex. Participants in the orlistat group (+2312 g) gained a similar amount of fat-free body mass as those in the placebo group (+2116 g). However, participants in the orlistat group lost significantly more fat mass than those in the placebo group (–2401 g in the orlistat group vs. –380 g in the placebo group; $p = 0.03$).
Quality and comments	All participants were given a multivitamin tablet.

1

McDuffie 2004 Before and after study	
Results	At 6 months, mean total cholesterol levels had decreased from 4.46 (SD 0.03) to 3.88 (SD 0.12) mmol/l ($p < 0.0001$), and LDL decreased significantly ($p < 0.001$) from 3.01 (SD 0.03) to 2.51 (SD 0.03) mmol/l. No significant changes were seen for HDL-cholesterol, HDL/LDL ratios or serum triacylglycerol. Fasting insulin and fasting glucose were significantly ($p < 0.02$ and $p < 0.003$, respectively) after treatment. No significant changes were seen in serum vitamin A and E levels. Serum iron rose ($p < 0.02$) but was within the normal range. Mean vitamin D levels were significantly reduced ($p < 0.02$) after 1 month of orlistat treatment.
Quality and comments	Converted mg/dl to mmol/l.

2

Norgren 2003 Before and after study	
Results	Plasma cholesterol and triacylglycerol did not change significantly during treatment. Neither did the cholesterol and triacylglycerol content of the high-, low- or very-low-density lipoprotein fractions. Serum levels of vitamin D (1,25-hydroxycholecaliferol) did not decrease significantly, while the levels of vitamin E and A showed minor U-shaped variation profiles. The eating attitudes of the participants were influenced by treatment, as investigated by the Children's Eating Attitudes Test (ChEAT). The maximal total score is 78, and a score above 20 has been taken to suggest anorexia nervosa. The mean ChEAT score of randomly selected Swedish

	children of similar age as the participants in this study (fifth graders) is 2.0 for girls and 2.5 for boys. The median total score of the participants increased from 7 to 10 ($p = 0.011$). The median score reflecting 'dieting' increased from 3 to 5 ($p = 0.041$) and the score reflecting 'oral control' (personal and social control of eating behaviour) from 3 to 4 ($p = 0.034$), while the score reflecting 'bulimia' did not change. There was no indication of clinical depression before or after treatment as assessed by Children's Depression Inventory (CDI). Instead, treatment resulted in a non-significant trend towards improved self-image. After treatment, the children identified their own physique with a thinner silhouette, while the silhouette they aspired to remained the same. In addition, they perceived losing weight to be less difficult after treatment, and there was a non-significant trend towards increased motivation to lose weight.
Quality and comments	–

1

Ozkan 2004 Quasi-RCT	
Results	No other outcomes reported.
Quality and comments	–

2

Zhi 2003 RCT	
Results	Dietary fat absorption was inhibited by approximately 27%. No significant changes were seen in mineral balance between the groups, or in serum or urine electrolytes, or urinary creatinine excretion.
Quality and comments	–

3 **Reported harms**

Chanoine 2005 RCT	
Harms	In total, 97% of participants in the orlistat group and 94% in the placebo group reported at least one adverse event during the 1-year study. Twelve orlistat and three placebo participants discontinued treatment because of adverse events. The most common adverse events were gastrointestinal tract-related; these were more common in the orlistat group. The majority of participants reporting gastrointestinal tract adverse events reported one event. Gastrointestinal tract adverse events were mostly mild to moderate in intensity and led to discontinuation in 2% of the orlistat group. The decrease in BMI was not affected by gastrointestinal tract adverse events in the orlistat group. Overall, 3% of participants in each group had at least one serious adverse event. The five serious adverse events in the placebo group were acute demyelinating encephalomyelitis, facial palsy, pneumonia, worsening of asthma, and pain in the right side. The 11 serious adverse events in the orlistat group were pilonidal abscess, depression ($n = 2$), asthma attack,

	seizure, admission for repair of deviated nasal septum, appendicitis, cholelithiasis, gallbladder disorder followed by cholecystectomy, adenoidal hypertrophy and aseptic meningitis. Only the symptomatic cholelithiasis that led to cholecystectomy in a 15-year-old girl treated with orlistat was considered possibly related to study medication by the investigators; the patient had lost 15.8 kg by the time of the adverse event. Ultrasound revealed multiple tiny gallbladder calculi but no gallbladder thickening, pericholecystic fluid, or dilated biliary tree. No child developed acute cholecystitis during the study. One placebo and ten orlistat recipients developed abnormalities during the study that were detected on electrocardiograms. None of these were believed to be related to the medication based on review by an independent cardiologist. Pulse (76 beats per min) and QT segment length (410 ms) were similar in both groups and were not affected by the intervention.
Quality and comments	–

1

McDuffie 2004 Before and after study	
Harms	One participant withdrew due to gastrointestinal events. At 3 months, gastrointestinal events were generally mild and transient.
Quality and comments	–

2

Norgren 2003 Before and after study	
Harms	All suffered diarrhoea on at least one occasion, but only after intake of high-fat products. Two children had frequent diarrhoea and two children reported mildly increased flatulence.
Quality and comments	–

3

Ozkan 2004 Quasi-RCT	
Harms	Mild gastrointestinal complaints were experienced in all participants receiving orlistat. Seven withdrew due to intolerable side effects.
Quality and comments	–

4

Zhi 2003 RCT	
Harms	Fifteen orlistat and 13 placebo participants experienced at least one adverse event. Incidence was similar in both groups for most body systems. But a higher proportion of those in the orlistat group experienced gastrointestinal events (25 vs. 13). Adverse events were of mild or moderate intensity, and

	resolved without discontinuation of treatment. No serious adverse events were reported. No clinically significant findings were noted in vital signs or laboratory test parameters.
Quality and comments	–

1 **Generalisability**

Chanoine 2005 RCT	
Country and setting	Canada and USA? Institutions with paediatric obesity programmes.
Participants (included/excluded)	Included if adolescents (aged 12–16 years) with BMI 2 units or higher than the US weighted mean for the 95th percentile based on age and sex, had a parent or guardian prepared to attend study visits with them, and were willing to be actively involved in behavioural modification. Excluded if BMI ≥44 kg/m^2 (to increase homogeneity of the group); body weight of ≥130 or <55 kg; weight loss of ≥3 kg within 3 months prior to screening; diabetes requiring antidiabetic medication; obesity associated with genetic disorders; history or presence of psychiatric disease; use of dexamphetamine or methylphenidate; active gastrointestinal tract disorders; ongoing bulimia or laxative abuse; and use of anorexiants or weight-reduction treatments during the 3 months before randomisation.
Recruitment	Advertisements in clinics, direct referrals from family physicians, newspaper advertisements.
Intervention (mode and intensity)	Eighteen visits total – every 2 weeks for first four months, then every 2 months until study end.
Duration of active intervention	52 weeks (2-week pre-treatment phase).
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Dietitian spoke with participants about compliance with diet at each study visit. Behavioural psychologist spoke about compliance with the exercise programme at each study visit. Staff at the study centres supported and reinforced the behavioural modification techniques regularly.
Dropout rates	34% orlistat and 35% placebo at 12 months.
Treatment of dropouts (return to baseline, or last measurement?)	Last observation carried forward.

2

McDuffie 2004 Before and after study

Country and setting	USA.
Participants (included/excluded)	Included if BMI greater than the National Health and Nutrition Examination Survey (NHANES) I (1971 to 1974) 95th percentile for age, sex, and race and the presence of one of the following obesity-related co-morbidities: hypertension, type 2 diabetes or glucose intolerance, hyperinsulinaemia (insulin 15 μU/l), hyperlipidaemia (total triacylglycerol 200 mg/dl, total cholesterol >200 mg/dl or LDL-cholesterol 130 mg/dl), hepatic steatosis or sleep apnoea documented by a formal sleep study. Excluded if a major pulmonary, hepatic, cardiac or musculoskeletal disorder, had a history of substance abuse or other psychiatric disorder that would impair compliance with the study protocol, had used an anorexiant in the past 6 months, or had lost weight in the past 2 months. Each adolescent, along with a parent, gave written consent for protocol participation.
Recruitment	Newspaper advertisements and letters to local physicians.
Intervention (mode and intensity)	6 months – three inpatient assessments (baseline, 3 months and 6 months). Follow-up evaluations every month after end of 12-week behavioural programme.
Duration of active intervention	6 months.
Control (mode and intensity)	No control group.
Delivery of intervention/control (who)	Registered dietitian gave and reviewed dietary advice. Behavioural modification programme led by two registered dietitians, one of whom had graduate psychology training, and a recreation therapist who was also a health fitness instructor. Clinical system pharmacist reviewed medication and unexpected events.
Dropout rates	15% at 6 months.
Treatment of dropouts (return to baseline, or last measurement?)	Last observation carried forward.

1

Norgren 2003 Before and after study	
Country and setting	Sweden. National Centre for Childhood Obesity.
Participants (included/excluded)	Included if aged 7–12 years and primary obesity with a body mass index standard deviation score (BMI SDS) of more than 4 SD above normal Excluded if recognisable syndromes, chromosomal aberrations, eating disorders, severe psychological disorders, endocrine disorders other than those generally considered

	secondary to obesity, growth retardation and severe asthma.
Recruitment	Successive referrals to the centre.
Intervention (mode and intensity)	Assessed at the clinic at weeks 1, 2, 4, 8, 12. Weekly telephone contact.
Duration of active intervention	12 weeks.
Control (mode and intensity)	No control.
Delivery of intervention/control (who)	Weekly telephone contact with a specialist paediatric nurse.
Dropout rates	0% at 12 weeks.
Treatment of dropouts (return to baseline, or last measurement?)	No missing data.

1

Ozkan 2004 Quasi-RCT	
Country and setting	Turkey. Study centres – no details.
Participants (included/excluded)	Included if aged 10–16 years, severe exogenous obesity (weight for height index >140%), otherwise healthy, Tanner stage 2 or higher. Excluded if obesity associated with endocrinopathy, genetic syndromes or medications.
Recruitment	Recruited from referrals – no further details.
Intervention (mode and intensity)	Seen monthly by the dietitian and in the outpatient clinic every 2 months.
Duration of active intervention	Varied (approximately 10–11 months).
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Programme administered by paediatric endocrinologist, paediatrician and dietitian at each centre.
Dropout rates	32% orlistat and 25% control at study end.
Treatment of dropouts (return to baseline, or last measurement?)	Not reported.

2

Zhi 2003 RCT	
Country and setting	USA. Research centre.
Participants	Included if aged 12–16 years, obese (BMI ≥85th centile

(included/excluded)	adjusted for age and gender), otherwise healthy. Excluded if menstruating or expected to menstruate within study period (due to differences in mineral balance).
Recruitment	No details.
Intervention (mode and intensity)	Inpatient unit for 21 days.
Duration of active intervention	21 days.
Control (mode and intensity)	As above.
Delivery of intervention/control (who)	Dietitian prepared diet regimen.
Dropout rates	6% orlistat, 6% placebo at 21 days.
Treatment of dropouts (return to baseline, or last measurement?)	Not reported.

1
2

1.5.2 Sibutramine

Weight loss

Berkowitz 2003	
Aim	To assess whether increased weight loss in obese adolescents is induced when sibutramine is added to a family-based, behavioural weight control programme.
Participants	Eighty-two boys and post-menarcheal girls aged 13–17 years who had a BMI of 32 to 44 kg/m^2.
Intervention	Thirty-nine assigned to receive BT and placebo, and 42 assigned to receive BT and sibutramine. Behavioural programme: Both groups received the same family-based behavioural weight-loss programme.[8] In phase 1 participants attended 13 weekly group sessions followed by six biweekly group sessions. In phase 2, group sessions were held biweekly from months 7 to 9 and monthly from months 10 to 12. Diet: Both groups were instructed to consume a 1200–1500 kcal (5.02–6.28 MJ)/day diet of conventional foods, with approximately 30% of energy from fat, 15% from protein, and the remainder from CHO. PA: Goal of walking or similar aerobic activity for 120 min per week or more. Drug: During phase 1 all participants received placebo the first week. At week 2, they received either placebo or 5 mg of sibutramine/day. In the treatment group, sibutramine was increased to 10 mg/day at week 3 and to 15 mg/day at week 7. In participants whose systolic or diastolic blood pressure increased from baseline by 10 mmHg or more for two or more visits had their dosage reduced in 5 mg decrements until acceptable blood pressure and pulse rate were restored. Sibutramine was discontinued in participants in whom dose reductions did not reverse the 10 mmHg or more increase or in which systolic or diastolic blood pressure increased 20 mmHg or more at any single visit.
Control	Behavioural protocol and placebo up to 6 months. Following this all the participants received the same titration schedule as for phase 1.
Length of follow-up	12 months.
Results	At month 6, participants in the BT and sibutramine group had a mean weight change of –7.8 (SD 6.3) kg and had a mean change of –8.5 (SD 6.8)% in BMI, which was significantly more than weight change of –3.2 (SD 6.1) kg and change in BMI of –4.0 (SD 5.4)% in the BT and placebo group ($p = 0.001$). From months 7 to 12, adolescents initially treated with sibutramine had a mean weight change of 0.8 (SD 10.5) kg, corresponding to a BMI change of 0.2 (SD 5.4)%, with continued use of the medication, whereas those who switched from placebo to sibutramine had an additional weight change of –1.3 (SD 5.4) kg, corresponding to a mean BMI change of –2.4 (SD 5.0)%. The difference between groups was not significant. From baseline to month 12, participants with BT and sibutramine had a

[8] Need to tease out more details.

	weight change of –7.0 (SD 9.3) kg equal to a BMI change of –8.6 (SD 9.9)%. Participants in the BT and placebo group who changed at month 7 to sibutramine had a weight change of –4.5 (SD 8.8) kg corresponding to a BMI change of –6.4 (SD 8.3)%. The difference between groups was not significant.
Quality and comments	Randomised, double-blind, placebo-controlled trial. Parents, participants and all study personnel were blinded to treatment condition during phase 1, with only the research pharmacist being aware of the process. Placebo capsules were identical to the sibutramine ones, and were dispersed in the same way. Adolescents with a BMI >44 kg/m^2 or who had already developed type 2 diabetes were excluded.
Sponsor details	Grant from the NIH and grant from the General Clinical Research Centre of the Children's Hospital of Philadelphia. Knoll Pharmaceutical Co. and Abbott Laboratories provided sibutramine and placebo and unrestricted educational grant.

1

Godoy-Matos 2005	
Aim	To determine the efficacy and safety of sibutramine in obese adolescents.
Participants	Sixty boys and girls aged 14–17 years, with a BMI of 30–45 kg/m^2. $n = 30$ to each group.
Intervention	Diet: All patients received dietary counselling to achieve an energy deficit of 500 kcal (2.10 MJ)/day at the start of the run-in phase. The recommended diet composition was approximately 30% of energy from fat, 20% from protein and 50% from CHO. PA: Aerobic moderate exercises for at least 30 min/day. Drug: During the single-blind run-in period, all participants received a placebo capsule. Subjects who completed the run-in period and returned less than 25% of the prescribed capsules were randomised to receive sibutramine (10 mg/day) or matching placebo capsules without regard to weight loss during the run-in period. Subjects were instructed to take their capsule in the morning.
Control	Placebo and same diet and PA as described above.
Length of follow-up	4 weeks followed by 6 months.
Results	Compared with baseline, participants in the sibutramine group had a weight change of –10.3 (SD 6.6) kg, and those in the placebo group –2.4 (SD 2.5) kg ($p < 0.001$). The mean BMI change was also significantly greater in the sibutramine group –3.6 (SD 2.5) kg/m^2 than in the placebo group –0.9 (SD 0.9) kg/m^2; $p < 0.001$.
Quality and comments	Randomised, double-blind, placebo-controlled trial.
Sponsor details	Abbott Laboratories.

2

1.5.3 Other outcomes

Berkowitz 2003	
Results	Significantly greater reductions in hunger ($p = 0.002$) also were reported by participants who received BT and sibutramine. There were no differences between groups during phases 1 or 2 in changes in lipids, triacylglycerol, serum insulin, serum glucose or homeostasis model of insulin sensitivity. At month 12 there was a significant increase in HDL-cholesterol ($p = 0.001$) and significant reductions in serum insulin ($p < 0.001$). Systolic blood pressure decreased 3.6 (SD 8.6) mmHg at 3 months in the BT and placebo compared with a significant increase of 1.8 (SD 10.7) mmHg in the sibutramine group. At month 6 values were –4.0 (SD 8.9) and 0.4 (SD 9.0) mmHg, respectively. There were no other significant differences between groups at any period in changes in systolic or diastolic blood pressure
Quality and comments	–

Godoy-Matos 2005	
Results	No statistical difference was observed between groups in cardiovascular parameters. Nonetheless, systolic and diastolic pressures as well as heart rate tended to decrease more in the placebo than in the sibutramine group. There was a significant decrease in triacylglycerol and very-low-density-lipoprotein-cholesterol levels at week 24 ($p < 0.05$) in the sibutramine group compared with the baseline figures.
Quality and comments	–

1.5.4 Reported harms

Berkowitz 2003	
Results	Sibutramine was discontinued in ten participants (six due to increased blood pressure and or pulse rate; two for ecchymoses, one had ventricular premature complexes (VPCs), and 1 due to rash of unclear aetiology. One participant had VPCs after 6 months of treatment, and continued to have VPCs in the following 6 months after discontinuation. A second adolescent reported to have VPCs at month 9, 3 weeks after discontinuation of the medication because of elevation of blood pressure and pulse rate.
Quality and comments	–

Godoy-Matos 2005	
Results	The only difference that was statistically significant between groups was for constipation ($p = 0.039$), having 40% in the sibutramine group and 13% in the placebo group. No significant event was reported or withdrawal due to adverse events.
Quality and comments	–

1.5.5 Generalisability

Berkowitz 2003	
Country and setting	USA. University outpatient research weight control programme.
Participants (included/excluded)	Contraindications for participation in the study: cardiovascular disease; type 1 or 2 diabetes mellitus, major psychiatric disorders; pregnancy; use of a weight-loss medication or a weight-loss of ≥5 kg in the previous 6 months; use of medications promoting weight gain; use of medications contraindicated with use of sibutramine; or cigarette smoking.
Recruitment	Not clear.
Intervention (mode and intensity)	Behavioural programme: Both groups received the same family-based behavioural weight-loss programme. In phase 1 participants attended 13 weekly group sessions followed by six biweekly group sessions. In phase 2, group sessions were held biweekly from months 7 to 9 and monthly from months 10 to 12. Groups were led by dietitians, psychologists or psychiatrists. Diet: Both groups were instructed to consume a 1200–1500 kcal (5.02–6.23 MJ)/day diet of conventional foods, with approximately 30% of energy from fat, 15% from protein, and the remainder from CHO. PA: Goal of walking or similar aerobic activity for 120 min per week or more. Drug: During phase 1 all participants received placebo the first week. At week 2, they received either placebo or 5 mg of sibutramine/day. In the treatment group, sibutramine was increased to 10 mg/day at week 3 and to 15 mg/day at week 7. In participants whose systolic or diastolic blood pressure increased from baseline by 10 mmHg or more for two or more visits had their dosage reduced in 5 mg decrements until acceptable blood pressure and pulse rate were restored. Sibutramine was discontinued in participants in whom dose reductions did not reverse the 10 mmHg or more increase or in which systolic or diastolic blood pressure increased 20 mmHg or more at any single visit.
Duration of active intervention	12 months.
Control (mode and intensity)	Behavioural protocol and placebo up to 6 months. Following this all the participants received the same titration schedule as for phase 1.
Delivery of intervention/control (who)	Behavioural assessment performed by staff psychologist or psychiatrist. Adolescent's primary care physician performed a history and physical examination to exclude the possible contraindications.
Dropout rates	12%
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed using the baseline-carried forward technique.

1

Godoy-Matos 2005	
Country and setting	Brazil. Outpatient University Research Centre.
Participants (included/excluded)	Boys and girls aged 14–17 years, with a BMI of 30–45 kg/m^2. To avoid growth variation, all participants were required to have adult bone age, determined by left-hand radiography. Contraindications to be enrolled in the study were: diabetes mellitus, endocrine disease predisposing to obesity, severe hyperlipidaemia, systemic of major psychiatric disorders, history of bulimia or anorexia, uncontrolled hypertension or other cardiovascular diseases, weight loss of ≥3 kg within 2 months or use of weight loss or weight gain drugs within 3 months before recruitment, drug or alcohol abuse, recent tobacco cessation or intention to quit during study period, and pregnancy or lactation.
Recruitment	Not reported.
Intervention (mode and intensity)	Diet: All patients received dietary counselling to achieve an energy deficit of 500 kcal (2.09 MJ)/day at the start of the run-in phase. No additional visits to the dietitian were allowed. The recommended diet composition was approximately 30% of energy from fat, 20% from protein, and 50% from CHO. This study was designed to reproduce a regular clinical setting so structured behavioural counselling was not employed. PA instructions were delivered by the attendant doctor in a brief written protocol aimed to obtain mainly aerobic moderate exercises for at least 30 min/day. Drug: During the single-blind run-in period, all participants received a placebo capsule. Subjects who completed the run-in period and returned less than 25% of the prescribed capsules were randomised to receive sibutramine (10 mg/day) or matching placebo capsules without regard to weight loss during the run-in period. Subjects were instructed to take their capsule in the morning
Duration of active intervention	4 weeks followed by 6 months.
Control (mode and intensity)	Placebo and same diet and PA as described above.
Delivery of intervention/control (who)	Dietary counselling provided by dietitian. PA instruction was delivered by the attendant doctor.
Dropout rates	16.6%
Treatment of dropouts (return to baseline, or last measurement?)	ITT analysis was performed using the last observation carried forward technique.

2
3

1.6 Surgery

1.6.1 Restrictive Surgery

Laparoscopic adjustable gastric banding

Abu-Abeid 2003	
Aim	To evaluate the surgical management of severe morbid obesity in adolescents.
Country and setting	Israel.
Participants	Eleven adolescents aged 11–17 years, mean BMI was 46.6 (range 38–56.6) kg/m^2 and all patients fulfilled the NIH criteria for morbid obesity. One patient suffered from heart failure and pulmonary hypertension. Two additional patients had amenorrhea and another had gallstones. Three patients suffered from recurrent boils, two from skin rashes, and another seven from stretch marks. The most common complaint of patients before surgery was offensive body odour and unpleasant appearance.
Intervention	Before referral to the centre, the adolescents had been under the care of a dietitian for at least 1 year and had failed to loose weight even with a low-energy diet of 800 kcal (3.35 MJ)/day. Additionally three patients had their jaws wire-clamped, and two patients had been hospitalised for protracted fasting of 3 to 6 months. All patients underwent psychological evaluation preoperatively, and were counselled with their families about the lifestyle change that need to occur as a result of the surgery. Postoperative emotional support was provided for patients and their families in addition to the appropriate physical follow-up. All patients underwent laparoscopic adjustable gastric banding (LAGB). Patients were observed for 24 hours postoperatively and then were discharged after and additional meeting with a dietitian. Abdominal ultrasound scan was done 6 months postoperatively in all patients. All patients received vitamin supplements after surgery and were followed up closely for deficiencies.
Length of follow-up	23 months.
Results	Mean BMI fell to 32.1 kg/m^2 during the 23-months follow-up.
Other outcomes	The two patients with high triacylglycerol levels before surgery, had normal levels after weight reduction; however, cholesterol levels remained elevated in the patient with abnormal preoperative

	levels. There was one patient who was very ill with debilitating heart failure and pulmonary hypertension, and did very well after the surgery and was able to return to school without being hospitalised since surgery. All adolescents reported and improvement in overall well-being; they were more physically active, more socially involved with their peers and reported feeling happier than before surgery. Four girls required additional iron supplements for iron deficiency anaemia and menstruation began in the two girls suffering from amenorrhea before surgery.
Reported Harms and complications	One patient remained under observation for and additional 24 hours because of severe postoperative co-morbid disease. No patient suffered perioperative complications, and there were no late complications during the follow-up period. None of the patients had choleslithiasis during the follow-up period.
Quality and comments	Overall very poor case series. No statistical power information given. No information on excess weight loss.

1

Dolan 2003 (only adolescents) and 2004	
Aim	To compare LAGB in adolescents and adults.
Country and setting	Australia.
Participants	Adolescents aged 12–19 years, median weight and BMI were 127.9 (range 82.9–218.8) kg and 42.2 (range 30.3–70.5) kg/m^2, respectively. The ages of the adults ranged from 23 to 70 (median 41) years. Preoperatively, their median weight and BMI were 110.9 (range 77.2–221.5) kg and 41.8 (range 30.1–71.5) kg/m^2, respectively.
Intervention	Before referral to the centre, the adolescents had been under the care of a dietitian for at least 1 year and had failed to lose weight even with a low-energy diet of 800 kcal (3.35 MJ)/day. Additionally three patients had their jaws wire-clamped, and two patients had been hospitalised for protracted fasting of 3 to 6 months. All patients underwent psychological evaluation preoperatively, and were counselled with their families about the lifestyle change that need to occur as a result of the surgery. Postoperative emotional support was provided for patients and their families in addition to the appropriate physical follow-up. All patients underwent LAGB. Patients were observed for 24 hours postoperatively and then were discharged after and additional meeting with a dietitian. Abdominal ultrasound scan was done 6 months postoperatively in

	all patients. All patients received vitamin supplements after surgery and were followed up closely for deficiencies
Length of follow-up	25 months for adolescents and 26 months for adults.
Results	Postoperatively there were no significant differences in weight loss between the adolescents and the adults. BMI fell to 32.3 (range 22.4–52.6) kg/m^2 at 12 months and further to 30.2 (range 22.6–39.4) kg/m^2 at 24 months, compared with 32.5 (range 25.5–54.0) kg/m^2 and 33.1 (range 28.1–41.3) kg/m^2 in adults. Adolescents lost a median of 49 (range 30.1 to 82.3)% of their excess weight body weight at 12 months, compared with 43.6 (range 23.9–80.6)%. In adults. At 24 months, excess weight loss was 69.3 (range 46.8–111.8)% in adolescents and 52.8 (range 29.9 to 84.4)% in adults. At 24 months follow-up, 81.8% of adolescents and 63.6% of adults had lost ≥50% of their excess body weight.
Other outcomes	No other outcomes reported.
Reported Harms and complications	In one patient, the band slipped 11 months after insertion and was repositioned laparoscopically; another patient required replacement of a leaking port. Only one adult suffered a port site infection.
Quality and comments	Overall very poor case series. No statistical power information given.

1

Horgan 2005	
Aim	To describe the first US experience in LAGB in morbidly obese adolescents.
Country and setting	USA.
Participants	Four patients (two adolescent girls aged 17 and 19 years, and two adolescent boys aged 17 and 18 years). Mean weight and BMI were 147 ± 25 (range 118–165) kg and 51 ± 9 (range 40–61) kg/m^2 respectively. Two patients had symptoms of heartburn without documented gastroesophageal reflux disease and two patients complained of joint and musculoskeletal complaints requiring over-the-counter antacids and analgesics for symptom relief. One patient had a previous laparoscopic cholecystectomy.
Intervention	All patients were fully ambulating within 1 hour after surgery and discharged on the same day.
Length of follow-up	Up to 30 months.

Results	The first patient had a 57% excess weight loss at 30 months, the second patient had a 34% excess weight loss at 12 months and the third patient at 7 months had a excess weight loss at 87%. The fourth reported 15% at 4 months.
Other outcomes	No other outcomes reported.
Reported harms and complications	No early complications were reported. A late complication occurred in the patient with the most rapid weight loss who developed a cholecystitis 6 months postoperatively and was discharged uneventfully after outpatient laparoscopic cholecystectomy.
Quality and comments	Retrospective case series. Poor quality, no statistical power information provided.

1

Widhalm 2004	
Aim	To evaluate LAGB in severely obese adolescents.
Country and setting	Germany.
Participants	All patients had previously underwent several therapies such as diet camps, diet counselling and BT, some where placed on very-low-energy diets and some took drugs like sibutramine or orlistat for a short period of time. All gained weight after the time. Furthermore, the patients had psychological problems and did not want to continue with any kind of dietary programme. One patient with Prader–Willi syndrome was also included due to continuous weight gain despite treatment with sibutramine. The Depression Inventory for Adolescents (DIKJ) showed that all the patients suffered from depressive symptoms and a very low self-esteem.
Intervention	Psychological tests were carried out in order to exclude eating disorders and to find out if there were any psychological disturbances.
Length of follow-up	10.5 ± 6 months.
Results	The mean weight loss was 25.0 ± 3.8 kg, which corresponds to 15.9% reduction of the initial body weight.
Other outcomes	All parents reported that the adolescents were now able to eat without having extreme hunger or appetite, and that they felt that loosing weight was after all possible.
Reported Harms and complications	In all eight patients, no major problems were reported.
Quality and comments	Case study. Poor quality, poor statistical power information provided.

1

Knerr 2002	
Aim	To evaluate LAGB in a 13-year-old girl with severe obesity and end-stage renal insufficiency.
Country and setting	Germany.
Participants	13-year-old girl with type 2 diabetes mellitus and arterial hypertension, present with nausea and chronic fatigue. Weight 101 kg, BMI 36.7 kg/m^2, Tanner stage 4, age at menarche 12 years, uraemic odour, pallor and arterial hypertension were evident (blood pressure 149/99 mmHg, hypertensive retinopathy grade IV). End-stage renal failure with renal anaemia hyperkalaemia, metabolic acidosis and preserved diuresis with isostenuria. A hand radiograph revealed features of renal osteopathy due to severe secondary hyperparathyroidism. Therapy with antihypertensive drugs was started and vitamin D, calcium supplementation, calcium acetate, bicarbonate, iron and erythropoietin were given. A renal biopsy was not possible due to the patient's extreme fat mass and fibrotic, hypoplastic kidneys. Normal growth.
Intervention	From the start, dietary recommendations (restriction of energy intake to 1200 kcal (5.02 MJ)/day, restriction of fat, potassium and phosphate) and psychological support for handling the diagnosis and weight reduction were given, and PA was recommended. The severe obesity did not improve even with in-patient exercise programme, dietary restriction to 800 kcal (3.35 MJ)/day for 6 weeks. Daily energy intake was still restricted to 1200 kcal (5.02 MJ)/day and PA was recommended at least twice per week. A token system was started for positive feedback and psychological supervision was given once per week.
Length of follow-up	Up to 30 months.
Results	Changes in her eating habits led to a weight stabilisation at 100 kg. During the following 3 months a weight loss of 14 kg was observed. Her total weight loss was 24 kg. Her weight after 3 months was 80 kg, and BMI 28 kg/m^2 (2.2 SDs, 97–99.5th percentile).
Other outcomes	No other outcomes reported.
Reported harms and complications	Eight weeks after the implantation the gastric band was tightened with a single injection of 2 ml of physiological saline solution. A Cimino stunt was installed for renal replacement therapy, but disturbed wound healing and shunt thrombosis led to early shunt impairment.
Quality and	Case study. Poor quality, poor statistical power information

comments	provided.

1
2

Angrisani et al. 2005	
Aim	The aim of this study is to evaluate results of LAGB in obese teenagers
Country and setting	Italy. Italian Collaborative Study group.
Participants	Criteria for patients to be considered for surgery were as follows: BMI ≥40 or ≥35 kg/m^2 with co-morbidities, supportive family environment, failure to obtain weight loss after ≥1 years of conservative medical treatment, psychological maturity of patients with demonstration of decisional capacity, and willingness to be operated on and to follow postoperative guidelines. Preoperative assessment was obtained by a multidisciplinary team on the basis of internist and psychiatric evaluations. Patients affected by psychiatric or genetic disorders (i.e. Prader–Willi syndrome) were excluded. Fifty-eight (1.5%) of 3813 patients operated on with the Lap-Band System from January 1996 to December 2003 were ≤19 years old. There were 47 female/11 male; mean age was 17.96 ± 0.99 (range 15–19) years; mean BMI was 46.1 ± 6.31 (range 34.9 – 69.25) kg/m^2; and mean % excess weight was 86.4 ± 27.1 (range 34–226). Sixteen of the 58 (27.5%) patients were super-obese (BMI ≥50 kg/m^2). In 27/58 (46.5%) patients, one or more co-morbidities were diagnosed: anxiety or depression (*n* = 11), hypertension (*n* = 8), dyslipidaemia (*n* = 6), diabetes (*n* = 8), osteoarthropathy (*n* = 12), sleep apnoea (*n* = 10) and amenorrhea (*n* = 4).
Intervention	The band was placed via perigastric access in all but three patients, in whom the pars flaccida technique was completed. On the first postoperative day, intravenous saline, proton pump inhibitors and antiemetics were given. Patients were discharged when able to tolerate oral fluids with oral therapy.
Length of follow-up	Up to 7 years.
Results	Patient follow-up at 1, 3, 5, and 7 years was 48/52 (92.3%), 37/42 (88.1%), 25/33 (75.7%) and 10/10, respectively. At the same times, mean BMIs were 35.9 ± 8.4, 37.8 ± 11.27, 34.9 ± 12.2 and 29.7 ± 5.2 kg/m^2. Mean %EWL at the same time was 45.6 ± 29.6, 39.7 ± 29.8, 43.7 ± 38.1 and 55.6 ± 29.2. Five of 25 (20%) patients had ≤25% EWL at 5 years follow-up, while none of the ten patients subject to follow-up at 7 years had ≤25% EWL.
Other outcomes	No other outcomes reported.
Reported harms	Laparotomic conversion was necessary in one patient with gastric

and complications	perforation on the anterior wall during perigastric band positioning. This patient did not report intragastric migration in following controls. The overall postoperative complication rate was 6/58 (10.3%): band slippage was observed in one patient and was treated by laparoscopic repositioning after 4 days, gastric pouch dilatation was observed in two patients and was treated by band repositioning, and intragastric migration was observed in three patients and was treated with band removal. The band also was removed in two patients for psychological intolerance, and one patient was converted 2 years after surgery (BMI 31 kg/m^2) to laparotomic gastric bypass. The overall band removal rate was 6/58 (10.3%). Biliopancreatic diversion (BPD) with gastric preservation and band left in situ (Band–Inaro) was performed in two patients (3.4%)
Quality and comments	Retrospective study. Poor quality, poor statistical power information provided.

Restrictive/malabsorptive

Gastric bypass

Breaux 1995	
Aim	To undertake a retrospective review on bariatric surgery in children with and without sleep apnoea.
Country and setting	USA.
Inclusion/exclusion criteria	BPD was done only on super-obese sleep apnoea patients.
Participants	Twenty-two children aged 8–18 years, with an average BMI >40 kg/m^2.
Intervention	Vertical banded gastroplasty (VBG), Roux-en-Y gastric bypass (RYGBP) and BPD were performed. All patients having RYGBP or BPD were placed on a supplemental multivitamin, vitamin B_{12} 1000 µg, ferrous sulfate 325 mg, and two calcium tablets per day. Additionally BPD patients were instructed to take three capsules daily of water-dispersed vitamin A and D.
Length of follow-up	50 months.
Results	The gallbladder was removed in five patients who were found to have gallstones and in two patients as part of the BPD. One female patient with sleep apnoea had a tumour of the brain-stem, which was biopsied 5 years prior to obesity surgery. In the group without sleep apnoea, BMI was improved from 56.4 kg/m^2 to a mean postoperative BMI of 35.5 kg/m^2. The mean percentage excess weight loss was 59%. In the group with sleep apnoea, BMI improved from 70.3

	kg/m^2 to a mean of 46.5 kg/m^2 for an average excess weight loss of 45%.
Other outcomes	In the nine sleep apnoea patients, the low oxygen saturation during sleep improved from a mean of 73% to a mean of 93% BMI ranging from 65 to 195 kg/m^2. Of the nine patients who had long-term follow-up, all had resolution of sleep apnoea.
Reported harms and complications	One male patient from the without apnoea group who weighed 145 kg at age 17 years and lost 100 kg by age 18 years, regained 145 kg at age 28 years and requested further therapy. One female patient had a VBG at age 16 years and developed gallstones at age 22 years. Since she had only lost 26% of her excess weight, she requested further surgery at the time of the cholecystectomy. Revision was done in one sleep apnoea patient. There were nine postoperative complications. The two vitamin deficiencies in two BPD patients responded to supplementation. Protein deficiency occurred in three BPD patients. There were two late deaths (one as complications arising out of morbid obesity and the other with a multisystem organ failure).
Quality and comments	Poor quality. Retrospective review. No statistical power information.

1

Strauss 2001	
Aim	To review retrospectively all patients undergoing surgery at a large university medical centre.
Country and setting	USA.
Participants	All adolescents were well informed, motivated and had demonstrated serious attempts at weight loss in diet and behaviour modification programmes. All families were instructed to contact patients in a gastric bypass support group who had undergone the operation. All adolescents were developmentally and genetically normal, with no evidence of Prader–Willi syndrome or other genetic obesity-related syndromes. All adolescents were >100% above their IBW, and all were at least 100 lb (45.4 kg) over their IBW and had previously been unsuccessful in multiple attempts at weight loss. The men weight before surgery was 148 ± 37 kg. Co-morbid included severe sleep apnoea, hypertension, vertebral fracture, and severe school avoidance. Three children had undergone psychological evaluation before surgery.

Intervention	After surgery all children started a 1000 kcal (4.19 MJ)/day modified liquid diet for 4 to 6 weeks. Subsequently, adolescents were given a new diet consisting of a variety of low-energy, soft-solid foods.
Length of follow-up	Up to 12 months.
Results	The mean weight loss was 53.6 ± 25.6 kg for the nine adolescents who had persistent weight loss, representing approximately 62% of their excess weight.
Other outcomes	Not reported.
Reported Harms and complications	No early postoperative complications occurred. The most serious complication occurred in one patient with a distal gastric bypass who had protein–energy malnutrition and micronutrient deficiency (vitamin A, vitamin D, iron and zinc) approximately 1 year after gastric bypass. Two adolescents had symptomatic cholelithiasis requiring laparoscopic cholecystectomy. Minor nutritional complications included iron deficiency in five adolescents, and transient folic acid deficiency occurred in three adolescents.
Quality and comments	Poor quality. Retrospective review. No statistical power information provided. Patients were identified through a computerised database of all patients undergoing bariatric surgery from April 1985 to May 1999.

1

Stanford 2003	
Aim	To examine the outcome of adolescents undergoing laparoscopic RYGBP.
Country and setting	USA.
Participants	Patients under the age of 20 years, which met the established criteria by the NIH for candidacy for bariatric surgery. Patients also had to have: BMI of 35 kg/m^2 with co-morbid conditions or >40 kg/m^2 with or without co-morbid conditions; have a co-morbidities that should be improved by the surgery; be able to comprehend the risks and benefits and the surgical procedure; have no glandular aetiology for their obesity; have attempted to lose weight by conventional mean and be willing to be observed over a long period.
Intervention	On postoperative day 1, patients had an upper gastrointestinal study to look for an anastomotic leak and or delayed emptying. Patients with a normal study finding were started on a clear liquid diet, and their diet would be advanced as tolerated.

Length of follow-up	2 years.
Results	The patients lost an average of 87% of their excess body weight. Excluding one patient, the mean BMI postoperatively was 28 kg/m^2. The patients with a follow-up of almost 2 years maintained their weight loss.
Other outcomes	Co-morbid conditions identified in the group: sleep apnoea, hypertriacylglycerolaemia, hypercholesterolemia, degenerative joint disease, gastroesophageal reflux disease and asthma.
Reported Harms and complications	No complications or harms were reported.
Quality and comments	Poor quality. Retrospective review. No statistical power information provided.

1

Rand 1994	
Aim	To evaluate obesity surgery in adolescents.
Country and setting	Appears to be USA.
Participants	All adolescents that were studied were morbidly obese patients in private practice. Age ranged from 11 to 19 years. Preoperatively, patients weighed an average of 131 kg and had an average BMI of 47 kg/m^2. Almost all patients (94%) felt unattractive before surgery.
Intervention	Patients received either the RYGB or the VBG between January 1979 and December 1990.
Length of follow-up	6 years.
Results	At follow-up, patients average BMI was 32 kg/m^2. Patients average excess body weight loss was 66%, 73% of patients had an excess body weight loss of approximately 50%.
Other outcomes	76% of the patients reported their current physical health as excellent or good, problems reported were hypoglycaemia, anaemia, gallbladder disease, probable anaemia and thyroid problems. The large majority of patients (82%) consider themselves attractive after the operation. Most patients (74%) felt less embarrassed about their appearance after the operation than before.
Reported harms and complications	Patients were hospitalised for 5 or 6 days postoperatively, although no major postoperative complication was reported. During the follow-up period, three patients with inadequate weight loss had revisional surgery to reduce the size of the

	stomach pouch. An additional two patients who had regained more than 18 kg were scheduled for revisional surgery to have the stomach pouch size reduced. Thirty of the adolescents received the RYGB, only 13% reported taking vitamin B_{12} and calcium as instructed. 73% took multivitamins and 70% took vitamin B_{12}.
Quality and comments	Poor quality. Retrospective review. No statistical power information provided.

1

Soper 1975	
Aim	To review experience with gastric bypass operations in 25 morbidly obese children and adolescents.
Country and setting	USA.
Participants	Twenty-five morbidly obese patients ≤20 years of age, with a median preoperative weight of 143 kg. For purposes of comparison the patients were divided into two groups: 18 genetically normal individuals and seven children with Prader–Willi syndrome. Children had to have at least double weight for 5 years, absence of severe disease which not be improved by weight loss, and absence of a primary endocrine cause for obesity. Due to the natural history of the Prader–Willi syndrome, the twice ideal weight requirement for acceptance was not applied in the seven patients.
Intervention	–
Length of follow-up	Up to approximately 36 months.
Results	Genetically normal children lost more weight than children with Prader–Willi syndrome. Genetically normal males lost significantly more weight than did females ($p < 0.005$).
Other outcomes	–
Reported harms and complications	Early: Three wound infections, three patients with respiratory difficulty, one patient with thrombophlebitis, one patient with upper gastrointestinal tract bleeding, one patient with urinary tract infection and one patient with protracted vomiting. Late: Four patients with incisional hernia. Subsequent operations include: Four revisions, three panniculectomies, three incisional hernias, three cholecystectomy and one appendectomy.
Quality and comments	Poor study. Only *p* value for difference between weight loss in males vs. females.

2

Anderson 1980	
Aim	To summarise experience with gastric bypass in 41 children and adolescents.
Country and setting	USA.
Participants	Forty-one morbidly obese adolescents and children aged <20 years old. Of these, 30 were genetically normal and 11 had Prader–Willi syndrome. The criteria for selection included: twice IBW; good health except for obesity related disorders; and potential for PA.
Intervention	A liquid diet was recommended for the first 6 weeks following gastroplasty and a soft diet for 6 weeks following gastric bypass. Cautious dietetic counselling was given to each patient and his parents prior to discharge from the hospital.
Length of follow-up	5 years.
Results	For the 30 genetically normal patients their preoperative weight was 238% IBW, which dropped to an average of 171% IBW. By 5 years postoperatively, the average weight was back up to 187% IBW. For the Prader–Willi patients, the average preoperative weight was 231% IBW and at 5 years was 176% IBW.
Other outcomes	–
Reported Harms and complications	Early stage: Three wound infections; two were slow to 'open' due stomach obstruction, and one required revision; atelactasis developed in three patients and pneumonia in two others; one patient developed a subphrenic abscess. Subsequent operations included: Four revisions, three panniculectomies, three incisional hernia, three cholecystectomy and one appendectomy Three deaths occurred. One of them died on the third day possibly due to massive pulmonary embolism; another died suddenly and unexpectedly at 36 months; and the single death among the Prader–Willi patients was caused by congestive heart failure 50 months postoperatively.
Quality and comments	Poor quality. No statistical power information provided.

1

1 **Malabsorptive/restrictive**

2 **Duodenal switch and biliopancreatic diversion**

Breaux 1995	
Aim	To undertake a retrospective review on bariatric surgery in children with and without sleep apnoea.
Country and setting	USA.
Inclusion/exclusion criteria	BPD was done only on super-obese sleep apnoea patients.
Participants	Twenty-two children aged 8 to 18 years, with an average BMI >40 kg/m^2.
Intervention	VBG, RYGBP and the BPD were performed. All patients having RYGBP or BPD were placed on a supplemental multivitamin, vitamin B_{12} 1000 µg, ferrous sulfate 325 mg, and two calcium tablets per day. Additionally BPD patients were instructed to take three capsules daily of water-dispersed vitamin A and D.
Length of follow-up	50 months
Results	The gallbladder was removed in five patients who were found to have gallstones and in two patients as part of the biliopancreatic diversion. One female patient with sleep apnoea had a tumour of the brain stem that was biopsied 5 years prior to obesity surgery. In the group without sleep apnoea, BMI was improved from 56.4 kg/m^2 to a mean postoperative BMI of 35.5 kg/m^2. The mean percentage excess weight loss was 59%. In the group with sleep apnoea, BMI improved from 70.3 kg/m^2 to a mean BMI of 46.5 kg/m^2 for an average excess weight loss of 45%.
Other outcomes	In the nine sleep apnoea patients, the low oxygen saturation during sleep improved from a mean of 73% to a mean of 93% BMI ranging from 65 to 195 kg/m^2. Of the nine patients who had long-term follow-up, all had resolution of sleep apnoea.
Reported Harms and complications	One male patient from the without apnoea group who weighed 145 kg at age 17 and lost 100 kg by age 18 years, regained 145 kg at age 28 years and requested further therapy. One female patient had a VBG at age 16 years and developed gallstones at age 22 years. Since she had only lost 26% of her excess weight, she requested further surgery at the time of the cholecystectomy. Revision was done in one sleep apnoea patients. There were nine postoperative complications. The two vitamin deficiencies in two BPD patients responded to supplementation. Protein deficiency occurred in three BPD

	patients. There were two late deaths (one as complications arising out of morbid obesity and the other with a multisystem organ failure).
Quality and comments	Poor quality. Retrospective review. No statistical power information.

1.7 Harms associated with weight loss or weight management programmes

1.7.1 Effects of professionally prescribed weight loss programmes on eating behaviour

Weight loss

Braet 2003 [801]	
Aim	To assess the effect of an inpatient multi-component treatment programme for obese children and adolescents on their weight and psychological well-being.
Participants	Seventy-six children and adolescents were referred to the centre. Median age in both groups was 13 (range 10–17) years. At baseline median BMI of the study group was 33 (range 22–46) kg/m^2 and the control group 33 (range 24–51) kg/m^2. Children with Prader–Willi syndrome were not recruited
Intervention	Every fifth children on the alphabetical list of patients starting treatment in September 1996, 1997 and 1998 was included in this study, resulting in a sample of 38 patients, or 20% of the total group treated. The diet consisted of 30% energy as fat, 15% energy as protein, and 55% energy as CHO, consisting of servings of fruits, three servings of vegetables, 100 g of meat or 150 g of fish, semi-skimmed milk and low-fat cheese and high fibre staples. It provided 1500–1800 kcal (6.28–7.53 MJ)/day. All children received an adapted individual PA training programme for 4 hours per week. Before and after school, the children were encouraged to exercise for 10 hours per week or even more if they wanted. Children also received a 12-week CBT programme in small groups, followed by personalised problem-solving-based booster sessions every week. To change their lifestyles, the children were taught self-regulation skills, such as self-observation, self-instruction, self-evaluation and self-reward. A problem-solving approach was introduced to teach the children how to cope with different high-risk situations, and they were trained to cope with different stressful situations, such as feeling hungry. Interaction with parents was limited, and children saw the parents

	every 2 weeks. They received leaflets on how to prepare healthy food and how to (re)organise their shopping habits. Children stayed in the centre for one school year (10 months), and twice per month the children returned home for the weekend. The other two weekends and half of the school-holidays they stayed in the centre.
Control	For each 38 children, a case-control (based on age and gender) was selected from the waiting list of the centre.
Length of follow-up	14 months.
Results	During treatment, the children in the study group showed a decrease in the median adjusted BMI of –48 (range –4 to –102)%. Median weight loss was –19 (range +2 to –41) kg. At 6 months after finishing the treatment, the median adjusted BMI was 135 (range 105–192)% and at 14 months it was 143 (range 104–198)%. This was a result of an increase in the adjusted BMI at 6 months follow-up of +6 (range –19 to –37)% and at 14 months follow-up an additional increase of +4 (range –30 to +41)%. At 14% follow-up, 13/27 children showed an increase in their overweight of less than 10% or continued to lose weight compared with their post-treatment weight and 14/27 children had an increase of more than 10% overweight (up to +41%).
Quality and comments	The therapists were blinded for the study. Not randomised study. Overall poor quality study.

1

Braet 2000 [804]	
Aim	The primary aim of the study was to prevent further weight gain. Furthermore, a cognitive-behavioural modification programme was designed to help the child change his of her lifestyle, to enhance self-regulation skills and specific problem-solving skills in different eating situations.
Participants	Subjects were children seeking for obesity treatment at the local University Children's Hospital. All children involved in the stuffy (n = 136) were involved in the follow-up. At baseline, children had a mean age of 11 (SD 2.5) (range 7–17) years. Mean weight of the subjects was 62 (SD 16) kg and mean height was 150 (SD 12) cm. Mean overweight was 55 (SD 21)% and all subjects were at least 20% overweight. All children were White and of normal intelligence and they did not suffer from any syndromic obesity.
Intervention	Subjects were assigned to three different treatment groups: individual treatment, group treatment and summer camp training group. For some families, the treatment was not feasible because of other family plans, so children could be assigned to and advice in one session group.

	In all treatment conditions children received the same package of information. Parents were given a treatment manual for parents of obese children and the child had his own workbook. Self-instructions, self-observation, self-evaluation and self-reward techniques were introduced in each session. Modelling, behaviour rehearsal and homework were used to train self-regulation skills. Problem-solving skills were taught in different high-risk eating situations. Contracts were established including what a child would receive if it followed the programme. Parents were asked to praise their children for good performance. Children were taught about the benefits of exercise and energy expenditure. Exercises were promoted with a frequency of 30 min each day in combination with lifestyle changes such as taking the stairs, walking instead of going by car, helping in the garden or cleaning the house. Moderate intensity in order to keep the exercises up for 30 min, and children were not instructed to exercise at a particular intensity. Changes in eating habits were proposed in small steps, and children were given the chance to make their own choices. They were instructed on how to eat in a healthy way many times a day including many vegetables. 'Counting calories' was not permitted.
Control	Three treatment groups.
Length of follow-up	4.6 years.
Results	Two types of psychological measurements were used in the 4.6 years follow-up, and three at baseline. Both the parent version of the DEBQ and the EDI were given at the follow-up. At baseline, children were also given the Perceived Competence Scale for Children (PCSC). At baseline, mean % overweight were as follows; group $n = 19$, 53 (SD 13); individual $n = 13$, 50 (SD 19); summer camp $n = 30$, 60 (SD 23); and advice $n = 47$, 52 (SD 22). At 4.6 years follow-up, mean % overweight were as follows; group $n = 19$, 34 (SD 19); individual $n = 13$, 39 (SD 24); summer camp $n = 30$, 45% (SD 21); and advice $n = 47$, 45% (SD 30). Total children had a mean percentage overweight of 42. Paired t tests revealed significant time effects in four different treatment groups at 4.6 years follow-up: treatment in group ($p < 0.001$); individual treatment ($p < 0.05$); summer camp ($p < 0.001$); and advice group ($p < 0.001$). No significant results were found in comparing the 1-year follow-up with the 4.6 year follow-up.
Quality and comments	The therapists were blinded for the study. Subjects who dropped out had a higher degree of overweight at baseline ($p < 0.05$), lower self-esteem ($p < 0.01$), and a higher score on a general scale of psychopathology, as measured by the Child Behaviour Checklist (CBCL).

1

Levine 2001 [803]	
Aim	To evaluate the acceptability and feasibility of a family-based intervention for severely obese children.
Participants	Children between the ages of 8 to 12 years, along with at least one parent or guardian. To be eligible, children had to be heavier than 160% of their IBW for their age, height, and gender according to WHO charts. Moreover, children who endorsed current psychiatric symptomatology and that were on a weight control programme were excluded. Twenty-four families completed initial assessment.
Intervention	Children completed the Child Depression Inventory, the State Trait Anxiety Inventory for Children (STAIC) (at pre-treatment, post-treatment and follow-up) and the ChEAT (at pre-treatment and follow-up session). The ChEAT is designed to assess respondents' attitudes toward their eating and dieting behaviour. The ChEAT measures perceived body image, obsessions/concerns with food, and dieting practices. Before initiating the group intervention, all children completed self-report questionnaires about depression, anxiety and eating attitudes and behaviours. Families participated in a 10–12-session behavioural group intervention targeted to increase healthy eating behaviours and PA. Focus on peer teasing using role-plays and problem-solving techniques were also given. At the beginning of each session, children and parents reviewed with group leaders their self-monitoring books for both eating and exercise. Initial sessions focused on self-monitoring of eating and activity and understanding the stoplight diet. Children were given energy intake goals for the week, based on the child's initial body weight and were set at 1200–1500 kcal (5.02–6.28 MJ)/day. They were also given exercise goals and worked toward 30 min of activity 5 days per week. Goals to decrease sedentary activity were also provided.
Control	Only one cohort.
Length of follow-up	Follow-up meeting occurred between 4 and 13 months after the final week of the treatment programme.
Results	Children lost and average of 2.5 ± 3.5 kg during the brief intervention programme. BMI changed from 34.5 (SD 5.2) to 32.8 (SD 5.7) kg/m^2. Weight losses were not maintained over the follow-up period. Children gained an average of 8.6 ± 5.2 kg between the end of treatment and their follow-up visit, although as children grew an average of 1.6 ± 0.7 in this period, these changes do not reliably reflect degree of obesity.
Quality and	Overall limited quality study. Observational study

comments

1

Epstein et al. 1994 [805]	
Aim	Main aim of the study was the presentation of 10-year outcomes for obese children treated in four randomised studies. The secondary aim of this study was to identify variables associated with long-term weight regulation and to extend the research on predictors of 5-year changes in percentage overweight.
Participants	At baseline participants' percentage overweight was not different across groups ($p > 0.05$). Significant differences were observed in age ($p = 0.001$), height ($p < 0.001$) and weight ($p = 0.004$).
Intervention	In study 1, children were randomised to one of three groups: both the parent and child were targeted for weight loss, only the child was targeted for losing weight, or a non-specific target. Targeting included contingency management for habit and weight change, with contingencies for the parent and child group arranged so that both the parent and child had to change habits and lose weight. Study 2 randomised families to regimens of diet and lifestyle exercise or diet alone or to a no-treatment control. The exercise programme increased energy expenditure by the equivalent of 6.4 km of walking per day, or 2800 kcal (11.72 MJ) per week for a 150 lb (68.0 kg) person. The diet-alone group was given information on low expenditure and stretching but were not reinforced for any exercise changes. Study 3 assessed the effects of parental weight status and child self-control on child weight loss. Contingencies were directed toward child weight change, with no requirement for joint parent and child behaviour or weight change. In the study 4, children were randomised to one of three groups: aerobic exercise, lifestyle exercise and callisthenics control group. The groups were similar in exercise time, goal setting and feedback, but the control group required considerably less energy expenditure than the isoenergetic aerobic or lifestyle groups.
Control	Not applicable for this study.
Length of follow-up	This was a 10-year follow-up
Results	For study 1, the parent and child group had significantly greater changes than the non-specific control at both 5 and 10 years ($p = 0.009$). The parent and child group was significantly different from the child-only group at 5 years ($p = 0.025$), but not at 10 years. Children in the parent and child group decreased their percentage overweight by 15.3% whilst children in the control group increased by 7.6%. No significant differences for change in percentage overweight were observed between groups in studies 2 and 3 after 5 or 10 years.

	In study 4, children in the lifestyle or aerobic exercise ($p < 0.05$) had a greater 10-year change from 5 to 10 years than the callisthenics group.
Quality and comments	10-year assessment of four randomised studies. Self-reported data was used in 18% of the cases, although height and weight were adjusted with sample-specific equations. No ITT was performed.

1

Epstein et al. 2001 [710]	
Aim	To assess the effects of behavioural, family-based treatment on disordered eating and child behaviour problems for obese 8- to 12-year-old children
Participants	Sixty-seven families were randomised to three groups (25 boys and 22 girls). Participants had a mean BMI of 27.4 ± 3.2 kg/m^2, a mean percentage overweight of 60.0 ± 16.5 and a mean age of 10.3 ± 1.1 years.
Intervention	Three groups: problem-solving taught to parent and child, problem-solving taught to child only, and no additional problem-solving. All participants were given similar information about diet, activity, and behaviour change techniques, with the problem-solving training being different across groups. The traffic light diet was given, and the lifestyle programme was based on increasing lifestyle PA. Parents and children were taught to praise increases in targeted eating and lifestyle activity behaviours and to use reciprocal contracts based on meeting the goal. The CBCL, the SCL-90 and the Kid's Eating Disorder Survey (KEDS) were used.
Control	No additional problem-solving
Length of follow-up	2 years.
Results	At 2 years follow-up, percentage overweight changed by –12.5 ± 13.5 ($p < 0.001$) and weight changed by 8.3 ± 6.4 kg ($p < 0.001$).
Quality and comments	Parents deposited US$75, which was returned contingent upon completion of 75% of the treatment sessions and attendance at the 6- and 12-month follow-up. Families were paid US$50 at the 24-month follow-up.

2

3 **Other outcomes**

Braet 2003	
Results	Eating behaviours showed no increase in eating psychopathology during the 10-month treatment. On the subscales of the EDI, a significant reduction on the drive for thinness (DT) subscale was

	reported ($p < 0.001$) and no change was reported on the bulimia subscale. The scores on the emotional eating and restrained eating showed an insignificant trend, whilst the scores on the subscale 'external eating' declined significantly, $p < 0.001$. The scores on the SPPC, the scores on three subscales increased significantly during the 10 months treatment: physical appearance $p < 0.001$; athletic competence $p < 0.05$; and social competence $p < 0.05$. On the subscales academic competence, behavioural conduct and global self-worth, no significant trends were found.
Quality and comments	–

1

Braet 2000	
Results	Paired *t* test on the subscales of the DEBQ revealed a significant reduction in external eating ($p < 0.001$), a significant increase in restrained eating ($p < 0.001$), and no difference between pre-testing and the 4.6 follow-up for emotional eating. Mean score on the drive for thinness (DT) subscale of the EDI was 5.6 (SD 5); for the body dissatisfaction (BD) subscale the mean score for the total sample was 13.2 (SD 7), and for the bulimia (B) subscale the mean score was 1.2 (SD 3).
Quality and comments	–

2

Levine 2001	
Results	Children reported significant improvement in psychosocial measures, as both self-reports of depressive symptoms and state anxiety declined from pre-treatment through the follow-up period ($p < 0.03$). These improvements in self-reported depression and anxiety were maintained despite the trend in regaining weight following end of treatment. An analysis between changes in weight between post-treatment and the follow-up period (co-varied) indicate similar decreases in self-reported depressive symptoms.
Quality and comments	–

3

Epstein 1994	
Results	Six girls reported that they were treated for eating disorders. One child had been treated for depression, and another had sought treatment for alcohol abuse. Nineteen other children developed major psychiatric disorders that required hospitalisation or long-term medication use. One child was treated for irritable bowel syndrome.
Quality and	–

comments	

1

Epstein 2001	
Results	The significant reductions for CBCL total behaviour problems and internalising behaviour problems were associated with a decrease in the percentage of children within the borderline clinical range. There were no significant overall change in total KEDS scores There were no significant changes for weight dissatisfaction or restricting/purging scales.
Quality and comments	–

2

3 **Reported harms**

Braet 2003	
Results	No harms were reported.
Quality and comments	–

4

Braet 2000	
Results	No harms were reported.
Quality and comments	–

5

Levine 2001	
Results	No harms were reported.
Quality and comments	–

6

Epstein 1994	
Results	No harms were reported.
Quality and comments	–

7

Epstein 2001	
Results	No harms were reported.
Quality and comments	–

8

1 **Generalisability**

Braet 2003	
Country and setting	Belgium. Inpatient treatment centre.
Participants (included/excluded)	See above
Recruitment	By referral from physicians for inpatient treatment due to obesity.
Intervention (mode and intensity)	
Duration of active intervention	10 months.
Control (mode and intensity)	For each 38 children, a case-control (based on age and gender) was selected from the waiting list of the centre.
Delivery of intervention/control (who)	Standardised treatment was developed and supervised by two behaviour therapists and two medical doctors. It was carried out with the help of one dietitian, one psychologist, one social worker, one medical doctor, one physiotherapist and six group leaders.
Dropout rates	Seven children left the programme during the study. At 6 months, data for three children could not be collected, and at 14 months one additional children could not be traced.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only from those who completed the study.

2

Braet 2000	
Country and setting	Belgium. Outpatient and inpatient.
Participants (included/excluded)	No specific inclusion/exclusion criteria
Recruitment	Majority of the subjects heard about the study from the media, and 15% were referred by physicians.
Intervention (mode and intensity)	Treatment consisted of 12 steps spread over 12 sessions of 60 min or six sessions of 90 min. For the outpatient groups, the programme consisted of six biweekly sessions of 90 min, spread over 3 to 4 months. In the summer camp the children followed the 12-session programme in the morning. They received balanced healthy food (1500 kcal [6.28 MJ]/day) and daily lifestyle exercises (5 hours/day). All children were asked to attend the monthly follow-up sessions. The children that were not able to participate in the treatment programme (n = 58, 43%) were assigned to an advice-in-one-session group. After the initial 3-hour intake session, these parents and their children received the same information during a

	90 min family session. The experimental groups consisted of 36 subjects spread over two summer camps, 26 subjects spread over six outpatient group programmes, and 16 subjects in the individual treatment programme.
Duration of active intervention	Not clear duration of treatment.
Control (mode and intensity)	See above
Delivery of intervention/control (who)	Standardised treatment was carried out by the authors and students in psychology, trained and supervised by the first author. Medical and dietary supervision was given at every session by the second author and a dietitian.
Dropout rates	19.9% at 4.6 years, which accounted for 27 children.
Treatment of dropouts (return to baseline, or last measurement?)	Analyses done with data from subjects who completed the follow-up.

1

Epstein 1994	
Country and setting	USA. University Research Centre
Participants (included/excluded)	Children had to be aged 6 to 12 years, 20 to 100% overweight for age, sex and height, no current psychiatric diagnosis or treatment, no learning disability, and one parent willing to participate in treatment with the child. Parents or children with current psychological problems were referred for treatment before entrance in the study. Parents or children could have had psychiatric problems that had been treated or were in remission when they entered treatment. Families that participated in study 1 were intact, and families who participated in the exercise studies could not have a medical problem that limited exercise.
Recruitment	Subjects were participants in one of four weight-control studies.
Intervention (mode and intensity)	Four different randomised studies.
Duration of active intervention	Four different randomised studies.
Control (mode and intensity)	Four different randomised studies.
Delivery of intervention/control (who)	Not reported.

Dropout rates	25% dropouts registered at the 10-year follow-up
Treatment of dropouts (return to baseline, or last measurement?)	No ITT performed.

1

Epstein 2001	
Country and setting	USA. University research centre
Participants (included/excluded)	Children between 8 and 12 years; between 20 and 100% overweight based on comparisons of the BMI to the 50th percentile BMI for age and sex; neither parent over 100% overweight; one parent willing to attend treatment meetings; no family member participating in an alternative weight-control programme; no parent or child with current psychiatric problems as assessed by health history questionnaire and standardised interview; no restrictions on the participating parent or child that prevent exercise; and child able to read at the third-grade level.
Recruitment	Not clear.
Intervention (mode and intensity)	The treatment included 16 weekly meetings, followed by two biweekly meetings and two monthly meetings during the 6 month treatment
Duration of active intervention	6 months.
Control (mode and intensity)	Same as treatment.
Delivery of intervention/control (who)	Individual therapist.
Dropout rates	24% at 2 years follow-up.
Treatment of dropouts (return to baseline, or last measurement?)	No ITT was performed.

2

Levine 2001	
Country and setting	USA. University research centre
Participants (included/excluded)	See above
Recruitment	Participants were recruited through advertisements in local newspapers and letters distributed to local paediatricians and family physicians.
Intervention (mode and	See above

intensity)	
Duration of active intervention	Follow-up meeting occurred between 4 and 13 months after the final week of the treatment programme.
Control (mode and intensity)	Only one cohort.
Delivery of intervention/control (who)	Not reported
Dropout rates	33.3%
Treatment of dropouts (return to baseline, or last measurement?)	Only data from those who finished treatment programme.

1.7.2 Effects of professionally prescribed weight loss programmes on child/adolescent growth

Weight loss

Dao 2004 [280]	
Aim	To determine if a multidisciplinary weight loss programme in adolescents with severe obesity allows adequate growth and development and avoids lean mass loss.
Participants	Fifty-five (33 girls and 22 boys) adolescents aged 9 to 17 years.
Intervention	Patients were housed at the therapeutic unit except during the weekends that were spent at home, for 9 ± 3 (range 6–12) months where they participated on a voluntary basis in a weight reduction programme. Participants were given specific dietary and PA advice.
Control	Only one cohort.
Length of follow-up	Up to 12 months
Results	The mean BMI dropped in boys from 34.5 ± 3.2 to 25.5 ± 2.3 kg/m^2 and in girls from 38.4 ± 4.1 to 28.4 ± 4.1 kg/m^2. At baseline, the mean total fat mass content and percentage body fat were marginally higher in girls and boys ($p = 0.06$). After weight loss, both differences reached significance ($p < 0.01$). The total fat mass decreased by 42.7 ± 7.6% in girls and 51.9 ± 11.4% in boys ($p < 0.0001$). At baseline, percentage fat contents of the upper limbs and trunk were significantly higher in girls than in boys ($p = 0.05$). After weight loss, percentage fat mass in all regions was higher in girls than in boys ($p < 0.05$), whilst in absolute value fat mass contents were higher in the trunk and lower limbs only ($p < 0.02$). Trunk to legs fat mass ratio decreased in both sexes ($p < 0.0001$) and remained higher in girls than in boys either before (1.14 ± 0.21 vs.

	1.02 ± 0.16, $p = 0.01$) or after weight loss (0.89 ± 0.24 vs. 0.68 ± 0.17, $p = 0.001$). In the upper limbs, lean mass decreased slightly in boys ($p = 0.06$) and girls ($p = 0.06$) and was correlated with the corresponding local decrease of fat mass in both sexes ($p = 0.06$ and $p = 0.037$). Lean mass increased with increasing Tanner stage either before of after weight loss in girls ($F = 18.7$, $p = 0.0001$; $F = 4.6$, $p = 0.01$) and boys ($F = 9.1$, $p = 0.007$; $F = 22.8$, $p = 0.0001$).
Quality and comments	Overall poor quality study.
Sponsor details	Not applicable.

1

Dietz 1985 [806]	
Aim	To retrospectively compare height velocity before and during weight reduction in a cohort
Participants	Fourteen girls and 5 boys treated in the weight control programme.
Intervention	The energy intake in all cases was about two-thirds of the usual daily intake, estimated from either a 24-hour dietary recall or a 7-day dietary diary. During weight reduction, protein intakes were maintained at 1.5 to 2.0 g/kg of IBW per day. During weight reduction period, children were seen every 2 to 4 weeks. Annual rates of height velocity were calculated by extrapolating the rate for the period measured to a 1-year interval,
Control	No control.
Length of follow-up	Mean duration of treatment was 9.7 months.
Results	The mean weight losses were 4.5 ± 5.3 kg, resulting in a mean decrease of 29% IBW. Height velocity before weight reduction was calculated over a mean period of 20 months. The mean *z*-score for height velocity before weight reduction was 2.32 (SD 2.47) units. During weight reduction, the mean *z*-score for height velocity decreased significantly to 0.62 (SD 2.37) units ($p < 0.01$). A high correlation between the change in *z*-scores of height velocity prior to and during weight reduction and the change in weight was observed ($p < 0.01$).
Quality and comments	Retrospective case series.

2

Other outcomes

Dao 2004	
Results	Not reported.
Quality and comments	–

Dietz 1985	
Results	Not reported.
Quality and comments	–

Reported harms

Dao 2004	
Results	No harms were reported.
Quality and comments	–

Dietz 1985	
Results	No adverse effects were reported in any patient.
Quality and comments	–

Generalisability

Dao 2004	
Country and setting	France. Inpatient research centres.
Participants (included/excluded)	Children/adolescents with severe primary obesity; agreement of the child and its family to participate on a voluntary basis in a weight reduction programme. The exclusion criteria were as follows: identified genetic, metabolic or endocrine disease, obesity secondary to a brain tumour.
Recruitment	Not reported.
Intervention (mode and intensity)	Participants were advised to restrict energy intake to 1600–1800 kcal (6.70–7.53 MJ)/day during weight reduction phase. An increase of up to 1800–2200 kcal (7.53–9.1 MJ)/day was required during the stabilisation phase in order to stop weight loss and achieve a stable body weight. This was reached, on an individual basis, by increasing caloric intake by steps of 200 kcal (0.84 MJ)/day until a stable weight was reached. Nutrition training was also addressed to the parent. Parents were provided the same documents as their children in addition to which meetings took place every 6 weeks and

	phone calls were made by the dietitian and the parents were encouraged to call of they needed extra information. PA training session took place three times a week, with 90 min and included alternatively swimming, gymnastics, walking and recreational team sports
Duration of active intervention	6 to 12 months.
Control (mode and intensity)	No control.
Delivery of intervention/control (who)	Phone calls were made by the dietitian and the parents were encouraged to call of they needed extra information.
Dropout rates	Not reported.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to be only with data of those who completed.

1
2

Dietz 1985	
Country and setting	USA. University research centre.
Participants (included/excluded)	To be included, participants had to have: use of a balanced energy-deficit diet, height measurements recorded at least 1 year before and on at least one 4-month interval during weight reduction, and weight change of maintenance to achieve a reduction of 10% or more in IBW for height (%IBW).
Recruitment	Appears to be from children who were attending a weight control programme at the Boston's Children's Hospital from 1981 to 1983.
Intervention (mode and intensity)	The energy intake in all cases was about two-thirds of the usual daily intake, estimated from either a 24-hour dietary recall or a 7-day dietary diary. During weight reduction, protein intakes were maintained at 1.5 to 2.0 g/kg of IBW per day. During weight reduction period, children were seen every 2 to 4 weeks. Annual rates of height velocity were calculated by extrapolating the rate for the period measured to a 1-year interval
Duration of active intervention	Mean 9.7 months.
Control (mode and intensity)	N/A

Delivery of intervention/control (who)	Not clear.
Dropout rates	Not clear.
Treatment of dropouts (return to baseline, or last measurement?)	Appears to have been only from those who finished treatment. No dropouts seem to have occurred, or were not reported.

Appendix 14

2 Excluded studies

2.1 Measures other than body mass index

References were excluded from this review because they did not evaluate the utility of the measure of interest compared with body mass index (BMI), but compared with some other measure of overweight or obesity. For a full list of excluded references, please contact the Methods Team.

2.2 Measures and morbidity in ethnic populations

TO CHECK when expert comments back

2.3 Lifestyle interventions

TO BE CHECKED

Study	Reason for exclusion
Bailes JR, Strow MT, Werthammer J, McGinnis RA, Elitsur Y (2003) Effect of low-carbohydrate, unlimited calorie diet on the treatment of childhood obesity: a prospective controlled study. *Metabolic Syndrome and Related Disorders* 1:221–225.	Less than 6 months study.
Balagopal P, Bayne E, Sager B, Russell L, Patton N, George D (2003) Effect of lifestyle changes on whole-body protein turnover in obese adolescents. *International Journal of Obesity and Related Metabolic Disorders* 27:1250–7.	Not only obese children as participants.
Ball SD, Keller KR, Moyer-Mileur LJ, Ding YW, Donaldson D, Jackson WD (2003) Prolongation of satiety after low versus moderately high glycemic index meals in obese adolescents. *Pediatrics* 111:488–94.	No weight outcomes reported.
Barbeau P, Gutin B, Litaker MS et al. (2003) Influence of physical training on plasma leptin in obese youths. *Canadian Journal of Applied Physiology* 28:382–96.	Weight outcomes were only reported at baseline.
Barbeau P, Litaker MS, Woods KF et al. (2002) Hemostatic and inflammatory markers in obese youths: effects of exercise and adiposity. *Journal of Pediatrics* 141:415–20	Only body fat percentage was reported.
Barbeau P (2002) Hemostatic and inflammatory markers in obese youths: effects of exercise and adiposity. *Journal of Pediatrics* 141(3)	No weight outcomes reported such as BMI, percentage overweight, or weight.
Becque MD, Katch VL, Rocchini AP, Marks CR, Moorehead C (1988) Coronary risk incidence of obese adolescents: reduction by exercise plus diet intervention. *Pediatrics* 81:605–12.	Less than 6 months (treatment and follow-up).
Berg-Smith 1999***(- to add details)***	Less than 6 months

Study	Reason for exclusion
	duration.
Berg-Smith SM, Stevens VJ, Brown KM et al. (1999) A brief motivational intervention to improve dietary adherence in adolescents. ***Health Education Research, Vol. 14, No. 3, 399-410, June 1999***	Participants were not overweight/obese.
Bhargava A, Sachdev HS, Fall C et al. (2004) Relation of serial changes in childhood body-mass index to impaired glucose tolerance in young adulthood. *New England Journal of Medicine* 350.	Not children or adolescents.
Braet C, Mervielde I, Vandereycken W (1997) Psychological aspects of childhood obesity: a controlled study in a clinical and nonclinical sample. *Journal of Pediatric Psychology* 22 (1):59–71	???
Braet C, Wydhooge K (2000) Dietary restraint in normal weight and overweight children. A cross-sectional study. *International Journal of Obesity*;24: 314–318.	Not controlled study.
Brandou F, Dumortier M, Garandeau P, Mercier J, Brun JF (2003) Effects of a two-month rehabilitation program on substrate utilization during exercise in obese adolescents. *Diabetes and Metabolism* 29:20–7.	Less than 6 months duration (treatment and follow-up).
Cairella (1991) ***[details]***	Language other than English.
Davis K, Christoffel KK, Vespa H, Pierleoni MP, Papanastassiou R (1993) Obesity in preschool and school-age children. *Clinical Nutrition* 23:000	Only IBW measures.
Deforche B, Bourdeaudhuij I, Tanghe A, Debode P, Hills AP, Bouckaert J (2005) Post-treatment phone contact: a weight maintenance strategy in obese youngsters. *International Journal of Obesity* 29:543–6.	Less than 6 months study.
Deforche B, Bourdeaudhuij I, Tanghe A et al. (2003) Changes in fat mass, fat-free mass and aerobic fitness in severly obese children and adolescents following a residential treatment programme. *European Journal of Pediatrics* 162: 616–622.	Not controlled study.
Deforche B, Bourdeaudhuij I, Tanghe A, Debode P, Hills AP (2004) Changes in physical activity and psychosocial determinants of physical activity in children and adolescents treated for obesity. *Patient Education and Couseling* 55:407–415.	Not controlled study.
Dietz WH, Gortmaker SL (1985) Do we fatten our children at the TV set? Television viewing and obesity in children and adolescents. *Pediatrics* 75:000.	Cohort study.
DISC (1995) ***[detail?]***	Participants were

Study	Reason for exclusion
	not overweight/obese.
DISC Collaborative Research Group (1993) Dietary intervention study in children (DISC) with elevated low-density-lipoprotein cholesterol. AEP ***[?]***3:000.	Participants were not overweight/obese.
Ebbeling CB, Leidig MM, Sinclair KB, Hangen JP, Ludwig DS (2003) A reduced-glycemic load diet in the treatment of adolescent obesity. *Archives of Pediatrics and Adolescent Medicine* 157:773–9.	No age stratification for the participants.
Effective Public Health Practice Project (2004) ***[details?]***	Participants were not overweight/obese.
Emes C, Velde B (1990) An activity based weight control program. *Adapted Physical Activity Quarterly* 7.	Less than 6 months duration (treatment and follow-up).
Endo H, Tagaki Y, Nozue T, Kuwahata K, Uemasu F, Kobayashi A (1992) Beneficial effects of dietary interventions on serum lipid and apolipoprotein levels in obese children. *American Journal of Diseases of Children* 146:000.	Less than 6 months duration and no weight outcomes.
Epstein (1986) ***[details]***	Appears to be before and after study.
Epstein (1996) ***[details]***	Narrative review.
Epstein LH, McCurly J, Wing RR, Valoski A (1990) Five-year follow-up of family-based behavioral treatments for childhood obesity. *Journal of Consulting and Clinical Psychology* 58(5):661–664.	No precise figures of changes in percentage overweight were reported.
Ewart CK, Young DR, Hagberg JM (1998) Effects of school-based aerobic exercise on blood pressure in adolescent girls at risk for hypertension. *American Journal of Public Health* 88:000.	Participants were not overweight/obese.
Faith MS, Berman N, Heo M et al. (2001) Effects of contingent television on physical activity and television viewing in obese children. *Pediatrics* 107:1043–8.	Less than 6 months duration (treatment and follow-up).
Fanaria P, Somazzi R, Nasrawi F et al. (1993) Haemorheological changes in obese adolescents after short-term diet. *International Journal of Obesity* 17:487.	Less than 6 months duration (treatment and follow-up).
Fernandez-Paredes (1987) ***[details]***	Language other than English.
Foreyt J (1991) Cuidando El Corazon – a weight reduction intervention for Mexican Americans. *American Journal of Clinical Nutrition* 53:000.	No weight outcomes reported such as BMI,

Study	Reason for exclusion
	percentage overweight or weight.
Foster GD, Wadden TA, Brownell KD (1985) Peer-led program for the treatment and prevention of obesity in the schools. *Journal of Consulting and Clinical Psychology* 53:538–40.	Intervention delivered by non clinical professionals in non-clinical setting.
Frenn M, Malin S, Bansal NK (2003) Stage-based interventions for low-fat diet with middle school students. *Journal of Pediatric Nursing* 18:000.	Health promotion.
Gilbertson HR, Thorburn AW, Brand Miller JC, Chondros P, Werther GA (2003) Effect of low-glycemic-index dietary advice on dietary quality and food choice in children with type 1 diabetes. *American Journal of Clinical Nutrition* 77:000.	No weight outcomes reported.
Goldfield GS, Kalakanis LE, Ernst MM, Epstein LH (2000) Open-loop feedback to increase physical activity in obese children. *International Journal of Obesity and Related Metabolic Disorders* 24:888–92.	No weight outcomes reported.
Gortmaker SL (1999) Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Archives of Pediatrics and Adolescent Medicine* 153(4):000.	Non RCT with aim other then to treat childhood obesity.
Graf C, Sylvia VR, Benjamin K et al. (2005) Data from the StEP TWO programme showing the effect on blood pressure and different parameters for obesity in overweight and obese primary school children. *Cardiology in the Young* 15:291–8.	Not controlled study.
Gutin B (2002) Effects of exercise intensity on cardiovascular fitness, total body composition, and visceral adiposity of obese adolescents. *American Journal of Clinical Nutrition* 75(5):000.	Only body mass composition and fat mass were reported.
Hartmuller VW (1994) Creative approaches to cholesterol lowering used in the dietary intervention study in children. *Topics of Clinical Nutrition* 10:71.	Participants were not overweight/obese.
Hills AP, Parker AW (1988) Obesity managemeny via diet and exercise intervention. *Child: Care, Health and Development* 14:409.	Less than 6 months duration (treatment and follow-up).
Hoerr (1988) ***[details]***	No comparison. No control group reported.
Hopper CA, Gruber MB, Munoz KD, Herb RA (1992) Effect of including parents in a school-based exercise and nutrition program for children. *Research Quarterly for Exercise and Sport* 63:000.	Intervention delivered by non-clinical professionals in non-clinical setting

Study	Reason for exclusion
Hunter GR, Weinsier RL, Bamman MM, Larson DE (1998) A role for high intensity exercise on energy balance and weight control. *International Journal of Obesity* 22:489.	Narrative review.
Isnard P, Michel G, Frelut ML et al. (2003) Binge eating and psychopathology in severely obese adolescents. *International Journal of Eating Disorders* 34:000.	Non-RCT with aim other than treatment of childhood obesity.
Johnson WG (1997) Dietary and exercise interventions for juvenile obesity: long-term effect of behavioral and public health models. *Obesity Research* 5: 257–261.	Less than 6 months duration intervention. Five year follow-up weight data was self-reported.
Lappe JM, Rafferty KA, Davies M, Lypaczewski G (2004) Girls on a high-calcium diet gain weight at the same rate as girls on a normal diet: a pilot study. *Journal of the American Dietetic Association* 104:1361.	Participants were not overweight or obese.
Lauer RM, Obarzanek E, Hunsberger S, Horn S (2000) Efficacy and safety of lowering dietary intake of total fat, saturated fat, and cholesterol in children with elevated LDL cholesterol. *American Journal of Clinical Nutrition* 72:000.	Participants were not overweight/obese.
Lazzer S, Boirie Y, Poissonier C et al. (2005) Longitudinal changes in activity patterns, physical capacities, energy expenditure, and body composition in severely obese adolescents during a multidisciplinary weight-reduction program. *International Journal of Obesity* 29:37–46.	Not controlled study.
Lozano (1997) ***[details]***	Language other than English.
Ludwig DS, Majzoub JA, Al Zahrani A, Dallal GE, Blanco I, Roberts SB (1999) High glycemic index foods, overeating, and obesity. *Pediatrics* 103:E26.	No weight outcomes reported.
Maffeis (2004) ***[details?]***	Weight outcomes only reported at baseline.
Matheson DM (2004) Children's food consumption during television viewing. *American Journal of Clinical Nutrition* 79(6):000.	Non-randomised trial with aim other than to treat childhood obesity.
Moon YI (2004) Effects of behavior modification on body image, depression and body fat in obese Korean elementary school children. *Yonsei Medical Journal* 45:61–67.	Only 8 weeks duration.
Mo-suwan L, Pongprapai S, Junjana C, Puetpaiboon A (1998) Effects of a controlled trial of a school-based exercise program	Intervention delivered by non-

Study	Reason for exclusion
on the obesity indexes of preschool children. *American Journal of Clinical Nutrition* 68:1006.	clinical professionals in non-clinical setting.
Nelson G. Evaluation of a social problem-solving skills program for third and fourth grade students (1988) *American Journal of Community Psychology* 16(1):000.	Participants were not obese.
Nuutinen O (1991) Long-term effects of dietary counselling on nutrient intake and weight loss in obese children. *European Journal of Clinical Nutrition* 45:287. Nuutinen O, Knip M (1992) Long-term weight control in obese children: persistence of treatment outcome and metabolic chnages. *International Journal of Obesity* 16:000. Nuutinen O, Knip M (1992) Predictors of weight reduction in obese children. *European Journal of Clinical Nutrition* 46:785–94.	Results from each group were combined. No clear conclusions can be drawn.
Obarzanek E (2001) Long-term safety and efficacy of a cholesterol-lowering diet in children with elevated low-density lipoprotein cholesterol: seven year results of the dietary intervention study in children (DISC). *Pediatrics* 107:256.	Participants were not overweight/obese.
Owens S, Gutin B, Allison J et al. (1999) Effect of physical training on total and visceral fat in obese children. *Medicine and Science in Sports and Exercise* 31:143–8.	Less than 6 months duration (treatment and follow-up).
Patrick K, James MS, Sallis JF et al. (2001) A multicomponent program for nutrition and physical activity change in primary care. *Archives of Pediatrics and and Adolescent Medicine* 155:000.	Weight loss or reduction of BMI not reported.
Patrick K, Norman GJ, Calfas KJ et al. (2004) Diet, physical activity, and sedentary behaviors as risk factors for overweight in adolescence. *Archives of Pediatrics and and Adolescent Medicine* 158:385–90.	Participants were not overweight/obese.
Pena M, Bacallao J, Barta L, Amador M, Johnston FE (1987) Fiber and exercise in the treatment of obese adolescents. *Journal of Adolescent Health Care* 10:30.	Less than 6 months duration (treatment and follow-up).
Robinson TN (1999) Behavioral treatment of childhood and adolescent obesity. *International Journal of Obesity* 23(2):000.	Narrative review.
Rocchini AP, Katch V, Anderson J et al. (1988) Blood pressure in obese adolescents: effect of weight loss. *Pediatrics* 82:16–23.	Less than 6 months duration (treatment and follow-up).
Rocchini AP, Katch V, Schork A, Kelch RP (1987) Insulin and blood pressure during weight loss in obese adolescents. *Hypertension* 10:267–73.	Less than 6 months duration (treatment and follow-up).
Rudolf MCJ, Greenwood DC, Cole TJ et al. (2004) Rising	Cohort study.

Study	Reason for exclusion
obesity and expanding wasitlines in schoolchildren: a cohort study. *Archives of Disease in Childhood* 89:235.	
Sahota, P (2001) Evaluation of implementation and effect of primary school based intervention to reduce risk factors for obesity. *British Medical Journal* 323:000.	Health promotion programme.
Sahota, P (2001) Randomised controlled trial of primary school based intervention to reduce risk factors for obesity. *British Medical Journal* 323:000.	Health promotion programme.
Sallis JF, McKenzie TL, Alcaraz JE, Kolody B, Hovell MF, Nader PR (1993) Project SPARK. Effects of physical education on adiposity in children. *Annals of the New York Academy of Sciences* 699:127–36.	Intervention delivered by non-clinical professionals in non-clinical setting.
Sasaki J, Shindo M, Tanaka H, Ando M, Arakawa K (1987) A long-term aerobic exercise program decreases the obesity index and increases the high density lipoprotein cholesterol concentration in obese children. *International Journal of Obesity* 11:339.	Intervention delivered by non-clinical professionals in non-clinical setting.
Sondike SB, Copperman N, Jacobson MS (2003) Effects of a low-carbohydrate diet on weight loss and cardiovascular risk factor in overweight adolescents.[see comment]. *Journal of Pediatrics* 142:253–8.	Less than 6 months (treatment and follow-up).
Sothern MS (1993) An effective multidisciplinary approach to weight reduction in youth. *Annals of the New York Academy of Sciences* 699:000.	No details of interventions.
Sothern MS, Hunter S, Suskind RM, Brown R, Udall JR, Blecker U (1999) Motivating the obese child to move: the role of structured exercise in pediatric weight management. *Southern Medical Journal* 92:000.	Not comparing to any other intervention.
Sothern MS, Udall JR, Suskind RM, Vargas A, Blecker U (2000) Weight loss and growth velocity in obese children after very low calorie diet, exercise, and behaviour modification. *Acta Paediatrica* 89:000.	Before and after study.
Stallings VA, Archibald EH, Pencharz PB, Harrison JE, Bell LE (1988) One-year follow-up of weight, total body potassium, and total body nitrogen in obese adolescents treated with the protein-sparing modified fast. *American Journal of Clinical Nutrition* 48:91–4.	Before and after study.
Sung RY, Yu CW, Chang SK, Mo SW, Woo KS, Lam CW (2002) Effects of dietary intervention and strength training on blood lipid level in obese children. *Archives of Disease in Childhood* 86:407–10.	Less than 6 months duration (treatment and follow-up).
Suskind RM, Sothern MS, Farris P et al. (1993) Recent advances	Cohort study.

Study	Reason for exclusion
in the treatment of childhood obesity. *Annals of the New York Academy of Sciences* 699:181.	
Suttapreyasri D, Kanpoem J, Suthontan N, Krainam J, Boonsuya C (1990) Weight-control training models for obese pupils in Bangkok. *Journal of the Medical Association of Thailand* 73:000.	Intervention delivered by non-clinical professionals in non-clinical setting.
Tucker LA (1986) The relationship of television viewing to physical fitness and obesity. *Adolescence* 21:000.	Non RCT with aim other then to treat childhood obesity.
Vandongen R, Jenner DA, Thompson C et al. (1995) A controlled evaluation of a fitness and nutrition intervention program on cardiovascular health in 10 to 12 year old children. *Preventive Medicine* 24:9.	Not overweight/obese children.
Warren JM, Henry CJ, Lightowler HJ, Bradshaw SM, Perwaiz S (2003) Evaluation of a pilot school programme aimed at the prevention of obesity in children. *Health Promotion International* 18:287–96.	Prevention of obesity in children.
Warren JM, Henry JK, Simonite V. Low-glycemic index breakfasts and reduced food intake in preadolescent children (2003) *Pediatrics* 112:414.	No weight outcomes reported.
Watts K, Beye P, Siafarikas A et al. (2004) Exercise training normalizes vascular dysfunction and improves central adiposity in obese adolescents. *Journal of the American College of Cardiology* 43:1823–7.	Less than 6 months duration.
Watts K, Beye P, Siafarikas A et al. (2004) Effects of exercise training on vascular function in obese children. *Journal of Pediatrics* 144:620–5.	Less than 6 months duration.
Zametkin XXX (2004) Psychiatric aspects of child and adolescent obesity: a review of the past 10 years. *Journal of the American Academy of Child and Adolescent Psychiatry* 43(2):000.	Narrative review.

2.4 Pharmacological interventions

We also scanned reference lists of other guidelines and reviews for additional studies and recommendations on both orlistat and sibutramine. These are listed below for completeness.

Study	Source	Reason
Barlow SE. Dietz WH (1998) Obesity evaluation and treatment: Expert Committee recommendations. The Maternal and Child Health Bureau, Health Resources and Services	Searches	Drug treatment not mentioned.

Study	Source	Reason
Administration and the Department of Health and Human Services. *Pediatrics* 102(3):E29.		
Batch JA, Baur LA (2005) Management and prevention of obesity and its complications in children and adolescents. *Medical Journal of Australia* 182(3):130–5.	Searches	No additional references.
Daniels, S (2001) Pharmacological treatment of obesity in paediatric patients. [Review] [33 refs]. *Paediatric Drugs* 3(6):405–410.	Searches	No additional references.
Daniels S (2005) Regulation of body mass and management of childhood overweight. *Pediatric Blood and Cancer* 44(7):15.	Searches	No additional references.
Daniels SDK, Arnett RH, Eckel SS et al. (2005) Overweight in children and adolescents: Pathophysiology, consequences, prevention, and treatment. *Circulation* 111(15):19.	Searches	No additional references.
Cuttler LJL, Whittaker XXX, Kodish ED (2005) The overweight adolescent: Clinical and ethical issues in intensive treatments for pediatric obesity. *Jouranal of Pediatrics* 146(4):2005.	Searches	No additional references.
Hayman LL. Hughes S (2004) Obesity: focus on prevention and policy**.** *Journal of Cardiovascular Nursing*19(3):217–8.	Searches	No additional references.
Kolagotla L, Adams W (2004) Ambulatory management of childhood obesity. *Obesity Research* 12(2):275–83.	Searches	Drug treatment not mentioned.
Michaud PA, Suris JC, Viner R (2004) The adolescent with a chronic condition. Part II: healthcare provision. *Archives of Disease in Childhhood* 89(10):943–9.	Searches	General healthcare for adolescents, not obesity.
Rudolf MCJ, Greenwood DC, Cole TJ et al. (2004) Rising obesity and expanding waistlines in schoolchildren: a cohort study. *Archives of Disease in Childhood* 89(3):235–7.	Searches	No additional references.
Speiser PW (2005) Childhood obesity. Consensus Development Conference. Guideline. Journal Article. Practice Guideline ***[delete?].*** *Journal of Clinical Endocrinology and Metabolism* 90(3):1871–87.	Searches	No additional references.
Suris JC, Michaud PA, Viner R. The adolescent with a chronic condition. Part I: developmental issues. *Archives of Disease in Childhood* 2004;89 (10):938–942.	Searches	General healthcare for adolescents, not obesity.

Study	Source	Reason
Trent ME, Laufer MR (2000) Obesity in adolescent girls – Emerging role of reproductive health professionals. *Journal of Reproductive Medicine* 45(6):445–53.	Searches	No additional references.
Vieweg WV (2005) Newer antipsychotic drugs and obesity in children and adolescents. How should we assess drug-associated weight gain? *Acta Psychiatrica Scandinavica* 111(3):177–84.	Searches	Not treatment of obesity, but link between antipsychotic drug treatment and weight gain.
Viner R (2005) Managing obesity in secondary care: a personal practice. *Archives of Disease in Childhood* 90;385–90.	Searches	No additional references.
Yanovski JA (2003) Treatment of pediatric and adolescent obesity. *Journal of the American Medical Association* 9;289(14):1851–3.	Searches	No additional references.

2.5 Surgery [reorder alphabetically?]

Study	Source	Reason
Yanovski A, Yanovski JA (2001) Intensive therapies for pediatric obesity. [Review] [62 refs] *Pediatric Clinics of North America* 48:1041–53.	Searches	Narrative review. No additional references.
Albanese CT (2005) The 'skinny' on adolescent bariatric surgery. *Journal of Laparoendoscopic and Advanced Surgical Techniques* Part A:15.	Searches	Narrative review. No additional references.
Alvarez-Leite JL (2004) Nutrient deficiencies secondary to bariatric surgery. [Review] [93 refs] *Current Opinion in Clinical Nutrition and Metabolic Care* 7:569–75.	Searches	Narrative review. No additional references.
Strauss BJ (2002) Gastric bypass surgery in adolescents with morbid obesity. *Nutrition in Clinical Practice* 17:43.	Searches	See Strauss 2001.
Rothschild B, Masheb R, Brody M, Toth C, Burke-Martindale C, Grilo C (2004) Childhood maltreatment in severely obese male and female bariatric surgery candidates. *Obesity Research* 12:A75.	Searches	Abstract only. See Grilo 2005.
Barlow SE (2004) Bariatric surgery in adolescents: for treatment failures or health care system failures? *Pediatrics* 114:252–3.	Searches	Narrative review. No additional references.
Grilo CM, Masheb RM, Brody M, Toth C,	Searches	Participants were not

Study	Source	Reason
Burke Martindale CH, Rothschild RS (2005) Childhood maltreatment in extremely obese male and female bariatric surgery candidates. *Obesity Research* 13:123–30.		children or adolescents.
Daviglus ML, Pirzada A (2005) In the long run, healthcare costs appear to be related to overweight and obesity at younger ages. *Expert Review of Pharmacoeconomics and Outcomes Research* 000:5.	Searches	Not relevant to topic.
Fielding G (2004) Laparoscopic adjustable gastric banding as surgical treatment for severely obese adolescents – Initial experience with 44 children. ***[Details]***	Searches	Abstract only. See Dolan 2004/2003.
Flodmark FE (2004) New insights into the field of children and adolescents' obesity: The European perspective. *International Journal of Obesity* 28:000.	Searches	Narrative review. Checked references. Added Hayr 2003 for assessment.
Garcia VF, Langford L, Inge TH. Application of laparoscopy for bariatric surgery in adolescents. [Review] [125 refs], *Current Opinion in Pediatrics* 2003;15:248–55.	Searches	Narrative review.
Greenstein RJ, Rabner JG (1995) Is adolescent gastric-restrictive antiobesity surgery warranted? *Obesity Surgery* 5:000.	Searches	Not clear when BMI and weight were measured in the follow-up period.
Haynes B (1959) Creation of a bariatric surgery program for adolescents at a major teaching hospital. *Pediatric Nursing* 31:21–22.	Searches	Case-study with no reports on weight loss values.
Hayr T (2003) ***[details]***	Flodmark.***[?]***	Abstract only. No published references found July 2005.
Ippisch H (2004) Does gastric bypass surgery decrease cardiac risk factors in morbidly obese young patients? Conference abstract.***[details?]***	Searches	Abstract only.
Kaur H (2003) Childhood overweight: an expanding problem. *Treatments in Endocrinology* 2:000.	Searches	Narrative review. No additional references.
Klish WJ, Brandt ML, Helmrath MA (2004) Obesity surgery in pediatrics. *Journal of Pediatric Gastroenterology and Nutrition* 39:2–4.	Searches	Narrative review.
Malaysian HTAU (2004) ***[details?]***	Searches	HTA ***[?]***. No additional references.

Study	Source	Reason
Yap N, Frydenberg H (2004) Obesity in adolescence – Is surgery a good option. *Obesity Surgery* 14:931.	Searches	Abstract only.
Reichard K (2004) Bariatric surgery in morbidly obese adolescents. *Maryland Medicine* 5:16–18.	Searches	Narrative review. No additional references.
Rigg CA (1975) Proceedings: Jejunoileal bypass by morbidly obese adolescent. *Acta Paediatrica Scandinavica* Suppl:62–4.	Searches	Comment.
Rodgers BM (2004) Bariatric surgery for adolescents: a view from the American Pediatric Surgical Association. *Pediatrics*114:255–6.	Searches	No clear values on weight loss.
Sugerman HJ, Sugerman EL, DeMaria EJ et al. (2003) Bariatric surgery for severely obese adolescents. *Journal of Gastrointestinal Surgery* 7:102–107.	Searches	Gastroplasty, distal gastric bypass, and long-limb gastric bypass.
Inge TH, Donnelly LF, Vierra M, Cohen AP, Daniels SR, Garcia VF (2005) Managing bariatric patients in a children's hospital: Radiologic considerations and limitations, *Journal of Pediatric Surgery* 40:000.	Searches	Narrative review.
White J, Cheek D, Haller AJ (1974) Small bowel bypass is applicable for adolescents with morbid obesity. *American Surgeon* 40:000.	Searches	Small bowel bypass procedure.

2.6 Harms

Study	Reason for exclusion
Daee et al. ***[details]*** (2002) Psychologic and physiologic effects of dieting in adolescents. *Southern Medical Journal* 95:000.	Not relevant
Faith et al.***[details]*** (2004) Parent–child feeding strategies and their relationships to child eating and weight status. *Obesity Research*12:000.	Not relevant
Field et al. ***[details]*** (1999) Relation of peer and media influences to the development of purging behaviours among preadolescent and adolescent girls. *Archives of Pediatric and Adolescent Medicine*153:000.	Not relevant
Field et al. (2003) ***[details]***	Not professionally delivered weight loss programme.

Study	Reason for exclusion
Hill (2004) ***[details]***	Review. References checked
Irving et al (2002) ***[details]***	Narrative review on prevention of eating disorders.
Keller XXX, Stevens XXX (1996) Assessment, etiology, and intervention in obesity in children. *Nurse Practitioner* 21:000.	Narrative review.
Lowe XXX, Timko XXX (2004) ***[details]***	Review. References checked.
Neumark-Sztainer et al. ***[details]*** (2004) Are family meal patterns associated with disordered eating behaviors among adolescents? *Journal of Adolescent Health*35:000.	Not professionally delivered weight loss programme.
Neumark-Sztainer et al. ***[details]*** (2002) Weight-related concerns and behaviors among overweight and non-overweight adolescents: implications for preventing weight-related disorders. *Archives of Pediatrics and Adolescent Medicine* 2002:156:000.	Not relevant.
Patton et al ***[details]*** (1999) Onset of adolescent eating disorders in overweight and obese adults: population based cohort study over 3 years. *British Medical Journal* 318:000.	Not professionally delivered weight loss programme.
Pesa. ***[details]*** (1999) Psychosocial factors associated with dieting behaviors among female adolescents. *Journal of School Health* 69:000.	Not professionally delivered weight loss programme.
Pugliese et al (1983) ***[details]***	Not effect of weight management programme – underweight children with fear of obesity as a cause of short stature or delayed puberty.
Reilly et al. ***[details]*** (2003) Health consequences of obesity. *Archives of Disease in Childhood* 88:000.	Not relevant systematic review. References checked.
Stice et al ***[details]*** (1999) Naturalistic weight-reduction efforts prospectively predict growth in relative weight and onset of obesity among female adolescents. *Journal of Consulting and Clinical Psychology* 67:000.	Not professionally delivered weight loss programme.
Stice et al. ***[details]*** (2000) Naturalistic weight-reduction efforts prospectively predict growth in relative weight and onset of obesity among female adolescents. *Journal of Consulting and Clinical Psychology* 67:000.	Not relevant.
Stice et al. ***[details]*** (2005) Effects of a weight maintenance diet on bulimic symptoms in	???

Study	Reason for exclusion
adolescent girls: an experimental test of the dietary restraint theory. *Health Psychology* 24:000.	
Szwarc ***[details]*** (2004) Putting facts over fears: examining childhood anti-obesity initiatives. *International Quarterly of Community Health Education* 23:000.	Not relevant.
White et al. ***[details]*** (2000) Eating disorders in elementary and middle school children: risk factors, early detection, and prevention. *Journal of School Nursing* 16:000.	Literature review. References checked.

1
2