Interventions for treating obesity in children (Review)

Oude Luttikhuis H, Baur L, Jansen H, Shrewsbury VA, O'Malley C, Stolk RP, Summerbell CD

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[Intervention Review]

Interventions for treating obesity in children

Hiltje Oude Luttikhuis[1], Louise Baur[2], Hanneke Jansen[3], Vanessa A Shrewsbury[2], Claire O'Malley[4], Ronald P Stolk[3], Carolyn D Summerbell[5]

[1]Beatrix Children's Hospital and Department of Epidemiology, University Medical Center Groningen, Groningen, Netherlands. [2]Department of Paediatrics and Child Health, The University of Sydney, Westmead, Australia. [3]Department of Epidemiology, University Medical Center Groningen, Groningen, Netherlands. [4]School of Medicine and Health, Wolfson Research Institute, Durham University , Stockton-on-Tees, UK. [5]School of Medicine and Health, Wolfson Research Institute, Durham University, Stockton-on-Tees, UK

Contact address: Hiltje Oude Luttikhuis, Beatrix Children's Hospital and Department of Epidemiology, University Medical Center Groningen, PO Box 30.001 (CA80), 9700RB, Groningen, Netherlands. h.oudeluttikhuis@bkk.umcg.nl.

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ABSTRACT

Background

Child and adolescent obesity is increasingly prevalent, and can be associated with significant short- and long-term health consequences.

Objectives

To assess the efficacy of lifestyle, drug and surgical interventions for treating obesity in childhood.

Search methods

We searched CENTRAL on *The Cochrane Library* Issue 2 2008, MEDLINE, EMBASE, CINAHL, PsycINFO, ISI Web of Science, DARE and NHS EED. Searches were undertaken from 1985 to May 2008. References were checked. No language restrictions were applied.

Selection criteria

We selected randomised controlled trials (RCTs) of lifestyle (i.e. dietary, physical activity and/or behavioural therapy), drug and surgical interventions for treating obesity in children (mean age under 18 years) with or without the support of family members, with a minimum of six months follow up (three months for actual drug therapy). Interventions that specifically dealt with the treatment of eating disorders or type 2 diabetes, or included participants with a secondary or syndromic cause of obesity were excluded.

Data collection and analysis

Two reviewers independently assessed trial quality and extracted data following the Cochrane Handbook. Where necessary authors were contacted for additional information.

Main results

We included 64 RCTs (5230 participants). Lifestyle interventions focused on physical activity and sedentary behaviour in 12 studies, diet in 6 studies, and 36 concentrated on behaviorally orientated treatment programs. Three types of drug interventions (metformin, orlistat and sibutramine) were found in 10 studies. No surgical intervention was eligible for inclusion. The studies included varied greatly in intervention design, outcome measurements and methodological quality.

Meta-analyses indicated a reduction in overweight at 6 and 12 months follow up in: i) lifestyle interventions involving children; and ii) lifestyle interventions in adolescents with or without the addition of orlistat or sibutramine. A range of adverse effects was noted in drug RCTs.

Authors' conclusions

While there is limited quality data to recommend one treatment program to be favoured over another, this review shows that combined behavioural lifestyle interventions compared to standard care or self-help can produce a significant and clinically meaningful reduction in overweight in children and adolescents. In obese adolescents, consideration should be given to the use of either orlistat or sibutramine, as an adjunct to lifestyle interventions, although this approach needs to be carefully weighed up against the potential for adverse effects. Furthermore, high quality research that considers psychosocial determinants for behaviour change, strategies to improve clinician-family interaction, and cost-effective programs for primary and community care is required.

PLAIN LANGUAGE SUMMARY

Treating obesity in children

Childhood obesity affects both the physical and psychosocial health of children and may put them at risk of ill health as adults. More information is needed about the best way to treat obesity in children and adolescents. In this review, 64 studies were examined including 54 studies on lifestyle treatments (with a focus on diet, physical activity or behaviour change) and 10 studies on drug treatment to help overweight and obese children and their families with weight control. No surgical treatment studies were suitable to include in this review. This review showed that lifestyle programs can reduce the level of overweight in child and adolescent obesity 6 and 12 months after the beginning of the program. In moderate to severely obese adolescents, a reduction in overweight was found when either the drug orlistat, or the drug sibutramine were given in addition to a lifestyle program, although a range of adverse effects was also noted. Information on the long-term outcome of obesity treatment in children and adolescents was limited and needs to be examined in some high quality studies.

BACKGROUND

The prevalence of obesity and overweight is increasing in both adult and child populations throughout the world (Lobstein 2004; Wang 2006; WHO 2000). The 2004 report from the International Obesity Taskforce (IOTF) on worldwide prevalence rates, and a subsequent update, show that the paediatric obesity epidemic has spread globally, with some countries in economic transition having prevalence rates higher than those in the United States (Lobstein 2004; Wang 2006). Using the IOTF standard definition of paediatric overweight and obesity, the worldwide prevalence of overweight (including obesity) in children and young people aged 5-17 years is approximately 10%, with that of obesity alone being 2-3%. Certain regions and countries have particularly high rates of paediatric obesity: more than 30% of children and adolescents in the Americas, and approximately 20% of those in Europe, are overweight or obese, with lower prevalence rates being seen in sub-Saharan Africa and Asia (Lobstein 2004).

Within countries socio-demographic gradients in overweight have been observed. Overweight tends to be more prevalent among socio-economically disadvantaged children in developed countries (Shrewsbury 2008) and children of higher socio-economic status in developing countries (Lobstein 2004; Wang 2002). Among countries in economic transition obesity is more prevalent among higher income groups and in urban, compared with rural, communities (Hong 2007; Wang 2002), but there are indications that this burden may be shifting towards the poor, in adults at least (Popkin 2004) . With regards to ethnicity, data from the United States indi-

cate that differences in prevalence of obesity exist among Hispanic (21.8%), African American (21.5%) and white children (12.3%), with the sharpest increases occurring among African American and Hispanic children (Strauss 2001).

Overweight and obesity in childhood are known to have significant impact on both physical and psychosocial health. For example, hyperlipidaemia, hypertension, insulin resistance and abnormal glucose tolerance occur with increased frequency in obese children and adolescents (Freedman 1999; Reilly 2003; Weiss 2004). In addition, childhood obesity is associated with a range of medical conditions, including poor pulmonary function, advanced growth and early maturity, hepatic steatosis and cholelithiasis asthma, low grade systemic inflammation, sleep apnoea, polycystic ovary disease and orthopaedic complications (Dietz 1998; Ebbeling 2002; Lobstein 2004; Reilly 2003). Overweight children are known to become targets of early discrimination (Dietz 1998; Puhl 2007; Tang-Peronard 2008). In addition, obesity in childhood is an independent risk factor for adult obesity (Parsons 1999; Singh 2008; Whitaker 1997). A systematic review by Singh 2008 found that in high quality studies the risk of overweight children remaining so in adulthood was at least twice that for normal weight children, with the risk generally higher for adolescents and those who were obese during childhood. Furthermore, there is evidence of an association between adolescent obesity and increased risks for health in adult life (Must 1992; Must 1999; Power 1997). For example, Must and colleagues, in considering long-term morbidity and mortality of overweight adolescents, found that adolescent overweight predicted a broad range of adverse health effects, independently of adult BMI (Must 1992). The relative risks among men aged 68 to 73 were 1.8 (95% CI: 1.2 to 2.7; P = 0.004), for mortality from all causes and 2.3 (95% CI: 1.4 to 4.1; P = 0.002), for mortality from coronary heart disease. It is noteworthy that being overweight in adolescence was a more powerful predictor of risk than being overweight in adulthood. Metabolic and inflammatory markers are risk markers of future cardiovascular and endocrinological disease an can therefore be helpful in monitoring treatment success in terms of reducing complications.

Treatment of childhood overweight and obesity is important, given the significant health and social consequences both in the short- and long-term. Ultimately treatment shares the same fundamental principles as treatment in adults i.e. to decrease caloric intake and increase energy expenditure. However, the primary goal of treatment (i.e. weight reduction or deceleration of weight gain) and the recommended mode of intervention is variable and dependent on the child's age and initial level of overweight, among other considerations. In order to support clinicians in determining the most appropriate form of treatment, paediatric weight management guidelines exist in many countries to promote best practice, but at present many of these recommendations are based on low grade scientific evidence.

The first version of this systematic review was published in 2003 (Summerbell 2003) and included analysis of childhood obesity treatment studies published up until July 2001. Many of the studies included in the review had small sample sizes, high drop-out rates, unreliable or limited outcome measurements or sampling problems, raising concerns about validity and generalisability of the findings. Furthermore, the wide range of interventions tested made comparison of studies difficult. No direct conclusions could be drawn from the review.

The aim of this current review was to update the previous 2003 review. A new feature of this review is the consideration of drug trials and surgical interventions for the treatment of obesity in children and adolescents, reflecting both the increasing use of such therapies in clinical management and the emergence of published studies. Since the Review was first published there have been a number of trials of drug therapy in children, and especially adolescents, who are obese. In addition there have been several case reports and retrospective case series of bariatric surgery in adolescents.

This review complements the systematic review of long-term outcomes for the treatment of adult obesity (Avenell 2004) and includes studies that were part of a 2006 Cochrane review of dietetic interventions in child obesity (Collins 2006). The results of the current review and other systematic reviews will provide information on which to underpin clinical guidelines and health policy on the treatment of childhood obesity.

OBJECTIVES

To assess the efficacy of a range of interventions designed to treat obesity in children and adolescents, specifically the evaluation of any combination of lifestyle (dietary, physical activity, behavioral therapy), drug or surgical interventions, compared with any other combination of these interventions or no treatment.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs). The value and appropriateness of RCTs in assessing the efficacy of lifestyle interventions is a contentious issue. However, there is strong evidence that RCTs provide the least biased estimate of effect size (Stephenson 1998). For lifestyle interventions, only RCTs that were specifically designed to treat obesity in children and observed participants for a minimum of six months were included. The rationale for introducing this criterion arose from the belief that many interventions

appear to be effective in the short term (up to three months), but not in the long term (Glenny 1997). It seemed to be more important to evaluate the longer term effects of treatments, as this would provide a more valuable indication of effectiveness, given the chronic nature of obesity. For drug trials, we included trials that had at least three months of drug therapy and follow up at six months. Data were extracted for outcomes at 6, 9, 12 and 24 months where possible, and other time points where appropriate. This timeframe refers to the intervention itself or to a combination of the intervention with a follow-up phase.

Types of participants

Participants in study groups with a mean age less than 18 years at the commencement of the intervention were included, recognising that some interventions may target families inclusive of all children and some studies in adolescents include participants aged up to 21 years of age. Pregnant females and the critically ill were excluded, as were children with obesity due to a secondary or syndromic cause (for example Prader-Willi syndrome).

Types of interventions

Strategies: Lifestyle (dietary, physical activity and/or behavioral therapy interventions), drug (orlistat, metformin, sibutramine, rimonabant) and surgical interventions. Drug therapy had to be provided for at least 3 months. Alternative therapies were not considered in this review.

Topics: Diet and nutrition, exercise and physical activity, lifestyle and social support, involving children themselves with or without associated family members. Interventions that dealt with the treatment of eating disorders such as anorexia nervosa and bulimia nervosa were excluded, as were interventions that dealt with the treatment of type 2 diabetes in youth.

Settings: Interventions could be community, school or clinic-based.

Delivery: There was no restriction on who delivered the interventions. These may have included researchers, primary health physicians, nutrition/diet professionals, teachers, physical activity professionals, health promotion agencies, health departments or specialist doctors.

Types of outcome measures

To be included, studies had to report one or more of the following primary outcomes, presenting a baseline and a post-intervention measurement. Self-reported measurements of height and weight were not included.

Primary outcomes

The primary outcome measures for this review were measured (not self-reported) height and weight. If conducted by the same, trained operator, these measures are reasonably reliable. To account for sex- and age-related changes over time, we chose body mass index standard deviation score (BMI-SDS or BMI-Z-score) and percentage overweight to compare studies in the results section of this review. Studies were also included if they reported measures of body fatness (in percent or kilograms) by dual energy X-ray absorptiometry (DXA) or bioelectrical impedance analysis (BIA).

Secondary outcomes

- Measures of body fat distribution, like abdominal (visceral) or subcutaneous adiposity (measured by DXA or BIA) or waist and hip circumference.
- Measures of metabolic changes (or markers of future cardiovascular and endocrinological disease), for example, lipid profile, glucose and insulin metabolism, leptin, adipocytokines and other obesity or inflammatory markers.
- Behaviour change - for example, changes in weekly activity levels or energy intake.
- Participants views of the intervention.
- Measures of self-esteem, health status and well being, quality of life.
- Measures of harm associated with the process or outcomes of the intervention.
- Cost effectiveness/costs of the intervention.

Search methods for identification of studies

For the original version of this review published in 2003, the search strategy developed by Glenny 1997 was used. This involved extensive consultation with identified experts in the field in conjunction with information scientists in the NHS Centre for Reviews and Dissemination (NHS CRD). A range of databases were searched from 1985 to 2001. These search strategies are shown in Appendix 1 and Appendix 2. In addition, the reference lists of two reviews (Glenny 1997; SIGN 2003) were screened to identify any additional papers. A full description of this process was published in the original version of this review (Summerbell 2003).

For this current update in 2008, we used similar search strategies making some necessary changes because of changes in database indexing terms. Alternative therapies were not considered in this review, therefore terms in the original search describing alternative therapies were removed. As only RCTs were eligible for inclusion, filter terms for identifying RCTs in MEDLINE (Higgins 2006) were used.

The following electronic databases were searched in May 2008 (full search strategies can be found in Appendix 3).

1. Cochrane CENTRAL Register of Controlled Trials Register (CENTRAL) on *The Cochrane Library* Issue 2, 2008;
2. MEDLINE (Ovid) (2001 to May 2008);
3. EMBASE (Ovid) (2001 to May 2008, week 21);

4. CINAHL ARC Service (WinSPIRS online) (2001 to May 2008);
5. PsycINFO Silver Platter (WebSPIRS) (2001 to May 2008);
6. ISI Web of Science (2001 to May 2008); and
7. DARE (Database of Abstracts of Reviews of Effects), NHS EED (National Health Service Economic Evaluation Database), and Health Technology Assessment database on *The Cochrane Library* Issue 2, 2008.

In addition, the reference list of a systematic review on effectiveness of weight management programs in children and adolescents (Whitlock 2008) was scanned for relevant references. No new studies for inclusion were identified from this report; however three surgical studies were identified which were not eligible for inclusion because they were not randomised controlled trials (Lawson 2006, Sugerman 2003, Tsai 2007).

Data collection and analysis

Methods described in the Cochrane Handbook were used (Higgins 2008). Assessment of search strategy data was undertaken independently by two reviewers (HOL screened all, the second review was performed by all other authors by dividing all titles and abstracts into equal batches). Study data extraction and information on a number of measures of methodological quality of the included studies was assessed independently by two reviewers; study design, statistical power, method of allocation concealment, blinding of outcome assessment, comparability of participants baseline variables, and drop out rates between study arms. Where there was uncertainty, authors were contacted to clarify aspects of study design. Differences between reviewers were resolved by discussion. In cases where the two reviewers did not reach consensus, the study was presented to a third independent reviewer for a final decision.

Most of the included studies were too small to have the power to detect efficacy. In an attempt to overcome this problem, we compared studies that included children in the same age group, dealt with comparable interventions, and had a similar duration of intervention at the follow up moment for meta-analysis. Data needed to be reported at 6, 9, 12 or 24 months for the same outcome measurements (BMI-SDS or percentage overweight). Since few data on BMI-SDS were available in adolescents, we chose absolute changes in BMI as a second measure of fatness to compare results obtained in adolescents. Only studies providing similar analyses based on intention-to-treat principles (for example with baseline- or last-observation-carried-forward or imputed data by mixed model analysis) were considered. Studies fulfilling all these criteria were pooled in meta-analyses. Results were reported independently if studies were not pooled. Where key details or data were missing authors were contacted, or data were imputed based on methods described in the Cochrane Handbook (Higgins 2008).

RESULTS

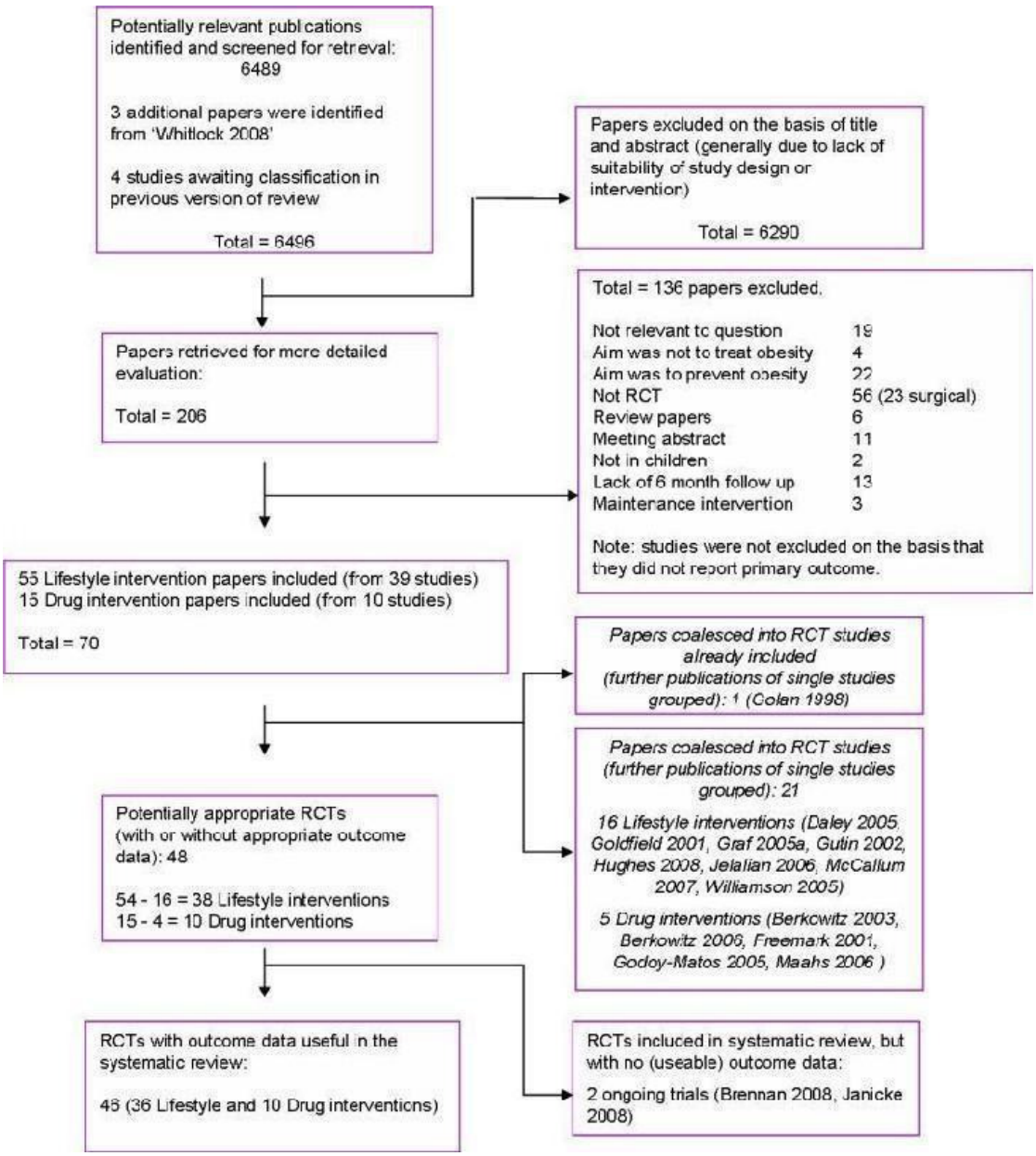
Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

The updated search of electronic databases performed in 2008 found 6496 abstracts. From these the full text of 206 papers were assessed. The results of the 2008 searches are detailed in Figure 1.

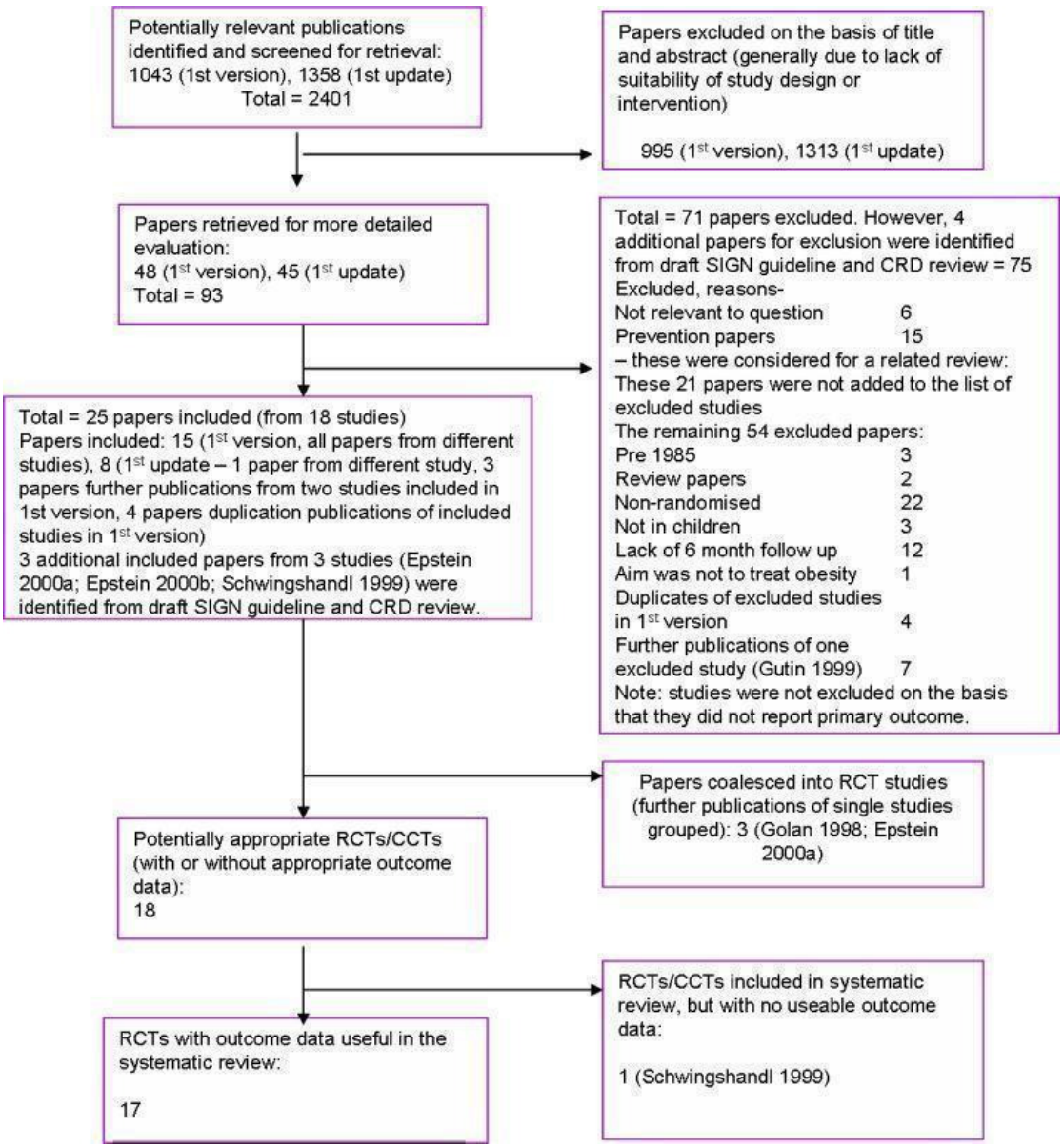
Figure 1. 2008 Quorom statement flow diagram [revised 29/08/08] Interventions for Treating Obesity in Childhood



All papers for which hard copies were obtained but which failed to meet the inclusion criteria (n=136 papers) were excluded from this review (see Characteristics of excluded studies). Nineteen papers were clearly not relevant to the aim of this review (nine papers were on treatment of other conditions like PCOS, type 2 diabetes, fatty liver disease, eating disorders and precocious puberty, six papers on predictors of success or failure after weight loss-intervention, two on alternative therapies, one laparoscopy technique description and one paper on a functional meal test). In four papers the aim was other than to treat childhood obesity and 22 papers focused on the prevention of childhood obesity or preventative health. Fifty-six papers were excluded because they were not randomised controlled studies. These included all studies on surgical interventions (n=23). Two papers were identified that were interventions in participants other than children. In 13 papers the participants were followed less than six months. Six review type papers and 11 meeting abstracts were excluded. These include three studies that were pending assessment in the original review (Ball 2000; Coates 1982; Taitano 1998). For another study pending assessment in the original review, a published paper was found and included (Jelalian 2006). Three studies were excluded because they considered maintenance treatment after an obesity intervention (Deforche 2005; Van Egmond-Frohlich 2006; Wilfley 2007). The remaining 70 papers (55 on lifestyle interventions, 15 on drug interventions) reported 49 different studies (39 on lifestyle interventions, 10 on drug interventions). One lifestyle intervention paper was an additional report of an existing included study (Golan 1998).

Brief details of the results of the searches for the previous version of the review can be found in Figure 2.

Figure 2. 2002 Quorom statement flow diagram [revised 20/08/02] Interventions for Treating Obesity in Childhood



Included studies

Eighteen studies were included in the first version of the review (Duffy 1993; Epstein 1985a; Epstein 1985b; Epstein 1985c; Epstein 1994a; Epstein 1995; Epstein 2000a; Epstein 2000b; Flodmark 1993; Golan 1998; Graves 1988; Israel 1985; Israel 1994; Mellin 1987; Schwingshandl 1999; Senediak 1985; Wadden 1990; Warschburger 2001). They all involved lifestyle interventions to treat obesity in children or adolescents (Figure 2). An additional 46 studies that met the inclusion criteria were found in 2008. Therefore a total 64 studies are included in the current review. Two additional papers were ongoing trials, both involving lifestyle interventions, but these studies could not be included in the present review because outcomes measures were not yet available (Brennan 2008; Janicke 2008, see Characteristics of included studies).

Overall, 54 studies reported on lifestyle interventions, ten on drug interventions (with or without combination with lifestyle intervention) i.e. sibutramine (n=5), orlistat (n=3) and metformin (n=2). None of the surgical intervention studies met the inclusion criteria. No randomised controlled trials of bariatric surgery have been reported in adolescents. Neither have there been any published reports of a controlled clinical trial, a controlled before and after study or an interrupted time series study (as defined by Cochrane EPOC criteria). Hence, surgical interventions are not further considered in this review.

The total number of participants in the 64 included studies with outcome data was 5230, of which 3806 participated in the lifestyle studies and 1424 in the drug trials. Ages ranged from 3 to 21 years. Thirty-four lifestyle studies included children with a mean age below 12 years. All but one drug trial involved adolescents aged 12 to 19 years. One study included children aged 9 to 18 years, but the mean age of children was 12.5 years (Srinivasan 2006).

Of the lifestyle intervention studies, 12 focused on exercise, physical activity or the reduction of sedentary behaviours, 6 focused on diet and 36 concentrated on behaviorally orientated treatment programs. The lifestyle interventions ranged in duration from 1 month to 24 months, with 14 having a duration less than 6 months. Forty interventions lasted 6 months or longer, 6 of which continued for one year. Four interventions lasted at least two years. Thirty of the 54 lifestyle studies took place in the USA and Canada (29 in the USA, one in Canada). Twelve studies were conducted in Europe (three in Germany, two in United Kingdom, one each in Austria, Belgium, Finland, France, Italy, Sweden and Switzerland). Seven studies took place in Australia and Asia (four in Australia, two in China and one in Japan). The other five studies were conducted in South America (one in Brazil) or the Middle-East (all four in Israel).

Two studies on sibutramine were conducted in the USA, two in Central America (both in Mexico) and the other one in Europe (the Netherlands). One of the studies with orlistat took place in the USA and one was a multicenter trial in the USA and Canada, the third study took place in Central Eurasia (Turkey). The two metformin trials were conducted in the USA or Australia.

A wide range of behavioural approaches have been examined. These include family therapy, cognitive-behavioural treatment, problem-solving approaches and multicomponent behavioural programs which incorporate a variety of behavioral techniques. The specific details of the behavioral programs vary widely between the studies. The target of intervention was the child in nine studies (all but one in adolescents).Two studies did not clearly report their target of intervention but it appeared to be the child (Schwingshandl 1999; Warschburger 2001). Six studies examined the effects of the level of parent and/or child participation (Golan 1998; Israel 1985; Israel 1994; Golan 2006; Munsch 2008; Wadden 1990). In one study the target of intervention was the parent (McCallum 2007). However, in most studies (n=40) the target of intervention was the family or the child with a parent. In the drug trials the drugs were only administered to the child. Two drug trials reported the family as the target of the lifestyle intervention component (Berkowitz 2003; Berkowitz 2006).

For details of included studies, see the Characteristics of included studies table.

Risk of bias in included studies

All 64 included studies were RCTs. All studies included in this review had some methodological weaknesses according to the criteria set out in the Cochrane Handbook (Higgins 2008), and thus did not fulfil all quality criteria.

Allocation

Allocation to the intervention or control group was reported to be concealed in 14 of 54 lifestyle studies. However, allocation concealment was unclear in 38 of 54 studies and two studies reported that allocation was not concealed (i.e. chosen by lot, Graf 2005a; i.e. coin toss, Grey 2004). In all but two drug intervention studies, allocation to intervention or control was concealed; in one sibutramine study allocation concealment was unclear (Godoy-Matos 2005) and one orlistat study reported an unconcealed allocation to intervention or control (i.e. alternating patients were randomised to intervention or control, Ozkan 2004).

Of the 54 lifestyle studies with useful outcome data, the unit of allocation was the child in 38 and family in 13 studies. One study randomised family physicians to intervention and control (Nova 2001) and two studies randomised schools to intervention and control (Berry 2007; Graf 2005a). In all ten drug interventions the unit of allocation was the child.

Blinding

Blinded outcome assessment was reported in five of the 54 lifestyle intervention studies. Outcome assessment was not blinded in seven studies and unclear in the other 42 studies. Outcome assessment was blinded in seven of the drug trials. In the other three it was unclear (Garcia-Morales 2006; Godoy-Matos 2005; Ozkan 2004).

Incomplete outcome data

One study reported that no participants were lost to follow-up (Weintraub 2008). Drop-out rates reported at the end of intervention ranged from 0 to 42%. Lost-to-follow-up rates at 6 months ranged from 1 to 42%, at 9 months from 8 to 34% and at 12 months from 7 to 43%. Dropout rates after 12 months of follow up ranged from 12 to 52%. Twenty-seven studies reported a completion of intervention rate of more than 80%. Four other studies did not adequately describe attrition (Grey 2004; Rooney 2005; Warschburger 2001; Woo 2004). Twenty-one lifestyle intervention studies reported analysis based on intention-to-treat principles to account for missing data. In general, drop-out rates in drug intervention trials were higher; at the end of intervention they ranged from 4 to 35%, but in only four of the drug trials, data at follow up measurements represented more than 80% of the baseline sample. All but three drug trials performed analysis based on intention-to-treat principles (Freemark 2001; Ozkan 2004; Srinivasan 2006).

Other potential sources of bias

The sample sizes of studies ranged from 16 to 218 participants in the lifestyle interventions, and from 24 to 539 participants in the drug trials. Power calculations were only discussed in 15 lifestyle studies included in this review. Two of which did not report statistical power ((De Mello 2004 (n=38); Nova 2001 (n=186)) and three did not reach the statistical power calculated ((Kalavainen 2007 (n=70); Munsch 2008 (n=56); Weintraub 2008 (n=21)). Sample sizes for studies with power calculations ranged from 27 to 209 participants. Thirty-eight of 54 lifestyle interventions randomised less than 30 children to at least one study arm. Four of the drug intervention studies did not discuss power. In the other six drug trials power was not reported in one ((Godoy-Matos 2005 (n=60)) and ranged from 80 to 93% in the others. Most drug trials included in this review had small sample sizes; six out of ten drug trials randomised less than 30 children to at least one study arm.
Baseline differences between intervention and control groups were discussed in most studies, four lifestyle studies found a significant difference in body composition between the experimental and control group (Ebbeling 2003, fat mass; Graf 2005a, BMI; Nova 2001, percentage overweight and BMI; Rodearmel 2007, waist circumference). In four studies, baseline differences between study arms were found in terms of socio-economic status (McCallum 2007), lifestyle behaviours (De Mello 2004 - higher spontaneous leisure activity in control group; Nova 2001 - higher propensity for snacks in the control group), and child perceptions of parenting styles (Epstein 2008a). Two drug studies found a significant difference in body composition between the experimental and control group at baseline (Freemark 2001, BMI; Ozkan 2004, BMI and weight for height). One study found a baseline difference in mean baseline heart rate between the two study arms (Garcia-Morales 2006). None of these baseline differences between groups were taken into account in analyses reported in the original papers, neither in the lifestyle, nor in the drug trials.
Seven studies (Braet 2004; Grey 2004; Gutin 2002; Johnston 2007a; Johnston 2007b; Williamson 2005) reported measures undertaken to minimise contamination between study arms. One study reported that protection against contamination was not done, but it was assessed and found to be minimal (McCallum 2007). Forty-six studies did not discuss the potential of contamination between study groups. In drug interventions in which allocation to intervention or placebo is concealed, contamination might not be a problem. Furthermore, most of these studies compared drug treatment with placebo treatment, with participants in both arms also receiving the same lifestyle intervention. The two studies in which allocation concealment was unclear or not done (Godoy-Matos 2005; Ozkan 2004), did not report measures against contamination between study groups.
Only five of 16 lifestyle studies published after 2005, and two of the drug trials reported a clinical trials registration number. Forty-four lifestyle studies reported funding or financial disclosure. This is an important issue since there could be a conflict of interest when the operators of a specialist clinic also carry out research which might well be seen as evaluating the work of the clinic. In addition, some of the included studies may have been poorly funded, which may explain the small sample sizes found in many studies. However, no conflicts of interest of any note were reported. Most studies were funded by national health institution research grants. All drug trials reported funding sources. Most of these studies were industry-sponsored but four studies reported non-industry sources of funding (Freemark 2001; Maahs 2006; Ozkan 2004; Srinivasan 2006).

Effects of interventions

The studies included in this review varied greatly in intervention design, outcome measurements and methodological quality. Most studies demonstrated beneficial effects of interventions on child adiposity from baseline to the end of intervention or follow up. The challenge is to determine which intervention is most effective. In this section effects of interventions on child adiposity are described. Measures of harm are also discussed. Secondary outcome data for studies will be included in future revisions of this review. Primary results are reported in the table Characteristics of included studies.

Lifestyle intervention studies

Two-thirds of lifestyle studies were conducted in children (defined as having a mean age less than 12 years, n=37), with one-third of studies including adolescents (defined as having a mean age at or above 12 years, n=17).

Three types of lifestyle interventions were identified: dietary, physical activity and behavioural interventions. Behavioural therapy was defined as therapy aimed at changing thinking patterns and actions, especially in relation to dietary intake and eating, physical activity and sedentary behaviours, and the family's food and physical environment. If interventions did not specifically include a behavioural program they were classified as a dietary or physical activity intervention as appropriate. If diet and physical activity were combined in an intervention, classification for meta-analysis was based on the intensity of the diet or physical activity and the comparison made between the study arms, for example Rolland-Cachera 2004 consisted of both a diet and a physical activity program, but comparison between study arms was made based on the diet in the experimental and the control group and therefor this study is classified under dietary interventions.

Follow-up measurements were most often reported at 6, 9, 12 and 24 months. As a primary outcome, 41lifestyle intervention studies reported either BMI-SDS (n=22) or percentage overweight (n= 17), 11 studies reported absolute BMI, one reported fat mass, and one BMI percentile. Eleven lifestyle studies included fat distribution (waist circumference, waist circumference-SDS, waist-to-hip ratio and subcutaneous or abdominal subcutaneous fat distribution) as a secondary outcome. One study reported intima media thickness as a secondary outcome (Woo 2004). Including these kinds of secondary measures may help to establish a full risk profile for the child. Furthermore, from a research perspective, it will help to further delineate the mechanisms by which interventions may be working.

Interventions in children under 12 years old

Dietary interventions

Four studies concerning a dietary intervention were identified (Epstein 2008a; Gillis 2007; Nova 2001; Satoh 2007). Epstein 2008a and Nova 2001 fulfilled all the criteria for pooling in a meta-analysis, but they involved different comparisons i.e. Epstein 2008a compared two interventions whereas Nova 2001 compared dietary intervention to self-help. Epstein 2008a demonstrated beneficial effects in both the 'making healthy food choices' group and the 'decrease high energy dense foods' group at 6, 12 and 24 months on child weight status. However, after 12 months follow up, the effects were superior for the children in the 'healthy food choices' group. Nova 2001 demonstrated beneficial effects on child adiposity of a dietary intervention compared to an intervention with general health and obesity information leaflets at 6 and 12 months of follow up.

Activity-based interventions

Nine studies focused mainly on the activity content of the intervention (Epstein 1985a; Epstein 1985b; Epstein 1995; Epstein 2000b; Rodearmel 2007; Rooney 2005; Schwingshandl 1999; Weintraub 2008; Woo 2004). Epstein 2000b; Rodearmel 2007; Schwingshandl 1999 and Weintraub 2008 fulfilled the earlier mentioned quality criteria, but dealt with incomparable study designs and interventions. Schwingshandl 1999 did not report useful outcome data at six months of follow up or later. Both Epstein 2000b and Rodearmel 2007 found beneficial effects on adiposity from baseline to six months in all the intervention groups. However, no significant differences between groups were found. Rodearmel 2007 compared an intervention where families were guided to achieve two small lifestyle changes (mainly focused on pedometer walking) with a self monitoring group. Both interventions seemed effective after six months, but to the same degree. At 6 and 24 months follow up, Epstein 2000b reported similar findings: no differences in adiposity change from baseline were found between interventions (high and low dose) that focused on decreasing sedentary activity or interventions targeting increasing physical activity. Weintraub 2008 compared an after school soccer program to an 'active placebo' i.e. a health and nutrition education program. Six months after commencing the intervention, children in both groups had increased their absolute BMI, with a significant smaller increase in favour of the soccer group.

Behavioural interventions

Twenty-four studies incorporated interventions with a large behavioural component, but only eight reported analyses based on intention-to-treat principles (Epstein 2005; Flodmark 1993; Golan 2006; Golley 2007; Hughes 2008; Kalavainen 2007; McCallum 2007; Munsch 2008). Of these eight, five studies fulfilled all criteria to be pooled in meta-analysis to establish the effect on change in BMI-SDS of a behavioural family program compared to standard or minimal care (Epstein 2005; Golan 2006; Golley 2007; Hughes 2008; Kalavainen 2007) at 6 months follow up. However, data for change in BMI-SDS for study 1 by Epstein 2005 were presented in figures only and could not be included. Epstein 2005 found significant decreases in BMI-SDS over time in both intervention groups, but the rate at which they changed was the same in both groups, suggesting no additional effects of positively reinforcing youth for increasing alternative behaviours (any freely chosen activity that did not involve simultaneous eating) to eating in a standard family-based treatment of paediatric obesity. Meta-analysis of the remaining four studies including 301 participants, showed a small favourable effect of -0.06 (95% CI: -0.12 to -0.01) in BMI-SDS in the parent-focused behavioural group intervention over standard care (Z=2.14, P=0.03; Analysis 1.1) [Note: the experimental (behavioural intervention for parents only) and control (behavioural intervention for the parent and child) groups of Golan 2006 were exchanged to assure that

all experimental interventions grouped for meta-analysis involved similar parental and child participation].

McCallum 2007 found no beneficial effect on adiposity either when compared to baseline or between groups at nine months of follow-up, when a three-month solution-focused brief counselling intervention delivered by general practitioners was compared to a control condition (no intervention). Munsch 2008 compared a behavioural program addressed to mother and child, or to mothers only. At nine months of follow up, the authors reported amelioration of weight status in both groups, but the temporal course of changes did not differ between groups.

Outcomes at 12 months of follow up were reported by Flodmark 1993; Golley 2007; Hughes 2008; Kalavainen 2007; McCallum 2007 and at 24 months of follow up by Epstein 2005 and Golan 2006. In all studies, results found at the end of intervention persisted until 12 or 24 months of follow-up. Three studies reporting change in BMI-SDS in 264 participants at 12 months were pooled in meta-analyses (Golley 2007; Hughes 2008; Kalavainen 2007). No additional beneficial effect of a parent focused behavioural group intervention over standard care was found on BMI-SDS at 12 months follow up (Analysis 1.2).

Flodmark 1993 compared a school-based family treatment to conventional therapy or a control group without intervention. At the end of intervention (14 to 18 months) the family therapy group demonstrated a significantly smaller increase in BMI, than the conventional therapy group (controls were not measured at this time point). At follow-up one year after the end of intervention the increase in BMI was significantly smaller in the family therapy group when compared to the untreated control group, but no significant differences were found between the family therapy and conventional therapy group, or between the conventional therapy compared to the untreated control group.

Interventions in children 12 years and older

Dietary interventions

Two studies which focused on dietary interventions in adolescents were included (Ebbeling 2003; Rolland-Cachera 2004). Only Ebbeling 2003 performed analysis based on intention-to-treat. At 12 months follow up, the authors found a favourable effect on absolute BMI and fat mass of a dietary intervention with reduced glycaemic index when compared to a standard dietary intervention with reduced fat load (both in combination with behavioural therapy). Changes were significant from baseline to twelve months for the reduced glycaemic index group only and between groups as well, in favour of the reduced glycaemic index intervention.

Activity-based interventions

Three studies compared an experimental activity program to an 'active placebo' or control intervention (Carrel 2005; Daley 2006; Gutin 2002). Daley 2006 fulfilled all quality criteria. The authors compared an after school activity program to an 'active placebo' (relaxation therapy) and a control group without intervention. At six months follow up, no significant changes in BMI-SDS, neither from baseline to end of follow up, nor between groups, were found.

Behavioural interventions

Twelve lifestyle interventions in adolescents with a behavioural component as the main focus of intervention were identified. Seven fulfilled the above mentioned criteria to be pooled in meta-analysis (Grey 2004; Jelalian 2006; Johnston 2007a; Johnston 2007b; Saelens 2002; Savoye 2007; Williamson 2005). However, only four studies reported similar outcome measures at six months (Johnston 2007a; Johnston 2007b; Savoye 2007; Williamson 2005). At six months follow up, Johnston 2007a and Johnston 2007b reported a favourable effect of the nutrition education and physical activity program with behavioural strategies over the self-help control condition on BMI-SDS. Savoye 2007 showed decreases in absolute BMI in a family-based, intensive lifestyle program with a behavioural modification component compared to increases in BMI in the control condition at six months after the beginning of the intervention. Williamson 2005 found more moderate changes between groups for BMI-SDS, when an internet-based behavioural program for teenage girls was compared to an internet-based control program. Data at six months follow up from Johnston 2007b; Savoye 2007 and Williamson 2005 were pooled in a meta-analysis. The overall effect on BMI-SDS found in 291 participants was -0.14 (95% CI: -0.17. to -0.12, Z=11.51, P<0.00001; Analysis 2.1). The same studies also presented changes in absolute BMI at 6 months follow up. Pooled data for meta-analysis in 362 participants demonstrated an overall effect of a behavioural intervention over standard care or control condition of -3.04 (95% CI: -3.14 to -2.94) kg/m^2on absolute BMI (Z= 61.57, P<0.00001) as presented in Analysis 2.2)

Saelens 2002 reported non-significant decreases in BMI-SDS in the adolescents engaging in a four-month behavioural weight control intervention (phone and email contact), compared with significant increases in BMI-SDS in adolescents in the standard single physician care. This led to a significant between groups difference at the end of intervention (four months). At seven-months follow up, however, there were no significant interactions of condition by time or main effects of time for any secondary outcomes from baseline to post-treatment to follow-up.

Jelalian 2006 hypothesized that peer-enhanced adventure therapy would have an additional effect on adolescent adiposity, when compared to standard care. Although significant changes in BMI from baseline were found at ten-months follow up, no difference was shown in rate of BMI change between groups.

Three studies provided outcome data for BMI at 12 months follow-up (Grey 2004; Savoye 2007; Williamson 2005). At 12-months follow up, Grey 2004 did not demonstrate effectiveness

of adding coping skills training to a four-month behavioural program for children aged 7-17 years. Neither change in absolute BMI from baseline to 12 months, nor between groups, was significantly different. Savoye 2007 and Williamson 2005 were comparable based on intervention type and length, and 12-month data from these studies were pooled for meta-analysis. Savoye 2007 and Williamson 2005 demonstrated that significant changes in BMI-SDS and absolute BMI in favour of the behavioural weight management program at six months after commencement of the intervention remained significant at the 12 month follow up). Pooled data for meta-analysis in 321 participants demonstrated an overall effect of a behavioural intervention over standard care or control condition of -0.14 on BMI-SDS (95% CI: -0.18. to -0.10, Z= 7.11, P<0.00001, Analysis 2.3) and -3.27 kg/m^{2}on absolute BMI (95% CI: -3.38 to -3.17, Z= 60.10, P<0.00001, Analysis 2.4).
However, in their comparison of an internet-based behavioural program for teenage girls to an internet-based control program, Williamson 2005 demonstrated that earlier significant differences between groups in favour of the internet-based behavioural program had disappeared at 18 months to 24 months follow up, since girls in the intervention group regained weight.

Drug intervention studies

All drug studies were performed in adolescents (defined as having a mean age at or above 12 years). Three types of medication were identified in included drug trials: metformin, a hypoglycaemic agent (Freemark 2001; Srinivasan 2006); orlistat, a gastrointestinal lipase inhibitor (Chanoine 2005; Maahs 2006; Ozkan 2004); and sibutramine, a serotonin and noradrenalin reuptake inhibitor (Berkowitz 2003; Berkowitz 2006; Garcia-Morales 2006; Godoy-Matos 2005; Van Mil 2007).
The following measures of fatness were reported in the drug trials: BMI-SDS, change in absolute BMI, percentage change in initial BMI and the proportion of participants achieving more than 5% or more than 10% decrease in initial BMI, and fat-mass (absolute and percentage). Six drug studies also included fat distribution (waist circumference [with or without SDS] and subcutaneous or abdominal subcutaneous fat distribution) as a secondary outcome.

Metformin

Both included metformin trials (Freemark 2001; Srinivasan 2006) did not perform analysis based on intention-to-treat. Therefore these data were not pooled in meta-analysis.

Orlistat

Both Chanoine 2005 and Maahs 2006 fulfilled the quality criteria. Pooled meta-analysis in 579 participants, found an additional effect of orlistat over placebo on absolute BMI at 6 months follow up, when given in combination with a lifestyle intervention (-0.76 kg/m^2, 95% CI: -1.07 to -0.44, Z= 4.70, P<0.00001; Analysis 3.1).

Sibutramine

Four of five sibutramine trials were comparable based on our quality criteria (Berkowitz 2003; Berkowitz 2006; Garcia-Morales 2006; Godoy-Matos 2005). Berkowitz 2003 and Berkowitz 2006 also reported BMI-SDS outcomes (figures only). All four studies reported changes in absolute BMI at 6 months but Berkowitz 2003 and Berkowitz 2006 only reported change in absolute BMI and BMI-SDS outcomes in figures and therefore were not included in a meta-analysis. Both of these studies found a significant between groups effect of sibutramine in combination with a lifestyle intervention over placebo in combination with a lifestyle intervention. Outcome data at six months of Garcia-Morales 2006 and Godoy-Matos 2005 in 111 participants were pooled in a meta-analysis. A favourable effect on absolute BMI of sibutramine over placebo was found of -1.66 kg/m^2 (95% CI: -1.89 to -1.43, Z= 14.23, P<0.00001; Analysis 4.1).
Berkowitz 2006 was the only study reporting long-term outcome data. At 12 months follow up, the authors found an estimated mean change in BMI for sibutramine plus behavior therapy of -2.9 kg/m^2 versus -0.3 kg/m^2 for placebo plus behavior therapy. When data were expressed as BMI-SDS a statistically significant treatment difference of 0.22 favoured sibutramine.
Van Mil 2007, as opposed to the other trials in which duration of drug intervention was six months, only gave sibutramine for three months; the authors report the decrease in BMI-SDS was comparable in both groups at three months. From three to six months follow up there was an increase in BMI-SDS in the sibutramine group in contrast to a further decrease in the placebo group, but this was not significant in the intention-to-treat analysis. The cumulative change in BMI-SDS from baseline to end of follow up at six months was not reported.

Adverse effects

Reporting of harm was noticeably absent in lifestyle studies. Only 18 out of 54 lifestyle studies reported measures of harm such as occurrence or deterioration of disordered eating, depression or anxiety. However, changes in linear height growth over time and reasons for dropouts were commonly reported in lifestyle studies. In contrast, the majority of drug studies reported total adverse events and possible medication-related adverse events.

Lifestyle interventions

None of the lifestyle studies reported an adverse effect on linear height growth.
Ten lifestyle studies (Braet 2004; Epstein 1985a; Epstein 1985c; Golan 1998; Israel 1985; Israel 1994; Jelalian 2006; Munsch 2008; Saelens 2002; Williamson 2005) reported measures of disordered

eating and/or behaviours. The duration of the intervention in these studies ranged from 4 to 24 months. Braet 2004 found significant improvements for drive for thinness, bulimia, body dissatisfaction, external eating, eating concern, weight concern and shape concern. Furthermore, the total number of binges per month decreased significantly from pre- to post intervention. Considerable improvements were maintained in the majority of adverse effects until follow up at 14 months. Similarly, Epstein 1985a and Epstein 1985c found significantly improved eating behaviours at 6, 12 and 24 months of follow up. Golan 1998, Israel 1985 and Israel 1994 collectively reported positive changes in eating styles and habits post treatment, yet no differences were apparent across groups. Adolescents in the internet-based behavioural program demonstrated lower scores of emotional eating and overeating, whereas changes in the levels of concern relating to dieting remained unchanged, compared to lower levels of concern relating to dieting and weight loss in the adolescents in the internet-based control program (Williamson 2005). No adverse changes were reported in any of the studies.

Measures of psychological well-being, like global self-worth, self-esteem, quality of life and absence of depressive symptoms or internalising behaviour problems were provided in 11 studies (Braet 2004; Daley 2006; Epstein 2000a; Hughes 2008; Jelalian 2006; McCallum 2007; Mellin 1987; Munsch 2008; Wadden 1990; Warschburger 2001; Weintraub 2008). Intervention duration for the aforementioned studies ranged from 3 to 24 months. Braet 2004 recorded positive changes in global, athletic and physical well-being and Epstein 2000a recorded improvement in child problem solving, internalising behaviours and total competence in both study arms at the end of treatment and persisting at follow up. Jelalian 2006 found that adolescents randomised to both treatment conditions demonstrated significant improvements on dimensions of global self-concept, physical appearance, and physical self-worth over time. Depression scores were recorded in five studies (Daley 2006; Mellin 1987; Munsch 2008; Wadden 1990; Weintraub 2008). A reduction in depression scores was evident in all studies. However, the decrease over time reported by Daley 2006 was not significant. Munsch 2008 recorded a decrease in both groups, with a significant decrease identified in the children from the behavioural therapy for mother only study arm. This decrease was also noted to be particularly prominent in the early intervention stages. Depressive symptoms were shown to be slightly higher in the control group than that of the soccer group at six months by Weintraub 2008. However this change was not reported as being significant. Hughes 2008, McCallum 2007 and Warschburger 2001 found significant improvements in quality of life by child- and/-or parent-report over time, without differences across groups. None of the studies reported adverse changes in the children's psychological well-being.

Jelalian 2006 reported that no adverse events or untoward side effects occurred in either the peer-enhanced cognitive behaviour therapy or the standard cognitive behaviour therapy study arm during the intervention. Furthermore, drop-out rates in both groups were similar. The standard care arm of the study was discontinued due to patient and parent concerns with treatment acceptability and associated significant difficulties with retention. In Munsch 2008, study arms consisted of behavioural therapy delivered to mother and child compared to behavioural therapy delivered to the mother only, with drop outs recorded as 31% and 70% respectively at six months (p=0.004), even though suitability ratings at this time-point did not differ between groups. In contrast, Golan 2006 reported a higher full attendance rate for the parents-only group vs the parents and children group and no difference in dropout rate per group. In Golan 1998, the attendance rate for both groups (behavioural therapy for parents only vs behavioural therapy for children only) was similar, but there were nine (30%) drop-outs in the behavioural therapy for children only group, compared to one (3%) in the behavioural therapy for parents only group. The majority of studies specified reasons for drop out e.g. lost to follow up due to moves, family problems, no longer interested, car accidents or lack of motivation.

Weintraub 2008 was the only lifestyle study to report withdrawals due to adverse events. In total three participants withdrew from the intervention group and six from the control. Headaches, rash and pain were among the complaints made. However it was specified that all recorded adverse events, both for the intervention and control groups, were unrelated to the intervention.

Metformin

Participants received metformin for 6 months at a daily dose of 1g (0.5g twice daily) (Freemark 2001) or 2g (1g twice daily) (Srinivasan 2006). Median adherence to metformin was 78% (range 15-99%) in one study which was not different from the placebo group (Srinivasan 2006). There were no withdrawals due to adverse events in either study; however, medication dose was lowered due to nausea in three participants (Freemark 2001 n=1; Srinivasan 2006 n=2). In both studies there was no adverse effect on serum lactate, or measures of liver or renal function. Freemark 2001 reported that there were no episodes of vomiting or lactic acidosis. Srinivasan 2006 reported that there was no biochemical evidence of metformin toxicity. In one study, three metformin treated patients, and one placebo patient, complained of transient abdominal discomfort or diarrhoea that resolved within the first one to two weeks of therapy and another participant may have had an exacerbation of migraine (Freemark 2001).

Orlistat

Participants in each study received 120mg orlistat three times a day as well as a daily multivitamin supplement (Chanoine 2005; Maahs 2006; Ozkan 2004). Adherence to orlistat was assessed in two studies and shown to be 73% (Chanoine 2005) and >80% (Maahs 2006). The duration of the intervention in the three studies was 6 months, 12 months and between 5-15 months. In all

studies, withdrawals due to adverse events were higher in the orlistat intervention compared with the placebo/control intervention (Chanoine 2005: 3.4% vs 1.7%; Maahs 2006: 15% vs 0%; Ozkan 2004: 31.8% vs 0%). Chanoine 2005 reported serious adverse events in 3.1% of those receiving orlistat and 2.7% of those receiving placebo, with only the symptomatic cholelithiasis that led to cholecystectomy in a 15 year old girl being considered possibly related to orlistat by the investigators. The same author reported that at least one adverse event was reported by 97% and 94% of participants in the orlistat and placebo interventions respectively (Chanoine 2005); equivalent data were not reported in the other studies.

The most common types of adverse events in all three studies were associated with the gastrointestinal tract (GIT) and were more prevalent in the orlistat intervention compared with the placebo intervention. The most common GIT adverse events were fatty/oily stool or evacuation, oily spotting, increased defecation, cramps and abdominal pain. Changes in blood vitamin A, D, and E levels were reported in two studies and all levels increased or stayed the same, except in one study where vitamin D levels decreased in both the orlistat and placebo interventions (Maahs 2006).

Chanoine 2005 also measured estradiol levels, cardiovascular effects, gallbladder structure, renal structure, bone mineral content/density, and other non-GIT adverse events. Girls in the orlistat group had a statistically significant decrease in estradiol compared with a slight increase shown in the placebo intervention. Ten participants in the orlistat intervention and one participant in the placebo intervention developed abnormalities during the study that were detected on electrocardiograms; none of these was believed to be related to the medication based on review by an independent cardiologist. No other adverse cardiovascular effects were found. At the end of the study, six participants in the orlistat intervention (compared with one participant in the placebo intervention) were found to have asymptomatic gallstones not seen at baseline; five of these patients had lost large amounts of weight (8.2-29.4 kg) and two were siblings. Another patient had multiple gallstones on ultrasound at day 167 after a 15.8 kg weight loss and had a subsequent cholecystectomy. Ultrasound also identified two additional new renal abnormalities in the orlistat intervention group (mild left hydronephrosis and 6-mm echogenic focus without evidence of renal calculus). There were no differences in bone mineral content/density between the two interventions. Most other non-GIT adverse events were also more prevalent in the orlistat group compared with the placebo group but the difference between groups was less pronounced than for GIT adverse events; the most common adverse events in this category were headache, upper respiratory tract infection, and nasopharyngitis.

Sibutramine

Across studies, participants received sibutramine at a dose of 10g or 15g for the majority of the intervention period which ranged from 3 to 12 months (Berkowitz 2003; Berkowitz 2006; Garcia-Morales 2006; Godoy-Matos 2005; Van Mil 2007). Medication adherence was measured in all studies but only reported in four: mean 79.1% (Berkowitz 2003); mean 89.1% (Berkowitz 2006); and 90-100% (Garcia-Morales 2006); all participants >60%(Godoy-Matos 2005).

Three studies reported a safety protocol relating to blood pressure and pulse rate cut-offs that would be used to initiate withdrawal of participants from the study or a sibutramine dose reduction (Berkowitz 2003; Berkowitz 2006; Garcia-Morales 2006). In three studies there were withdrawals due to adverse effects/events. One study had two (4.7%) withdrawals in the sibutramine group due to adverse effects, one in the first 6 months (ventricular premature complexes) and another in the second 6 months (increases in blood pressure [BP] and pulse rate); there were no withdrawals in the placebo control group (Berkowitz 2003). In the same study 19 participants had a sibutramine dose reduction in the first 6 months in response to elevations in BP, pulse rate or both. During the full 12 month study, sibutramine was reduced to 10 mg in 16 participants, to 5 mg in seven additional adolescents and discontinued in 10 participants (six because of increased BP and/or pulse rate, two for ecchymoses, one for ventricular premature complexes and one because of rash) (Berkowitz 2003). In the study by Berkowitz 2006 there were 22 (5.7%) withdrawals due to adverse events in the sibutramine group (2.4% were due to tachycardia and 1.4% due to hypertension) and seven (5.4%) withdrawals in the placebo group (1.5% were due to tachycardia; and none was due to hypertension). In the same study an adverse event was reported by 89% of participants in the sibutramine group and 85% of participants in the placebo group; the proportion of serious adverse events in each group was 2.7% and 0.8% respectively and the incidence of excessive nausea and vomiting in one patient was considered to be the only serious adverse event possibly related to study medication and resulted in premature discontinuation. In the same study, there was one incidence of suicide in both the sibutramine and placebo groups which were considered unlikely to be related to the study drug and 1.4% and 0.8% of participants in both groups respectively were found to have depression (Berkowitz 2006). In the study by Van Mil 2007, symptoms of clinical depression led to the withdrawal of one subject (out of 12) - as was confirmed by both the mother and the participant, these symptoms disappeared thereafter; there were no withdrawals in the placebo group or reports of sibutramine dose reduction for safety concerns. In the same study 41 participants in the sibutramine group, compared with 22 in the placebo group reported adverse events but the difference was not statistically significant (Van Mil 2007). Two studies had no withdrawals due to adverse events (Garcia-Morales 2006; Godoy-Matos 2005) although four participants in both the sibutramine and placebo groups in one study had an elevated diastolic blood pressure or pulse that disappeared within one week (Garcia-Morales 2006).

All studies reported data on cardiovascular variables including ab-

solute values or change in systolic blood pressure, diastolic blood pressure, and pulse rate. Greater reductions in these variables were generally seen in the placebo group compared with the sibutramine group and these were statistically significant at various time points in some studies: systolic blood pressure (Berkowitz 2003), diastolic blood pressure (Berkowitz 2006; Van Mil 2007), and pulse rate (Berkowitz 2003; Berkowitz 2006). Echocardiography data were reported in three studies but changes were not statistically or clinically significant (Berkowitz 2006; Godoy-Matos 2005; Van Mil 2007). In one study the increase in ST segment of the electrocardiogram in both the sibutramine and placebo group was statistically significant (Garcia-Morales 2006).

Most of the studies also reported the prevalence of non-cardiovascular adverse events. Symptoms that were more prevalent in the sibutramine group compared with the placebo group in two or more studies were dry mouth (Berkowitz 2006: 11% versus 6%; Garcia-Morales 2006: 14.3% versus 5.3%; Godoy-Matos 2005: 23.3% versus 10%), dizziness (Berkowitz 2006: 8% versus 4%; Godoy-Matos 2005: 10% versus 6.7%; Van Mil 2007: 25% versus 8.3%), and some form of rash (Berkowitz 2003: 2.3% versus 0%; Berkowitz 2006: 7% versus 5%; Van Mil 2007: 16.7% versus 0%), For other adverse events a higher incidence ($P<0.05$) was found in the sibutramine group compared with the placebo group for abdominal complaints (Van Mil 2007: 58.3% versus 0%) and constipation (Godoy-Matos 2005: 40.0% versus 13.3%).

DISCUSSION

Sixty-four randomised controlled studies were included in this review (and a further two trials met our criteria but are ongoing and have yet to report outcomes), sharing similar overall goals and objectives. However, there were multiple differences in terms of study design (particularly intervention comparisons), quality (particularly sample size and thus power) and outcome measures. Most studies reported beneficial effects of the intervention on adiposity from baseline to end of intervention or follow up. The challenge is to ascertain which intervention is more effective than another. Although we have not been able to fully answer this, we have identified further evidence as to the effectiveness of various strategies for treating childhood obesity. The importance of a combined dietary, physical activity and behavioural component has been highlighted by several studies included in this review (Epstein 2005; Flodmark 1993; Golan 2006; Golley 2007; Hughes 2008; Jelalian 2006; Johnston 2007a; Johnston 2007b; Kalavainen 2007; McCallum 2007; Munsch 2008; Saelens 2002; Savoye 2007; Williamson 2005). Parental involvement has been recognised as an important feature of behavioural programs, particularly in pre-adolescent children (Golan 1998; Golan 2006; Munsch 2008).

Positive outcomes for treating obesity in children were achieved in several studies, including high quality studies. Meta-analysis in children under twelve years of age showed that family-targeted behavioural lifestyle interventions decreased BMI-SDS more than did standard care at six months follow up. The effect size was small but statistically significant and clinically relevant. In these studies (Golan 2006; Golley 2007; Hughes 2008; Kalavainen 2007) new behavioural interventions were compared to established standard care, thus providing an additional effect. The effect size found in meta-analysis at 12 months was no longer significant, although decreases in BMI-SDS persisted in the three pooled studies (Golley 2007; Hughes 2008; Kalavainen 2007). In adolescents, a similar pattern was seen, albeit with an even greater effect size, given that behavioural interventions were compared to a self-help condition (Johnston 2007a; Johnston 2007b; Savoye 2007; Williamson 2005). In adolescents the effect size remained significant at 12 months after beginning of the intervention, demonstrating that beneficial effects of the behavioural program persisted in the longer-term. In addition, in the meta-analyses of included drug trials, both orlistat and sibutramine, as an adjunct to a lifestyle intervention, led to significant improvements in adiposity in adolescents, although a range of adverse events was also noted.

It is important to note that interventions to reduce obesity may vary in effect depending on the age of the child, due to differences in metabolism, nutritional needs, physical maturation and psycho-social development throughout childhood. Some studies reported delivering interventions separately to different age groups (Berry 2007; Weyhreter 2003). Three studies developed interventions in line with their target group behaviour, such as a phone or internet-based facility or peer-enhanced activity training (Jelalian 2006; Saelens 2002; Williamson 2005). It is very likely that the level of parental involvement will change with age and developmental stage. Therefore it is a priority to develop interventions that account for these differences throughout child and adolescent development. An important finding in this review was the lack of interventions for preschool-aged children and the relatively low number of lifestyle interventions targeted at adolescents.

Most studies were underpowered (44 out of 64 randomised less than 30 children to at least one group) and only 15 out of 54 lifestyle studies reported power calculations. In these circumstances it is possible that small study biases will arise, in particular a tendency to publish positive studies more than negative studies. As so few common interventions could be pooled it was not feasible to examine this formally using Funnel plots and Begg and Eggar tests. Most studies did not account for missing data in analyses and less than half (n=28) of all included studies performed analysis based on intention-to-treat principles. This might be an important issue, since many of the studies dealt with high dropout rates; only 31 studies reported follow up of more than 80% of the baseline participants. It is possible that participants with a successful intervention experience or outcome may be more likely to return for follow up assessments, whereas participants who fail to change their adiposity status may not return for follow-up, leading to an

overestimation of the treatment effect. However, in most studies dropout rates were not significantly different between comparison groups. Many of the included trials were run from a specialist obesity clinic within a hospital setting. Some studies reported transportation to the clinic as a barrier to participate in the intervention or follow up assessment (e.g. Berry 2007). It is possible, that community interventions, which may be provided closer to home and thus may be more accessible, might lead to a greater proportion of specific target groups being reached.

One important research challenge in this area has been the variations in the definitions of fatness in children. Although a positive trend towards a consistent approach to the measurement of childhood obesity has been noted in studies included in this review, many different methods are still used to estimate body fatness or relative weight and changes over time. A further limitation is the large proportion of included studies that did not adjust calculated changes in adiposity for age and sex. The International Obesity Taskforce BMI for age cut-points (Cole 2000) are increasingly used for epidemiological studies and the WHO has recently introduced the Child Growth Standards for children aged 0 to 5 years, and the WHO growth reference for 5 to 18 year olds (De Onis 2007a; De Onis 2007b). However, the use of a consistent approach to the measurement of childhood obesity remains a priority issue in this field (Barlow 1998).

A new feature in this update was the inclusion of drug interventions and the consideration of surgical interventions for the treatment of adolescent obesity. While no surgical study met the inclusion criteria, several drug interventions were ultimately included in the review. In comparison with the lifestyle interventions, the drug trials generally met more of the CONSORT criteria (Moher 2001) and several had relatively large sample sizes. We were also able to undertake meta-analyses for two of the drug interventions (orlistat and sibutramine). The adverse event profile of the drug trials was well documented.

The proposed relationship between treating obesity and eating disorders, particularly in young populations, is a vital area of consideration. Although eating disorders are clearly of public significance and while dieting may be a risk factor for eating disorders in some people, the literature about this relationship remains equivocal, with some studies finding no association (Schleimer 1983) and others suggesting that an association does exist in some women (Patton 1990; Killen 1994). In this review ten lifestyle studies (Braet 2004; Epstein 1985a; Epstein 1985c; Golan 1998; Israel 1985; Israel 1994; Jelalian 2006; Munsch 2008; Saelens 2002; Williamson 2005) that reported on measures of disordered eating, did not find any adverse changes. It is important to acknowledge that the proportion of the population who are obese far exceeds the proportion of the population who have eating disorders and most obesity treatments are not about "dieting". However, obesity treatments should make assessments of potential unintended effects since there is a lack of data on this aspect of treating obesity in children and adolescents. Nevertheless, one-third of the lifestyle intervention studies included in this review reported measures of harm, but no adverse effects on linear growth, eating behaviours or psychological well-being were noted.

Furthermore, measurement of predicted antecedent behaviours in the area of obesity treatment, such as dietary intake and physical activity, remains relatively weak. The development and use of appropriate measures in future studies is likely to be affected by limited sources. Given that the quality of these measurements ultimately predicts the quality of study findings, the importance of funding the design, validation and use of appropriate tools for this age group cannot be overstated.

While we agree that research in the area of obesity treatment is difficult to conduct, this must be considered against a background which acknowledges that obesity is now considered to be a global epidemic (WHO 2000). Halting this epidemic may ultimately be determined by the quality and co-ordination of a range of obesity treatment initiatives, alongside an effective obesity prevention strategy. It is desirable, from both ethical and fiscal perspectives, to understand how interventions can most effectively and appropriately halt the population trend to fatness. However, the heterogeneity of data at hand make it difficult to conclude that one particular strategy, or combinations of strategies, is or are more important than others in the treatment of child and adolescent obesity, although several strategies appear promising. The mismatch between the high prevalence and significance of the condition and the limited knowledge base from which to inform treatment strategies remains a feature of this review. The potential outcome of effective obesity treatment interventions for children and adolescents include both short and long-term health benefits. Studies are needed that are designed to disentangle the relative importance and effects of targeted antecedent behaviours in paediatric obesity treatment. In addition, study designs must adopt current knowledge regarding the most appropriate theoretical underpinnings of behavioral change. When interpreting the results of such studies the role of general health promotion programmes as potential confounding factors needs to be assessed. In assessing drug interventions in adolescents, the adjunctive role of lifestyle change interventions needs to be further investigated, and the effectiveness of intervention needs to be weighed up against the impact of potential adverse events. The role of surgical interventions in severely obese older adolescents also requires detailed study. All such issues are important in terms of identifying the most cost-effective and sustainable range of interventions.

AUTHORS' CONCLUSIONS

Implications for practice

While there are relatively limited quality data to ascertain which intervention is more effective than another in child and adoles-

cent obesity treatment programs, several strategies are recognised as being potentially useful. A combined dietary, physical activity and behavioural component appears effective. Evidence from this review shows that family-based, lifestyle interventions with a behavioural program aimed at changing diet and physical activity thinking patterns provide significant and clinically meaningful decrease in overweight in both children and adolescents compared to standard care or self-help in the short- and the long-term. In obese adolescents, consideration should be given to the use of either orlistat or sibutramine, in the context of a lifestyle change program, although such therapy needs to be carefully weighed up against the potential for adverse events.

With many of the studies included in this review, it is unlikely that the implications for practice can be directly extrapolated from one group to another. The practicalities of delivering effective advice on lifestyle changes to obese children and adolescents will vary with the wide span of social, ethnic and economic circumstances, as well as with the many variations in available resources for local health service delivery. In terms of validity, a number of the studies had small sample sizes, a likelihood of small study biases, relatively high drop-out rates, and unadjusted outcome measurements. The findings from many of the included studies may be non-generalisable owing to sampling problems - the majority of research in the field has been conducted in motivated, middle class, Caucasian populations. A positive tendency to address these lifestyle and/or drug interventions at specific target populations was noted (Munsch 2008; Weintraub 2008; Williamson 2005). The failure to address and measure vital and important psychological and social factors in these intervention studies hinders the potential for intervention effectiveness. Other than in the drug trials, adverse effects of the interventions were infrequently considered, and reporting of long-term outcomes beyond one year is also limited.

Implications for research

The validity and generalisability of several of the studies included in this review remain questionable. The questions that remain largely unanswered by this review are:

- What interventions are most effective at different levels of obesity severity and at different ages and developmental stages?
- What strategies are most effective for long-term maintenance of healthy weight or reduced weight following initial treatment of obesity?
- What are the family characteristics that promote success in the treatment of child and adolescent obesity?
- What interventions are most effective for specific ethnicities, religious groups or culturally diverse populations?
- What is the role of psychological and social factors such as self-esteem and the family's capacity to change behaviour in the treatment and management of child and adolescent obesity?
- What are the most cost- and resource-effective methods of treating child and adolescent obesity in different health care settings?
- What is the role of bariatric surgery in the treatment of severely obese adolescents?
- What are the potential harms as well as benefits of different interventions?

Governments, non-government organisations, industry and research bodies must recognise that:

- Child and adolescent obesity has reached epidemic proportions and, as such, requires commensurate resources in prevention and treatment in order to achieve change for individuals, families and the population.
- Treatment of obesity in children and adolescents remains a relatively new science necessitating careful review of the evidence-base in terms of what appears to be effective as well as carefully designed and evaluated innovative programs of research.
- Trials that are conducted following the criteria of the CONSORT statement and are designed with enough power are required to provide the necessary evidence base.
- Innovative non-RCT interventions with a rigorous external evaluation may also provide useful evidence.
- Qualitative research employed within interventions will provide a powerful evidence-base on the views of participants: patients and families as well as providers, highlighting why interventions may be more or less successful.
- The cost-effectiveness of treatment programs for children and their families needs to be incorporated into programs of research or non research action. Cost measures need to include child, family and community opportunity costs over the short and long term.
- Appropriate short- and long-term outcomes need to be defined for children and youth at various weight levels, rather than using conventional or adult-oriented outcomes. Weight loss (or failure to gain) may not be an appropriate measure of therapeutic interventions for all growing children, and behaviours such as habitual physical activity, healthy eating, and improved psychosocial outcomes are likely to be more meaningful, until their growth and development stabilise.
- Interventions are likely to be more relevant, successful and less harmful if interventions are pre-tested with groups similar to those intended to receive the intervention.
- Studies should include process indicators which provide information on whether the study was adhered to and conducted as it was intended. If variation is observed, researchers should

consider the implication of this on the effectiveness of the intervention. The importance of statistical analyses that account for dropouts and missing data can not be overstressed in this matter.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[author-defined order]*

Berry 2007

Methods	**Random allocation:** yes, telephone numbered, opaque sealed envelopes **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Yes **Length of intervention and follow up:** 12 weeks, follow up at 3 months (after intervention) and at 6 months **Unit of allocation:** Individual child + parent **Unit of analysis:** Individual child + parent **Protection against contamination:** Not clear **Drop outs:** end of intervention 25% [20/80], follow up at 6 months: 25% [20/80]
Participants	**n=** 80 **randomised**, 60 **completed** **Age range (mean):** · **child:** 7-17 years (experimental group 11.9±2.5, control group 11.9±2.3) **% Male:** · **child:** 58.8% **Weight entry criteria:** BMI >85th percentile for children **Weight on entry (mean):** not reported **Setting:** Outpatient clinic **Geographic Region:** Yale, USA
Interventions	**Intervention:** Bright Bodies weight management program with and without addition of Coping Skills Training for obese multiethnic parents **Intervention:** Bright Bodies weight management program **Target of intervention:** Child & parent **Behavioural or psychological component:** - *Children* in both groups attended additional (after the first six weekly NEEP classes) six weekly 45-minute NEEP classes with behaviour modification without parents. The Bright Bodies' registered dietitians taught this behaviour modification classes with NEEP. Behaviour modification focused on improving self-image and learning new skills such as self-awareness, stress control and stress management. - The CST classes were taught to *the parents* in the experimental group by an advanced practice nurse in sic weekly 60-minute classes. The CST classes included an introduction, cognitive behaviour modification and exercise, social problem solving and barriers to weight loss, assertiveness training and how to motivate oneself, conflict resolution and rebounding from relapse, and social problem solving and weight maintenance. **Physical activity:** - The Bright bodies' registered dietitians taught the NEEP (Nutrition and Exercise Education Program) classes once a week. Exercise education focused on increasing physical activity and decreasing sedentary behaviours. *Parents and children* in both groups attended six weekly 45 minute classes together. - *Children* in both groups attended 12 twice-a-week 45-minute exercise classes. The Bright Bodies' exercise physiologists taught the exercise classes twice a week. The exercise classes for the children

	were held in an exercise room at the hospital or at a local middle-school gymnasium. Activities included basketball, dancing, tag, walking, and stair climbing. - *Parents* in both groups were encouraged by the research assistant to walk between 30 and 60 minutes a day and keep track of their progress in their pedometer logbooks. **Nutrional advice:** The Bright bodies' registered dietitians taught the NEEP (Nutrition and Exercise Education Program) classes once a week. Nutrition education focused on making better food choices, ethnic menu plans, lowering fat and calories, and portion control. *Parents and children* in both groups attended six weekly 45 minute classes together. **Other:** No **Usual care/ alternative intervention:** Control group **Target of intervention:** Child & parent **Behavioural or psychological component:** As above, but parents did not attend the CST. **Physical activity:** As above **Nutrional advice:** As above **Other:** No
Outcomes	Height (cm), weight (kg), BFP (Body Fat Percentage) (%)**,** BMI (kg/m^2), Family Assessment Device (FAD), Eating Self-Efficacy Scale (ESES), Health-Promoting Lifestyle Profile II (HPLPII) , pedometer steps (count of steps)
Results	At 6 months, children in the experimental group demonstrated trends toward decreased BMI (p= 0.08) and BFP (p=0.1) and increased pedometer steps (p=0.2) (completers only)
Funding and financial disclosure	**Funding/Support**:This study was supported, in part, by Grants R21DK59248, R01NR004009, R01NR008244, and T32NR008346 to Margaret Grey; by Grant MO1RR06022 to the General Clinical Research Center; and by Grant RO1HD40787 to Sonia Caprio
Notes	Small changes in BMI and BFP in children. Intervention seems to work better for the parents than the children

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	Telephone numbered, opaque sealed envelopes

Braet 2004

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 10 months, follow up 24 months (from commencement of intervention) **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Done **Drop outs:** end of intervention 19% [28/150], follow up at 9 months: 19% [28/150]
Participants	**n=** 150 **randomised,** 122 **completed** **Age range (mean):** 7-17 years (12.7±2.3) **% Male:** Unclear **Weight entry criteria:** BMI > 95^{th} percentile according to age and gender **Weight on entry (mean):** 84.7kg (19.7), mean BMI 32.5 (5.3), degree of obesity 77% (SD 29) **Setting:** Inpatient clinic **Geographic Region:** Ghent, Belgium
Interventions	**Interventions:** Inpatient treatment program plus cue exposure therapy vs inpatient treatment program plus cognitive therapy vs inpatient treatment program without coping strategies **Intervention:** Cue exposure treatment (within the normal treatment program) **Target of intervention:** Children + parents **Behavioural or psychological component:** During the first 4 months of treatment, all children received a 12 week cognitive-behavioral treatment (CBT) program, in small groups. As part of the CBT program, the children were taught about the energy balance as a model to understand the mechanism of obesity. To achieve lifestyle changes, the children were taught self-regulation skills, such as self-observation, self-instructions, self-evaluation and self-reward. The children were invited to design a personal plan for managing their eating habits on the weekends. Parents were seen on a 2-week basis, when they visited the centre. They were requested to assist their child in adopting a new lifestyle. For this purpose, they were provided with leaflets that gave information on how to prepare healthy food, how to organize shopping habits, and ho to organize aerobic exercises The protocol developed by Jansen et al, 1993 describes in vivo exposure sessions with relevant food cues. It included the following steps: The participant is invited to bring in the typical food that he or she finds difficult to resist; next the participant is allowed to open up the different packages, take the food in the hands and smell it. It is hypothesized that if the exposure lasts long enough, the craving for food slowly diminishes after 30-50 minutes. **Physical activity:** Before and after school hours, the children were encouraged to exercise. The centre offers organized sport events for 2 h a day or 10 h a week. Apart from that, each child received 4 h of individual guided exercises, such as swimming (1 h/week), cycling on a home trainer, jogging at their own speed, and performing abdominal exercises, with the aim being for each child to reach a heart rate that was 20% lower than his or her maximum heart rate. Although individual variations were possible, all children had facilities to take part in exercise programs for at least 14 h per week. **Nutrional advice:** The children ate three meals a day and two snacks. The children were encouraged to drink water, preferably up to 1.5 L a day. Total intake was about 1400 to 1600 cal per day. During each meal, fruit or vegetables were offered, and the children were allowed to decide

	for themselves wether they wanted a small or large portion. At home, the children were allowed some consumption of soft drinks and high-calorie foods, albeit in limited portions, which meant they were left to make their own choices. **Other:** No **Usual care/ alternative intervention:** Cognitive protocol (within the normal treatment program) **Target of intervention:** Children + parents **Behavioural or psychological component:** During the first 4 months of treatment, all children received a 12 week cognitive-behavioral treatment (CBT) program, in small groups. As part of the CBT program, the children were taught about the energy balance as a model to understand the mechanism of obesity. To achieve lifestyle changes, the children were taught self-regulation skills, such as self-observation, self-instructions, self-evaluation and self-reward. The children were invited to design a personal plan for managing their eating habits on the weekends. Parents were seen on a 2-week basis, when they visited the centre. They were requested to assist their child in adopting a new lifestyle. For this purpose, they were provided with leaflets that gave information on how to prepare healthy food, how to organize shopping habits, and ho to organize aerobic exercises The cognitive protocol teaches the children to analyse emotional situations with cognitive techniques, and it helps them to cope with antecedents of their problem behaviour. In contrast to the standard treatment program, where only high risk eating situations were analysed, problem situations were no extended to a variety of problems(loneliness, bullying by peers). Included were relaxation exercises that the children could use to assist them in coping with emotional antecedents. **Physical activity:** See above **Nutrional advice:** See above **Other:** No **Usual care/ alternative intervention:** Standard treatment protocol **Target of intervention:** Children **Behavioural or psychological component:** 12 week cognitive-behavioral treatment (CBT) program, as above. **Physical activity:** See above **Nutritional advice:** See above **Other:** As above
Outcomes	Height (cm), weight (kg), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness, behaviour changes (Child Behaviour Checklists (CBCL), Dutch Eating Behaviour Questionnaire (DEBQ), Eating Disorder Inventory (EDI), Eating Disorder Examination (EDE)), measures of self esteem, health status, QOL - describe if stated validated measure, name, effect size etc (Self-perception profile (SPPS))
Results	For the primary outcome variable of percentage overweight, the multivariate repeated measures analysis revealed a significant effect of the within-subject Time factor, $F(2, 89) = 231.88$, $p < .001$, at the end of intervention. The children lost 49.0% of their weight during the course of treatment Comparing pretest and follow-up scores at 24 months from commencement of intervention, contrast analyses revealed that the children still had lost a significant percentage of weight (31.7%, SD = 24.7; range = −33-100%). Their BMI was reduced by 4.9 kg/m^2. The amount of weight loss was 7.4 kg, and the children had grown an average of 5.6 cm. Of the children, 82% still lost 10% or more of their weight (completers only).

Funding and financial disclosure	**Funding/Support**: not reported
Notes	This inpatient treatment program seems to work, but data are only presented for groups overall. No conclusions can be made regarding the value of the different cognitive behaviour treatment programs (the extended coping programs) because of small treatment effects and lack of power

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	No description of randomisation process.

Carrel 2005

Methods	**Random allocation**: No description of randomisation process **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 9 months **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Not clear **Drop outs:** end of intervention 6% [3/53], follow up at 6 months: 6% [3/53] (intervention group: 0, control group: 3)
Participants	**n=** 53 **randomised**, 50 **completed** **Age range (mean):** 11- 14 years (intervention group 12.5±0.5), control group 12.5±0.7) **% Male:** 52% **Weight entry criteria:** BMI > 95^{th} percentile **Weight on entry (mean):** Not reported **Setting:** Rural middle school and an academic children's hospital **Geographic Region:** probably Wisconsin, USA
Interventions	**Intervention:** Lifestyle focused, fitness-oriented gym classes **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** Participants in the intervention group were in class sizes limited to 14 students to ensure adequate supervision and more direct time spent with each instructor. Classes were designed to make fitness and good nutrition fun and achievable and to maximize the amount of movement during the class period Class size was limited to allow for increased instructor attention, increased opportunity for motivation, and less time standing in line. The curriculum was personalized to match the student's skill levels and encourage student participation. Competitive games were de-emphasized, and lifestyle-focused activities (walking, cycling, and snowshoeing) were encouraged. A consistent warm-up plan brought students into movement participation as quickly as possible soon after they entered the gym. Typical movement time was 42 minutes of a 45-minute class period, as children did no

	change clothes for this class to increase activity time. Skills were taught with the class broken down into groups of 2 for promoting more movement and less time watching. The ethos of the class encouraged physical fitness, less self-conscious focus on appearance, and full group participation The frequency of the classes was 5 times every 2 weeks for a 45-minute class period. **Nutritional advice:** Students randomised to fitness classes also received a small nutrition education component. This consisted of educational handouts to participants to develop healthier eating habits. The nutrition portion focuses on the Food Guide Pyramid, recommended servings of food, appropriate portion sizes, healthier food choices, and the benefits of those choices. **Other:** No **Usual care/ alternative intervention:** Standard gym classes **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** Control subjects participated in the traditional physical education classes of 35-40 students. After accounting for the time changing clothes, taking attendance, and giving instructions, movement time averaged 25 minutes of the 45-minute period. The same class topics (e.g. football, mile run/walk, kickball) were taught as in the intervention group, but in a different format, as typical issues in the traditional class were a greater range of skill levels, longer lines during skill development drills, and larger numbers of students on teams when games were played. These issues tended to result in less movement and a tendency for students to hold back and not enter into play. **Nutritional advice:** No **Other:** No
Outcomes	Height (cm), weight (kg), BMI (%), cardiovascular fitness assessment (ml/kg per minute), insulin (µlU/ml), glucose (mg/dl)
Results	Figure 2 illustrates a significantly greater decrease in the percentage of body fat in the treatment group (−4.1% ± 3.4%) compared with the control group (−1.9%±2.3%; P=.04) after completion of the 9-month intervention, resulting in end-of-treatment percentage of mean body fat measures of 32.6%±6.4% and 34.5%±5.8%, respectively. The BMI was 33±10 and 30±5 at the end of the study in the treatment and control groups, respectively (P=.10 compared with baseline). (completers only, but see note)
Funding and financial disclosure	**Funding/Support**: This study was supported by grants from Genentech Center for Clinical Research in Endocrinology, South San Francisco, Calif, and the University of Wisconsin Sports Medicine Classic Fund, Madison
Notes	BMI increased in the experimental group and remained stable in the control group, whereas body fat percentage significantly lowered in the experimental group compared to the control group

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process.

Daley 2006

Methods	**Random allocation:** An independent researcher performed the randomisation procedures by allocating participants to groups according to a computer generated random list **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 8 weeks, follow-up at 14 weeks and 28 weeks after baseline **assessments** **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Not clear **Drop outs:** end of intervention 7% [6/81], follow up at 6 months: 11% [9/81]
Participants	**n=** 81 **randomised**, 71 **completed** **Age range (mean):** 11-16 years, mean age 13.1 years. **% Male:** 44.4% **Weight entry criteria:** BMI > 98^{th} percentile for age and gender **Weight on entry (mean):** Not given **Setting:** Outpatient clinic, trial centre **Geographic Region:** UK
Interventions	**Intervention:** Exercise therapy **Target of intervention:** Child **Behavioural or psychological component:** Exercise counselling for behavior change, was also an integral part of the exercise sessions. In line with the transtheoretical model, weeks 1 to 4 focused on cognitively based intervention strategies such as cognitive reappraisal and consciousness raising. During weeks 5 to 8, more behaviorally based interventions were introduced, for example, goals setting, self-monitoring, and finding social support. Participants followed a broad structured curriculum of topics over the course of the intervention. The researcher also encouraged participants to discuss their thoughts and feelings about exercise, to assist with problem-solving. **Physical activity:** The exercise therapy group participated in a range of aerobic exercise activities (e.g. stepping, cycling, rowing, dance mat, and walking) and were asked to exercise intermittently at a moderate intensity (40-59% of heart rate (HR) reserve) for 30 minutes 3 times per week for 8 weeks (24 sessions). Minigames were also included in the sessions; these were designed primarily with fun in mind, but they also gave participants the opportunity to see personal development throughout the program and to introduce a small self-referenced competitive element into the sessions After participants completed their 8-week interventions, they were given an individualized home exercise program to follow on their own for an additional 6 weeks (14 weeks follow-up period). No researcher contact was provided during the home program phase. **Nutritional advice:** Sensible eating habits were encouraged as part of the exercise therapy intervention. All participants were given a brief dietary advice information sheet, prepared by a dietician, at entry into the trial. **Other:** Financial incentives: To facilitate recruitment and retention, a £25 sports store voucher was given to participants at the end of the intervention phase, and a contribution of £2.50 toward travel expenses to attend intervention sessions and assessments was made for each visit to the trial centre. An additional £10 sports store voucher was given to participants when they completed their final follow-up assessment.

	Usual care/ alternative intervention: Exercise placebo group **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** Participants performed light body-conditioning/stretching exercises, during which HR was maintained at <40% of HR reserve, and no exercise counselling or behavioural change advice was given. This group also participated in other sedentary activities, such as balance and catching tasks, pool, darts, and table football After participants completed their 8-week interventions, they were given an individualized body conditioning program to follow on their own for an additional 6 weeks (14 weeks follow-up period). No researcher contact was provided during the home program phase. **Nutritional advice:** All participants were given a brief dietary advice information sheet, prepared by a dietician, at entry into the trial. **Other:** As above **Usual care/ alternative intervention:** Usual care **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** No **Other:** The usual care group were asked to continue with their lives as normal
Outcomes	Height (cm), weight (kg), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness, BMI SD score, Physical Self-Perceptions (physical self worth (PSW)), global self worth, sport/ athletic competence, conditioning /stamina competence, attractive body adequacy, strength competence), depression and affect score's (depression, positive affect, negative affect), self-perceptions (scholastic competence, social competence), physiologic outcomes (resting HR, aerobic function, physical activity)
Results	There were no significant changes in BMI-zscore neither from baseline, nor between groups
Funding and financial disclosure	**Funding/Support**: This study was supported by a research award to the first and fourth authors from The Health Foundation: grant number 2402/957
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	An independent researcher performed the randomization procedures by allocating participants to groups according to a computer generated random list

De Mello 2004

Methods	**Random allocation:** No description of randomisation process. After explanation of the study, without specifying the two types of treatment, subjects were then allocated to one of two groups by lottery. **Blinding:** · **Children:** Yes · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Participants in both groups attended monthly meetings for six months, follow up 6 months **Unit of allocation:** Individual child (+ family) **Unit of analysis:** Individual child (+ family) **Protection against contamination:** Not clear **Drop outs:** end of intervention 42% [28/66], follow up at 6 months: 42% [28/66]
Participants	**n=** 66 **randomised**, 38 **completed** **Age range (mean):** 7-13 years (9.9±1.5) **% Male:** 57,9% **Weight entry criteria:** BMI> IOTF cut off for obesity in children **Weight on entry (mean):** BMI: intervention group 29.0 ± 3.5, control group 28.9 ± 3.7 **Setting:** outpatient clinic based in a University School of Medicine **Geographic Region:** Residents in the state Rio Grande del Sul who sought out the Pediatrics service at the Hospital of Poto Alegre
Interventions	**Interventions:** Group education program versus Individual outpatient care **Intervention:** Education Program (PG) **Target of intervention:** Parent and child **Behavioural or psychological component:** Parents and guardians were put into groups in order to discuss their problems and techniques for changing feeding habits. The program compromised six meetings (45 min). The subjects covered were: what obesity is and what its complications are, foodstuffs and the food guide pyramid, food substitutes and modes of preparation, how to be more active, and behavioral, postural and self-esteem related aspects and how to maintain healthy habits that had been suggested. **Physical activity:** After the lesson the children were divided by sex and aged into four fixed groups and performed tailored activities under the supervision of the research assistant. **Nutritional advice:** See behavioural component; only little nutrition advice **Other:** No **Usual care/ alternative intervention:** Outpatient care (OG) **Target of intervention:** Child only? **Behavioural or psychological component:** No **Physical activity:** the individual outpatient treatment consisted of monthly meetings of the children in which they received guidance on increasing physical activity. **Nutritional advice:** the individual outpatient treatment consisted of monthly meetings of the children in which they received guidance on nutritional intake management. **Other:** Children were weighed and measured monthly. Each subject was given a manual with the main features of treatment and in which directions were noted
Outcomes	Height, weight, estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness, behaviour changes, metabolic health outcomes (total cholesterol, HDL, triglycerides)

De Mello 2004 (*Continued*)

Results	Reduction of body mass index, obesity index and caloric intake was similar in both groups (BMI p=0.49). Changes from baseline in BMI were not significant in both groups (p=0.2 for group treatment and p=0.9 for individual treatment). (completers only)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process. After explanation of the study, without specifying the two types of treatment, subjects were then allocated to one of two groups by lottery

Duffy 1993

Methods	**Random allocation:** no description of randomisation process. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** 8 Weeks and 6 Months **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 22% [6/27], follow up at 6 months: 37% [10/27] (unclear how many children were randomised to each treatment group. 8 children in BT group and 9 children in CBT group remained at 6 months)
Participants	**n=** 27 **randomised**, 17 **completed** **Age range (mean):** 7-13 years (118.71 months±20.16) **% Male:** 21% **Weight entry criteria:** 15% overweight for age, height and sex **Weight on entry (mean):** 48.6% overweight for age, height and sex (SD 22.12) **Setting:** Not clear, probably clinic **Geographic Region:** Australia
Interventions	**Interventions:** behaviour therapy plus cognitive self-management vs behaviour therapy plus attention placebo control **Intervention:** behaviour therapy plus cognitive self-management **- Target of intervention:** child and parent **- Behavioural or psychological component:** Both groups had behavioural therapy (8 week 90 minute sessions) - the intervention group had additional cognitive self-management. Parents were also taught to use goal setting and positive reinforcement strategies to facilitate behaviour change

	with a financial arrangement. Parents children and therapists signed written agreements. The Cognitive component of the non-placebo intervention included monitoring of negative thoughts, restructuring of maladaptive or negative thoughts, problem solving skills and self instructional training, and self reinforcement. Overall, there was a financial incentive paid to both parents and children for their participation in elements of the program (children) and the follow ups at 3 and six months. A behavioural contract approach was used in which parents paid a redeemable $30 **- Physical activity:** Information and target setting relating to increased lifestyle, callisthenic and aerobic exercise. Children also monitored their exercise to record energy expenditure **- Nutrional advice:** The Epstein Traffic Light system was used **- Other:** No **Usual care/ alternative intervention:** behaviour therapy plus attention placebo control **- Target of intervention:** child and parents **- Behavioural or psychological component:** As above, but instead of additional cognitive self-managment the control group received relaxation training **- Physical activity:** The placebo group received progressive muscular relaxation training, commencing in week 4 **- Nutrional advice:** As above **- Other:** No
Outcomes	Weight status: Weight (kg) and % overweight presented at pre treatment, post treatment, 3 and 6 months follow up
Results	Percentage overweight decreased from 45.96 (18.55) to 37.02 (24.85)% in the intervention group and from 46.28 (19.32) to 37.09 (21.71)% in the control group, at six months from commencement of intervention. There was a significant time effect from pre- to posttreatment, and to follow up, but no group by time effect. (completers only)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	no description of randomisation process.

Ebbeling 2003

Methods	**Random allocation:** no description of randomisation process. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 6 months intervention, follow up 12 months from commencement of intervention **Unit of allocation:** Individual patients **Unit of analysis:** Individual patients **Protection against contamination:** Not clear **Drop outs:** end of intervention 13% [2/16], follow up at 6 months: 13% [2/16] (intervention group 1, control group 1)
Participants	**n=** 16 **randomised**, 14 **completed** **Age range (mean):** 13 to 21 years (intervention group 16.9 ± 1.3, control group 15.3 ± 0.9) **% Male:** 31.25%**Weight entry criteria:** BMI that exceeds sex-and age-specific 95^{th} percentiles **Weight on entry (mean):** intervention group 103.5 ± 6.0, control group 104.7 ± 4.8 **Setting:** In general clinical research centre of the children's hospital **Geographic Region:** Boston, USA
Interventions	**Intervention:** Ad libitum reduced-glycaemic load (GL) diet **Target of intervention:** Child **Behavioural or psychological component:** Social cognitive therapy provided a framework for the educational and behavioural components of the treatment and was consistent between both groups. Counseling focused on enhancing self-efficacy for dietary change using the concepts of behavioral capability and self-control. Patient expectations, expectancies and perceptions of environmental influences were discussed during treatment sessions. During dietary counselling sessions, written materials were provided on various food-related topics and menu choices/lists which were tailored toward the each group. For experimental group, lists corresponded to food groups delineated by a reduced GL food pyramid. In contrast, for the conventional group, the lists corresponded to the diabetes food pyramid and were presented as an exchange system. The select-a-meal menu contained recipes and ideas for meal planning to complement the food choice lists. **Physical activity:** One module was devoted to physical activity, with subjects in both groups receiving information based on current recommendations. **Nutritional advice:** The reduced-GL prescription emphasized selection of carbohydrate-containing foods (e.g. non-starchy vegetables, fruits, legumes, nuts, and dairy) that are characterized by a low to moderate GI. Patientes were instructed to balance consumption of carbohydrates with protein and fat at every meal and snack. The prescription was no energy restricted. Rather, subjects were advised to eat to satiety and to snack when hungry. The targeted proportion of energy from carbohydrate and fat were 45% to 50% and 30 to 35%, respectively, with the remainder from protein. Delivered in the form of modules by the study dietitian (12 dietary counselling sessions in first 6 months, then 2 dietary counselling sessions in the 6 month follow-up phase). **Other:** No **Usual care/ alternative intervention:** Energy restricted reduced fat diet **Target of intervention:** Child **Behavioural or psychological component:** Same as for intervention. **Physical activity:** Same as for intervention **Nutritional advice:** The reduced-fat prescription was based on current recommendations for

	weight loss and diabetes prevention, with emphasis on limiting dietary fat intake and increasing the intake of grains, vegetables , and fruits. Meal plans were designed to elicit a negative energy balance of 250 to 500 kcal/day. Energy requirements were estimated using the Harris-Benedict equation with an activity factor of 1.5 and consideration of baseline dietary intake. Subjects were counselled to obtain 55% to 60% of energy from carbohydrates, 25% to 30% from fat and the remainder from protein. **Other:** No
Outcomes	Height (cm), weight (body mass, kg), BMI, total body mass and fat mass by DEXA, HOMA estimation of insulin resistance (Mm/L)
Results	At 12 months, mean ± SEM BMI (−1.3±0.7 vs 0.7±0.5; P=.02) and fat mass (−3.0±1.6 vs 1. 8±1.0 kg; P=.01) had decreased more in the experimental (reduced glycaemic index) compared with the conventional group, differences that were materially unchanged in an intention-to-treat model (n=16) (BMI, P=.02; fat mass, P=.01). Of interest, there was no weight regain between 6 and 12 months for the experimental group
Funding and financial disclosure	**Funding/Support**: This study was supported by grants 1R01DK59240 and 1K01DK62237, from the National Insitute of Diabetes and Digestive Kidney Diseases (Bethesda, Md); the Charles H. Hood Foundation (Boston, Mass); pilot and feasibility project grant DK46200 from the Boston Obesity and Nutrition Research Center (Boston); and grant M01 RR02172 awarded by the National Institutes of Health (Bethesda) to support the General Clinical Research Center at Children's Hospital Boston, Boston
Notes	

Epstein 1985a

Methods	**Random allocation:** no description of randomisation process. **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 8 week treatment followed by 10 month maintenance and 12 and 24 month follow up **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 15% [6/41], follow up at 24 months: 15% [6/41]
Participants	**n=** 41 **randomised,** 35 **completers** **Age range (mean):** 8 to 12 years **% Male:** 40% **Weight entry criteria:** > 20% bodyweight for height **Weight on entry (mean):**123.9 kg, 48% overweight for height **Setting:** No details **Geographic Region:** USA

Epstein 1985a (*Continued*)

Interventions	**Interventions:** Different exercise regimes (3 groups: lifestyle, aerobic and callisthenics) + diet and behaviour modification **Intervention:** Aerobic exercise programme **- Target of intervention:** child and parent **- Behavioural or psychological component:** Self-monitoring: food diaries, chart weight daily, parent asked to review diaries for accuracy and completeness. Praise and modelling: parents and children asked to behave as appropriate models for each other. Therapist contact; seen before treatment meetings (first 8 weeks) to review habit books and give feedback on past weeks progress, + phone calls once a week during treatment period and once a month during maintenance period. Parent management: instructing parents to use modelling and reinforcement for child behaviour change and maintenance **- Physical activity:** Aerobic exercise: walk, run, bicycle or swim, based on family preference. 3 times per week advancing to 3 miles of running/walking 6 miles cycling, 75 miles of swimming in regular intervals **- Nutrional advice:** Traffic Light diet, 1200 Kcal daily. Each treatment session had a lecture and discussion on nutrition, diet and behaviour management techniques. Traffic Light Diet (calorie-based food exchange system) colour coded: green = foods <20 Kcal per serving, yellow = staple foods, red = high fat/high sugar foods **- Other:** Financial incentives: Contracting $85 was deposited before treatment and returned piecemeal at treatment/assessment sessions, parents also asked to use non-monetary reinforcers as incentives for weight loss **Usual care/ alternative intervention:** Lifestyle exercise program **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above **- Physical activity:** Lifestyle (isocaloric to aerobic programme) participants chose from the exercise menu and chose own intensity and could include school activity **- Nutrional advice:** As above **- Other:** As above **Usual care/ alternative intervention:** Calisthenics program **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above **- Physical activity:** Callisthenics: 6 of 12 callisthenics 3 times per week. Repetitions increased in intervals similar to aerobic exercise programme **- Nutrional advice:** As above **- Other:** As above
Outcomes	Height, weight, BMI, % overweight (based on ideal weight for height, age and sex [Metropolitan life Insurance company 1959 and Robinson 1968]), Eating Behaviour Inventory and Physical work capacity
Results	The child results showed significant differences between the 3 groups only at the 24 month follow up (in favour of the lifestyle group). However, all groups lost weight at the six months follow up, only the lifestyle group managed to maintain the achieved changes. (completers only)
Funding and financial disclosure	**Funding/Support**: This work was supported in part by Grant HD12520 from the National Institute for Child Health and Human Development
Notes	

Epstein 1985a (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	no description of randomisation process.

Epstein 1985b

Methods	**Random allocation:** Stratified by age, % overweight and physical work capacity **Blinding**: · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 8 weeks treatment and 10 months maintenance and 12 months follow up **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 13% [3/23], follow up at 12 months: 17% [4/23]
Participants	**n=** 23 **randomised**, 19 **completed** **Age range (mean):** 8 to 12 years **% Male:** 0% **Weight entry criteria:** > 20% overweight for height and age **Weight on entry (mean):** 53.86kg, 48.05% overweight for age and height **Setting:** No details **Geographic Region:** US
Interventions	**Interventions:** Diet + controlled exercise vs diet without exercise **Intervention:** Diet + controlled exercise **- Target of intervention:** child and parent **- Behavioural or psychological component:** Self-monitoring: food diaries, chart weight daily, parent asked to review diaries for accuracy and completeness. Praise and modelling: parents and children asked to behave as appropriate models for each other. Therapist contact; seen before treatment meetings (first 8 weeks) to review habit books and give feedback on past weeks progress, + phone calls once a week during treatment period and once a month during maintenance period. Parent management **- Physical activity:** Aerobic programme 3 times per week for 6 weeks. 10 min of stationary aerobic exercise, warm up games, + 3 mile walk/run (parents instructed to walked once a week with therapists + two other times). Children and parents also got exercise session at the maintenance meetings (10 months) **- Nutrional advice:** Traffic Light diet, 900-1200 kcal daily. Each treatment session had a lecture and discussion on nutrition, diet and behaviour management techniques. Traffic Light Diet (calorie-based food exchange system) colour coded: green = foods <20 kcal per serving, yellow = staple foods, red = high fat/high sugar foods. Daily intake: 900-1200 kcal. Two rules: 1. stay within the prescribed calorie range; 2. No more than 4 red foods per week **- Other:** Contracting $80 was deposited before treatment and returned piecemeal at treatment/

Epstein 1985b (*Continued*)

	assessment sessions, parents also asked to use non-monetary reinforcers as incentives for weight loss **Usual care/ alternative intervention:** Diet **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above **- Physical activity:** No **- Nutrional advice:** As above **- Other:** As above
Outcomes	Weight status: Weight (kg) and % overweight (% overweight based on ideal weight standards) presented at 0, 2, 6 and 12 months Others: Leisure time activity survey questionnaire and Physical work capacity
Results	Significant decreases in percent overweight were observed for children in the diet and exercise group 1 from 0 to 2 months (P<0.01), with further decreases from 2 to 6 months (P<0.01). The decreases from baseline shown at 6 months were maintained at 12 months (P <0.01). Children in the diet only group showed decreases in percent overweight from 0 to 2 months (P <0.01); these changes were maintained, but not further decreased, at 6 and 12 months. Significant (P<0.05) differences between the groups in percent overweight were shown at 6 months. At 12 months, nine of 19 children (47%) were <20% over ideal weight, with no differences in the exercise group (five of 10, 50%) or the no-exercise group (four of nine, 44%). (completers only)
Funding and financial disclosure	**Funding/Support**:This work was supported in part by Grant HD16411 from the National Institute for Child Health and Human Development
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	Stratified by age, % overweight and physical work capacity

Epstein 1985c

Methods	**Random allocation:** no description of randomisation process, but assumed to be the same stratified method as other papers **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 12 month treatment program, no follow up. **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 25% [6/24], follow up at 12 months: 25% [6/24]
Participants	**n=** 24 **randomised**, 5 dropped out before treatment and mothers measurements for one child include in analysis **Age range (mean):** 5 to 8 years **% Male:** 0% **Weight entry criteria:** No details given **Weight on entry (mean):** 40.55% overweight, 22.75kg/m^2 **Setting:** No Details **Geographic Region:** US
Interventions	**Interventions:** family based behavioural treatment vs family-based non-behavioural programme **Intervention:** family based behavioural treatment **- Target of intervention:** family **- Behavioural or psychological component:** Both groups received the same amount of therapist time. Therapist contact; seen before treatment meetings (first 6 weeks) to review habit books and give feedback on past weeks progress, + phone calls once a week during treatment period and once a month during maintenance period. Contracting $90 was deposited before treatment and returned piecemeal at treatment/assessment sessions. Intervention group also received following methods of parent management techniques and Social Learning principles: Self-monitoring: food diaries, chart weight daily, parent asked to review diaries for accuracy and completeness. Parents asked to keep diet diaries for themselves. Praise and modelling: parents and children asked to behave as appropriate models for each other. Positive social reinforcement. Contracting: parents assigned points for children meeting desired criteria e.g. staying within daily cal. Intake. Points exchanged for non-monetary reinforcements **- Physical activity:** Education programme: lifestyle activities designed to increase typical daily expenditure (based on Cooper Aerobics Point System, 1977). Both groups: exercise six times per week with activity point goals to meet. These points were increased twice over a 12 week period **- Nutrional advice:** Traffic Light diet, children < 7 years had an upper limit of 1000 kcal daily and >7, 1200 kcal daily. Both groups treated identically. Each treatment session had a lecture and discussion on nutrition, diet and behaviour management techniques. Traffic Light Diet (calorie-based food exchange system) colour coded: green = foods <20 kcal per serving, yellow = staple foods, red = high fat/high sugar foods. Daily intake: 1000-1200 kcal. Two rules: 1. stay within the prescribed calorie range, 2. No more than 4 red foods per week **- Other**: Financial incentive. At the first meeting, each parent deposited 90 dollars, with one 15-dollar cheque to be returned for each of the following: a) attending 5 of 6 (one introductory meeting and 5 treatment meetings) weekly treatment meetings, b) attending 8mo assessment, c) attending 12mo assessment. A 5-dollar check was returned each time the parent and child attended 1 of the 9 monthly maintenance meetings

Epstein 1985c (*Continued*)

	Usual care/ alternative intervention: family-based non-behavioural programme **- Target of intervention:** family **- Behavioural or psychological component:** As above. In addition to the therapist contact time, parents were additional health information - reading labels, shopping, sugar, salt, health risks of obesity. Any behaviour management questions were reflected back to parents for discussion **- Physical activity:** As above. **- Nutrional advice:** As above. **- Other:** As above.
Outcomes	Weight status: % Overweight (based on reference to child [Robinson 1968] and adult [Metropolitan life insurance company 1959] standards) and BMI presented at 0, 4, 8 and 12 months Others: eating behaviour, self control, parents % overweight, parents BMI and parents self control
Results	There was a significant interaction of treatment by time for percentage overweight [F(3,51)=5.43, p<0.005] and BMI [F(3,51)=5.39, p<0.005], indicative of better weight loss time for time for children in the behavioural treatment group. Post hoc analyses revealed significant differences between groups for percentage overweight and BMI at 8 and 12 months follow up. (completers only)
Funding and financial disclosure	**Funding/Support**: This work was supported in part by Grant HD16411 from the National Institute for Child Health and Human Development
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	no description of randomisation process

Epstein 1994a

Methods	**Random allocation:** no description of randomisation process. **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 26 weeks treatment and 6 monthly follow ups to 2 years **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 11% [5/44], follow up at 6, 12, 24 months: 11% [5/44]
Participants	**n=** 44 **randomised**, 39 **completed** **Age range (mean):** 8 to 12 years (10.2 ± 1.1) **% Male:** 26% **Weight entry criteria:** Between 20% and 100% overweight for height

	Weight on entry (mean): 59.6% ± 22.0% over the 50th percentile for BMI **Setting:** Unclear, probably outpatient clinic and university medical school **Geographic Region:** US
Interventions	**Interventions:** Comparison of behavioural treatments: mastery criteria vs contingent reinforcement **Intervention:** Targeted for mastery of behaviours **- Target of intervention:** child and parents **- Behavioural or psychological component:** Manual (self-monitoring, diet, exercise, parenting and maintenance in 22 modules). Behavioural principles used at weekly meetings to reinforce appropriate behaviour changes. Behaviour changes divided into 5 Levels. Parents and children in experimental group had to demonstrate mastery of behavioural skills before progressing to next level. (Subjects who reported eating less and doing more, but who did not lose weight were not reinforced or advance to next level. Similarly, neither were subjects who lost weight but who did not demonstrate mastery of behavioural skills at that level.) Treatment given over 26 weekly meetings and 6 monthly meetings **- Physical activity:** Lifestyle activities. Subjects choose aerobic activities (walking, swimming, tennis) that can be incorporated into their daily routine. Programme goal progression: 50 kcal per day for 7 days to 300 kcal per day for 5 days, recorded in habit books **- Nutrional advice:** Traffic Light diet. 900-1800 kcal daily on Level 1 down to 900-1200 kcal by Level 4, Level 5 individually adjusted for maintenance. Daily food records **- Other:** Quizzes based on information in intervention manuals, parent skills lottery (tickets for local cultural activities with more chance of winning with greater mastery). No mention of money **Usual care/ alternative intervention:** Contingent reinforcement. Yoke to intervention - moved on when 50% of intervention group showed mastery of behaviours **- Target of intervention:** child and parents - **Behavioural or psychological component:** Intervention for control group was the same except for the timing of moving to the next level of behavioural skills. The presentation of new information and introduction of new skills was carried out when 50% of the intervention group had mastered the skills at each level (i.e. the controls were yoked to the experimental group). The control group progressed through the intervention at the same rate as the experimental group **- Physical activity:** As above. **- Nutrional advice:** As above. **- Other:** As above.
Outcomes	Weight status: Weight (kg) and % over the 50^{th} percentile for BMI (as the reference child and adult weight for height based on population standards [Must et al 1991]), presented at 0, 6, 12, 18 and 24 months Others: parental knowledge.
Results	Child percent-overweight showed a significant interaction of Group by Time (F[3,108] = 2.70, p < .05), and a main effect of Time (F[3,108] = 21.09, p< .00l). Linear contrasts suggested that the groups were different after 6 (F[1,36] = 4.90, p<0.05) and 12 months (F[1,36] = 4.19, p<0.05). While the experimental group still had approximately one-third more change than the control group at 24 months, they were no longer significantly different (F[1,36 = 1.17, p=0.29). The differences from baseline for the experimental and control groups were -30.1 and -20.0 at 6 months, -26.5 and -16.7 at 12 months, and -15.4 and -10.6 at 24 months. (completers only)

Epstein 1994a (*Continued*)

Funding and financial disclosure	**Funding/Support**: this work was supported in part by grant HD R0I 23713 awarded to the first author
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	no description of randomisation process

Epstein 1995

Methods	**Random allocation:** no description of randomisation process **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 4 month treatment and 1 year follow up **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 7% [44/61], follow up at 12 months: 10% [6/61]
Participants	**n=** 61 families **randomised**, 2 dropped out during treatment, 2 refused to take part in follow up, 1 child had a leg injury and in 1 family a parent died **Age range (mean):** 8 to 12 years (10.1y) **% Male:** 27% **Weight entry criteria:** Between 20% and 100% overweight **Weight on entry (mean):** 51.8% overweight for height **Setting:** Unclear, probably outpatient clinic at University medical school **Geographic Region:** US
Interventions	**Interventions:** Comparisons of diet and physical activity reinforcement regimes. 3 groups: decreasing sedentary behaviours vs increasing active behaviours vs targeting both **Intervention:** decreasing sedentary behaviours **- Target of intervention:** child and parent **- Behavioural or psychological component:** Mastery approach to teaching. Manuals divided into modules. Self-monitoring: weight daily and graph weight. Habit book for food and caloric intake, number of red foods and time spent in active or sedentary activity. Sedentary group recorded minutes, Exercise group recorded points, both group recorded minutes and points. Stimulus control: Parents and children model appropriate eating and activity behaviours. Change environment (cues: decrease red foods or make cycles more accessible, turn TV to wall). Reinforcement: review habit book nightly, reciprocal contracting between parents and children (mutually agreed reinforcers for when behavioural criteria are met) **- Physical activity:** All 3 groups received same PA information. Sedentary group: reinforced for decreasing time in sedentary behaviours. Activities targeted were those that compete with active behaviours (e.g. watching TV, playing computer games or board games, talking on the phone,

	not listening to music, homework or reading) **- Nutrional advice:** Traffic Light diet, 1000-1200 kcal daily, red foods limited to 7 or fewer per week and eat balanced meals (using food pyramid) **- Other:** Quizzes based on manual information. **Usual care/ alternative intervention:** increasing active behaviours **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above. **- Physical activity:** Exercise group: reinforced for increasing PA beyond those at school **- Nutrional advice:** As above. **- Other:** As above. **Usual care/ alternative intervention:** targeting both **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above. **- Physical activity:** Both groups: reinforced for decreasing sedentary and increasing active behaviours **- Nutrional advice:** As above. **- Other:** As above.
Outcomes	Weight status: % overweight (based on height and weight data [Hamil et al 1977]) presented at 0, 4, 8 and 12 months Others: % body fat, waist-to-hip circumference and physical work capacity
Results	At 1 year, the sedentary group had a greater decrease in percentage overweight than did the combined and the exercise groups (-18.7 vs -10.3 and -8.7) and greater decrease in percentage of body fat (-4.7 vs -1.3). Significant between-group differences in the rate of change were observed for percentage overweight, F(4,102) =3.14, p = .026, and percentage of body fat, F(4,94) = 2. 67, p =.037.1. Post hoc tests showed significant differences (p <0.05) in percentage overweight for children in the sedentary group versus children in the exercise group at 4 months and the exercise and combined groups at 1 year. Percentage of change in body fat showed significant (p <0.05) between-group differences observed between the sedentary and exercise groups at 1 year. (completers only)
Funding and financial disclosure	**Funding/Support**: This research was supported in part by Grant HD 25997 awarded to Leonard H. Epstein at the department of psychiatry, University of Pittsburgh School of Medicine
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	no description of randomisation process

Epstein 2000a

Methods	**Random allocation:** Families stratified by gender and degree of child and parent obesity **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** unclear **Length of intervention and follow up:** 6 months treatment and follow up at 12 and 24 months **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 7% [5/67], follow up at 24 months: 14% [15/67] (5 children had self-reported heights and weights at 24 months)
Participants	**n=** 67 **randomised**, 52 **completed** **Age range (mean):** (10.3 years, SD 1.1) **% Male:** 48% **Weight entry criteria:** 20% overweight **Weight on entry (mean):** 59.8 kg (SD 53.1) **Setting:** No details **Geographic Region**: US
Interventions	**Interventions:** family-based behavioral weight-control program + parent and child problem solving vs family-based behavioral weight-control program + child problem solving vs family-based behavioral weight-control program without additional problem solving **Intervention:** family-based behavioral weight-control program + parent and child problem solving **- Target of intervention:** family **- Behavioural or psychological component:** The 6-month treatment program included 16 weekly meetings followed by two monthly meetings. At treatment meetings, family members were weighed, met with an individual therapist for 15 to 30 minutes, and attended separate 30-min group meetings (one for parents and one for children). All of the parents and children were provided workbooks with information on the traffic light diet, a 1,200-kcal diet based on the food pyramid, with foods color-coded to the traffic light on the basis of nutrient density, lifestyle physical activity, and behavior changes techniques, including self-monitoring, positive reinforcement, stimulus control, and preplanning Problem-solving was integrated into the group and individual content of the groups in several ways. Didactic training in problem solving was provided in group formats for parents and/or children. In the problem-solving group and individual family sessions, group leaders and therapists used problem-solving methods when a question was asked. In group and individual family sessions in which problem solving was not assigned, group leaders or therapists used didactic methods to address problems to make contrast with problem solving as distinct as possible. 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 **- Physical activity:** See behavioral component. **- Nutrional advice:** See behavioral component. **- Other:** Parents deposited $75, which was returned contingent on completion of 75% of the treatment sessions and attendance at the 6- and 12-month follow-up. The families were paid $50 for their attendance at the 24-month follow-up **Usual care/ alternative intervention:** family-based behavioral weight-control program + child

	problem solving **- Target of intervention:** family **- Behavioural or psychological component:** Described above. **- Physical activity:** See behavioral component. **- Nutrional advice:** See behavioral component. **- Other:** Parents deposited $75, which was returned contingent on completion of 75% of the treatment sessions and attendance at the 6- and 12-month follow-up. The families were paid $50 for their attendance at the 24-month follow-up **Usual care/ alternative intervention:** family-based behavioral weight-control program without additional problem solving **- Target of intervention:** family **- Behavioural or psychological component:** Described above, but no problem-solving training. **- Physical activity:** See behavioral component. **- Nutrional advice:** See behavioral component. **- Other:** Parents deposited $75, which was returned contingent on completion of 75% of the treatment sessions and attendance at the 6- and 12-month follow-ups. The families were paid $50 for their attendance at the 24-month follow-up
Outcomes	Weight status: Weight (kg) and BMI z scores presented at 0, 6, 12 and 24 months Others: child problem solving, parent problem solving, child psychological problems (CBCL), parent psychological problems (SCL-90) and use of behaviours related to weight control (Adherence Questionnaire)
Results	Both groups showed similar decreases at 6 months, but the standard group showed smaller increases in weight from 6 to 24 months ($p < 0.005$) and smaller total increases in weight from 0 to 24 months ($p < .04$). Standardized BMI showed linear changes between the parent + child group versus the standard group, $F(1,49) = 5.25$, $p < 0.03$. Contrasts of means showed that the standard group had larger decreases from 0 to 24 months ($p < 0.02$) because of smaller increases from 6 to 24 months ($p < 0.02$) or because of smaller increases from 12 to 24 months ($p < 0.005$). (completers only)
Funding and financial disclosure	**Funding/Support**: This research was supported in part by Grant HD20829.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	no description of randomisation process, families stratified by gender and degree of child and parent obesity

Epstein 2000b

Methods	**Random allocation:** Families stratified by gender and degree of child and parent obesity **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 6 month treatment and 2 year follow up **Unit of allocation:** Family **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 11% [10/90], follow up at 12 months: 12% [11/90] and at 24 months follow up 19% [17/90] (Activity group = 4/22 in low dose, 4/23 in high dose and 4/23 in low dose and 2/22 in high dose, 3/76 measures were parent-reported at the 2 year follow up.)
Participants	**n=** 90 families **randomised**, 76 **completed** **Age range (mean):** 8 to 12 years (10.5 years, SD 1.2) **% Male:** 32% **Weight entry criteria:** Between 20 % and 100% overweight **Weight on entry (mean):** 60.6, SD 10.9 kg **Setting:** Childhood obesity research clinic **Geographic Region:** US
Interventions	**Interventions:** Comprehensive family-based behavioral weight control program with varied targeted behaviours and treatment dose: (1) increase physical activity - low vs (2) increase physical activity - high vs (3) decrease sedentary behavior - low vs (4) decrease sedentary behavior - high **Intervention:** (1) increase physical activity - low **- Target of intervention:** family **- Behavioural or psychological component:** The 6-month treatment included 16 weekly meetings, followed by 2 biweekly and 2 monthly meetings. Families received parent and child workbooks, which included introduction to weight control and self-monitoring, the Traffic Light Diet, the specific activity program, behavior change techniques and maintenance of behavior change. At treatment meetings participating family members were weighed, their weight was graphed, they met with an individual therapist for 15-30 minutes, and they attended separate 30-minute parent and child group meetings. During the individual meetings, therapists reviewed weekly weight change and diet, targeted physical or sedentary activities, and the behavioral contract. 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 (or child) based on meeting the goal **- Physical activity:** Participants assigned to the increase physical activity group were reinforced for increasing physical activities in addition to those engaged in at the onset of the program. Physical activities done as a required part of the work or school day were not counted in meeting activity goals Low dose for the increase physical activity group was the equivalent expenditure of 16.1 km per week **- Nutrional advice:** The Traffic Light Diet was used to decrease energy intake and promote a balanced diet. Foods are categorized on the basis of their caloric and nutrient content. While they were attempting to lose weight, children and overweight parents were instructed to consume between 4184 and 5021 kJ/day, to limit red foods to 10 or fewer per week, and to maintain nutrient balance by eating the recommended servings based on the food pyramid. Families were provided additional nutritional information, including reading food labels and shopping, and

	were taught stimulus control to reduce access to high-calorie foods and increase access to healthy lower-calorie foods. Preplanning was taught to facilitate decision making and problem solving for difficult eating and activity situations, such as parties, holidays, and school or work functions **- Other:** Parents deposited $75 to be returned contingent on completing 75% of the treatment sessions and attending the 6- and 12-month follow-up. Families were paid $50 for their attendance at the 24-month follow-up **Usual care/ alternative intervention:** (2) increase physical activity - high **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** As above. High dose for the increase physical activity group was the equivalent expenditure of 32.2 km per week **- Nutrional advice:** As above. **- Other:** As above. **Usual care/ alternative intervention:** (3) decrease sedentary behavior - low **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** Participants assigned to the decrease sedentary behavior group were reinforced for reducing sedentary behaviours that compete with being active or set the occasion for eating (watching television/videotapes, playing computer games, talking on the telephone, or playing hard board games). Not all sedentary activities were targeted, so that participants could substitute non-targeted sedentary activities for targeted sedentary behaviors Low dose for the decrease sedentary behavior group was 10 h/week of targeted sedentary behaviors **- Nutrional advice:** As above. **- Other:** As above. **Usual care/ alternative intervention:** (4) decrease sedentary behavior - high **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** As above. High dose for the decrease sedentary behavior group was 20 h/week of targeted sedentary behaviors **- Nutrional advice:** As above. **- Other:** As above.
Outcomes	Weight status: Weight (kg) and % overweight (based on comparison of subjects BMI to the 50th BMI percentile based on subject sex and height) presented at baseline, 6, 12 and 24 months Others: % body fat and physical work capacity.
Results	Significant (P<0.001) decreases in percent overweight were observed from baseline to 6 months through 2 years. Percent overweight decreases of 25.5% at the end of treatment represented a reduction of 41% from baseline, which was associated with average child growth of about 3.5 cm and average weight loss of 6.0 kg (Table 2). During 2 years the average child grew 11.4 cm and gained 9.0 kg, which was related to a decrease in percent overweight of 12.9%, and a reduction in percent overweight from baseline of 20.8%. Intention-to-treat analyses showed significant changes from baseline through 2 years (P.001), with decreases in percent overweight of 22.7% at the end of 6 months and a decrease of 10.9% overweight at 2 years
Funding and financial disclosure	**Funding/Support**: This research was supported in part by grants HD20829 and HD 25997 from the National Institute of Child Health and Human Development, Bethesda, Md (Dr Epstein)

Epstein 2000b (*Continued*)

Notes	Unclear whether a sub sample of the participants in this study also took part in the previous Epstein 1995 paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	no description of randomisation process, families stratified by gender and degree of child and parent obesity

Epstein 2004

Methods	**Random allocation:** no description of randomisation process. **Blinding:** · **Children/family:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 6 months intensive treatment. Follow up at 12 months. **Unit of allocation:** Child/family **Unit of analysis:** Child/family **Protection against contamination:** Not clear **Drop outs:** end of intervention 15% [11/72], follow up at 12 months: 17% [12/72]
Participants	**n=** 72 **randomised**, 60 **completed** **Age range (mean):** 8 to 12 years (mean(SD): 9.8(1.3)) **% Male: 37.1%** **Weight entry criteria:** over 85^{th} BMI percentile **Weight on entry (mean):** 57.6 (7.8) kg stimulus control, 57.1 (11) kg reinforced reduce sedentary **Setting:** Unclear, but assume outpatient clinic **Geographic Region:** Not clear
Interventions	**Interventions:** behavioural therapy with stimulus control vs behaviour therapy with reinforced reduce sedentary behaviours **Intervention:** Stimulus control **Target of intervention:** Child/family **- Behavioural or psychological component:** The treatment program included 16 weekly meetings, followed by two biweekly meetings and two monthly meetings during the 6-month intensive treatment. Families received parent and child family-based weight control workbooks, which included four main sections, (a) introduction to weight control and self-monitoring, (b) the Traffic Light Diet (described below), (c) behavior change techniques, and (d) maintenance of behavior change. Families in both groups were taught to praise children for meeting goals specific to their group. In addition, children in both groups were provided a contract reinforcement system to motivate children for behavior 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. The stimulus control group received additional instructions to aid sedentary behavior change, which involved posting signs indicating the seden-

	tary limit and unplugging targeted sedentary activities such as televisions or computers. **- physical activity:** There was no specific activity program provided for the participants. They were provided general information on lifestyle and aerobic activities, but there were no specific goals for any participant. Participants did not self-monitor their activity, and they were not positively reinforced for increasing their activity. **- nutritional advice:** Families were instructed to record daily food intake (food description; amount; calories; and number of high-calorie high-fat, "Red," foods, described below) and targeted sedentary behavior times (TV/VCR/DVD, video games, and non-school use of a computer) in habit books. Parents were taught to review habit books during a daily meeting the parent had with the child. Families were also told to record and graph home weights at least once per week. The Traffic Light Diet (Epstein et al. 1998) was used to decrease energy intake, increase nutrient density, and balance nutrients in the participants' diet. This diet categorizes foods on the basis of their macro- and micronutrient content into the colors of a traffic light with similar meaning. The diet starts at 800-1,200 calories per day, with children encouraged not to go below 800 calories per day. The weight loss goal in this study was for children to lose 0.5 lbs. (0.2 kg) per week. If children are losing more than 2 lbs. (0.9 kg) per week for 3 or more weeks, the calorie range is adjusted upward. The goal is for children to gradually reduce the number of Red foods per week to 15 or fewer. Families who achieved non-overweight status were taught how to identify energy values that would facilitate maintenance of normal growth. Information regarding food labels and shopping were included in the diet instruction. **- Other:** No **Usual care/ alternative intervention:** reinforced reduce sedentary behaviours **- Target of intervention:** child/family **- Behavioural or psychological component:** As above, but In the reinforced reduction group positive reinforcement was contingent on reducing targeted sedentary behaviours, whereas in the stimulus control group positive reinforcement was contingent on recording targeted sedentary behaviours **- Physical activity:** As above. **- Nutrional advice:** As above. **- Other:** No.
Outcomes	Height, mean BMI z score and % overweight (SDs), mean waist circum (SDs), change BMI z score (SDs), change waist circum (SDs), behaviour changes (pa including sedentary behaviour, F&V, and red foods)
Results	There was a main effect of time for changes in z-BMI, F(2, 112) 59.91, p .001, with significant treatment effects observed at both 6 months, F(2, 56) 54.94, p .001, and 12 months, F(2, 56) 22.90, p .001, but there were no significant differences in the rate of change between groups. Z-BMI 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, whereas the values for the reinforced reduction group at the same time points were 3.2 (1.0), 2.2 (1.1), and 2.6 (1.0). Similar effects were observed for percentage overweight at 6 months, F(2, 56) 111.82, p .001, and 12 months, F(2, 56) 31.88, p .001
Funding and financial disclosure	**Funding/Support**: This research was supported in part by Grant HD 25997 awarded to Leonard H. Epstein
Notes	

Epstein 2005

Methods	**Random allocation:** Yes. No description of randomisation process. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Intervention: 2 years, but more intense early on. Follow up: 2 years from commencement of intervention. **Unit of allocation:** Families **Unit of analysis:** Families **Protection against contamination:** Not clear **Drop outs:** end of intervention 20% [9/44], follow up at 24 months: 20% [9/44]
Participants	**n=** 44 **randomised**, 35 **completed** **Age range (mean):** 8-12 at baseline (mean(SD) age (yr.) experimental group: 10.2 (1.1); mean (SD) age (yr.) standard treatment group: 10.1 (1.3)) **% Male:** 43.9% **Weight entry criteria:** > or = to 85^{th} percentile BMI **Weight on entry (mean):** mean(SD) weight on entry (lb) experimental group: 137.5 (24.8); mean (SD) weight on entry (lb) standard treatment group: 142.9 (23.7). **Setting:** Unclear, assume outpatient clinic **Geographic Region:** Unclear
Interventions	**Intervention:** experimental group using behavioral economic treatment **Target of intervention:** Family **- Behavioural or psychological component:** Children in both groups were provided a reinforcement system to motivate children for behavior change. Children could earn points only if they met behavioral goals and lost weight. The dual contingency of behavioral and weight goals was designed to minimize youth being reinforced for self-report of behavior change in the absence of true behavior change. All behaviours reinforced in the standard group were also reinforced in the experimental group. However, in addition, the experimental group also earned 1 point for each "Alternative Behavior to Eating," defined as any freely chosen activity lasting at least 30 minutes that did not or could not involve simultaneous eating. Participants who used physical activity as the incompatible behavior could earn an extra point in addition to the points for being active. Targeted sedentary behaviours (television watching, recreational computer use, and video or computer games) were not reinforced even if eating was not engaged in **- Physical activity:** Families were provided general information on lifestyle and aerobic activities and taught to increase physical activity and decrease targeted sedentary behavior (television watching, recreational computer use, and video or computer games). The activity program used was a lifestyle program. Participants were provided a list of activities and their associated caloric expenditures (metabolic equivalents, or METS) and were instructed to accumulate at least 30 minutes of moderate intensity (3 METS or greater) accumulated in increments of at least 10 min per bout at least 6 days/week. Participants could engage in traditional, high-intensity aerobic exercise on some days but would be expected to engage in lifestyle physical activity on other days. **- Nutritional advice:** All families were provided basic information about the Traffic Light Diet, Food Guide Pyramid, and healthy eating. The focus was on calorie reduction and reduction in intake of RED foods, and families were taught the importance of eating a balanced diet. The caloric target range was 1,000 to 1,500 kcal/day. Children and their parents started on a 1,200 to 1,500 kcal/day diet, and their individual calorie level was adjusted based on their weight change. If

Epstein 2005 (*Continued*)

	the children consistently lost more than 1 pound per week, or the adults lost more than 2 pounds per week over 3 weeks, the calorie level was increased; if the children did not lose at least 0.5 pounds/week and the overweight adults did not lose 1 pound/week, the calorie level was decreased to no less than 1,000 kcal/day. **- Other:** No **Usual care/ alternative intervention:** standard family-based behavioral intervention **- Target of intervention:** Family **- Behavioural or psychological component:** As above, but without reinforcement for alternative eating behaviours. **- Physical activity:** As above. **- Nutritional advice:** As above. **- Other:** No.
Outcomes	Height, weight, BMI, BMI-z-score, percent overweight, behaviour changes, physical activity
Results	There was a significant change in z-BMI over time in the intent to treat analysis, F(3, 117) = 25. 12, p < .001 , with no significant differences in rate of change by group (p =0.70)
Funding and financial disclosure	**Funding/Support**: This research was supported in part by grant HD 39792 awarded to Leonard Epstein
Notes	

Epstein 2008a

Methods	**Random allocation:** Randomization was implemented using a random number algorithm stratifying by gender **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Intervention: 6 months. Follow-up from commencement of intervention: 24 months **Unit of allocation:** Child **Unit of analysis:** Child + Parent **Protection against contamination:** Unclear **Drop outs:** end of intervention 34% [14/41], follow up at 12 and 24 months: 34% [14/41]
Participants	**n=** 41 **randomised**, 27 **completed** **Age range (mean)** 8-12 years **% Male:** 56% **Weight entry criteria:** Over the 85^{th} BMI percentile **Weight on entry (mean):** Increase healthy food group: mean (SD) zBMI 2.3 (0.3). Reduce High-Energy-Dense food group: mean (SD) zBMI 2.3 (0.2) **Setting:** Not clear **Geographic Region:** U.S.A.

Interventions	**Intervention:** Increase healthy food **- Target of intervention:** family **- Behavioural or psychological component:** Stimulus control for food recommendations for the healthy food group were to arrange a food environment to make it easier to increase their fruit, vegetables, and low-fat dairy food consumption. Parents were encouraged to model healthy behaviours for their children, and in addition to the point system, family members were encouraged to praise each other for practicing healthy behaviours. Preplanning and problem solving were taught to facilitate decision-making and handling of difficult eating and activity situations **- Physical activity:** Both groups received information about physical activity and positive effects of exercising. The goal was at least 60 minutes per day of moderate to vigorous intensity physical activity for 6 days a week, shaped in 15-minute increments beginning at 15-minutes of moderate to vigorous intensity physical activity per day **- Nutrional advice:** The Traffic Light Diet was used to decrease energy intake and promote a healthy diet for overweight children and their parents. Traffic Light Diet foods are categorized as Green, Yellow, and Red, based upon their amount of fat and sugar per serving. Serving sizes used in the Traffic Light Diet are derived from the serving sizes used in the food pyramid. Green foods are high in nutrient density and low in energy density. Most Green foods come from the fruit and vegetable groups. Yellow foods are higher in energy density than Green food, and Red foods are higher in energy density than Yellow and Green foods. Many Red foods come from the fats, oils, and sweets groups and are to be used sparingly. Overweight participants were instructed to consume between 1,000 and 1,500 calories per day. All participants were educated to maintain nutrient balance by eating the recommended number of servings based on the food guide pyramid. Families were provided education on reading food labels and healthy shopping. Each group received reinforcement for meeting their dietary goals through a point system. The increase healthy food group focused on replacing high-energy dense food with fruits, vegetables and low-fat dairy. They had a weight loss target, but no calorie goal **- Other:** No **Usual care/ alternative intervention:** Reduce High-Energy-Dense food **- Target of intervention:** family **- Behavioural or psychological component:** Stimulus control control recommendations were designed to reduce consumption of Red foods by limiting them in their home environment, reducing purchasing of Red foods, and alter food preparation and eating out. Family members were also encouraged to praise each other for practicing healthy behaviours, to model healthy behaviours and to use preplanning and problem solving to handle difficult eating and activity situations **- Physical activity:** As above. **- Nutrional advice:** As above. **- Other:** No
Outcomes	**Weight status:** Height, weight, BMI, zBMI, fruit/vegetable intake, RED food servings, low-fat dairy intake, minutes of general physical activity, minutes of MVPA, Parental feeding practices, Child-rearing behaviours
Results	The mixed effects regression model to predict changes in zBMI showed a linear interaction of group by months ($P < 0.01$), as the increase healthy food group showed greater reductions over time in comparison to the reduce high energy-dense food group. Analyses showed significant between group differences on changes from baseline to 12 ($P = 0.01$) and 24 ($P = 0.04$) months. Significant reductions in zBMI were also observed over time ($P < 0.001$), with overall reductions at 6 (coefficient = −3.33, $P < 0.001$) and 12 (coefficient = −2.22, $P = 0.037$) months. After

Epstein 2008a (*Continued*)

	six months the decrease high energy group regained, whereas the healthy food choices group continued decreasing. MRM analyses were also completed on percent overweight, and there was a significant linear interaction of group by months (P = 0.013), as subjects in the increase healthy food group showing a reduction in percent overweight of −17.5 ± 7.33, mean ± s.d.) −16.9 ± 10. 9 and −16.4 ± 21.6 at 6, 12, and 24 months, respectively, while those in the reduce high energy-dense food group showed reductions of −15.6 ± 13.1, −8.4 ± 14.9, and −2.0 ± 18.2 at 6, 12, and 24 months. A significant overall reduction in percent overweight was observed over time (P < 0.002), with overall reductions at 6 (coefficient = −3.34, P < 0.001), 12 (coefficient = −2.22, P < 0.001), and 24 (coefficient = −1.20, P=0.01) months
Funding and financial disclosure	**Funding/Support**: This research was supported by grant HD 39792 (to LHE) from the National Institute of Child Health and Human Development. Dr Epstein is a consultant to Kraft Foods **Financial disclosure:** The authors declared no conflict of interest.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	Randomization was implemented using a random number algorithm stratifying by gender

Flodmark 1993

Methods	**Random allocation:** Method not described **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 14-18 months treatment and one year follow up **Unit of allocation:** Children **Unit of analysis:** Children **Protection against contamination:** No details **Drop outs:** end of intervention 10% [9/94], follow up at 12 months: 10% [9/94] (Baseline and outcome measures for 39/44 treatment children and 48/50 control children [Table 1]) For all but 1 child height and weight data were available
Participants	**n=** 94 **randomised** (44 for treatment [family and conventional] and 50 for control), 87 **completed** follow up, (39 treatment and 48 control) **Age range (mean):** 10 to 11 years **% Male:** 48% **Weight entry criteria:** BMI > 23.0 **Treatment groups weight on entry (mean):** BMI 22.0 **Control group weight on entry (mean):** BMI 25.1 **Setting:** Screened in schools and attended sessions with paediatrician **Geographic Region:** Sweden

Interventions	**Interventions:** Standard care of comparable dietary counselling and medical checkups for a period of 14-18 months + family therapy vs standard care of comparable dietary counselling and medical checkups for a period of 14-18 months alone **Intervention:** Standard care of comparable dietary counselling and medical checkups for a period of 14-18 months + family therapy **- Target of intervention:** family **- Behavioural or psychological component:** Family therapy component included the treatment component below, plus an program across 14-18 months where families were seen every 2-3 months. 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 overall aim was to promote mutual respect and a confident atmosphere. Within the session, first the seriousness of the obese condition was defined for the family. Then the hierarchy of the family was adjusted with interventions focused on family structure. The de Shazer model, a brief solution-based therapy focusing, through language, on how to construct solutions. Failures, past or present are not discussed, allowing families to feel less like failures. **- Physical activity:** The importance of exercise was emphasized and exercise by the obese children was encouraged **- Nutrional advice:** Dietary counselling by a dietician (only half took up this option), and (assume) some dietary related advice from the paediatrician as they go on to say that the dietary component prescribed contained 15-1700 calories and families were advised to reduce the energy content of food to 30%. **- Other:** No **Usual care/ alternative intervention:** Standard care of comparable dietary counselling and medical checkups for a period of 14-18 months alone **- Target of intervention:** family **- Behavioural or psychological component:** No. **- Physical activity:** The importance of exercise was emphasized and exercise by the obese children was encouraged **- Nutrional advice:** Dietary counselling by a dietician (only half took up this option), and (assume) some dietary related advice from the paediatrician as they go on to say that the dietary component prescribed contained 15-1700 calories and families were advised to reduce the energy content of food to 30% **- Other:** No
Outcomes	Weight status: BMI presented at start, end and 1 year follow up Others: skin-fold thickness and physical fitness. Length of treatment was 14-18 months and follow up was one year after completion of treatment, hence > 1 year data that are presented
Results	At the end of treatment, the family therapy group manifested a significantly smaller increase in BMI (expressed in percent of the initial value) than the conventional treatment group (0.66% vs 2.31%; P =.042). At follow-up I year after the end of treatment, the mean BMI differed significantly between the family therapy and the untreated control groups (P = .046), and there was a significantly smaller increase of BMI (expressed in percent of the initial value) in the family therapy group than in the untreated control group (mean +5.1 vs + 12.0%; P = .022). (intention-to-treat?)

Flodmark 1993 (*Continued*)

Funding and financial disclosure	**Funding/Support**: This study was supported by the Golje Foundation, the Swedish Medical Association, the Albert Påhlsson Foundation, the Swedish Society of Medicine, the Johanna Andersson Foundation, "Förenade Liv" Mutual Group Life Insurance Company Stockholm, and the Medical Faculty of the University of Lund, Sweden.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Gillis 2007

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Six months duration, with healthy lifestyle talks at baseline and three months. Assessment and examinations were conducted at baseline and follow-up, six months. **Unit of allocation:** Individual children **Unit of analysis:** Individual children **Protection against contamination:** Not clear **Drop outs:** end of intervention 33% [9/27], follow up at 6 months: 33% [9/27]
Participants	**n=** 27 **randomised**, 18 **completed** **Age range (mean):** 7-16 years (intervention group 11.2 ± 2.5, control group 9.9 ± 2.0) **% Male:** Gender not stated **Weight entry criteria:** BMI>90th percentile **Weight on entry (mean):** Not stated. (BMI SDS: intervention group 1.98 ± 0.21, control group 2.16 ± 0.34) **Setting:** Two urban, primary care clinics in Jerusalem. **Geographic Region:** Jerusalem/Israel
Interventions	**Intervention:** Guidance-based intervention reinforcing nutrition and exercise modification **Target of intervention:** Child **Behavioural or psychological component:** Self-monitoring: diaries recording the contents of food ingested and the amount of exercise performed on one day of each week. Practitioner contact: talks/discussions based on healthy diet/exercise were held with the intervention group at baseline and at three months, together with weekly telephone calls to encourage adherence to the prescribed plan. **Physical activity:** Intervention was in the form of talks, at both baseline and 3 months, discussing the benefits of exercise/physical activity. Physical fitness was assessed by a modified Harvard step test (discussed later).

	Nutritional advice: Advice given to participants via talks at baseline and 3 months, together with reinforcement of 'ideal diets' via telephone calls on a weekly basis. As part of these calls, food diaries were reviewed with further advice if necessary. **Other:** No **Usual care/ alternative intervention:** Control group **Target of intervention:** Child **Behavioural or psychological component:** Control group received identical talks to the intervention at baseline and three months. Other elements of the study were specifically for the intervention group only. **Physical activity:** Advice provided in the form of talks at baseline and three months, based around the benefits and impact of exercise/physical activity. **Nutritional advice:** Advice provided in the form of talks at baseline and three months, regarding the benefits of healthy eating. **Other:** No
Outcomes	Height, weight, BMI, BMI SDS, lifestyle changes (food intake, physical fitness) LDL (mg/dl), HDL (mg/dl), triglycerides (mg/dl), CRP (mg/dl), ALT, AST, HbA1c, fasting glucose and insulin
Results	Change in BMI-SDS in experimental group mean (sd) -0.045 (0.19) at six months vs 0.075 (0.08) in control group. There was no statistically significant difference between the two groups when comparing the average BMI SDS change directly between the control and intervention groups. (completers only)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	None

Golan 1998

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** Not clear · **Providers:** Not clear · **Outcome assessors:** Not clear **Length of intervention and follow up:** One year **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Not clear **Drop outs:** end of intervention 17% [10/60], follow up at 6 months: 17% [10/60] (9/30 in control group, 1/30 in intervention group)
Participants	**n=** 60 children **randomised**, 50 **completed** **Age range (mean):** 6 to 11 years (9.2 years, SD 1.0) **% Male:** 38% **Weight entry criteria:** > 20% over expected weight for age, height and gender **Weight on entry (mean):** 39% overweight **Setting:** Not stated **Geographic Region:** Israel

Interventions	**Interventions:** Behavioural modification targeted at parents as agents of change (intervention) vs children as agents of change (control) **Intervention:** Behavioural modification targeted at parents as agents of change **- Target of intervention:** parent **- Behavioural or psychological component:** Parents taught to apply behaviour modifications, practice relevant parenting skills, + limits of responsibilities, parental modelling, cognitive re-structuring and coping with resistance. 2 subgroups of 15 parents. Each subgroup attended 14 one hour sessions; first 4 were weekly, next 4 biweekly, last 6 were once every 6 weeks. + family also attended 15 min individual sessions at certain points among the last 6 group sessions. (all siblings weighed and measured to emphasise growth and children told their Parents were on a health promotion course). '5 only's: eat only in the dining room, while sitting, proper plate, when not doing anything else and when hungry **- Physical activity:** Parents taught to alter sedentary lifestyle (no details). **- Nutrional advice:** Parents taught to decrease fats and reduce family's exposure to food stimuli. Parents controlled the quality and pattern of the food environment but not restrict the amount of food eaten **- Other:** No **Usual care/ alternative intervention:** Children as agents of change. **- Target of intervention:** child **- Behavioural or psychological component:** Children divided into 2 equal subgroups. Each subgroup attended 30, one hour sessions with a clinical dietician. First 8 weeks were held weekly and remaining 22, bi-weekly. Taught how to control food stimuli, self-monitoring techniques, practice problem solving, cognitive restructuring and make use of social support. Individual counselling was offered if child missed session of needed extra support **- Physical activity:** Taught how to increase exercise. **- Nutrional advice:** 6.3 MJ/d, taught how to follow a prudent diet, restrict energy intake **- Other:** No
Outcomes	Weight status: Weight (kg) and % overweight at baseline presented in earlier paper (ref 26, table 1) and outcome change in % overweight presented at 12 month follow up Others: Family Eating and Activity Questionnaire (designed for study) and parental weight
Results	Children in both groups showed a significant decrease in degree of overweight (-7.35; P<0.001 and -3.74; P<0.01, respectively), although, the change was significantly greater in the experimental intervention group (14.6% vs 8.4%) F(1,57)=5.0; P<0.05. At the 2-year follow-up visit, there was a mean reduction in overweight of 15% in children of the parent-only group and an increase of 2.9% in children in the child-oniy group (p<0.01). (completers only)
Funding and financial disclosure	**Funding/Support**: This study was supported by the Mrs Tzipora Ayalon Scholarship Grant of the Israel Association for Advancement of the Society
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Allocation concealment?	Unclear risk	No description of randomisation process.

Golan 2006

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Yes **Length of intervention and follow up:** 6 months, follow-up 18 months. **Unit of allocation:** Child. When 2 siblings from 1 family participated, they were both assigned to the same group. **Unit of analysis:** Child. When 2 siblings from 1 family participated, they were both assigned to the same group. **Protection against contamination:** Not clear **Drop outs:** end of intervention 16% [5/32], follow up at 6 months: 16% [5/32]
Participants	**n=** 32 **randomised**, 27 **completed** **Age range (mean):** 6 to 11 years (8.8 in intervention group, 8.7 in control group) **% Male:** Not clear **Weight entry criteria:** >20% overweight (BMI for age and sex over 85^{th} centile) **Weight on entry (mean):** Parent-only group: 47.1 (12.4); Parent-and-child group: 45.5 (15.9) **Setting:** Unclear but assume in a hospital outpatient setting **Geographic Region:** Israel
Interventions	**Intervention:** A family-based, health-centred orientation targeted at parents only vs targeted at parents and children **Intervention:** behavioural program targeted at parents only **Target of intervention:** Parent only **Behavioural or psychological component:** Parents in both groups were trained in coping techniques in order to encourage and foster an authoritative feeding style. Parents were also encouraged to de-emphasise thinness and focus on addressing their and the child's internal needs by expressing feelings and nurturing the child emotionally. **Physical activity/ Nutritional advice:** The programme emphasised healthy eating patterns (decrease exposure to obesogenic foods, establish designated times for family meals, set at least one family meal per day, allocate individual portions, etc), encouraged an increase in daily physical activity (a goal of 4 h/week), and a decrease in sedentary behaviours (3 h/d). **Other:** No **Usual care/ alternative intervention:** behavioural program targeted at parents and children **Target of intervention:** Parent and child **Behavioural or psychological component:** Both programmes were similar in content; however, the programme for the parents and children group was adapted to fit the children included (the same issues were discussed in a different manner). **Physical activity/ Nutritional advice:** As above. **Other:** No

Golan 2006 (*Continued*)

Outcomes	Height, weight, mean BMI, BMI z-score, %overweight (SDs), mean change BMI z score and % overweight (SDs), behaviour changes
Results	At the end of intervention the treatment effect was statistically significant with regard to the parents-only group. Overweight change was -9.5% (0.4 BMI Z score; P=0.003) in the parents-only group vs -2.4% (0.1 BMI Z score) in the parents-children group. The difference between the groups was statistically significant for both changes in percentage overweight and BMI Z score (F(1,28) =11.3, P<0=02; F(1,28) = 5.7, P=0.024, respectively). At the 1-year follow-up (18 months) meeting, an average reduction of 12 in percentage overweight and 0·5 BMI Z score was observed in the parents-only group (P=0·045; P=0·025, respectively) v. a 0·4 increase in the average percentage overweight status and 0·1 BMI Z score among children from the parents-children group (NS). The repeated-measurement analysis which assessed the change over time (0, 6, 18 months) indicated significant difference in children's percentage overweight and BMI Z scores between the groups (F(2,56) = 10·7, P,0·01; F(2,56)= 5·9, P=0·005, respectively) with significant group by time interaction on both percentage overweight and BMI Z scores (F(2,56) =7·5, P=0·001; F(2,56)=3·9, P=0·02, respectively)
Funding and financial disclosure	**Funding/Support**: not reported.
Notes	The authors state that parents only-group is the experimental group. However, for comparison in meta-analysis, we included the parents & children-group as experimental group tfor similar comparison to other studies that were pooled in meta-analysis

Goldfield 2001

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 20 weeks, follow up 6 and 12 months after treatment began **Unit of allocation:** Families **Unit of analysis:** Families **Protection against contamination:** Not clear **Drop outs:** end of intervention 23% [7/31], follow up at 6 months: 23% [7/31]
Participants	**n=** 31 **randomised**, 24 **completed** **Age range (mean):** 8 to 12 years (intervention group 9.8 ± 1.3, control group 10.3 ± 1.3) **% Male:** 29.2% **Weight entry criteria:** >20% over ideal weight for height and age **Weight on entry (mean):** intervention group 56.5 ± 15.1, control group 57.8 ± 9.7 **Setting:** Not stated **Geographic Region:** Not stated
Interventions	**Intervention:** Mixed (group and individual treatment) **Target of intervention:** Family **- Behavioural or psychological component:** Several types of reinforcement were used. Parents

and children were instructed to meet nightly to review the habit book and were trained to use praise to increase desired behaviours. A point system was used to help meet behavior goals. Each child and parent received points every time they lost weight and met a behavioral goal, and points were exchanged for reinforcers, which both children and parents had mutually agreed upon at the beginning of the program. Children and parents could earn two points (small reinforcer) by losing a half-pound of weight plus meeting both behavioral goals (e.g. red food goal and physical activity goal). Four points (medium reinforcers) were earned when participants lost one pound of weight and met behavioral goals, and six points (large reinforcers) were earned for a two pound loss combined with meeting behavioural goals. Participants who met weight loss goals but only met one behavior goal were given one, two, or three points depending on the degree of weight loss. No points were earned if the behavioral goals were achieved without a weight loss, so objective weight change was needed to corroborate changes in self-reported behaviours. Including weight loss as a criterion of reinforcement was based on the rationale that weight loss often occurs as a result of behavior change, but since change in behavior were measured by self-report and may be inaccurate, we did not want to provide reinforcement for changes that were not achieved. The sessions for participants in the mixed treatment consisted of 15 - 20 min individual sessions with a therapist and 40 min of group therapy.

- Physical activity: Participants in both groups received similar information through written manuals on the positive effects of increased physical activity and the negative effects of sedentary behaviours. All participants were reinforced for increasing physical activity; either programmed activity or lifestyle activity, done at moderate intensity or higher. Physical activities done as a required part of the work or school day were not included. Physical activity goals began at 30 min per week and increased by 30 min increments each time the goals were met, with 180 min per week preformed at moderate intensity or higher representing the highest activity goal.

- Nutritional advice: The Traffic Light Diet was used to decrease energy intake and promote a balanced diet. Foods are categorized as red, yellow or green on the basis of their calorie and nutrient content. Green foods (e.g. fruit and vegetables) are very low in calories. Yellow foods (e.g. yogurt, 2% milk) are higher in calories and include the dietary staples needed for a balanced diet. Red foods (e.g. potato chips, candy) are foods higher in calories with low nutrient density. Participants were instructed to consume between 1000 and 1200 calories per day, shaping a reduction in red foods to no more than 15 per week, and to maintain nutrient balance by eating the recommended servings based on the food pyramid. When participants, weight decreased to the non-obese range, they were instructed to eat additional 100 calories per day for a week until weight gain occurred, and they should attempt to maintain the caloric values associated with weight maintenance. Non-overweight parents had no caloric restriction, but were asked to limit red foods. Families were provided with additional nutritional information, including reading food labels and shopping.

- Other: Participants were instructed to weigh themselves daily at home and graph their weight. They were also taught to keep a habit book in which they recorded food and caloric intake, number of red foods and time spent on physical activity. Parents and children were instructed to model appropriate eating and activity behaviours. Families were encouraged to rearrange their environment e.g. encouraged to keep red foods out of the house in order to decrease consumption of these foods. Similarly, families were also instructed to keep exercise and athletic equipment easily accessible to serve as cues to increase physical activity. Suggestions, such as putting the television in a room with uncomfortable chairs. Individual therapy was designed to identify the behaviours that influenced their weight changes, to determine the accuracy of habit book recording, to evaluate whether program goals were met and reinforcers earned were delivered, to provide performance feedback, and to problem solve situations that hinder behavior change. Children were brought to the parent group for 15 - 20 min at the beginning of each group sessions so that parents and

Goldfield 2001 (*Continued*)

	children could collaboratively determine the number of points earned for weight loss and behavior change **Usual care/ alternative intervention:** Group treatment only **- Target of intervention:** Family **- Behavioural or psychological component:** As above, but participants did not receive individual attention. An additional 20 min of group treatment in order to equate time in treatment across groups. **- Physical activity:** As above **- Nutritional advice:** As above **- Other:** As above
Outcomes	Height (cm), weight (kg), estimates of % fat content i.e. BMI, Z-BMI and percentage overweight, cost effectiveness
Results	Analyses of variance showed a highly significant change in percent overweight (F(2,88)=18.01, P<0.001) and Z-BMI (F(2,88)=19.16, P<0.001) over time. There were no main effects or interactions due to group or generation. Overall change in percentage overweight mean (sd) and Z-BMI for children was -9.97 (8.74) and -0.59 (0.49) resp. at 6 months and -8.04 (10.27) and -0.64 (0.63) resp. at 12 months follow up. (completers only)
Funding and financial disclosure	**Funding/Support**: Preparation of the manuscript was funded in part by grant DK 53849 awarded to Dr Epstein by the National Institutes of Diabetes and Digestive Diseases, National Institute of Health
Notes	

Golley 2007

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Yes **Length of intervention and follow up:** Intervention 6 months, follow-up from commencement of intervention 12 months **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention 19% [22/115], follow up at 24 months: 21% [24/115]
Participants	**n=** 115 **randomised**, 91 **completed** **Age range (mean)** 6-9 years (8.2 ± 1.1) **% Male:** 37% **Weight entry criteria:** overweight according to IOTF criteria **Weight on entry (mean):** Parenting-skills training + life-style education group: mean (SD) BMI z-score 2.74 (0.58). Parenting-skills training alone group: mean (SD) BMI z-score 2.76 (0.58). Wait-list control group: mean (SD) BMI z-score 2.75 (0.39) **Setting:** Outpatient clinic **Geographic Region:** Adelaide, Australia

Interventions	**Intervention:** Parenting-skills training with intensive life-style education **- Target of intervention:** family **- Behavioural or psychological component:** Parenting-skills training was used to facilitate and support parents to undertake family lifestyle changes. Parents participated in the Positive, Parenting Program, a standardized and evaluated general parenting program. Triple P is based on child development theory and social learning principles and aims to promote parental competence to manage their child's behavior. The program consisted of 4 weekly 2-hour group sessions followed by 4 weekly, then 3 monthly 15- to 20-minut individual telephone sessions. Standard Triple P resource materials were used with program examples adapted to reflect dietary and activity behaviors. Application of Triple P to eating and activity behaviors was supported by provision of a general healthy lifestyle pamphlet **- Physical activity:** While parents attended the lifestyle sessions, children in the P+DA group attended structured, supervised activity sessions developed by physical activity experts. The sessions consisted of fun, non-competitive games designed around aerobic activity and development of fundamental motor skills. Sessions were designed as play rather than exercise and were diversional rather than interventional. The activities required minimal equipment and were deliverable by nonexpert staff and easily replicated at home **- Nutrional advice:** Parents in the P + DA group participated in an additional 7 intensive llifestyle support group sessions. These sessions commenced after completion of the 4 weekly parenting sessions, every 2 weeks at first, then monthly. These sessions focused on lifestyle knowledge and skills including the following: family-focused healthy eating with specific core food serve recommendations, monitoring, label reading, snacks, modifying recipes, being active in a variety of ways, roles and responsibilities around eating, managing appetite, self-esteem and teasing **- Other:** No **Usual care/ alternative intervention:** Parenting-skills training alone **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** No **- Nutrional advice:** No **- Other:** No **Usual care/ alternative intervention:** Wait-list control group **- Target of intervention:** family **- Behavioural or psychological component:** No. The WLC group received the same general healthy lifestyle pamphlet as het parenting (P) alone group. During the 12-month wait-listed period, the WLC group was contact by telephone 3 to 4 times for 5 minutes as a retention strategy **- Physical activity:** No **- Nutrional advice:** No **- Other:** No
Outcomes	Height, weight, BMI, BMI z-score, waist, waist z-score, total cholesterol, LDL, HDL triacylglycerol, SBP, DBP, glucose and insulin
Results	Over 12 months, the primary study outcome, BMI z score, reduced by 9% (range: 85% to 18%) in the PDA group, 6% (range: 48% to 49%) in the P group, and 5% (range: 78% to 16%) in the WLC group (linear mixed model, group by time, P=.76; Table 2). Forty-five percent of children in the WLC group increased their BMI z score over 12 months, compared with 19% and 24% in the PDA and P groups, respectively (P .03)

Funding and financial disclosure	**Funding/Support**: This research was funded by the Australian Health Management Group Assistance to Health and Medical Research Fund. Dr Golley was supported by Australian National Health and Medical Research Council Postgraduate Research Scholarship 229978
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	Telephone numbered, opaque sealed envelopes

Graf 2005a

Methods	**Random allocation:** cluster randomisation (7 schools out of about 150 out of the region of Cologne) further randomised by lot by lot - three intervention and four control schools. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Entire academic year Sep-July, follow up at 10 months from commencement of intervention **Unit of allocation:** School **Unit of analysis:** child **Protection against contamination:** Not clear **Drop outs:** 11% [21/195] at the end of intervention (=9 months follow up; 11/40 in intervention group, 10/155 in control group)
Participants	**n=** 195 **randomised**, 174 **completed** **Age range (mean):** 6 to 11 years (mean in intervention group 8.70, mean in control group 8.47) **% Male:** Not clear **Weight entry criteria:** Overweight was defined as BMI > 90^{th} centile, but less than 97^{th} centile. Obesity > 97^{th} centile (based on German centile charts). **Weight on entry (mean):** mean (sd) BMI-SDS intervention group: 1.99 (0.52), control group: 1.87 (0.41) **Setting:** School **Geographic Region:** Cologne, Germany
Interventions	**Interventions:** School and family based behavioural program vs regular school program. **Intervention:** School and family based behavioural program **- Target of intervention:** Child & family **- Behavioural or psychological component:** Step one consists of health education and physical activity taught by regular teachers during the normal school day.The so-called StEP TWO programme is the intervention designed for overweight and obese children. The educational contents included information about selecting healthy foods, and the importance of getting regular physical exercise. Parents were involved in events relating to overweight and obesity in childhood, for 1 evening, the importance of physical activity for 1 evening, healthy nutrition for 2 evenings, and psychosocial

	aspects of a healthy lifestyle, also for 2 evenings **- Physical activity:** After the meal (twice a week), the children undertook a programme of physical activity lasting for between 60 and 90 minutes. Examples for the activity used are aerobic dance, endless relay, and games like soccer, and so on. Two family events were organised where they learned and practised inline skating together **- Nutritional advice:** The specialists cooked and ate with the children twice a week, using a diet based on the OPTIMIX pyramidal programme for nutrition for children. Examples for lunch are raw fruits, vegetables, wholemeal products, and vegetarian food like the vegetarian hamburger and so on. **- Other:** No **Usual care/ alternative intervention:** Control group **- Target of intervention:** Child **- Behavioural or psychological component:** No **- Physical activity:** No **- Nutritional advice:** No **- Other:** just regular school program
Outcomes	Height, mean BMI and BMI z score (SDs), mean waist circum (SDs), change BMI and BMI z score (SDs), change waist circum (SDs), bioelectrical impedance, BP, waist, waist to hip, body weight
Results	Before the intervention, all the children were of comparable age, weight, and height and had comparable BMI-sd-scores. BMI was higher for those chosen for intervention (p 0.042). After the intervention, there were no differences in any of these parameters between the two groups. The increase in body mass index tended to be lower in those undergoing intervention (p 0.069), and the decrease in the standard deviation score was three times higher. BMI-SDS change - mean (sd) in the intervention group -0.15 (0.026) vs -0.05 (0.027) in the control group (p=0.028). BMI-SDS change for the 'non-participants' was -0.09 (0.31), this was not significantly different from the intervention group. (completers only)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	Proportion of those invited to take part in the intervention was very low, unlike the control group Study design should have included similar sessions and effort for the control group, but unrelated to body weight

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	High risk	cluster randomisation (7 schools out of about 150 out of the region of Cologne) further randomised by lot by lot - three intervention and four control schools

Graves 1988

Methods	**Random allocation:** Children were ranked according to % overweight for age sex and height and then assigned randomly from stratified blocks to treatment groups **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 8 weeks intervention and 6 months follow up **Unit of allocation:** Children **Unit of analysis:** Children **Protection against contamination:** Unclear **Drop outs:** end of intervention 3% [1/40], follow up at 6 months: 23% [9/40]
Participants	**n=** 40 children **randomised**, 39 (97.5%) completed treatment and 31 (77.5%) took part in the follow up **Age range (mean):** 6 to 12 years (9.3 years) **% Male:** No details given **Weight entry criteria:** At least 20% overweight for age, sex and height **Weight on entry (mean):** 124.5 (lb), 53.7% overweight for age, sex and height **Setting:** University **Geographic Region:** USA
Interventions	**Interventions:** Parents targeted for 1. problem solving (I) vs 2. Behavioural (I2) vs 3. Instruction only group (C) **Intervention:** Problem-solving group **- Target of intervention:** child and parent **- Behavioural or psychological component:** Means-end problem-solving: at sessions 1, 8 and 3 and 6-month follow ups, parents scored on ability to solve 5 weight loss problems (Shure and Spivack, 1972). Treatment 60 min sessions: 40 mins same as behavioural group (control - see below) 20 mins devoted to problem solving exercises directed at child weight control. Parents and children asked to identify problems related to session, list possible alternatives and develop plans. Parents instructed to choose measure of effectiveness and restructure plans each week if necessary **- Physical activity:** Record of activity using colour coded charts during 1st and 8th week of treatment. Point score derived from record **- Nutrional advice:** Record of dietary intake with parents help using colour coded charts (based on Traffic Light Diet) during 1st and 8th week of treatment. Point score derived from record **- Other:** Financial incentive $35 deposited. Amount returned at last follow-up was dependent on no. of sessions attended **Usual care/ alternative intervention:** Behavioral group **- Target of intervention:** child and parent **- Behavioural or psychological component:** Used puppets, stories and games etc. to present weight reduction methods such as self-monitoring, diet information, exercise information, stimulus control strategies, family support, cognitive restructuring, peer relations and maintenance strategies. 60 min sessions: 10 mins on reviewing previous week's diet and activity sheets, 20 mins of behavioural weight related methods, 10 mins children weighed, 20 mins parents swapped strategies **- Physical activity:** Record of activity using colour coded charts during 1st and 8th week of treatment. Point score derived from record **- Nutrional advice:** Record of dietary intake with parents help using colour coded charts (based

	on Traffic Light Diet) during 1st and 8th week of treatment. Point score derived from record **- Other:** Financial incentive $35 deposited. Amount returned at last follow-up was dependent on no. of sessions attended **Usual care/ alternative intervention:** Instruction only group **- Target of intervention:** child and parent **- Behavioural or psychological component:** Participants were presented with the same diet and exercise information as the problem-solving and behavior groups. Parents exchanged recipe and exercise ideas during the closing 20 min of each session **- Physical activity:** Subjects self-monitored exercise during the 1 st and 8th treatment weeks; however, this was not introduced as a behavior-change strategy. Exercise for 15 mins at the beginning of each session **- Nutrional advice:** Subjects self-monitored food consumption the 1 st and 8th treatment weeks; however, this was not introduced as a behavior-change strategy **- Other:** Financial incentive $35 deposited. Amount returned at last follow-up was dependent on no. of sessions attended
Outcomes	Assume baseline and outcome weight data presented for 31/40 (Table 1.) % overweight calculated as % above average weight for age, sex and height Others: BMI, diet charts, physical activity charts, parental problem-solving ability
Results	There was a significant Sessions X Group interaction on body weight, percentage overweight, and body-mass index, F(18, 232) = 2.07, p <0.05. Children in the problem-solving and behavioral groups decreased their body weights, percentages overweight, and bodymass indices significantly from pre- to posttreatment, whereas instruction-only children did not. Decreases in all three weight measures were significantly greater for children in the problemsolving group than for children in the behavioral and instruction-only groups. These significant body weight, percentage overweight, and body-mass differences between the groups were maintained for the pretreatment to 3-month and the pretreatment to 6-month follow-up sessions. (completers only)
Funding and financial disclosure	**Funding/Support**: This study was supported by the Memphis State University Center for Applied Psychological Research
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	B - Unclear

Grey 2004

Methods	**Random allocation:** A coin toss randomized schools to the experimental or control condition **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Partly. Trained research assistants, blinded to the study group, collected psychosocial data. Nurse practitioners in the school-based clinic, not blinded to the study group, collected BMI and central adiposity measurements **Length of intervention and follow up:** Intervention: 16 weeks. Follow-up from commencement of intervention: 12 months **Unit of allocation:** School **Unit of analysis:** Child and parent **Protection against contamination:** Unclear **Drop outs:** end of intervention 0% [0/41], follow up at 6 months: 0% [0/41], follow up at 12 months 22% [9/41]
Participants	**n=** 41 **randomised**, 41 **completed** the intervention, but 9 failed to attend follow up session **Age range (mean)** 10-14 years **% Male:** 37% **Weight entry criteria:** BMI > 95^{th} percentile **Weight on entry (mean):** Coping skills training group: mean (SD) BMI 35.8 (5.8). Control group: mean (SD) BMI 37.0 (7.1) **Setting:** School **Geographic Region:** New Haven/US
Interventions	**Intervention:** Experimental group: CST (Coping Skills Training) **- Target of intervention: child and parent** **- Behavioural or psychological component:** CST was taught in nutrition classes by a registered dietitian who was trained in CST techniques. Training included culturally sensitive weight management materials. Within each session participants were allowed ample time to "try out" new skills and set goals for applying these skills to their nutrition and exercise goals the coming week **- Physical activity:** The after school physical activity program was scheduled two days a week for 45 minutes over the 16 week period with a licensed personal trainer and research assistant. Adolescents were encouraged to partner with their parent an additional three days per week at home to increase their physical activity, and decrease sedentary behaviours. Coping skills training (CST) was reinforced by the personal trainer and research assistant opportunistically in the experimental group **- Nutrional advice:** A family-centred culturally sensitive interactive nutrition curriculum designed to slow weight gain and improve glucose metabolism was provided for 45 minutes weekly. A brief nutrition assessment was completed with each student and evaluated by the registered dietitian to elicit information regarding previous diets, food consumption habits, dining styles, and daily activities. A non-diet approach taught participants to incorporate a pattern of regular meals with a dietary goal of nutritious and satisfying meals that decreased portion size. Creation of weekly goals with assistance from the registered dietitian supported participants in taking small steps toward success. Particpants *and their parents* were encouraged to attend the weekly classes which used culturally appropriate materials for Hispanic and African American families **- Other:** During the summer, an advance practice nurse and registered dietitian telephoned participants in the experimental group once each week. Phone calls reinforced weekly nutrition and exercise goals and CST **Usual care/ alternative intervention:** Control group

	- Target of intervention: child and parent **- Behavioural or psychological component:** No **- Physical activity:** The after-school physical activity program was scheduled two days a week for 45 minutes over the 16 week period with a licensed personal trainer and research assistant. Adolescents were encouraged to partner with their parent an additional three days per week at home to increase their physical activity, and decrease sedentary behaviours. Coping skills training (CST) was reinforced by the personal trainer and research assistant opportunistically in the experimental group **- Nutrional advice:** A family-centred culturally sensitive interactive nutrition curriculum designed to slow weight gain and improve glucose metabolism was provided for 45 minutes weekly. A brief nutrition assessment was completed with each student and evaluated by the registered dietitian to elicit information regarding previous diets, food consumption habits, dining styles, and daily activities. A non-diet approach taught participants to incorporate a pattern of regular meals with a dietary goal of nutritious and satisfying meals that decreased portion size. Creation of weekly goals with assistance from the registered dietitian supported participants in taking small steps toward success. Particpants *and their parents* were encouraged to attend the weekly classes which used culturally appropriate materials for Hispanic and African American families **- Other:** During the summer, an advance practice nurse and registered dietitian telephoned participants in the control group once each month. Phone calls assessed nutrition and exercise goals
Outcomes	Glucose (120 min.; baseline three-hour oral glucose tolerance test), Insulin (120 min.; baseline three-hour oral glucose tolerance test), HOMA, HbA1c, total cholesterol, HDL, LDL, triglycerides, BMI, waist circumference, Revised Godin-Shepard Activity Survey, Dietary intake, Health promoting lifestyle profile, Health Behavior Questionnaire, Children's Depression Inventory (CDI)
Results	Weight and BMI increased in both groups but at a lower rate in the experimental group (p=0.4). (completers only; 9 participants did not complete metabolic data)
Funding and financial disclosure	**Funding/Support**: supported by grants R21DK59248 and M01-RR06022.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	High risk	A coin toss randomised schools to the experimental or control condition

Gutin 2002

Methods	**Random allocation:** Method not described **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** Intervention: 8 months. Follow-up from commencement of intervention: 8 months **Unit of allocation:** Individual adolescent **Unit of analysis:** Individual adolescent **Protection against contamination:** Done: Subjects from the 2 physical training groups were combined and the subjects in the LSE alone group were seen in separate sessions in alternating weeks to minimize contamination across the physical training and no physical training groups **Drop outs:** end of intervention 29% [21/80], follow up at 8 months: 29% [21/80]. assumptions made from results table (n=59)
Participants	**n=** 80 **randomised**, 59 **completed** **Age range (mean)** 13-16 years **% Male:** 31% **Weight entry criteria:** triceps skinfold greater than the 85^{th} percentile for sex, ethnicity and age **Weight on entry (mean):** Only given stratified by ethnicity and sex. White boys: mean (SD) weight (kg) 95.2 (8.7). White girls: mean (SD) weight (kg) 88.5 (4.6). Black boys: mean (SD) weight (kg) 100.2 (4.4). Black girls: mean (SD) weight (kg) 94.8 (2.9) **Setting:** Not clear, probably outpatient clinic **Geographic Region:** Not clear
Interventions	**Intervention:** LSE (Life-Style Education) + high-intensity physical training) **- Target of intervention:** child **- Behavioural or psychological component:** The 1 hour Life-Style Education-sessions were offered once every 2 weeks for the 8 months intervention; youths were paid $5 for each LSE class attended. The LSE included principles of learning and behavior modification, information about nutrition and physical activity, discussions of various aspects of the food consumption process, psychosocial factors related to obesity and problem solving and coping skills. The LSE sessions were taught by a licensed clinical psychologist who specializes in the treatment of eating disorders and obesity and has experience in providing LSE to children, adolescents, and adults **- Physical activity:** The physical training was offered 5 d/week, except during the weeks when the group was scheduled for LSE on 1d. The estimated EE was held constant at 1045 kJ (250kcal) per session, regardless of physical training group assignment. An exercise prescription was then developed for each subject on the basis of the data collected from the baseline treadmill test. First, the peak VO2 achieved by each youth on the treadmill test was identified, and the EE associated with 55-60% of peak VO2 *(moderate-intensity)* physical training or 75-80% *(high-intensity)* physical training was determined. Because the high-intensity physical activity group used more energy per minute, they were scheduled to exercise for fewer minutes per session than the moderate-intensity group. Each exercise session provided some flexibility for the youths to select activities of their preference. Activities included exercise on machines, aerobics, basketball, badminton, kickball and aerobic slide. The instructors helped the youths to modify the intensities to stay within their prescribed target heart zones. As an incentive ,each youth was awarded points for maintenance of target heart rates that were redeemed for prizes. To encourage attendance, each subject was paid $1 for each physical activity training class attended **- Nutrional advice:** No

	- Other: No **Usual care/ alternative intervention:** LSE + moderate-intensity physical training **- Target of intervention:** child **- Behavioural or psychological component:** As above. **- Physical activity:** As above, but moderate-intensity physical activity. **- Nutrional advice:** No **- Other:** No **Usual care/ alternative intervention:** Life-style education (LSE) only **- Target of intervention:** child **- Behavioural or psychological component:** As above. **- Physical activity:** No **- Nutrional advice:** No **- Other:** No
Outcomes	Height, weight, %fat mass, %bone mineral content, %fat-free soft tissue, %fat-free mass, VAT (visceral adipose tissue), SAAT(subcutaneous abdominal adipose tissue), cardiovascular fitness, free-living physical activity, dietary data (total energy, fat, carbohydrate, protein), plasma triacylglycerol, total cholesterol, VLDLC, HDLC, TC/HDLC, LDLC, ApoA1, ApoB, Lp(a), fasting insulin, glucose, LDL particle size, SBP, DBP, leptin
Results	The group difference in fat mass (kg) was nearly significant (P = 0.072); the changes in fat-free soft tissue were not significantly different between groups. Body fat percentage change in lifestyle education plus physical activity group mean (sd): -3.57 (0.80) and 0.19 (0.62) in the lifestyle education only group at 8 months after commencement of intervention (p<0.001). (completers only)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	Dropouts were excluded from analysis and only participants who attended at least 40% of lifestyle education and physical activity sessions, were analysed (N=37-41)

Hughes 2008

Methods	**Random allocation:** Yes, computer-generated randomization list **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Yes **Length of intervention and follow up:** 8 appointments (7 at outpatient clinic, 1 at home) over 26 weeks. Total patients contact time approx 5 hours, follow up 12 months from commencement of intervention. **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Not clear **Drop outs:** end of intervention 28% [37/134], follow up at 12 months: 36% [48/134] (intervention group 24, control group 24)

Participants	**n=** 134 **randomised**, 86 **completed** **Age range (mean):** 5 to 11 years (intervention group 9.1± 1.7, control group 8.5± 1.9) **% Male:** 44% **Weight entry criteria:** BMI $\geqq 98^{th}$ centile relative to UK 1990 reference data **Weight on entry (mean):** BMI-z-score (median plus range) intervention 3.2 (2.7 to 3.6), control group: 3.3 (2.8 to 3.6) **Setting:** Outpatient clinic **Geographic Region:** Edinburgh and Glasgow, United Kingdom
Interventions	**Interventions:** Individualised behavioural intervention vs standard dietetic care **Intervention:** Individualised behavioural intervention **Target of intervention:** Family **Behavioural or psychological component:** Family-centered counselling and behavioural strategies to modify diet, physical activity and sedentary behaviours **Physical activity:** Children were encouraged to increase their physical activity, and restrict their sedentary behavior (television viewing and playing computer/video games) to no more than 2 hours per day or the equivalent of 14 hours per week **Nutritional advice:** Children were encouraged to alter their diet by using a modified traffic-light approach [reduce intake of foods high in fat and sugar (red), increase intake of fruit and vegetables (green). **Other:** No **Usual care/ alternative intervention:** Standard dietetic care **Target of intervention:** Family, but directed toward the parents rather than the child **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** Concentrated on dietary change with minimal focus on physical activity or sedentary behavior, and involved a didactic "medical model" rather than a behavioral, client-centred approach. 3-4 outpatient appointments. Main focus on healthy eating. Total contact time approx. 1.5 hours **Other:** No
Outcomes	Height, weight, median (IQR) BMI z score, median (IQR) weight, change BMI z score (95% CIs), change weight (95% CIs), behaviour changes (total activity + time in sedentary behaviour, light activity and MVPA), measures of self esteem, health status, QOL
Results	There were no significant differences between the intervention and control groups for changes in BMI z score. and weight (kg) from baseline to 6 and 12 months. BMI z score significantly decreased in both groups from baseline to 6 months (intervention: 95% confidence interval [CI]: -0.18 to -0.07; control: 95% CI:-0.16 to -0.03) and baseline to 12 months (intervention: 95% CI: -0.22 to -0.04; control: 95% CI: -0.26 to -0.08)
Funding and financial disclosure	**Funding/Support**: This work was supported by a grant from the Scottish Executive Health Department. The funders had no role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review, or approval of the manuscript. The funder's role was limited to peer review of the original grant application
Notes	BMI-z-score median (se) are presented. Mean values provided by author for meta-analysis

Israel 1985

Methods	**Random allocation:** Randomly assigned to conditions from stratified blocks based on child % overweight and age **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** 9 Week, plus brief problem solving discussions and monthly telephone calls at 1, 2, 4, 6, 9 and 12 months post intervention. So follow up at 3, 4, 6, 8, 11 and 14 months from commencement of intervention. **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Not Clear **Drop outs:** 39% at end of intervention [13/33] children (Attrition rates for children are unclear as 33 children were split between 30 families and drop outs mention families not children)
Participants	**n=** 33 children (30 families = 24/30 were treatment families and 6/30 were initially control, 3/30 dropped out before session 9, another 7/30 (7/27) dropped out during follow up. 20/30 families completed, also equal to 20 children, WRO n= 9, PT n= 11. **Age range (mean):** 8 to 12 years (10.8 in WRO, 10.4 in ST) **% Male:** 30% **Weight entry criteria:** 20% Overweight for height **Weight on entry (mean):** Not stated **Setting:** No details **Geographic Region:** US
Interventions	**Interventions:** 3 cycles: experimental conditions included: behavioural weight reduction only (WRO), behavioural weight reduction plus parent training (PT), and waiting list control. **Intervention:** Behavioural Weight Reduction Only. **- Target of intervention:** child and parent **- Behavioural or psychological component:** Stimulus control cues **- Physical activity:** Exercise **- Nutrional advice:** Calories and nutrition **- Other:** Rewards. **- Overall:** Overall program described as: 9 weekly 90 minute sessions. Separate parent and child groups. A four-prong format (CAIR) was employed using stimulus control cues, activity (exercise) , food intake (calories, nutrition), and rewards were addressed at each session and individualised for each family. Subjects were requested to monitor food and caloric intake, energy expenditure, and adherence to recommended changes in weight-related habits. Depending on ability the responsibility for monitoring was divided between parent and child to encourage active participation while giving parent ultimate responsibility for record keeping. Homework was collected and reviewed at each treatment session. Parent and child's groups were conducted in lecture discussion format to provide individualised programming while facilitating exchange of information and experiences. After 9th weekly session, parents and children came in for weighing and brief problem solving discussions at 1,2,4,6,9 and 12 months. After the 4 month session phone calls were made monthly **Usual care/ alternative intervention:** Behavioural weight reduction plus parent training. **- Target of intervention:** child and parent **- Behavioural or psychological component:** Treatment included above plus parents in the PT

	attended two hour-long sessions in behavioural child management skills. Lectures were based on the presentation: Living with Children (Patterson 1976). Three brief quizzes were administered at the two initial sessions and at the first treatment session. Concepts were systematically referred to during the ensuing treatment program for PT groups only. **- Physical activity:** As above. **- Nutrional advice:** As above. **- Other:** As above. **Usual care/ alternative intervention:** Waiting list control. **- Target of intervention:** child **- Overall:** Waiting list control subjects were seen for measurement purposes at the beginning and end of the weight reduction program. After serving as controls they were offered treatment in the next cycle of the study
Outcomes	Weight status : Weight (kg) and % overweight presented at week 1, 9 and 1 year follow up % overweight based on the assumption that ideal weight was the weight at the same percentile as the child's height. Percentiles based on comparison norms (Hamil et al 1977) for child's sex and age (Foreyt and Goodrick 1981) Others: triceps skinfold (data not presented),parental weight, Eating Habit Checklist (EHC) and Knowledge of Behavioral Principles as Applied to Children Scale(KBPAC)
Results	At week 9, there were significant differences for the weight and percentage overweight measures F (2,29)=14.43, p<0.001 and F(2,29)=,15.15 p<0.001, respectively. Planned comparisons revealed that the weight measure indicated that the combined treatment condition differed significantly from the controls F(1,29)=31.92, p<0.001, but the two treatment groups did not differ from each other. Both treatment conditions gained weight during the one year follow up period F(1,18) =36.53, p<0.001, with no differences in weight gain between groups. However, for percentage overweight there was a significant interaction of treatment condition by time F(1,18)=4.65, p<0. 045. percentage overweight decreased (ns) in the parent training group and increased in the weight reduction only group F (1,18= 32.36, p<0.001). (completers only)
Funding and financial disclosure	**Funding/Support**: this research was supported by Grant number 1 RO1 HD13460 awarded by the National Institute for Child Health and Human Development
Notes	Control subjects only followed up for 9 weeks and then 6 families became treatment families but baseline data includes those families

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Israel 1994

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 26 weeks treatment and 1 and 3 years follow up **Unit of allocation:** Children **Unit of analysis:** Children **Protection against contamination:** Unclear **Drop outs:** 24% [8/34 families] at end of intervention, 41% at 1 & 3 years follow up [14/34 families, 7/18 in ST and 7/16 in ECI]
Participants	**n=** 36 families **randomised**, 34 families took part; 18 in ST and 16 in ECI **Age range (mean):** 8 years 11 months to 13 years 0 months (10 years 11 months) **% Male:** No details given **Weight entry criteria:** > 20% overweight for weight, height and sex **Weight on entry (mean):** 47% overweight for age, height and sex **Setting:** Assume outpatient clinic **Geographic Region:** US
Interventions	**Interventions:** Behavioral oriented treatment program in which parents were given primary responsibility for following program prescriptions (Sandard Treatment) vs enhanced child involvement condition (ECI) **Intervention:** Enhanced child involvement **- Target of intervention:** child and parent **- Behavioural or psychological component:** Parents and children met in separate groups comprising 5 to 7 families for 8 weekly 90-minutes sessions followed by 9 biweekly sessions for a total of 26 weeks of treatment. Treatment for both conditions was based on four-prong approach identified by the acronym CAIR consisting of discussions and homework assignments regarding Cue control, physical Activity, food Intake, and rewards. Families were asked to monitor children's food intake, activity and adherence to cue control rules, and parents were asked to reward appropriate behaviours such as staying under a prescribed calorie limit, and reaching an activity minimum. Parents also received training in general child-management principles (e.g.. identifying problem behaviours, planning a program to change behaviours, and implementing such a program) and were required to read the book Living with children which paralleled the content of parent training. The enhanced child involvement condition placed less emphasis on parental control and focused more attention on the children's management of their own weight loss efforts. Chilren received comprehensive training in self-management skills introduced sequentially throughout treatment with a particular emphasis after week 8 **- Physical activity:** See behavioral component, not further described. **- Nutrional advice:** See behavioral component, not further described. **- Other:** No. **Usual care/ alternative intervention:** Standard treatment **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above, Standard treatment included all the above mentioned components with emphasis on parent-responsibility for the completion of homework assignments and for the motivation of their children to follow program rules or prescriptions **- Physical activity:** See behavioral component, not further described.

Israel 1994 (*Continued*)

	- Nutrional advice: See behavioral component, not further described. **- Other:** No.
Outcomes	Weight status: % overweight (based on weight for age, height and sex) presented at week 1, 26 and year 1 and 3 Others: BMI (not described), triceps skinfold thickness, measures of self-regulation and self-control
Results	Collapsed across conditions the mean loss in % overweight during treatment was -13.08% (end of treatment, app. 6 months). There was a significant effect of time on percentage overweight $F(2,36)=8.52$, $p<0.001$, but no significant effect of condition or of condition by time emerged (completers only)
Funding and financial disclosure	**Funding/Support**: this research was supported in part by National Institute for Child Health and Human Development grant HD13460
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Jelalian 2006

Methods	**Random allocation:** A randomization procedure, with percent overweight and gender as covariates, was used to assign adolescents to treatment condition. Randomization was conducted by the study coordinator **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** Intervention: 16 weeks. Follow-up from commencement of intervention: 10 months **Unit of allocation:** child **Unit of analysis:** child **Protection against contamination:** Unclear **Drop outs:** end of intervention 21% [19/89], follow up at 10 months: 29% [26/89] (one treatment arm (standard care, n = 13) was discontinued due to patient and parents concern with treatment acceptability and associated significant difficulties with retention)
Participants	**n=** 89 **randomised**, 56 **completed** (n=13 discontinued) **Age range (mean)** 13-16 (14.51) years **% Male:** 29% **Weight entry criteria:** Between 20 and 80% overweight **Weight on entry (mean):** mean (SD) 86.41 (12.40) kg, BMI mean (SD) 32.48 (3.07) **Setting:** Outpatient clinic

	Geographic Region: Not clear
Interventions	**Intervention:** CBT (Cognitive Behavior Therapy) + PEAT (Peer-Enhanced Adventure Therapy) **- Target of intervention:** adolescent and parent **- Behavioural or psychological component:** Cognitive-behavioral weight loss intervention was standard across both group conditions and was modeled on child and adult weight control programs. Treatment groups were conducted by doctoral level psychologists with experience in adolescent weight management. Behavioral topics included self-monitoring, motivation for weight loss, goal setting, the importance of physical activity, implementation of stimulus control strategies, use of parent-teen contracts to support nutrition and physical activity goals, social influences on diet and exercise, the relationship between stress and eating, and relapse prevention. Nutrition topics included presentation of the exchange system, portion control, dining out, dietary fat, and healthy snack choices, and were presented by a dietitian. The parent meeting for both treatment conditions included didactic content that paralleled that presented to adolescents. In addition, parents were provided guidance regarding implementing change at a family level and supporting positive eating and physical activity habits in their adolescents. In the CBT+PEAT group, adolescents participated weekly in an additional session of the peer-based intervention, held separately from the above described 60-min. meeting. Peer-enhanced adventure therapy. The peer-based activity session consisted of an initial 'warm-up' activity that included physical activity followed by the primary challenge for the group, processing of the activity, and establishing weekly personal goals. Group activities consisted of both physical and mental challenges that were aimed at development of socials skills, problem solving abilities, and self-confidence. The goal of each activity was to increase individual self-confidence while developing trust among group members. Sessions were structured sequentially to target increasingly challenging activities **- Physical activity:** Participants were asked to gradually increase physical activity to a minimum of 30 min daily for 5 days a week. All adolescents participated in 30 minutes of on-site physical activity supervised by either an exercise physiologist or physical therapist. The goal of the brief exercise session was for adolescents to achieve a target heart rate of 40-60% above resting for a minimum of 20 min. **- Nutrional advice:** Adolescents were prescribed a balanced deficit diet (1400-1600kcal) based on the dietary exchange system **- Other:** No **Usual care/ alternative intervention:** CBT (Cognitive Behavior Therapy) + EXER (Aerobi exercise) **- Target of intervention: Adolescent and parent** **- Behavioural or psychological component:** As above, but not peer-enhanced. **- Physical activity:** In the CBT+EXER group, adolescents participated weekly in an additional session of supervised physical activity, held separately from the above described 60-min. meeting. Activities for the supervised exercise intervention included use of treadmills, stationary bicycles, and brisk walking within the hospital setting. Each session included a 10-min warm-up period, 30 min of physical activity, and a 20min wrap-up period that consisted of 'cool down' and review of weekly physical activity goals **- Nutrional advice:** As above. **- Other:** No
Outcomes	Height, weight, BMI, % overweight, self-concept, self-concept related to physical appearance, social support, peer-rejection

Results	ITT analyses replicated the pattern of findings with regard to absolute weight loss and changes in BMI for completers. Specifically, significant weight loss was observed in both treatment conditions over time, F=33.25, df=2, 72, P<0.01, and the interaction between time and condition was nonsignificant, F=1.81, df=2, 72, P=0.17
Funding and financial disclosure	**Funding/Support**: This research was supported by Grant R01 HL65132 from the National Institutes of Health/National Heart, Lung, and Blood Institute (to EJ)
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	An urn randomization procedure, with percent overweight and gender as covariates, was used to assign adolescents to treatment condition. Randomization was conducted by the study coordinator

Jiang 2005

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified. Height and weight measurements were performed by a trained researcher. **Length of intervention and follow up:** Monthly home visits during 24 months. Length of home visits not reported. Follow up 24 months. **Unit of allocation:** Individual child (+ family) **Unit of analysis:** Individual child (+ family) **Protection against contamination:** Not done; not specified, but very unlikely. **Drop outs:** end of intervention 9% [7/75], follow up at 24 months: 9% [7/75]
Participants	**n=** 75 **randomised**, 68 **completed** **Age range (mean):** 12-14 (intervention group 13.3 ± 0.6, control group 13.2 ± 0.7) **% Male:** 60,29% **Weight entry criteria:** Weight for height >= 120% of the Chinese reference **Weight on entry (mean):** intervention group 70.1 ± 5.7 kg, control group 71.2 ± 6.4 kg **Setting:** Middle school **Geographic Region:** Beijing, China
Interventions	**Interventions:** Family based lifestyle intervention (I) vs controls (C) with no intervention **Intervention:** Family based lifestyle intervention. **Target of intervention:** Child **Behavioural or psychological component:** One or two main behaviours which were related to obesity were chosen for each child based on an assessment of relevant dietary and exercise

	patterns at baseline. Then a new goal behaviour and interval behaviours were defined. Each goal and interval behaviour was discussed with the child and the parents and was agreed to by the child. A diary was kept by the children and their behaviour in order to monitor adherence to the recommended lifestyle changes. The parents monitored the diary and their child's progress in achieving the new behaviour(s). **Physical activity:** The intervention aimed to increase physical activity as well. Exercise for 20-30 minutes per day for four days per week was advised. Physical education teachers monitored intervention children's exercise after class. Children were also urged to decrease sedentary time, for example television viewing. **Nutritional advice:** No. Throughout the study the researchers visited the families once per month. They observed the family environment and looked for where foods were stored, cooking styles and what kinds of foods were used commonly in the family. A 'traffic light' food item list was given to the children to help decrease the energy intake and promote a balanced diet. 'Red light' foods were those high in fat or calories. 'Green light' products were low in fat and calories, 'yellow light' foods were intermediate. Children were urged to eat less 'red light' foods and more 'green light' foods. Parents were encouraged to buy more 'green light' foods and less 'red light' foods. Children and their parents were informed about daily calorie requirements, based on the Chinese recommended daily allowance. Also Chinese food composition tables were given to each family, so they could calculate the calorie intake of their child every day and compare with the calorie requirements. To avoid the feeling of hunger dietary behaviours like eating slowly, having soup, eating 'green light' foods first, were suggested to the families. What the child ate each day was recorded in the diary. The researchers checked the diaries at home visits and evaluated the dietary intake. Dietary suggestions were given after each evaluation. **Other:** No **Usual care/ alternative intervention:** Controls without any intervention **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** No **Other:** Controls without any intervention
Outcomes	Height (mm), weight (kg), estimates of % fat content e.g.. BMI, ponderal index, skin-fold thickness, blood pressure, metabolic health outcomes (total cholesterol, triglycerides, after overnight fast)
Results	There were significant differences in change of BMI-SDs between the two groups by repeated measures ANOVA (F=9.3 for groups, F=103.8 for times, F=50.9 for time and groups, p<0.001) . Compared with the initial value, the average BMI showed a significant reduction only in the treatment group (mean change=2.6, 95% CI 2.06 to 3.18, p<0.001).
Funding and financial disclosure	**Funding/Support**: not reported **Competing interests:** none declared
Notes	Rather big effect size compared to other studies, completers only

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Allocation concealment?	Unclear risk	No description of randomisation process.

Johnston 2007a

Methods	**Random allocation:** No description of randomisation process. An unbalanced randomisation (i. e. a greater number of participants were assigned to the behavioural intervention) was used. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 6 months, follow-up 6 months. **Unit of allocation:** Child. **Unit of analysis:** Child. **Protection against contamination:** interventions were held in separate classrooms (important since all children came from the same school) **Drop outs:** end of intervention 7% [5/71], follow up at 6 months: 7% [5/71]
Participants	**n=** 71 **randomised**, 66 **completed** (I = 44; C = 22) **Age range (mean):** 10 to 14 years (mean not given) **% Male:** Not clear **Weight entry criteria:** > or = to 85^{th} percentile BMI according to CDC guidelines. **Weight on entry (mean):** BMI-SDS: 1.86 (0.48) intervention group, 1.64 (0.44) in control group **Setting:** School **Geographic Region:** Houston, Texas.
Interventions	**Interventions:** Behavioural family treatment vs self help **Intervention:** **Target of intervention:** Family **Behavioural or psychological component:** An instructor/trainer-led intervention for 12 weeks of daily sessions (Monday until Friday) and l2 weeks of bi-weekly sessions. All instructors were trained to use contingency management, reinforcement, and modelling to encourage participant adherence. A graduate level student trained in behavior modification monitored and assisted interventionists on a daily basis, providing feedback to improve their use of these strategies. Parents were invited to attend monthly meetings to facilitate family adoption of healthy habits. For parents who did not attend meetings, information was sent home that was intended to be discussed between the parent and the child. Behavioral strategies were used to encourage adoption of program principles. A token economy system was implemented for reinforcing healthy changes. Participants received points for trying new fruits/vegetables, keeping their bodies moving during physical activity, and for meeting specific program goals. These points were exchanged weekly for prizes. Each point provided was worth approximately one cent with children typically accumulating 150 points on a weekly basis. Participants also learned to self-monitor, set goals, and control environmental stimuli to increase healthy actions. Behavioral techniques were additionally used with parents as they were expected to assist their families to improve health by providing healthier options for eating and activity. They were taught to use stimulus control strategies and how to reward dietary changes that promoted improved health. Behavior theory has been effective in modifying eating, exercise,

	and other factors that contribute to or maintain obesity. **Physical activity:** consisted of four physical activity lessons weekly. Children went outside for physical activity and were instructed by undergraduate students trained in physical activity/ nutrition. During weeks 1-6, the physical activity intervention was administered using a modified circuit training approach to maintain heart rate within a target zone (60-85% of heart rate reserve) and develop a basic level of physical fitness. Participants were at each station for no more than 2 minutes with participants rotating through all stations I to 2 times during the period. Activities included sports and fitness drills for building endurance, strength and flexibility during which time participants monitored heart rates to learn how to regulate intensity. During weeks 7-12, the stations were modified to focus on sport skill development for either school/ community sponsored teams (e.g. dance, soccer, softball) or leisure (e.g. jumping rope, basketball, kickboxing). **Nutritional advice:** consisted of one nutrition lesson and weekly. Nutrition instruction was held indoors and led by a bachelor level instructor trained in nutrition. In addition, children received snack bars for a daily afternoon school snack and a cereal for breakfast. Children and parents were encouraged to provide information regarding the foods they liked, and they were taught methods for modifying and/or substituting them with others available to promote improved health. Traditional Mexican American foods were modified to make them less calorically dense. Nutrition instruction focused on reading food labels, selecting appropriate portion sizes, establishing regular eating times throughout the day, and categorizing foods into groups with varying degrees of health benefit. The food groups were labelled "safety", "caution", and "danger" zone foods with rules for determining how to categorize them. Safety (i.e., foods that are more healthy for overall nutrition and maintaining a healthy weight) consisted of most fruits and non-starchy vegetables. Caution foods (i.e., use caution not to overeat) included low-fat meats, low-fat dairy, and complex carbohydrates. Danger (i.e., foods that were less healthy for overall nutrition and may lead to weight gain if overeaten) consisted of foods with 5 or more grams of fat or 15 or more grams of sugar per serving. **Other:** Biweekly quizzes were given to evaluate acquisition of the material. Children with absences, low quiz grades, and/or continued weight gain for more than 2 weeks received individual education and treatment planning **Usual care/ alternative intervention:** Self help **Target of intervention:** family **Behavioural or psychological component:** Participants in the self-help (SH) condition were given instructions to follow a 12-week parent-guided manual that included instructions for weight loss and maintenance. SH participants and their parents were instructed to use a book, Trim Kids, aimed at improving diet quality and increasing time spent doing physical activity. The program provided 12 weekly sessions followed by maintenance activities. **Physical activity:** No **Nutritional advice:** No **Other:** No
Outcomes	Height, weight, BMI, BMI Z score, change in BMI %ile, body fat % lipids, glucose, insulin, blood pressure
Results	Children in the intervention group significantly reduced their zBMI when compared with children in the self help group (F=6.15, p=0.004) with significant differences in zBMI change at both 3 and 6 months (F :5.74, p =0.019, F:12.61, p=0.001, respectively. Using an ITT model produced similar results for zBMI change (overall: F=6.01, p=0.004, 3-month: F=2.85, non-significant; 6-month: F=11.82, p<0.001) with the exception of 3-month differences, which were no longer statistically significant

Funding and financial disclosure	**Funding/Support**: This study was supported in part by a gift from the Kellogg Company and by a grant from the United States Department of Agriculture (ARS 2533759358).
Notes	

Johnston 2007b

Methods	**Random allocation:** No description of randomisation process. An unbalanced randomization (i.e. a greater number of participants were assigned to the behavioural intervention) was used. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 6 months, with follow up at 3 months and 6 months **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** interventions were held in separate classrooms (important since all children came from the same school) **Drop outs:** end of intervention 5% [3/60], follow up at 6 months: 5% [3/60]
Participants	**n=** 60 **randomised**, 57 **completed** **Age range (mean):** 10 to 14 years (mean not given) **% Male:** Unclear **Weight entry criteria:** > or = to 85^{th} percentile BMI according to CDC guidelines. **Weight on entry (mean):** zBMI (mean [SD]) intervention group: 1.6 (0.6) control group: 1.7 (0.6) **Setting:** School **Geographic Region:** Houston, Texas
Interventions	**Interventions:** Behavioural family treatment vs self help **Intervention:** **Target of intervention:** Family **Behavioural or psychological component:** An instructor/trainer-led intervention for 12 weeks of daily sessions (Monday until Friday) and l2 weeks of bi-weekly sessions. All instructors were trained to use contingency management, reinforcement, and modelling to encourage participant adherence'. A graduate level student trained in behavior modification monitored and assisted interventionists on a daily basis, providing feedback to improve their use of these strategies. Parents were invited to attend monthly meetings to facilitate family adoption of healthy habits. For parents who did not attend meetings, information was sent home that was intended to be discussed between the parent and the child. Behavioral strategies were used to encourage adoption of program principles. A token economy system was implemented for reinforcing healthy changes. Participants received points for trying new fruits/vegetables, keeping their bodies moving during physical activity, and for meeting specific program goals. These points were exchanged weekly for prizes. Each point provided was worth approximately one cent with children typically accumulating 150 points on a weekly basis. Participants also learned to self-monitor, set goals, and

	control environmental stimuli to increase healthy actions. Behavioral techniques were additionally used with parents as they were expected to assist their families to improve health by providing healthier options for eating and activity. They were taught to use stimulus control strategies and how to reward dietary changes that promoted improved health. Behavior theory has been effective in modifying eating, exercise, and other factors that contribute to or maintain obesity. **Physical activity:** consisted of four physical activity lessons weekly. Children went outside for physical activity and were instructed by undergraduate students trained in physical activity/ nutrition. During weeks 1-6, the physical activity intervention was administered using a modified circuit training approach to maintain heart rate within a target zone (60-85% of heart rate reserve) and develop a basic level of physical fitness. Participants were at each station for no more than 2 minutes with participants rotating through all stations I to 2 times during the period. Activities included sports and fitness drills for building endurance, strength and flexibility during which time participants monitored heart rates to learn how to regulate intensity. During weeks 7-12, the stations were modified to focus on sport skill development for either school/ community sponsored teams (e.g. dance, soccer, softball) or leisure (e.g. jumping rope, basketball, kickboxing). **Nutritional advice:** consisted of one nutrition lesson and weekly. Nutrition instruction was held indoors and led by a bachelor level instructor trained in nutrition. In addition, children received peanuts/peanut butter with a fruit or vegetable, to enhance satiety and to provide an opportunity for fruit/vegetable consumption, a daily afternoon school snack. Children and parents were encouraged to provide information regarding the foods they liked, and they were taught methods for modifying and/or substituting them with others available to promote improved health' Traditional Mexican American foods were modified to make them less calorically dense. Nutrition instruction focused on reading food labels, selecting appropriate portion sizes, establishing regular eating times throughout the day, and categorizing foods into groups with varying degrees of health benefit. The food groups were labelled "safety", "caution', and "danger" zone foods with rules for determining how to categorize them. Safety (i.e., foods that are more healthy for overall nutrition and maintaining a healthy weight) consisted of most fruits and non-starchy vegetables. Caution foods (i.e., use caution not to overeat) included low-fat meats, low-fat dairy, and complex carbohydrates. Danger (i.e., foods that were less healthy for overall nutrition and may lead to weight gain if overeaten) consisted of foods with 5 or more grams of fat or 15 or more grams of sugar per serving. **Other:** Biweekly quizzes were given to evaluate acquisition of the material. Children with absences, low quiz grades, and/or continued weight gain for more than 2weeks received individual education and treatment planning **Usual care/ alternative intervention:** Self help **Target of intervention:** family **Behavioural or psychological component:** Participants in the self-help (SH) condition were given instructions to follow a 12-week parent-guided manual that included instructions for weight loss and maintenance. SH participants and their parents were instructed to use a book, Trim Kids, aimed at improving diet quality and increasing time spent doing physical activity. The program provided 12 weekly sessions followed by maintenance activities. **Physical activity:** No **Nutritional advice:** No **Other:** No

Johnston 2007b (*Continued*)

Outcomes	BMI, zBMI, change in BMI %, body fat %, lipids, blood pressure, glucose, insulin
Results	Children in the intervention group significantly reduced their zBMI when compared with children in the self help group with significant differences in zBMI change at both 3 and 6 months. Using an intention-to-treat model produced similar results for zBMI change (overall: F 12.74, P <0. 001; 3-month: F 16.70, P<0.001; 6-month: F 24.18, P <0.001)
Funding and financial disclosure	**Funding/Support**: This work was supported by US Department of Agriculture grant ARS 2533759358. We thank the members of the Peanut Institute for their support of this study
Notes	

Kalavainen 2007

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes. Stratified on basis of weight for height in 4 blocks. Siblings (3 pairs in the study) were randomized together, based on the higher weight for height percentile. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** No. Performed by researcher, who was not blinded for treatment allocation. **Length of intervention and follow up:** The group program consisted of 15 sessions of 90 minutes in duration, held separately for parents and children. The first 10 sessions were held weekly, the next 5 sessions were held every two weeks for three months. In the routine care group two appointments in 6 months were held; at the end of fall and spring terms. Follow up 12 months. **Unit of allocation:** Individual child (+ family) **Unit of analysis:** Individual child (+ family) **Protection against contamination:** Not clear **Drop outs:** end of intervention 3% [1/70], follow up at 6 months: 3% [1/70] (intervention group 1, control group 0)
Participants	**n=** 70 **randomised**, 68 **completed** **Age range** (mean): 7 to 9 years (intervention group 8.1 ± 0.9, control group 8.0 ± 0.8) **% Male:** 40% **Weight entry criteria:** Weight for height 120-200% **Weight on entry (mean):** Intervention group 43.1 ± 8.7 kg, control group 40.4 ± 6.7 kg **Setting:** School **Geographic Region:** Kuopio, Finland
Interventions	**Interventions:** Two weight-management interventions: family based group treatment (FBT) vs routine treatment (C) **Intervention:** family based group treatment (FBT) **Target of intervention:** Parents, but separate program for children **Behavioural or psychological component:** The group program for parents consisted of 15 sessions covering behavioral, dietetic and physical activity topics. Themes included: benefits and sacrifices of weight management., ABC's of behavior modification, parenting skills, dealing with stress, goal-setting, parents as models, problem solving, self-monitoring, how to continue. Dietary topics included: regular meals, physical activities and sleep, healthy breakfast and school

	lunch, label reading, decreasing excessive intake of high-energy food, how to choose fats, increase consumption of fruits and vegetables, acceptance of new foods, portion control and emotional eating, snacks, festive seasons, usage of spices, light cooking. Physcial activity topics covered why, how and when to play and how to reduce sedentary activities. A separate program took place for children with similar topics. **Physical activity:** The children's sessions were adjusted to children's cognitive development and thus consisted of functional activities. Most sessions included non-competitive physical activities aimed to develop children's motor skills and to motivate them to increase recreational physical activity. **Nutritional advice:** No. The recommended meal pattern and quality of the diet were in line with recommendations given for Finnish families. **Other:** Homework was provided to both parents and children to give a chance to practice between sessions. Parents were provided with treatment models and children with workbooks. Material was modified from national 'Magnificent kids' and 'Magnificent Teens' material, from behavioral therapy workbook and self-developed material **Usual care/ alternative intervention:** routine treatment (C) **Target of intervention:** Child, but parents could attend sessions **Behavioural or psychological component:** Two individual appointments for children by school nurses where held at the end of fall and spring terms. The themes were self-knowledge and physical activity. The children fulfilled workbooks partly with the nurses and partly at home with the parents. **Physical activity:** No **Nutritional advice:** No **Other:** The program consisted of booklets for families, based on the national 'Magnificent kids' material and on a cognitive behaviour therapy workbook.. The booklets contained information about weight management, eating habits and physical activities. At the two individual appointments with children the heights and weights were measured
Outcomes	Estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness, height, weight, participants views of the intervention (parents ratings of sessions)
Results	Children attending the group treatment lost more weight than those receiving routine treatment also when assessed by BMI (on average, 0.8 vs 0.0, P=0.003) or BMI-SDS (on average, 0.3 vs 0. 2, P=0.022) as outcome measures. In the analysis of covariance, the difference between the two treatment groups remained significant for both BMI and BMI-SDS
Funding and financial disclosure	**Funding/Support**: This work was supported in part by grants from Kuopio University Hospital, the Scientific Foundation of Finnish Association of Academic Agronomists, Finnish Cultural Foundation of Northern Savo, Juho Vainio Foundation, Ministry of Social Affairs and Health and Social Insurance Institution
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Allocation concealment?	Low risk	Telephone numbered, opaque sealed envelopes. Stratified on basis of weight for height in 4 blocks. Siblings (3 pairs in the study) were randomized together, based on the higher weight for height percentile

McCallum 2007

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes. Randomisation was stratified by GP and overweight versus obese status (classified according to International Obesity Taskforce cut-points). Randomisation was performed by a third-party biostatistician using a pre-generated computerised sequence. Blinding was maintained throughout allocation and data collection. **Blinding:** · **Children:** No. By the nature of the intervention, care-givers and most of the patients were aware that they were either receiving an intervention (GP consultations and counselling) or not being seen by the GP. · **Providers:** No. By the nature of the intervention, care-givers and most of the patients were aware that they were either receiving an intervention (GP consultations and counselling) or not being seen by the GP. · **Outcome assessors:** Yes. Blinding was maintained throughout allocation and data collection. **Length of intervention and follow up:** Four GP consultations over a 12 week period. Follow-up at 9 and 15 months post-randomisation. **Unit of allocation:** Individual child and family **Unit of analysis:** Individual child and family **Protection against contamination:** Not done BUT assessed. General practice record audit to assess the extent of possible contamination (i.e., attendances by the control families for discussion of weight) showed minimal contamination. **Drop outs:** end of intervention 2% [3/163], follow up at 9 months: 6% [10/163] and follow up at 15 months 10% [17/163]
Participants	**n=** 163 **randomised**, 146 **completed** **Age range (mean):** 5.0 to 9.9 years (intervention group 7.5±1.6, control group 7.4±1.6) **% Male:** 48% **Weight entry criteria:** Identified as overweight or mildly obese on the BMI survey (IOTF cut-points). **Weight on entry (mean):** intervention group BMI 20.5±2.2 , control group 20.0±1.8 **Setting:** General practitioner clinics **Geographic Region:** Melbourne, Australia
Interventions	**Intervention:** Behavioral program, delivered by general practitioners **Target of intervention:** Child & family **Behavioural or psychological component:** Parents were asked to attend 4 consultations over a 12 week period. GPs used brief solution-focused counselling to set and record appropriate healthy lifestyle goals with the family, assisted by a personalised 20 page "Family Folder". This included 7 topic sheets, each targeting one area of behavioural change required to reduce overweight, and comprising a brief summary of supporting evidence, modelled solutions to challenges and additional suggestions as to how each goal might be achieved. The 7 topic areas were: Childhood overweight -what are the issues?; Water - the drink for children; Importance of breakfast, regular

	meals and snacks; Choosing the lower fat options; Healthy food for the family: avoiding battles; More Active - It's easy!; Doing Nothing: not a good option. **Physical activity:** The topic areas that GPs and parents could focus upon included two with a specific physical activity or sedentary behaviour focus: More Active ? It's easy!; Doing Nothing: not a good option. **Nutritional advice:** The topic areas that GPs and parents could focus upon included four with a specific nutrition focus: Water ? the drink for children; Importance of breakfast, regular meals and snacks; Choosing the lower fat options; Healthy food for the family: avoiding battles. **Other:** No **Usual care/ alternative intervention:** Standard care. **Target of intervention:** Child & family **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** No **Other:** Control families were notified of their status via letter and were not identified to the GPs at any time. General practice records of children in the control group were subsequently audited to assess the extent of possible contamination (i.e. attendances for discussion of weight)
Outcomes	Height (cm), weight (kg), BMI (kg/m^2), BMI z-score, behaviour changes (% time in moderate to vigorous activity ,daily physical activity, daily nutrition score, measures of self esteem, health status, QOL (PedsQL Parent Proxy, PedsQL Child Self-Report, body satisfaction, physical appearance and global self-worth)
Results	At 9 months, the adjusted BMI of the intervention group was 0.2 kg/m^2 less than that of the control group (95% CI: 0.6, 0.1; P=0.25), and there was a 0.09 BMI z-score relative decrement from baseline (95% CI: 0.20, 0.02; P=0.12). At 15 months, there was no difference in adjusted BMI of the intervention group compared with the control group (95% CI: 0.5, 0.5; P=1.00), and there was a 0.03 BMI z-score relative decrement from baseline (95% CI: -0.17, 0.10; P=0.62)
Funding and financial disclosure	**Funding/Support**: This study was funded by an Australian Health Ministers' Advisory Council Priority Driven Research Project Grant (AHMAC PDR 2001/15). The supporting source had neither involvement in the design and conduct of the study nor control or influence over the writing and submission of this manuscript **Financial disclosure:** There is no conflict of interest. **Sources of support**: Australian Health Ministers' Advisory Council Strategic Research Fund; National Health and Medical Research Council Public Health Postgraduate Scholarship
Notes	The first reported RCT of a GP intervention to treat overweight and mild obesity in pre-pubertal children. The study was carefully performed. The fact that patients were identified as overweight or obese by the study team and NOT by either the GP or the families (i.e. they were not treatment-seeking families) may make the findings more difficult to generalise to usual clinical situations. The "dose" of the intervention was low (4 sessions over 12 weeks) and this may also have contributed to the null findings

Mellin 1987

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** 3 month intervention and 12 follow up **Unit of allocation:** Children **Unit of analysis:** Children **Protection against contamination:** Unclear **Drop outs:** end of intervention 5% [3/66], follow up at 15 months: 16% reported in paper [unclear how this figure was reached, 7/14 sessions were attended by 97% of the subjects. 16% attrition would be 10/11 subjects i.e. 3 or 4/37 in test group so 7 or 8 /29 in control group]
Participants	**n=** 66 **randomised** [37/66 intervention group and 29/66 in control group], 55? **completed** **Age range (mean):** 12 to 18 years (15.6 years) **% Male:** 21% **Weight entry criteria:** No details **Weight on entry (mean):** 78kg and 33% overweight for age, sex and height **Setting:** No details **Geographic Region:** US
Interventions	**Interventions:** Shapedown program: Cognitive, behavioural, and affective and interactional techniques adapted to make successive small modifications in diet, exercise, communication and affect, that are sustainable vs no-treatment control group **Intervention:** Shapedown program **- Target of intervention:** child and parent **- Behavioural or psychological component:** The program employs a variety of cognitive, behavioral, affective, and interactional techniques adapted to the needs of adolescents. Using a self-directed change format, the program encourages adolescents to make successive, sustainable, small modifications in diet, exercise, relationships, lifestyle, communications, and attitudes. Very-low calorie or restrictive diets were avoided in the program. Parents are instructed on strategies for supporting their adolescents weight loss, including altering family dietary and activity patterns and improving parenting and communication skills. Group leaders conducted 14 weekly sessions for the adolescents and 2 parents sessions utilizing the materials (leaders guide, and two workbooks - parents and adolescent version) of the Shapedown program. Each 90-minute sessions included voluntary weigh-in, leader-facilitated group interaction, and an exercise period. **- Physical activity:** See behavioral component, not further described. **- Nutrional advice:** See behavioral component, not further described. **- Other:** Fees for the intervention were consistent with each site's normal charges for such services **Usual care/ alternative intervention:** No-treatment control group **- Target of intervention:** child and parent **- Overall:** Control group subjects received no treatment initially and were charged no fees but were informed they could enrolls in the next program that would commence in 6 months
Outcomes	Weight status: Weight (kg) presented at 3, 6 and 15 months. Others: relative weight (%), weight-related behavior, affect, weight management knowledge

Mellin 1987 (*Continued*)

Results	Relative weight decreased significantly during the 3 month intervention period, whereas relative weight of the control group remained stable. During the following 3 months (summer) both groups decreased their relative weight (no significant differences between groups). At the 15 months follow up mean relative weights of the treatment and control groups had diverged substantially. (Completers only, and only pre- and posttest statistics reported)
Funding and financial disclosure	**Funding/Support**: This work was supported in part by a grant from region IX, U.S. Department of Health and Human Services. Staff support was provided by the Division of Adolescent Medicine, Deparment of Pediatrics, School of Medicine, university of California, San Francisco, which is supported in part by a grant from the Maternal and Child Health Research and Training Branch, Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, U.S. Department of Health and Human Services
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Munsch 2008

Methods	**Random allocation:** Yes. Families were randomly assigned according to a permuted block design to either the mother-child (condition A) or the mother-only (condition B) cognitive behavioural therapy (CBT). **Blinding:** · **Children:** No · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 10 weekly sessions followed by 6 monthly sessions = 8. 5 months **Unit of allocation:** Families (parent-child dyads) **Unit of analysis:** Families (parent-child dyads) **Protection against contamination:** Done. Two independent raters (students of clinical psychology holding a bachelor's degree) separately judged group leaders' adherence to treatment protocol to assess whether the two interventions were different. The results showed that the progressive muscle relaxation training intervention received by children in condition B could be distinguished from the CBT received by children in condition A. **Drop outs:** end of intervention 34% [16/56] (intervention group 6/31, 13/25 control group), follow up at ca. 9 months: 52% [29/56] (intervention group 11/31, control group 18/25)
Participants	**n=** 56 **randomised**, 39 **completed** **Age range (mean):** 8 to 12 years (intervention group: children 10.3 $\pm$ 1.4 (n=28), mothers 40.9 $\pm$ 4.4 (n=29), control group: children 10.6 $\pm$ 1.5 (n=21), mothers 38.8 $\pm$ 6.0 (n=25)) **% Male:** children 39.62% **Weight entry criteria:** Body mass index >85th percentile adjusted for gender and age **Weight on entry (mean):** Only % overweight given: intervention group: children 55.4 $\pm$ 17.9

	(n=28), mothers 29.6 ± 7.5 (n=21), control group: children 62.4 ± 27.2 (n=21), mothers 26.9 ± 3.9 (n=17) **Setting:** Outpatient clinic **Geographic Region:** Basel & Bruderholz, Switzerland
Interventions	**Interventions:** Mother Cognitive Behavioral Therapy versus Mother-Child Cognitive Behavioral Therapy **Intervention:** Condition A: Mother-Child Cognitive Behavioural Therapy (CBT) **Target of intervention:** Mother & child **Behavioural or psychological component:** Mothers and children received CBT. The TAKE Program/Protocol was developed according to the guidelines of Barlow & Dietz (1998) & Summerbell *et al* (Cochrane, 2003). Treatment was tailored to the specific problems in the mother-child dyad according to the individual-treatment-in-group approach (Fiedler, 1996). **Physical activity:** Sessions 4, 5 and 6 were aimed at encouraging mothers to model physical activity in daily family life. **Nutritional advice:** During two sessions, the basic rules of regular and balanced nutrition were introduced using the stoplight diet, which categorises food as low, medium, or high fat and instructs users to eat freely from the low-fat category, cautiously from the middle category, and only rarely from the high-fat foods. To implement a functional feeding style, mothers were encouraged to follow three basic food rules for family meals (1) any food on the table may be eaten by all family members; (2) offer only restricted amounts of high-fat foods; and (3) offer a sufficient amount of low-fat food so that the child can eat until satiated. **Other:** No **Usual care/ alternative intervention:** Condition B (Control): Mother-only Cognitive Behavioural Therapy (CBT) **Target of intervention:** Mother only **Behavioural or psychological component:** Mothers received CBT. Children attended relaxation training (progressive muscle relaxation training, PMR) of equal frequency and duration to the disorder-specific CBT of children in condition A. This condition was chosen because PMR was shown to account for possible nonspecific effects of 'attention' in other studies. PMR for children. Followed Speck's Manual (2005), in which overweight or obesity or the management of these conditions were not targeted. The treatment took place in separate but parallel groups with up to 6 children and 6-12 mothers in each group. The treatment phase consisted of 10 weekly 120 minute sessions and 6 monthly sessions. **Physical activity:** As above. **Nutritional advice:** As above. **Other:** No
Outcomes	Weight, height, estimates of % fat content e.g.. BMI, ponderal index, skin-fold thickness (child: percent overweight, mother: BMI), behaviour changes (children's behavioural problems and competencies), views of the intervention, measures of harm (depression and anxiety ratings)
Results	Children in both treatment modalities reduced their percent overweight between baseline and end of 6 month follow up; app. 8.5 months ($p<0.001$ for linear trend). The temporal courses of the two treatment groups did not differ
Funding and financial disclosure	**Funding/Support**: the trial was funded by the Swiss National Science Foundation (SNF:3251-067078.01). Publication of the results is done independently of the SNF

Notes	Only brief information on the randomisation process is given. The process is of particular interest because there are difference in numbers enrolled in each condition (i.e. 31 vs 25) There was a high drop-out rate, in the mothers only intervention at the 6 month follow up vs mother-child intervention (71% vs 31%) The majority of participants were low/medium SES. It appears that the rate of psychological (mental) disorders in the population is rather high but no comparative data is given on rates in the general population Both interventions resulted in a significant decrease in children's mean % overweight (this measure accounted for age and gender) but there was no difference between groups. The reduction was greatest during the first 10 weeks. Note: absolute height and weight data were not presented

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	Families were randomly assigned according to a permuted block design to either the mother-child (condition A) or the mother-only (condition B) cognitive behavioural therapy (CBT)

Nemet 2005

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes. We allocated intentionally an unequal number of participants to each group, on the basis of our previous experience (with higher dropout in the intervention). Assigned with a computerized random number generator. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Intervention 3 months. Follow up 12 months. **Unit of allocation:** Individual child (+ family) **Unit of analysis:** Individual child (+ family) **Protection against contamination:** Not clear **Drop outs:** end of intervention 15% [8/54], follow up at 12 months: 26% [14/54] (intervention group 10, control group 4)
Participants	**n=** 54 **randomised**, 40 **completed** **Age range (mean):** 6 to 16 years (intervention group 10.9 ± 1.9, control group 11.3 ± 2.8) **% Male:** 56.52% **Weight entry criteria:** Obesity (no organic cause) **Weight on entry (mean):** intervention group 63.8 ± 19.1 kg, control group 63.4 ± 22.8 kg **Setting:** Child health and sports training center, Meir General hospital Tel Aviv **Geographic Region:** Tel Aviv, Israel
Interventions	**Intervention:** Combined dietary-behavioral-physical activity intervention **Target of intervention:** Parent and child **Behavioural or psychological component:** Four evening lectures were held; on childhood obesity, general nutrition, a therapeutic nutritional approach for childhood obesity and exercise and

	childhood obesity. **Physical activity:** All intervention subjects participated in a twice-weekly training program (1 hour per session). The intervention was designed to mimic the type and intensity of exercise that elementary and high school children would perform normally. The physicians who worked in the program participated regularly to encourage the children and provide examples. Participants were instructed to add an extra 30-45 min of walking or other weight-bearing sport activities at least once per week. Throughout the program subjects were encouraged to reduce sedentary behaviours. **Nutritional advice:** The participants met with the dietician 6 times during the 3-month program. The first appointment (45-60min) was dedicated to becoming acquainted. Learning about the reasons for childhood obesity, receiving information on food choices and dietary and cooking habits, understanding the motivation of weight loss and trying to enrol the whole family in the battle against overweight. The subsequent appointments (30-45min) were devoted mainly to nutritional education (food pyramid, food choices, food labels, food preparation and cooking, eating habits, regular meals, and controlling environments that stimulate overeating. The children received dietary information through sheets and flyers on important nutritional issues. The subjects received a balanced hypocaloric diet, with a caloric deficit of 30% less than the reported intake or 15% less than the estimated daily required intake. **Other:** No **Usual care/ alternative intervention:** Routine care **Target of intervention:** Parent and child **Behavioural or psychological component:** No **Physical activity:** Control group participants were instructed to perform physical activity 3 times per week on their own. **Nutritional advice:** Control subjects were referred to an ambulatory nutritional consultation at least once. **Other:** No
Outcomes	Height, weight, estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness, metabolic health outcomes (total cholesterol, HDL, LDL, triglycerides)
Results	After the 3-month intervention, there were significant decreases in body weight (from 63.8 (19.1) kg to 61.0 (18.3) kg), BMI (from 28.5 (4.1) kg/m^2 to 26.8 (3.9) kg/m^2), and body fat percentage (from 40.2 (7.3)% to 36.9 (8.0)%) among the intervention participants. In contrast, there were significant increases in body weight (from 63.4 (22.8) kg to 64.5 (24.1) kg) and body fat percentage (from 40.7 (7.9)% to 42.2 (9.9)%) among the control subjects, whereas BMI was not changed (from 27.8 (5.0) kg/m^2 to 27.6 (5.6) kg/m^2). One year after the combined dietary-behavioral-physical activity intervention, there were significant decreases in BMI and body fat percentage among the intervention participants, compared with increases among the control subjects. Body weight was maintained among the intervention participants, compared with a significant increase among the control subjects ($p<0.05$ for between group differences) (completers only)
Funding and financial disclosure	**Funding/Support**: This work was supported by a grant from the Israeli Heart Fund **Financial disclosure:** No conflict of interest declared.
Notes	
Risk of bias	

Nemet 2005 (*Continued*)

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	Telephone numbered, opaque sealed envelopes. We allocated intentionally an unequal number of participants to each group, on the basis of our previous experience (with higher dropout in the intervention). Assigned with a computerized random number generator

Nova 2001

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** No; Family paediatrician aware of protocol and application to participants. **Length of intervention and follow up:** Final follow-up at 24 months in both groups. Intervention duration not clearly reported. **Unit of allocation:** Individual family paediatricians (and enrolled children under each FP) **Unit of analysis:** Child **Protection against contamination:** Not clear **Drop outs:** end of intervention not reported, follow up at 6 months: 23% [43/186], follow up at 12 months 30% [56/186]
Participants	**n=** 18 family paediatricians **randomised,** enrolling 186 children, 130 **completed** **Age range (mean):** 3 to 12 years (intervention group 8.6 ± 1.9, control group 8.6 ± 2.1) **% Male:** 55.91% (intervention group 52.8% , control group 54.48%) **Weight entry criteria:** ≥20% of ideal body weight **Weight on entry (mean):** mean (SD) BMI intervention group: 23.75 (2.65); mean (SD) BMI control group: 22.37 (1.85). **Setting:** Family paediatricians of certain local health units **Geographic Region:** Lombardy, Northern Italy
Interventions	**Intrventions:** Two different treatment groups: Enhanced Approach (Group B, intervention group) and Routine Approach (Group A, control group) **Intervention:** Enhanced Approach **Target of intervention:** Family **Behavioural or psychological component:** In addition to food diaries, a subjective evaluation regarding the accuracy of filling in the diary was undertaken by the family paediatrician (good/ sufficient/poor), intended to reinforce the family's compliance with the proposed changes in eating behaviour. This was to help judge the degree of parental commitment to the changes, as were interviews with the participating families at the end of the follow-up visits. **Physical activity:** Detailed guidelines regarding physical activity was provided for Group B. **Nutritional advice:** In Group B, a specific diet (only one scheme suitable in composition and caloric input - approximately 1400 calories - for all the enrolled children). An alimentary diary with instructions for use was also given to this group. **Other:** No **Usual care/ alternative intervention:** Routine Approach

	Target of intervention: Family **Behavioural or psychological component:** No **Physical activity:** As part of general information-based leaflets, involving an 'invitation to practice some physical activity'. **Nutritional advice:** General advice on healthy eating as part of information leaflets given to Group A participants. **Other:** No
Outcomes	Height, weight, BMI, , percentage overweight, BMI SD score, behaviour changes (alimentary diaries given to Group B participants)
Results	Change in percentage overweight at six months -8.8 (6.62)% in the enhanced group, -2.95 (8. 47)% in the control group. At 12 months -8.5 (9.72)% in the enhanced and -2.92 (10.8)% in the control group (completers only). It is stated that the difference was maintained when an intention to treat analysis was performed (F=4.80, df=1, p=0.02)
Funding and financial disclosure	**Funding/Support**: not reported. **Financial disclosure:** There is no organization with a direct financial interest in the subject matter discussed in the manuscript
Notes	This trial reports on a 24 month intervention. Data are only presented including 12 month follow up

Rodearmel 2007

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** No **Length of intervention and follow up:** 6 months, families in both groups met with study staff 6 times during the intervention period, follow-up 6 months. **Unit of allocation:** Family **Unit of analysis:** Family **Protection against contamination:** Not clear **Drop outs:** end of intervention 16% [34/218], follow up at 6 months: 16% [34/218]
Participants	**n=** 218 **randomised**, 184 **completed** **Age range (mean):** 7 to 14 years (mean age 11.11 in intervention group and 11.28 in control group) **% Male:** Not clear **Weight entry criteria:** Families with at least 1 child ho was overweight or at risk fro overweight = BMI > or equal to 85^{th} centile **Weight on entry (mean):** zBMI: intervention group: 1.76 (0.45), control group: 1.68 (0.42) **Setting:** Not clear **Geographic Region:** Denver, Colorado, USA

Interventions	**Intervention:** 2 small behaviour changes. 1. increase steps/day by 2000. 2. replace sugar with sweeteners **Target of intervention:** Family **Behavioural or psychological component/physical activity/nutritional advice:** Families in both groups met staff on 6 occasions over the 6 month interventions (after a 2 week baseline period) . AOM families got pedometers to wear, and a lot of support and education around replacement of dietary sugars alone or in food with Splenda replacement products (study was funded in part by the company who makes these products - McNeil Nutritionals) **Other:** No **Usual care/ alternative intervention:** Control group **Target of intervention:** Family **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** No **Other:** a self monitoring group. This group were asked to use pedometers and record their pa, but they were not asked to change their pa levels or dietary habits
Outcomes	Height, mean BMI z score (95% CIs), mean %body fat and waist circum(95% CIs), change BMI z score (95% CIs), change %body fat and waist circum (95% CIs), behaviour changes (steps)
Results	Target children in both groups experienced clinically meaningful and statistically significant decreases in BMI for age z-score (-0.066 (0.166) in the AOM and -0.039 (0.169) in the self help group). Although a greater average reduction in BMI-for-age z score was observed in the AOM children compared with the SM children, the differences between groups were not statistically significant (p=0.282). (completers only?)
Funding and financial disclosure	**Funding/Support**: This study was funded by McNeil Nutritionals, LLC, and National Institutes of Health grant DK42549
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	Telephone numbered, opaque sealed envelopes

Rolland-Cachera 2004

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 9 Months weight loss treatment within the clinic/boarding school. Follow-up: 2yr and 9 months from commencement of intervention. **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Not clear **Drop outs:** end of intervention 18% [22/121], follow up at 21 months 31% [38/121], and follow up at 33 months 41% [50/121]
Participants	**n=** 121 **randomised**, 71 **completed** **Age range (mean):** 11 years to 16 years (mean(SD) age PROT-: 14.1(1.2); mean(SD) age PROT+: 14.4(1.3) **% Male:** 26.4% **Weight entry criteria:** > or = 97^{th} centile of French reference values **Weight on entry (mean):** Mean (SD) weight on entry PROT-: 96.1 (13.7); Mean (SD) weight on entry PROT+: 98.8 (14.3). **Setting:** 9 Month treatment in a medical centre (boarding school) plus a 2-year follow-up in free-living patients. **Geographic Region:** Not clear
Interventions	**Intervention:** inpatient program with low protein diet and physical activity vs high protein diet and physical activity **Intervention:** inpatient program with low protein diet and physical activity **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** Physical activity consisted in 7 h/week of vigorous sports (swimming, tennis, handball, aerobic) and 7 h/week of outdoor activities (such as walking or playing). Children had no possibility to watch TV in the centre. They alternatively could spend time reading, acting, singing, talking or trolling in the centre. Advice was given to maintain the same nutritional intake and physical activity at home during weekends and holidays **Nutritional advice:** Combination of dietary control and physical activity, consisting of 9-months of treatment with 2 year follow-up. Energy intake was restricted to 1750 kcal a day until reaching the body weight goal. Subsequently, daily energy intake was increased progressively, in 1-week steps, until about 2200 kcal on average (depending on age and sex). The maintenance diet was then followed during 4 weeks. The children and their parents were advised to maintain the same level of energy and nutrient intakes after leaving the centre. The nutrient content of the PROT- diet was 15% protein and 54% CHO. The respective values for PROT+ group were 19 and 50%. PROT+ diet was the habitual diet in the centre. The protein content in the PROT+ diet was 85 g/day. The protein content in PROT- diet (65 g/day when total energy was 1750 kcal) was decided taking into account the recommended dietary allowances (59 and 44 g in 15-18 y boys and girls, respectively). In the PROT+ diet, meat, fish or eggs were served twice a day, while in the PROT diet they were consumed only once a day. Fat content was identical in both diets (31%). The percentage of energy ingested over the four daily eating occasions was 20% at breakfast, 31% at lunch, 16% at the afternoon snack and 33% at dinner. Snacking out of these four main meals was very occasional in the centre.

	Other: No **Usual care/ alternative intervention:** inpatient program with high protein diet and physical activity. **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** As above. **Nutritional advice:**As above, but high protein diet **Other:** No
Outcomes	Height (m), weight (kg), BMI (kg/m^2), BMI (sd. z score), subscapular & triceps skinfold (mm) , SS/TRI, waist circumference & hip circumference (cm), waist/hip ratio, bioimpedance analysis (FM (kg), FFM (kg), FM (%), FFM (%)), behaviour changes (nutritional intake (kcal/day), physical activity (hr/week), daily energy distribution (%)), GH assays (pg/µl)
Results	Mean BMI z-scores decreased from 4.3 (0.6) (baseline) to 1.7 (0.6) (end of treatment). After treatment, mean BMI z-scores increased, reaching 2.5 (0.9) at 21 months after commencement of intervention and 2.8 (1.1) at 38 months follow up. No significant difference in BMI z-scores from baseline to end of follow up was recorded between the two dietary groups (P=0.47). The mean BMI decrease between baseline to end of follow up was 1.4 (1.0) z-scores. No differences between dietary groups 1.4 (1.0) in PROT- and 1.3 (1.0) in PROT+; P=0.86) or between genders (1.3 (1.0) in boys and 1.4 (1.0) in girls; P=0.60) were recorded
Funding and financial disclosure	**Funding/Support**: This study was supported by LESIEUR and NESTLE France Companies
Notes	

Rooney 2005

Methods	**Random allocation:** Yes. No description of randomisation process. **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Walk 10,000 steps daily for 12 weeks, follow-up 9 months. **Unit of allocation:** Families **Unit of analysis:** Families **Protection against contamination:** Not clear **Drop outs:** not clearly reported 10-29%
Participants	**n=** 98 families and 353 people **randomised**, number **completed** unclear **Age range (mean):** 5 to 12 years (intervention group (PE) 10.1, intervention group 2 (P) 9.4 , control group 9.6) **% Male:** Proportion not given **Weight entry criteria:** Included were families with at least one child between the age of 5 and 12 with a BMI over the 84^{th} percentile. **Weight on entry (mean):** average Child BMI percentile 82.2 **Setting:** Based in a University

	Geographic Region: USA
Interventions	**Interventions:** pedometer plus education (PE), pedometer (P), or control (C) **Intervention:** pedometer plus education (PE), pedometer (P) **Target of intervention:** Family **Behavioural or psychological component:** No **Physical activity:** Participants in the PE and P groups received a Digi-Walker pedometer and were told to wear it and encouraged to walk 10,000 steps daily for 12 weeks. To measure activities that the pedometer registers poorly (swimming) families received a minutes-to-steps conversion table. Families kept track of their steps and returned step logs every 2 weeks. PE group participants attended 6 one-hour, biweekly sessions concerning physical activity. Participants were surveyed about their knowledge and attitudes about physical activity prior to randomisation, at the end of the intervention and 9 months later. Their heights and weights were measured and BMI calculated. **Nutritional advice:** PE group participants attended 6 one-hour, biweekly sessions concerning nutrition. Participants were surveyed about their knowledge and attitudes about healthy eating prior to randomisation, at the end of the intervention and 9 months later. Their heights and weights were measured and BMI calculated. **Other:** Both the P and PE groups received a bi-weekly newsletter that complimented the educational theme and included fun activity tips. Families returning for assessment at interventions end were eligible to win a trip to Walt Disney World (valued around $4000). Families participating in the 9-month follow-up received a $25 stipend. Control families also received a pedometer for each participating member at this follow-up **Usual care/ alternative intervention:** control (C) **Target of intervention:** Family **Behavioural or psychological component:** No. **Physical activity:** No. **Nutritional advice:** No. **Other:** Families returning for assessment at interventions end were eligible to win a trip to Walt Disney World (valued around $4000). Families participating in the 9-month follow-up received a $25 stipend. Control families also received a pedometer for each participating member at this follow-up
Outcomes	Height, weight, estimates of % fat content e.g.. BMI, ponderal index, skin-fold thickness (BMI percentile), participants views of the intervention
Results	To assess the effect of pedometer on child BMI percentile, the pedometer plus education and pedometer groups were combined. Child BMI percentiles did not differ significantly between PE/P and C groups at baseline, end of intervention and 9-months follow up. Note: although not significant BMI-percentile increased 0.31 in the pedometer groups and decreased by 1.32 in the control groups from baseline to 9 months
Funding and financial disclosure	**Funding/Support**:This work was supported by the Children's Miracle Network and Gundersen Lutheran Medical Foundation
Notes	Numbers of children are not reported.
Risk of bias	

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	No description of randomisation process.

Saelens 2002

Methods	**Random allocation:** Opaque sealed envelopes **Blinding:** · **Children:** Not clear, not specified · **Providers:** Not clear, not specified · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** Four-month treatment period. Post-treatment (median 4.1 months after clinic visit) and follow-up (actual median = 7.2 months after paediatric clinic visit)**.** **Unit of allocation:** Individual adolescents **Unit of analysis:** Individual adolescents **Protection against contamination:** Not clear **Drop outs:** end of intervention 11% [5/44], follow up at 7 months: 16% [7/44]
Participants	**n=** 44 **randomised**, 37 **completed** **Age range (mean):** 12 to 16 years (14.2y) **% Male:** 59.09% **Weight entry criteria:** >20% over above median BMI for height and age **Weight on entry (mean):** intervention group 87.5 ± 16.0kg, typical care group 85.8 ± 14.6 kg **Setting:** Primary care setting **Geographic Region:** Southern California, US
Interventions	**Intervention:** Multiple component behavioural weight control intervention (Healthy Habits) **Target of intervention:** Child **Behavioural or psychological component:** Self-monitoring: writing down specific foods, amounts, calories, food categories (green, red, no colour) daily, weighing weekly, writing down type and amount of physical activity Goal setting: weekly establishment of goals for calories, green and red foods, and amount of physical activity Problem solving: identifying specific problems/barriers that prevent goal attainment, brainstorming solutions and ways to implement modified plan Stimulus control: modifying the food and physical activity environment to make healthy choices more available and less healthy choices more difficult to obtain Self-reward: rewarding self for achieving goals Pre-planning: establishing plans for high-risk situations (e.g.. parties) to decrease likelihood of unhealthy eating or lack of physical activity. **Physical activity:** Beginning at the fifth call, the 'Healthy Habits' intervention had a physical activity goal consisting a minimum of 60 mins of at least moderate physical activity on 5 days per week with gradual increases from baseline levels. **Nutritional advice:** Stoplight Diet, 1200-1500 kcal's daily, although flexible depending on initial weight. Food categorised and colour coded: green = foods <150 cals per serving, red = >5 grams of fat per serving or were diet version of high fat foods. **Other:** Financial incentives: Points system to award adolescents for meeting set goals and targets,

	with points converting to tickets for a 'lottery' - one randomly selected ticket receiving $50. In addition, adolescents received $25 for post-treatment and $25 for follow-up. **Usual care/ alternative intervention:** Single session of physician weight counselling (Typical Care TC) **Target of intervention:** Child **Behavioural or psychological component:** Typical Care (TC) group ? comprised of a single-session of physician weight counselling. **Physical activity:** Paediatricians conducted a review as part of the consultation based on recommended physical activity levels for adolescents (60 min/d of at least moderate intensity physical activity). **Nutritional advice:** Recommendations for more healthy eating consisting with the 'Food Guide Pyramid'. **Other:** No
Outcomes	Height (cm), weight (kg), estimates of % fat content e.g.. BMI, ponderal index, skin-fold thickness (BMI), behaviour changes (self-report questionnaire measuring sedentary behaviour), participants views of the intervention (rating intervention components via Likert scale items), physical work capacity, prediction of relative weight
Results	Mean BMI z-scores significantly increased among TC adolescents compared with the slight decrease of BMI z-scores among HH adolescents during the intervention period. Intent-to-treat analyses did not markedly alter these results ($F(1,42)=5.59$, $p<0.03$). With the inclusion of the follow-up assessment, the overall condition by time interaction for BMI z-scores remained statistically significant ($F(2,70)=4.08$, $p<0.03$, effect size $f=0.35$;). However, the baseline to follow-up contrast for BMI z-scores only approached statistical significance ($F(1,35)=3.50$, $p<0.070$, effect size $f=0.32$). Linear contrasts suggested no differential change in BMI z-scores by condition from post-treatment to follow-up, with mean BMI z-scores remaining generally stable from posttreatment to follow-up in both conditions. Intent-to-treat analyses only slightly attenuated the overall follow-up results ($F(2,84)=3.60$, $p<0.04$) and the baseline to follow-up contrast ($F(1, 42)=3.11$, $p<0.09$). The mean change in BMI-SDS from baseline to follow-up was -0.028 (SD = 0.214) for the adolescents engaging in the behavioural program and +.054 (SD = 0.109) for the adolescents in the single physician care
Funding and financial disclosure	**Funding/Support**:This research was supported in part by a Young Investigator's Grant awarded by the North American Association for the Study of Obesity to the first author
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	Opaque sealed envelopes

Satoh 2007

Methods	**Random allocation:** No description of randomisation process. **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 6 Months Intervention, follow-up 6 months. **Unit of allocation:** Individual patients **Unit of analysis:** Individual patients **Protection against contamination:** Not clear **Drop outs:** end of intervention 33% [14/43], follow up at 6 months: 33% [14/43]
Participants	**n=** 43 **randomised**, 29 **completed** **Age range (mean):** 8 to 14 years (intervention group 11.0±1.5, control group 12.4±1.6) **% Male:** 29 completers: 17 female and 12 male (41.4%) **Weight entry criteria:** Body weight exceeds 120% of standard body weight (corresponding to the height for age and sex obtained from national statistics for Japanese school children). **Weight on entry (mean):** intervention group 50±22, control group 49±16 **Setting:** In general clinical research center of the children's hospital. **Geographic Region:** Oodate city, Akita Prefecture, Japan.
Interventions	**Intervention:** Model nutritional balance chart (MNBC) **Target of intervention:** Child & family **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** Before starting dietary guidance, both the intervention and control subjects and their parents received conventional dietary guidance from nutritionists at the hospitals. Subsequently dietary guidance using MNBC once per month for 6 months. The MNBC is designed to outline a 6697kj intake according to recommendation by the Japan Obesity Society and demonstrates the ideal dietary distribution of 11 categories of food: meat, fish, eggs and milk (including dairy products), beans, green and yellow vegetables, light-coloured vegetables, fruits, grains (including potatoes), oil and sugar. The number of times a food category was consumed was marked with black dots; the foods eaten were recorded by category, but not amount. The MNBC includes food for 3 days. **Other:** No **Usual care/ alternative intervention:** control **Target of intervention:** Child & family **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** Conventional dietary guidance once a month (such as restriction of KJ and nutritional balance of carbohydrates, proteins and fat by nutritionist at hospital). **Other:** It states the controls received conventional treatment, in contrast it also states they only provided data and did not receive any intervention
Outcomes	Height, weight (kg), percentage overweight, participants views of the intervention (describe), blood examinations (total cholesterol (mg/dL), triglycerides (mg/dL), LDL-C (mg/dL), HDL-C (mg/dL), serum glucose (mg/dL), serum protein (g/dL), hemoglobin (g/dL)), food intake data
Results	The intervention group significantly decreased their percentage overweight from pre to post intervention ($p<0.01$). participants in the control group slightly increased their percentage overweight.

	However, this was not statistically significant
Funding and financial disclosure	**Funding/Support**: not reported.
Notes	Various data was not presented though stated that measurements were taken. Analysis based on completers only. No comparisons between groups are made

Savoye 2007

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** Intervention: 12 months. Follow-up from commencement of intervention: 12 months **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** end of intervention (= 12 months) 43% [90/209], follow up at 6 months: 35% [74/209] 32% One study arm was discontinued (n=35) at six months follow up. (total number of dropouts: n = 55; Intervention: n = 30, Control group: n = 25, discontinued study arm n= 35)
Participants	**n=** 209 **randomised**, 119 **completed** (drop outs n = 55 and discontinued arm n = 35) **Age range (mean)** 8-16 years **% Male:** 39% **Weight entry criteria:** BMI > 95^{th} percentile based on the CDC growth chart **Weight on entry (mean):** Weight management group: 87.0 (25.1). Control group: 91.2(23.3). **BMI:** weight management group: 35.8 (7.6), control group: 36.2 (6.2) **Setting:** Outpatient clinic **Geographic Region:** Yale, New Haven
Interventions	**Intervention:** Bright Bodies Weight Management Group **- Target of intervention:** family **- Behavioural or psychological component:** The behavior modification component was facilitated by the registered dietitian or social worker. Topics were provided from the Smart Moves Workbook, a curriculum developed for overweight children. Techniques included self-awareness, goal setting, stimulus control, coping skills training, cognitive behavior strategies and contingency management. Behavior classes for caregivers included topics that reflected the challenges parents verbalized. Coping skills training was the primary technique used as it has been used for the treatment of other chronic conditions, including diabetes. The classes emphasised the importance of the parents role in modelling healthy behavior change **- Physical activity:** The exercise component of the weight management program was facilitated by exercise physiologists. Each class consisted of a warm-up, high-intensity aerobic exercise, and a cool-down. The main objective of the high-intensity exercise was to sustain 65% to 80% of the age-adjusted maximal heart rate for the duration of the exercise. To ensure this, a heart rate monitor was worn by all participants and Borg's Perceived Exertion Scale was use to monitor exertion. Participants were also encouraged to exercise 3 additional days at home per week and to

	decrease sedentary behaviours. The minimum activity that each participant completed was 100 minutes per week for the first 6 months and 100 minutes twice per months for the last 6 months **- Nutrional advice:** The nutrition education component of the weight management program used a nondiet approach that emphasized low-fat, nutrient-dense foods of moderate portion sizes. The registered dietitians used the Smart Movies Workbook, which provided consistent structure for all class topics **- Other:** No **Usual care/ alternative intervention:** Control group **- Target of intervention:** family **- Behavioural or psychological component:** Brief psychosocial counselling by a social worker **- Physical activity:** Exercise counselling included decreasing sedentary activities and finding an activity the participant enjoyed enough to engage in regular basis **- Nutrional advice:** Nutrition counselling included decreasing intake of juice, switching to diet beverages, switching from whole to low-fat milk, and bringing lunch to school vs choosing hot lunch **- Other:** No
Outcomes	Heigth, weight, BMI, total body fat (% and kg), SBP, DPB, glucose, insulin, HOMA, total cholesterol, HDL, LDL and triglycerides
Results	Although mean body weight was essentially unchanged from baseline after 12 months in the weight management group (0.3 [95% CI, −1.4 to 2.0] kg), BMI change was −1.7 (95% CI, −2.3 to −1.1] due to continued growth in height. In contrast, BMI, body weight, and percent and total body fat increased in the control group. The difference between the 2 groups in changes in BMI (−3.3), body weight (−7.4 kg), body fat (−9.2 kg), and percent body fat (−6.0%) after 12 months were significantly different (P<.001)
Funding and financial disclosure	**Funding/Support**: This work was supported by NIH grants to General Clinical Research Center (M01-RR00125) and Dr Caprio (R01-HD28016 and R01-HD40787), Yale University School of Medicine, and an unrestricted gift from the McPhee Foundation, Bristol, Conn. **Role of the Sponsor:** The National Institutes of Health and the McPhee Foundation played no role in the concept or design of the study; in the acquisition, analysis, and interpretation of the data; in the drafting or revision of the manuscript; or technical support or supervision of the study **Financial Disclosures:** None reported.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Schwingshandl 1999

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 12 week treatment and dietary re-education at 6 and 12 months. Follow up at one year after treatment commencement **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** 33% [10/30]
Participants	**n=** 30 **randomised**, 20 available for follow up **Age range (mean):** 6 to 16 years (11.6 years) **% Male:** 43% **Weight entry criteria:** Non given **Weight on entry (mean):** 66.25 kg **Setting:** Unclear **Geographic Region:** Austria
Interventions	**Interventions:** Physical training program and dietary advice vs dietary advice alone **Intervention:** Physical training program and dietary advice **- Target of intervention:** child **- Behavioural or psychological component:** No. **- Physical activity:** Training sessions took place twice weekly (for 12 weeks) in a public gym , with a duration of approximately 60-70 minutes for each session. After a warm up period on either a stationary bike, treadmill, or rowing ergometer, and a light stretch, each child performed two sets out of the following exercises: lying leg press; seated leg extensions and leg curls; seated bench press; pulldown to the front and long pulley row; seated shoulder press; triceps pushdowns and triceps extensions at the dips machine; dumbbell biceps curls; calf raises seated and crunches. The volume (number of sets performed during training sessions) increased after two weeks, working up to as many as three to four sets for each exercise. Intensity was adapted during the time course of a strength gain. Sets were pyramided: starting with a light set, with each following set using a slightly higher load. Only the last set was performed until muscle failure. If the child was able to perform more than 10 repetitions in the final set, the resistance was increased for the next training session **- Nutrional advice:** Both groups participated in the same dietary education programme. General dietary advice was given by group teaching. This included: energy requirements; relation of the different nutrients in a balanced diet; and the importance of fibre, vitamins, minerals and fluids. Energy intake was restricted to 4180 kJ/day in both groups; children older than 14 years were restricted to 5016 kJ/day (girls) and 5852 kJ/day (boys). All participants received written information regarding an energy restricted, balanced diet, and detailed information of the daily allowance of each food component to avoid over consumption. At each visit each participant received dietary re-education on an individual basis **- Other:** No. **Usual care/ alternative intervention:** dietary advice alone **- Target of intervention:** child **- Behavioural or psychological component:** No.

Schwingshandl 1999 (*Continued*)

	- Physical activity: No. **- Nutrional advice:** Both groups participated in the same dietary education programme. General dietary advice was given by group teaching. This included: energy requirements; relation of the different nutrients in a balanced diet; and the importance of fibre, vitamins, minerals and fluids. Energy intake was restricted to 4180 kJ/day in both groups; children older than 14 years were restricted to 5016 kJ/day (girls) and 5852 kJ/day (boys). All participants received written information regarding an energy restricted, balanced diet, and detailed information of the daily allowance of each food component to avoid over consumption. At each visit each participant received dietary re-education on an individual basis **- Other:** No.
Outcomes	Weight status: Weight (kg) and BMI-SDS (Mean standard score for BMI) presented at baseline, 4, 8 and 12 weeks. No outcome data presented Others: fat free mass (kg).
Results	Mean change in BMI-SDS at 3 months was -0.53 (SE 0.11) in the physical training and dietary group (p=0.0003) and -0.51 (SE0.18) in the dietary advice only group (p=0.01). (No long-term results presented, completers only)
Funding and financial disclosure	**Funding/Support**: Only the "Fit For Life" Gym in Graz was acknowledged for providing the equipment during the training period. No other support reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Senediak 1985

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** Yes · **Providers:** Yes · **Outcome assessors:** Unclear **Length of intervention and follow up:** 4 weeks (15 weeks for gradual behavioural group) and 21 week follow up (10 weeks for gradual behavioural group) **Unit of allocation:** Children **Unit of analysis:** Children **Protection against contamination:** Unclear **Drop outs:** 31% [11/35 = 4/12 rapid group, 3/12 gradual group and 4/11 non specific control]
Participants	**n=** 45 **randomised**, 10 excluded from 26 week follow up (waiting list control) 25 completed. **Age range (mean):** 72 to 150 months (123.61 months) **% Male:** Approximately 66% **Weight entry criteria:** >20% overweight for height, age and sex

	Weight on entry (mean): 37.22% **Setting:** No details given **Geographic Region:** Australia
Interventions	**Interventions:** Four conditions: rapid behavioural group (1) vs gradual behavioural procedure (2) vs non-specific control condition (3) vs a waiting list control group (4) **Intervention:** Rapid behavioural group (1) **- Target of intervention:** child and parent **- Behavioural or psychological component:** Group basis, with 5 or 6 parent-child pairs attending each session. 2 therapists, a qualified clinical psychologist and a masters student in clinical psychology. Lifestyle changes such as minimising the use of energy-saving devices (e.g.. walking instead of riding in the car) Subjects recorded caloric intake and exercise activity each day during the treatment phase, with parents and children being encouraged to complete this task jointly when possible to increase the accuracy of self-monitoring. Behavioural contracting was used between parents and children with targets relating to improvement in eating and exercise habits as well as weight loss. Parents were instructed to serve as appropriate models for their children regarding eating and exercise activities and to use praise to reinforce desirable behaviour. Children were taught to use self-reinforcement skills for achievement of eating and exercise targets. Stimulus control techniques (Stuart and Davis) were encouraged, and attempts were made to modify negative cognitions which may contribute to obesity. Children were trained to engage in 'counter statements' in response to maladaptive thoughts relating to overeating or failure to exercise. The rapid behavioural group had 8 sessions conducted twice weekly for four weeks, 90 minutes duration **- Physical activity:** Aerobic exercise as outlined by Epstein and Wing (1980), subjects were instructed to engage in at least four, 30 min aerobic exercise sessions per week. Basic conditioning exercises were introduced to prepare subjects for the more strenuous aerobic exercises (Gatchell) **- Nutrional advice:** Diet based on the food exchange system (Langeluddecke) and the traffic light system (Epstein). **- Other:** Parents were required to deposit $30 at the beginning of the programme with $3 being returned at each of the sessions and follow up contacts, contingent upon attendance and completion of homework assignments. **Intervention:** Gradual behavioural procedure (2) **- Target of intervention:** child and parent **- Behavioural or psychological component:** Group basis, with 5 or 6 parent-child pairs attending each session. 2 therapists, a qualified clinical psychologist and a masters student in clinical psychology. Lifestyle changes such as minimising the use of energy-saving devices (e.g.. walking instead of riding in the car) Subjects recorded caloric intake and exercise activity each day during the treatment phase, with parents and children being encouraged to complete this task jointly when possible to increase the accuracy of self-monitoring. Behavioural contracting was used between parents and children with targets relating to improvement in eating and exercise habits as well as weight loss. Parents were instructed to serve as appropriate models for their children regarding eating and exercise activities and to use praise to reinforce desirable behaviour. Children were taught to use self-reinforcement skills for achievement of eating and exercise targets. Stimulus control techniques (Stuart and Davis) were encouraged, and attempts were made to modify negative cognitions which may contribute to obesity. Children were trained to engage in 'counter statements' in response to maladaptive thoughts relating to overeating or failure to exercise. For the gradual behavioural group, the 8 sessions were spaced so as to gradually fade out therapist contact, with increasingly extended intervals between meetings, over a 15 week period. Sessions 1

	to 4 occurred weekly, sessions 5 and 6 fortnightly and sessions 7 and 8 occurring after a three week interval. This group received only one follow up assessment, occurring 11 weeks after termination (week 26) which corresponded with the 21 week follow-up for the rapid group and non-specific control condition **- Physical activity:** As above. **- Nutrional advice:** As above. **- Other:** As above. **Usual care/ alternative intervention:** Non-specific control condition (3) **- Target of intervention:** child and parent **- Behavioural or psychological component:** The non-specific control group (3) were scheduled in the same manner as (1) i.e.. twice a week over four weeks. Same therapists were involved. Content of sessions involved a social support procedure which encouraged parents and children to discuss matters related to weight control amongst themselves, with the therapist facilitating discussion in a non-directive manner. Participants were also trained in progressive relaxation techniques (Bernstein and Borkovec), mood monitoring and will-power training (Jeffrey and Christensen) **- Physical activity:** No. **- Nutrional advice:** No. **- Other:** A monetary deposit was also required, contingent on attendance and completion of homework tasks. At the final follow-up assessment, participants were provided with dietary and exercise information for use by those who had not lost weight **Usual care/ alternative intervention:** Waiting list control group (4) **- Target of intervention:** child **- Overall:** Subjects in the waiting list control group were informed that, because of their overwhelming response to the programme, there would be a delay in the commencement of therapy. Assessments were carried out at weeks 1 and 4, before and after onset of (1). No contact was made between these occasions. For ethical reasons, the waiting list period was not extended beyond a 4 week interval. Members of the waiting list group received a behavioural programme after week 4 but ceased to form part of the present study
Outcomes	Weight Status: Weight and % overweight presented at 1, 4, 15 and 26 weeks % overweight based on the average weight for children of the same sex, age and height (Jones et al 1973) Others: subscapular skinfold thickness, % normel subscapular skinfold thickness, caloric intake and activity output
Results	At 26 weeks, the behavioural procedure (gradual and rapid procedures combined) was found to produce significant greater reductions on all measures than the non-specific control group (percentage overweight F= 5.39, p<0.05). However, no significant differences were found between the gradual and the rapid behavioural group over week 1 to 26 on all measures. Mean changes in percentage overweight at 26 weeks were -19.22%, -13.00% and -5.86% for the gradual, he rapid and the control procedures resp. (completers only)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	Wait list control were only followed up for 4 weeks, thereafter they received a behavioural program and ceased to take part in the study
Risk of bias	

Senediak 1985 (*Continued*)

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	No description of randomisation process

Wadden 1990

Methods	**Random allocation:** Method not described **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 16 weeks treatment plus 6 monthly follow up meetings in which participants were weighed and attended group sessions. Final follow up at 10 months from commencement of intervention. **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** 23% [11/47] at end of intervention and 40% [19/47] at 10 months follow up
Participants	**n=** 47 **randomised**, 36 **completed** treatment and 28 completed the follow up **Age range (mean):** 12 to 16 years (13.8y) **% Male:** All female **Weight entry criteria:** > 10kg overweight for age, sex and height **Weight on entry (mean):** 95.1kg **Setting:** Unclear **Geographic Region:** US
Interventions	**Interventions:** Parent-involved behavioural program: girls alone without mothers present (1) vs mothers and daughters together (2) vs daughters alone with mothers attending a concurrent, separate group meeting(3) **Intervention:** Girls alone without mothers present (1) **- Target of intervention:** child **- Behavioural or psychological component:** Treatment was delivered in groups of 8 to 10 persons; sessions were held on Wednesdays after school and Saturdays. All subjects received the same treatment with the exception of parental involvement. Weekly 1hr sessions followed treatment principles described in the manual for the Weight Reduction and Pride program, a 16 week program developed specifically for these children. All subjects received a copy of the 100 page manual, which instructed them in the subcomponents below. Each weekly lesson from the manual was accompanied by a homework assignment and quiz, which were reviewed in the following week's session. Subjects were weighed at the monthly follow-up visits and invited to discuss during their group meetings any difficulties or successes related to weight control. In addition, therapists briefly reviewed pertinent materials from previous treatment sessions. Limiting times and places of eating; slowing their rate of eating; modifying self-defeating thoughts concerning weight and food. Children were rewarded with stars for completing the assignments; stars could be exchanged on a monthly basis for small prizes or saved toward a big prize to be awarded at the end of the program. (1) Girls alone: girls in this condition attended all sessions alone and received the treatment program described above. They were encouraged to discuss the treatment materials with their

	parents, who did not otherwise participate in the program **- Physical activity:** Increasing physical activity by walking and other lifestyle behaviours. **- Nutrional advice:** Measuring foods and beverages; recording their food and calorie intake; consuming low-fat well-balanced meals of 4200 to 6300kJ (1000-1500kcal)daily; understanding macronutrients, vitamins and minerals; limiting their consumption of high-calorie snacks and fast-foods. **- Other:** In addition, subjects received $1 for each treatment session they attended and 50 cents for each half pound they lost. The $35 deposit was used to pay these costs **Usual care/ alternative intervention:** Mothers and daughters together (2) **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above. (2) Mothers and daughters together: Children and mothers attended all sessions together (with four or five children and mothers per group). They were told that this was a useful approach that would teach mothers to understand their daughters's weight problem and help them with it. Mothers were given weekly reading materials and homework assignments, which included modelling appropriate eating and exercise habits, praising their daughters homework assignments with them (if asked), preparing low-calorie snacks, and limiting their purchases of high calorie beverages and snacks. This was summarised in a 16 week mothers manual. Mothers were given the option of losing weight and weighing-in each week **- Physical activity:** Increasing physical activity by walking and other lifestyle behaviours **- Nutrional advice:** Measuring foods and beverages; recording their food and calorie intake; consuming low-fat well-balanced meals of 4200 to 6300kJ (1000-1500kcal)daily; understanding macronutrients, vitamins and minerals; limiting their consumption of high-calorie snacks and fast-foods. **- Other:** As above. **Usual care/ alternative intervention:** Daughters alone with mothers attending a concurrent, separate group meeting(3) **- Target of intervention:** child and parent **- Behavioural or psychological component:** As above. (3) Daughters alone with mothers attending a concurrent, separate group meeting: The mothers and children met concurrently in separate groups. They were told that separate meetings would allow both parties to freely express their thoughts and feelings. Children and mothers received th treatment manuals previously described, and group sessions were structured accordingly. The mother's meeting was for social support and discussion of daughter's eating and exercise habits **- Physical activity:** Increasing physical activity by walking and other lifestyle behaviours **- Nutrional advice:** Measuring foods and beverages; recording their food and calorie intake; consuming low-fat well-balanced meals of 4200 to 6300kJ (1000-1500kcal) daily; understanding macronutrients, vitamins and minerals; limiting their consumption of high-calorie snacks and fast-foods. **- Other:** As above.
Outcomes	Weight status: Weight (kg) and BMI presented at 0, 1, 2, 3 and 4 months and outcome weight presented at 6 months Others: % fat, fat free mass, self esteem, cholesterol and blood pressure, and depression
Results	At the end of intervention (4 months) BMI declined significantly (P <0.001) as a function of time, but there were no statistically significant differences among treatment conditions. The mean BMI at the 6-month follow-up examination for these subjects was 35.4, which did not differ significantly from the value of 35.2 with which they began the program. Thus, taken as a whole,

Wadden 1990 (*Continued*)

	subjects returned to the same degree of overweight at the time of follow-up with which they had begun the study. Additional analyses showed that 54% of subjects were below their baseline BMI at the 6-month follow-up examination, but only 11% showed a reduction in BMI of 5% or more, as compared with 37% of subjects at the end of treatment. Forty-six percent of subjects showed an increase in BMI from baseline to the 6-month follow-up examination, and 21% showed an increase of 5% or more. We were unable to identify any subject or treatment factors that predicted successful long-term weight control. (completers only)
Funding and financial disclosure	**Funding/Support**: This study was supported by a National Institute of Mental Health Research Scientist Development Award and by grants from the National Institute of Child Health and Human Development (HD20152), the MacArthur Foundation's Network on Health Promoting and Disease Preventing Behaviors, and the Sandoz Nutrition Cornpany (to Dr Wadden)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	No description of randomisation process

Warschburger 2001

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** Unclear · **Providers:** Unclear · **Outcome assessors:** Unclear **Length of intervention and follow up:** 6 weeks treatment, 6 and 12 months follow up **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** No details given
Participants	**n=**197 (121/197 experimental group, 76/197 comparison group) **Age range (mean):** 9 to 19 years (13.8 years SD 1.1) in experimental group, (13.1, SD 1.1) in the control group) **% Male:** No details **Weight entry criteria:** >20% overweight for height **Weight on entry (mean):** % overweight experimental group 63.8+/- 25.4, control group 64.6 +/ - 23.7 **Setting:** rehabilitation hospital **Geographic Region:** Germany
Interventions	**Interventions:** Six week in-patient rehabilitation + cognitive-behavioural treatment program vs six week in-patient rehabilitation + muscle relaxation training **Intervention:** Six week in-patient rehabilitation + cognitive-behavioural treatment program

	- Target of intervention: child **- Behavioural or psychological component:** The programme included specific skills to facilitate behaviour change and also behaviour management skills to encourage habit change. Self-monitoring, contract-managment, stimulus-control, modelling, eating-managment and reinforcement principles were used. OVer 6 sessions the children and adolescents learned to understand why they had become overweight and what they could do to lose weight and feel better. In groups with around 8-10 children of the same sex and age they talked about psychosocial problems associated with obesity and how to change their eating and activity habits. The primary goal was to increase their self-managment skills in order to handle the different requirements. Children and adolescents were given written material (completed by the participants) and were asked to inform their parents at home about the main aspects of the training programme (e.g. what to eat, how to do sports) **- Physical activity:** Both groups stayed for 6 weeks in a rehabilitation hospital. They received a calorie-reduced diet and took part in an exercise programme **- Nutrional advice:** Both groups stayed for 6 weeks in a rehabilitation hospital. They received a calorie-reduced diet and took part in an exercise programme **- Other:** No. **Usual care/ alternative intervention:** Six week in-patient rehabilitation + muscle relaxation training **- Target of intervention:** child **- Behavioural or psychological component:** Muscle relaxation training. **- Physical activity:** Both groups stayed for 6 weeks in a rehabilitation hospital. They received a calorie-reduced diet and took part in an exercise programme **- Nutrional advice:** Both groups stayed for 6 weeks in a rehabilitation hospital. They received a calorie-reduced diet and took part in an exercise programme **- Other:** No.
Outcomes	Weight status: % overweight and BMI presented at pre-treatment, post-treatment and 6 and 12 months follow-up Others: Obesity-specific self-efficacy scale, quality of life questionnaire and an eating behaviour scale
Results	Both groups reduced their percentage overweight after the intervention (6 weeks) (xEG=15.47, sd=13.32, xCG=14.03, sd=10.00) and showed a stable course (F16.51, P<0.01). Six months after intervention, 14.8% of the children and adolescents in the EG could be classified as non-obese (but overweight) compared to 9.7% in the CG. Nearly three percent of the children in the CG remained super-obese (more than 100% overweight), none in the EG. These differences were not statistically significant (w22.55, P=0.47). (drop outs not reported)
Funding and financial disclosure	**Funding/Support**: not reported.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Weintraub 2008

Methods	**Random allocation:** After completing baseline assessments, children were randomised 'using a computer by the database manager'. **Blinding:** · **Children:** No · **Providers:** It is not possible to blind carers or children to this type of group allocation · **Outcome assessors:** No. Owing to limited staffing for this pilot study, data collectors were not blinded at follow up assessment. **Length of intervention and follow up:** 6 months intervention. Follow-up 6 months. **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Not clear **Drop outs:** zero dropouts reported
Participants	**n=** 21 **randomised**, 21 **completed** **Age range (mean):** intervention group 9.50±0.58 years, control group 10.34±0.84 years **% Male:** Gender distribution not given. **Weight entry criteria:** BMI >85th centile for age (USCDC 2000 growth reference). **Weight on entry (mean):** intervention group BMI 27.17±4.96 , control group 29.01±4.77. **Setting:** Schools **Geographic Region:** A low-income community in northern California, USA.
Interventions	**Intervention:** Randomised controlled trial of a six-month school-based soccer program. **Target of intervention:** Child **Behavioural or psychological component:** There was an emphasis on respect for self and others, inclusion and teamwork. At the conclusion of the program, children received certificates of accomplishment and medals. **Physical activity:** Soccer program, initially offered 3 days per week, and then increased to 4 days per week during month 5 of the 6 month intervention. One day per week was game day, with the other days being practice days. Sessions were approximately 2¼ hours long and started with a homework period followed by 75 minutes of activity. The activity period began with a supportive team-building check-in followed by 15 minutes of warm-up and stretching. The remainder of the practice session was devoted to learning soccer skills (fun skill-building exercises, concluding with a scrimmage). There was an emphasis on respect for self and others, inclusion and teamwork. Shin guards, uniforms and water bottles given to each player. Matches were held quarterly. At the conclusion of the program, children received certificates of accomplishment and medals. **Nutritional advice:** No **Other:** Shin guards, uniforms and water bottles were given to each player **Usual care/ alternative intervention:** Six-month health and education intervention. **Target of intervention:** Child **Behavioural or psychological component:** As above. In the 'active placebo' control intervention, children received a 25 session, state-of-the-art, information-based nutrition and health education intervention consisting of weekly after-school meetings conducted by trained volunteer undergraduate and medical students. Program content included materials and activities promoting healthful nutrition and physical activity produced by federal health agencies and national nongovernmental health organisation. **Physical activity:** No. **Nutritional advice:** See behavioural component. **Other:** No

Outcomes	Height (cm), weight (kg), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness (mean±SD), BMI (kg/m^2), BMI z-score, behaviour changes (10-item Children's Depression Inventory, overconcerns with Weight sub-scale of the McKnight Risk Factor Survey , 10-item Rosenberg Self-esteem Scale), participants views of the intervention, measures of harm (parent reports of adverse events), total activity, 7am-10pm (counts/min), moderate physical activity, 7am-10pm, 3000-5200 counts/min (minutes), vigorous physical activity, 7am-10pm, >5200 counts/min (minutes), television and other screen time (hours per week)
Results	All 9 children randomised to the soccer group and 5 of 12 children (42%) randomised to the health education group had lower BMI z scores at 3 and 6 months.There were significant baseline BMI z-scores by treatment interactions at 3 months (P=0.03) and 6 months (P=0.04)
Funding and financial disclosure	**Funding/Support**: This project was supported under a cooperative agreement from the Centers for Disease Control and Prevention through the Association of American Medical Colleges (grants U36/CCU319276 andAAMC ID MM-0851-05/05) **Financial Disclosure:** None reported.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	After completing baseline assessments, children were randomised 'using a computer by the database manager'

Weyhreter 2003

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** No **Length of intervention and follow up:** Intervention: 6 months. Follow-up from commencement of intervention: 28.76 (10.49) months from end of intervention (35 months after commencement of intervention **Unit of allocation:** Child **Unit of analysis:** Child and parent **Protection against contamination:** Done. Participants in the two treatment arms never met together and there was very little opportunity for contamination across the treatment arms **Drop outs:** 37% (total: n = 26)
Participants	**n=** 70 **randomised**, 44 **completed** **Age range (mean)** 2-16 years (10.3 years, **SD** 3.3) **% Male:** 0% **Weight entry criteria:** BMI at or exceeding the 97^{th} percentile for age and gender **Weight on entry (mean):** BMI-SDS 4.78 $\pm$ 1.16 for the whole group of children

	Setting: clinic-based **Geographic Region:** Germany
Interventions	**Interventions:** 3 different behavioral treatments **Intervention:** Behavioral treatment, with parent meeting and cooking classes **- Target of intervention:** family **- Behavioural or psychological component:** Behaviourally oriented strategies. One parent evening education meeting (C) **- Physical activity:** physical activity advice based on diaries kept by children (supervised by parents) **- Nutrional advice:** nutritional advice based on diaries kept by children (supervised by parents). Cooking classes for parents and children **- Other:** No. **Usual care/ alternative intervention:** Behavioral treatment, with parent meeting (B) **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** As above. **- Nutrional advice:** As above, but no cooking classes. **- Other:** No **Usual care/ alternative intervention:** Standard behavioral treatment (A) **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** As above. **- Nutrional advice:** As above, but no cooking classes. **- Other:** No
Outcomes	
Results	Mean change in BMI-SDS in group C -0.94 (0.58), group B: -0.53 (0.57) and group A: -0.49 (0.44) at the end of intervention (6 months). This was statistically significant comparing group C with group A (F=3.48, p=0.038)
Funding and financial disclosure	**Funding/Support**: not reported
Notes	Follow up self reported height and weight data over telephone

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Williamson 2005

Methods	**Random allocation:** Participants were randomly assigned to the treatment arms using a stratified randomisation strategy based on BMI percentile and age **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** No **Length of intervention and follow up:** Intervention: 24 months. Follow-up from commencement of intervention: 24 months **Unit of allocation:** Child **Unit of analysis:** Child and parent **Protection against contamination:** Done. Participants in the two treatment arms never met together and there was very little opportunity for contamination across the treatment arms **Drop outs:** 30% (total: n = 17; Intervention: n = 10, Control group: n = 7)
Participants	**n=** 61 **randomised**, 40 **completed** **Age range (mean)** 11-15 years (13.2 years, **SD** 1.4) **% Male:** 0% **Weight entry criteria:** BMI at or exceeding the 85^{th} percentile for age and gender **Weight on entry (mean):** 93.3 (22.5) kg, BMI 36.4 (7.9) **Setting:** Community **Geographic Region:** Baton Rouge, LA, Unites States of America
Interventions	**Intervention:** Interactive behaviour therapy **- Target of intervention: family** **- Behavioural or psychological component:** The website provided nutrition education and behavior modification for adults and adolescents using a family-oriented format, i.e., a program that invited the parents, the child, and other members of the family to be involved using mutual problem solving and behavioral contracting. Counseling for behavior modification was accomplished primarily via asynchronous email communications. The behavioral condition incorporated behavior modification techniques and heavy emphasis on email communication with as case manager who had at least graduate level clinic psychology training specializing in weight management. Specific weekly topics in the behavioral condition included self-monitoring, goal setting for eating and physical activity, problem solving, behavioral contracting, and relapse prevention **- Physical activity:** Participants were encouraged to engage in regular physical activity. In the behavioural group, participants established physical activity goals that were incorporated into behavioural contracts **- Nutrional advice:** Participants were instructed to complete daily food records and submit them using an automated form housed on the Web site. Food records were submitted to the project dietitian, who recorded them for accuracy and compliance with the recommended calorie levels. In addition automated feedback was provided such that after submission of the forms, a computer program embedded in the form generated an image of the Food Guide Pyramid and indicated the extent to which the food record complied with the recommended nutritional values **- Other:** The adolescent participant and her overweight parent (in both treatment conditions) were scheduled to attend four face-to-face counselling sessions during the first 12 weeks of the program, at weeks 1, 3, 6, and 12. Participants in both arms were reinforced (with small gifts) for attendance at face-to-face therapy sessions. For the behavioural group these 4 sessions focused on: 1. introduction to food monitoring and goal setting for nutrient intake 2. introduction to monitoring of exercise and goal setting to yield a minimum of 150 minutes of exercise per week by week 20; 3. introduction to Behavioural Contracting with a goal of modelling appropriate

	strategies for behavioural contracting; and 4. review of progress and problem-solving to address poor adherence **Usual care/ alternative intervention:** Passive health education **- Target of intervention: family** **- Behavioural or psychological component:** No. Participants in the control group received nutrition education from a registered dietitian, but were not prescribed behavioural tasks to yield weight loss **- Physical activity:** The control condition was primarily educational in nature and provided basic information about nutrition and physical activity. Participants were encouraged to engage in regular physical activity **- Nutrional advice:** Participants in the control group were provided health education in a co-ordinated program between face-to-face sessions and links to a variety of websites promoting healthy lifestyle. The control website did not provide explicit prescriptions for behaviour change, behavioural contracts, or opportunities for self-monitoring. The control condition was primarily educational in nature and provided basic information about nutrition and physical activity. Participants in the control condition logged in to a separate Web site and were managed by registered dietitian. In the control condition, topics include lessons pertaining to serving sizes, the food guide pyramid, hidden calories and understanding food labels **- Other:** As above.
Outcomes	Heigth, weight, BMI, % body fat, Weight Loss Behavior Scale, Measure of exercise confidence, total daily energy intake, fat intake, protein intake and carbohydrate intake (all measured in adolescents en parents)
Results	The groups differed in BMI changes, with the BMI decreasing -0.19 (24) kg/m^2 in the intervention group and increasing in the control group by 0.65 (0.23) over the 6 months intervention period ($p<0.05$). During the next 18 months, adolescent participants in both groups gained weight, and at 2 years, the weight/fat of the two treatment groups did not differ
Funding and financial disclosure	**Funding/Support**: This project was support by National Institues of Health grant 5 RO1 HD39104-03
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Woo 2004

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** No · **Providers:** Yes. Both groups (children and parents) participated in the same diet education program and were interviewed by the same dietitian, who was blinded to the exercise program allocation · **Outcome assessors:** Unclear **Length of intervention and follow up:** Intervention: 6 weeks and subsequently 1 year. Follow-up: 1 year **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear **Drop outs:** Not reported
Participants	**n=** 82 **randomised**, 82 **completed** (n = 41 diet + exercise and n =41 diet for 6 weeks. Thereafter: n = 22 continued exercise + diet; n = 41 diet, and n = 19 diet + detraining) **Age range (mean)** 9-12 years **% Male:** 66% **Weight entry criteria:** BMI $\geqq$ 21 **Weight on entry (mean):** Diet only: 50.3 (8.5). Diet + exercise: 54.6 (9.5). **BMI:** Diet only: mean (SD) 24.5 (2.9), Diet + exercise: mean (SD) 25.4 (3.1) **Setting:** Outpatient clinic **Geographic Region:** probably Hong Kong, China
Interventions	**Intervention:** Diet + exercise **- Target of intervention:** child and parent **- Behavioural or psychological component:** No **- Physical activity:** A fitness assessment test was carried out before commencement of the program. Each child's exercise ability was measured, and customized training was prescribed by trained physiotherapists. The exercise sessions were all carried out in the hospital and supervised by the same physiotherapist team and were of circuit style, with a preset sequence of 18 workout stations; each child had to go through 9 stations in each sessions, twice a week for 6 weeks and then once weekly for 1 year (for a subgroup). Aerobic exercise including dance was incorporated into the training. Each training sessions lasted 75 minutes, including 10 minutes of warm up, 30 minutes of resistance training, 10 minutes of aerobic exercise, 10 minutes of agility training, 5 minutes of cool-down, and short rest-periods between stations. All children maintained an exercise intensity at 60 to 70% of predicted maximum heart rate during the aerobic exercise **- Nutrional advice:** Both groups (children and parents) participated in the same diet education program and were interviewed by the same dietitian, who was blinded to the exercise program allocation, 2 weekly for the first 6 weeks and 2 monthly subsequently. The diet prescribed was a balanced hypocaloric diet that provided 900 to 1200 kcal daily. The menu varied according to the child's age and eating habits. It was low in fat (20-25%), high in complex carbohydrate (50-60%) , and sufficient in protein (25-30%) to support growth. A 3-day dietary recording was done by the children with the help of their parents at baseline and before each scheduled follow-up **- Other:** No **Usual care/ alternative intervention:** Diet only **- Target of intervention:** child and parent **- Behavioural or psychological component:** No **- Physical activity:** No

	- Nutrional advice: As above. **- Other:** No
Outcomes	Height, weight, BMI, waist-to-hip ratio, body fat %, fat free mass (kg), total cholesterol, triglycerides, HDL, LDL, LDL/HDL ratio, glucose, arterial reactivity and IMT
Results	BMI in kg/m^2 at baseline and 12 months follow up -mean (sd): Diet only 24.7 (3.1) and 24.5 (3.3) , Detraining 26.1 (4.0) and 26.1 (4.2), continuing training 25.3 (2.4) and 25.4 (2.4) respectively (differences not statistically significant).(dropouts not reported
Funding and financial disclosure	**Funding/Support**: This project was financially supported by the Hong Kong Institute of Heart Health Promotion, the Shaw Foundation, and the Research Grant Council of Hong Kong (CUHK4060/2000M)
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process

Freemark 2001

Methods	**Random allocation:** Computer-generated randomisation tables. **Blinding:** · **Children:** Yes. · **Providers:** yes · **Outcome assessors:** Yes. States that both the subject and research staff were blinded to the intervention. **Length of intervention and follow up:** Intervention 6 months, follow-up 6 months. **Unit of allocation:** Individual adolescent **Unit of analysis:** Individual adolescent **Protection against contamination:** Done. **Drop outs:** 9% [3/32] (intervention group 1, control group 2) end of intervention and 6 months follow up
Participants	**n=** 32 **randomised**, 29 **completed** **Age range (mean):** 12 to 19 years (intervention group 14.4±0.6, control group 15.4±0.5) **% Male:** 37.93% **Weight entry criteria:** BMI >30 kg/m^2 **Weight on entry (mean):** BMI: intervention group BMI 41.5±0.9 , control group 38.7±1.3 (P<0.05). **Setting:** Both inpatient and outpatient clinic of a (University School of Medicine) **Geographic Region:** Durham, North Carolina, USA
Interventions	**Intervention:** Metformin **Target of intervention:** Child

	Behavioural or psychological component: No **Physical activity:** No **Nutritional advice:** No **Medication: Describe:** Patients were randomised to either metformin 500 mg twice a day or 6 months, or placebo twice a day for 6 months. **Other:** No **Usual care/ alternative intervention:** Placebo **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** No **Nutritional advice:** No **Medication:** Yes, as above. **Other:** No
Outcomes	Height, weight, estimates of % fat content e.g.. BMI, ponderal index, skin-fold thickness (kg/m $_2$), BMI SD score (means ±SE given), measures of harm (metformin toxicity assessed by clinical review each month for 6 months, fasting blood tests at baseline and monthly for 6 months (liver and renal function tests), lactate, rapidly sampled intravenous glucose tolerance test, liver function tests
Results	Metformin caused a decline of 0.12 SD in BMI during the study, amounting to a mean decrease of 0.5 kg/m^2, or -1.3% from baseline. In contrast, BMI rose 0.23 SD, or 2.3% (mean + 0.9 kg/m^2) in the placebo group. The differences in absolute and percent change in BMI SDS in the 2 groups were statistically significant (P<0.02). (Completers only)
Funding and financial disclosure	**Funding/Support:** This study was supported by an investigator-initiated grant from Bristol-Myers Squibb Corporation and by General Clinical Research Center (Grant MO1RR-30)
Notes	Lifestyle intervention was not included. This is one of the first RCTs to suggest a role for metformin in this group of insulin resistant severely obese adolescents

Srinivasan 2006

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes. Computer-generated random number allocation, with both caregivers and investigators blinded to allocation. **Blinding:** · **Children:** Yes · **Providers:** Yes · **Outcome assessors:** Yes (not for scoring of acanthosis nigricans) **Length of intervention and follow up:** 6 months each for metformin and placebo, in a randomised crossover design, with a 2 week washout period in between. Follow-up 12 months from commencing either metformin or placebo (although active or placebo therapy only given for 6 months each). **Unit of allocation:** Individual child **Unit of analysis:** Individual child **Protection against contamination:** Done. **Drop outs:** concerning BMI data 23% [1/13] group A (Metformin first), 20% [3/15] group B (Placebo first)
Participants	**n=** 28 **randomised**, 24 **completed** **Age range (mean):** 9 to 18 years (12.5±2.2) **% Male:** 46.43% **Weight entry criteria:** Obesity (as defined by the International Obesity Taskforce criteria). **Weight on entry (mean):** 89.9±17.6 kg **Setting:** Outpatient clinic of a tertiary paediatric hospital (University teaching hospital) **Geographic Region:** Sydney, Australia
Interventions	**Interventions:** Metformin or placebo + "standardised information on healthy eating and exercise" **Intervention:** Metformin first **- Target of intervention:** Child **- Behavioural or psychological component:** No **- Physical activity:** All patients received "standardised information" on exercise **- Nutritional advice:** All patients received "standardised information" on diet **- Medication:** Metformin or placebo for 6 months each, in a cross-over design, with a 2 week washout period in between. Both metformin and placebo doses were built up over 3 weeks to 1 g twice daily. **- Other:** No **Usual care/ alternative intervention:** Placebo first **- Target of intervention:** Child **- Behavioural or psychological component:** No. **- Physical activity:** As above. **- Nutritional advice:** As above. **- Medication:** Metformin and placebo for 6 months each, in a cross-over design, with a 2 week washout period in between. Both metformin and placebo doses were built up over 3 weeks to 1 g twice daily. **Other:** No
Outcomes	Height (cm, z-score), weight (kg, z-score), BMI and BMIz-score (CDC2000 growth reference) , measures of harm (several different units of measurement), fasting insulin and glucose and parameters derived form the frequently sampled intravenous glucose tolerance test (IVGTT) (insulin (mU/L), glucose (mmol/L), insulin sensitivity ($[mU/L]^{-1}.min^{-1}$), glucose effectiveness (min^{-1}), acute insulin response ($mU/L^{-1}.min$), disposition index, glucose disposal), measures derived from magnetic resonance imaging (subcutaneous abdominal adipose tissue (cm^2), visceral

Srinivasan 2006 (*Continued*)

	abdominal adipose tissue (cm^2), body composition (percentage body fat).
Results	Metformin therapy had a significant beneficial treatment effect over placebo for weight, BMI and waist circumference, both as raw measures and z-scores. the effect size for BMI was: -1.26 (p=0. 002) and for BMI-SDS: -0.12 (p=0.005). (Completers only)
Funding and financial disclosure	**Funding/Support:** This work was supported in part by a National Health Medical Research Scholarship (to S.S.) and a Diabetes Australia Research Trust grant (to G.R.A. and L.A.B.)
Notes	Patients received "standardised information on diet and exercise" but otherwise did not have a detailed lifestyle intervention

Chanoine 2005

Methods	**Random allocation:** Participants were randomised at a 2 to 1 ratio to receive Orlisat or placebo. Patients were randomised centrally according to a computer generated randomisation schedule prepared by the study's sponsor, with stratification of body weight (<80kg or $\geq$ 80kg) on day 1 and by weight loss during the lead-in period <1 kg or $\geq$ 1 kg). The allocation process was triple-blind; the allotted treatment group was obtained through an automated telephone system. **Blinding:** · **Children:** Yes · **Providers:** Yes. First 2 weeks: single blind, placebo lead-in period. Next 52 weeks: double blind treatment period. · **Outcome assessors:** Yes **Length of intervention and follow up:** 54 weeks (August 2000- October 2002), 2 week single blind, placebo lead-in period, 52 week double blind treatment period, follow up 52 weeks. **Unit of allocation:** Individual adolescents **Unit of analysis:** Individual adolescents **Protection against contamination:** Done. **Drop outs:** 35% [190/539] (intervention group: 125, control group: 65)
Participants	**n=** 539 **randomised**, 349 **completed** **Age range (mean):** 12-16 years (intervention group 13.6 $\pm$ 1.3, control group 13.5 $\pm$ 1.2) **% Male:** 33% **Weight entry criteria:** BMI 2 units or higher than US weighted mean for the 95^{th} percentile based on age and sex (this was requested by the USFood and Drug Administration to ensure that only patients with the greatest potential for benefiting from the study were included) **Weight on entry (mean):** intervention group: 13.6 $\pm$ 1.3, control group: 13.5 $\pm$ 1.2 **Setting:** Clinical, 32 centres, institutions with established obesity treatment programs and clinical research expertise **Geographic Region:** US and Canada
Interventions	**Interventions:** Orlistat + diet + exercise + behaviour therapy vs Placebo + diet + exercise + behaviour therapy **Intervention:** Orlistat + diet + exercise + behaviour **Target of intervention:** Child. It is unclear as to what extent parents were involved in supporting the intervention. Although it is one of the inclusion criteria that subjects had to have a parent or guardian prepared to attend study visits with them.

	Behavioural or psychological component: All study centres had behavioral modification programs in place, but used a study-specific manual as a guideline. Programs generally involved recording food intake and activity; limiting high-calorie 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 at the study centres were to support and reinforce behavioral modification techniques regularly. **Physical activity:** Guidelines were provided to encourage regular physical activity and reduce sedentary behavior. Strength, flexibility, and aerobic activities were included as part of the exercise plan wherever possible. A behavioral psychologist spoke with patients about compliance with the exercise program at each study visit. **Nutritional advice:** Participants were maintained on a nutritionally balanced, hypocaloric diet designed to produce an initial weight loss of 0.5 to 1.0kg per week. The caloric distribution of the diet was 30%as fat (10% saturated, 10% monounsaturated, and 10% polyunsaturated; $\leq$70 g/d maximum), 50% as carbohydrate, and 20% as protein. Maximum intakes of cholesterol and calcium were 300 mg/d and 1300 mg/d, respectively. The caloric intake prescribed in this study was calculated to provide a reduction in estimated caloric requirements of approximately 40%. Caloric requirements were determined by sex and baseline body weight, using estimates of total energy requirements based on the World Health Organization's equations for basal metabolic rate and corrected for ... activity. Assigned caloric intake ranged from 1400 kcal/d (body weight <70 kg) to 1800 kcal/d (bodyweight >100kg) in boys and from 1200 to 1600 kcal/d in girls. The daily caloric intake was adjusted during the double-blind treatment period if the participant reached a BMI of 22 or if the participant was losing weight too rapidly (> 1 kg per week). At each study visit, the dietician spoke with the patient about compliance with diet. **Medication:** 120 mg of orlistat 3 times daily. Placebo and orlistat capsules looked identical and, except for the active ingredient, had exactly the same composition. Participants in both treatment groups received a commercially available daily multivitamin supplement (Centrum Kids Extra Calcium; Wyeth Consumer Healthcare, Madison, NJ) throughout the active period of the study. **Other:** No **Usual care/ alternative intervention:** Placebo + diet + exercise + behaviour therapy **Target of intervention:** As above. **Behavioural or psychological component:** As above. **Physical activity:** As above. **Nutritional advice:** As above. **Medication:** As above, but 120 mg of placebo medication 3 times daily. **Other:** No
Outcomes	Height (cm), weight (kg), Estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness (BMI: kg/m^2, BMC: g, BMD: $g/cm^{2,}$ fat-free body mass (FFM): g, fat mass (FM): g), waist (cm) , hip circumference (cm), secondary efficacy end-points: clinical laboratory test (total cholesterol; HDL; LDL; HDL to LDL ratio;triglycerides; glucose (mg/dL); insulin (µIU/ml)), vital signs (include blood pressure) (mm Hg), drug compliance rates, drug safety parameters, cardiac function, gall bladder and renal structure, tanner stage (graded 1 to 5), sex hormone levels (Estradiol (pg/mL), free testosterone, sex hormone-binding globulin), vitamin levels (A, D, E and beta carotine)
Results	By the end of the study, the least-squares mean BMI of participants treated with orlistat had decreased from baseline by 0.55 and increased by 0.31 in the placebo group (P=.001;mean change in BMI for orlistat versus placebo was -1.08 (2.05) kg/m^2 versus -0.31 (1.68) kg/m^2 at 6 months follow up. There was no difference between groups in terms of change in lipid levels, glucose or insulin. Use of Orlistat did not impair physical growth or

	maturation although there was a statistically significant decrease in estradiol levels in girls treated with Orlistat compared with girls in the placebo group. Gastrointestinal adverse events were more common in the orlistat group. The use of orlistat did not raise major safety issues. However, it should be noted that 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
Funding and financial disclosure	**Funding/Support:** This study was funded by F. Hoffmann- La Roche Ltd. **Financial Disclosures**: Dr Chanoine has received honoraria from Hoffmann-La Roche for speakers presentations. No other authors reported financial disclosures **Role of the Sponsor**: Hoffmann-La Roche was involved in the study design and conduct and in the analysis and interpretation of the data. All data were independently reanalyzed by an academic statistician. The sponsor was permitted to review the manuscript, but the final decision on content was with the corresponding author in conjunction with the other authors
Notes	This study was funded by F. Hoffmann-La Roche LTD. An independent statistical review of the raw data was conducted by Department of Statistics at the British Columbia Children's Hospital Baseline and change data for diet, exercise and behaviour measures were not reported This paper presents a thorough report of the safety outcomes of using orlistat in an adolescent population (majority female) It is not completely clear how often (possibly each visit) or how much time was allocated to the various lifestyle interventions. It is unclear as to what extent parents were involved in supporting the intervention

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	The allocation process was triple-blind; the allotted treatment group was obtained through an automated telephone system

Maahs 2006

Methods	**Random allocation:** Telephone numbered, opaque sealed envelopes. The GCRC statistician generated the randomisation sequence before the start of the study. The list of randomisation assignments was sealed and sent to the study pharmacist, who had contact with the study subjects. Two sets of subjects (a sister-sister pair and a girlfriend-boyfriend pair) were assigned to the same cohort, as determined by the order of entry of the first member of the pair; the next paired subject was blocked into the same cohort and given the next available number in the cohort. **Blinding:** · **Children:** Yes. Study subjects, parents, and all study personnel were blinded to treatment condition. Only the research pharmacist was aware of treatment status. In addition, orlistat was placed within an opaque sealed capsule identical to the capsule used for placebo, which was filled with an inert substance. · **Providers:** Yes. Study subjects, parents, and all study personnel were blinded to treatment condition. Only the research pharmacist was aware of treatment status. · **Outcome assessors:** Yes **Length of intervention and follow up:** 26 weeks (all subjects were recruited between Dec 2002 and Feb 2003 and completed the trial by Sept 2003). Monthly visits to the outpatient clinic involved BMI assessment, dietary and exercise counselling, pill counting, and screening for adverse events. At the 3 and 6-month visits, a fasting blood sample was obtained for determination of the same variables at baseline, and BIA was repeated. Follow-up 26 weeks. **Unit of allocation:** Individual adolescents, although two sets of subjects (a sister-sister pair and a girlfriend-boyfriend pair) were assigned to the same cohort, as determined by the order of entry of the first member of the pair; the next paired subject was blocked into the same cohort and given the next available number in the cohort. **Unit of analysis:** Individual adolescents, although two sets of subjects (a sister-sister pair and a girlfriend-boyfriend pair) were assigned to the same cohort, as determined by the order of entry of the first member of the pair; the next paired subject was blocked into the same cohort and given the next available number in the cohort. **Protection against contamination:** Done. **Drop outs:** 15% [6/40] (intervention group 4, control group 2)
Participants	**n=** 40 **randomised**, 34 **completed** **Age range (mean): 14 to 18 years (**intervention group 15.8 $\pm$ 1.5, control group 15.8 $\pm$ 1.4) **% Male:** 32.5% **Weight entry criteria:** BMI > 85^{th} percentile for age and sex **Weight on entry (mean):** intervention group 111.1 $\pm$ 22.9 kg, control group 114.3 $\pm$ 38.4 kg **Setting:** Overnight inpatient stay for baseline measures, followed by monthly visits to the outpatient clinic for 6 months. The study was conducted in the General Clinical Research Center at the University of New Mexico Hospital. **Geographic Region:** Albuquerque, US
Interventions	**Intervention:** orlistat + diet & exercise therapy **Target of intervention:** Child. It is unclear to what extent parents were involved in supporting the intervention. **Behavioural or psychological component:** No. **Physical activity:** Subjects in both study groups received the same exercise counselling. During the inpatient stay subjects were instructed to increase activity by using a paediatric activity pyramid (Park Nicollet HealthSource, Minneapolis, MN) and encouraged to exercise at least 3 times per week for at least 30 minutes on each occasion. At each monthly follow-up visit, all subjects met with a dietitian to reinforce the exercise plan. **Nutritional advice:** Subjects in both study groups received the same dietary counselling. The goal

	caloric intake was calculated using the Harris-Benedict equation with ambulating activity factor. From this expected caloric need, we subtracted 500 calories to determine daily calorie level for weight loss for each subject. During the inpatient stay, the subjects were instructed to consume a low-fat (30%) exchange diet and were give weekly log sheets to complete. At each monthly follow-up visit, all subjects met with a dietitian to reinforce the low-fat diet. Additional log sheets and dietary. **Medication:** Orlistat (120 mg orally 3 times a day). All subjects received a multivitamin to be taken daily. **Other:** All subjects were reimbursed $20 per subject visit. Additionally, Subjects in both arms of the study were offered incentive pay of $10 per kilogram of weight lost at 6 months in comparison with baseline weight. The incentive payment was capped for a maximal weight loss of 10% **Usual care/ alternative intervention:** placebo + diet & exercise therapy **Target of intervention:** Child. It is unclear to what extent parents were involved in supporting the intervention. **Behavioural or psychological component:** No. **Physical activity:** As above. **Nutritional advice:** As above. **Medication:** Placebo (120 mg orally 3 times a day). The placebo capsule was filled with an inert substance. All subjects received a multivitamin to be taken daily. **Other:** As above.
Outcomes	Height, weight (mean kg $\pm$ SE), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness (BIA, BMI), behaviour changes (diet, exercise), Measures of self esteem, health status, QOL (*QOL questionnaires:* brief symptom inventory (Derogatis et al, 1983), Parents and Children's KINDL (Ravens-Sieberer et al, 2001), IWQOL-Kids (based on Impact of Weight on Quality of Life (Kolotkin et al, 1997 & 2001), Global Ratings scale (no other details given) + change in health status questionnaire), measures of harm (screening for adverse effects), laboratory measurements (fasting: serum glucose, serum free insulin, c-peptide, A1C, high sensitivity CRP, lipids, vitamin D (25-hydroxyvitamin D), vitamin A (retinol) & E (alpha-tocopherol)
Results	Mean change in BMI for orlistat versus placebo was -1.3 (1.6) kg/m^2 (p=0.04) versus -0.8 (3.0) kg/m^2 (p=0.02) at 6 months follow up. The differences between groups were not significant. Adverse GIT symptoms were more common in the orlistat group
Funding and financial disclosure	**Funding/Support:** This research was sponsored by grants from the University of New Mexico Department of Pediatrics Research Committee; the Research Allocation Committe, university of New Mexico; and the University of New Mexico GCRC (National Institutes of Health and National Center for Research Resources GCRC grant M01-RR00997) **Financial disclosure**: The authors state this is the first non-industry-sponsored, randomised, double-blind, placebo controlled trial of its kind
Notes	The authors state this is the first non-industry-sponsored, randomised, double-blind, placebo controlled trial of its kind. This research was sponsored by various grants from the University of New Mexico The financial incentive for weight loss may have ultimately influenced the success that the authors attribute to the diet and exercise intervention. This type of incentive may have promoted potentially unhealthy weigh loss practices prior to monthly weight assessments It is unclear to what extent parents were involved in supporting the intervention This independent study found no difference between the orlistat group and placebo group in

	terms of decreased levels of weight, BMI and body fat. Although, measures of diet and exercise change were not reported in this study the authors attribute weight and body fat loss in both groups to these lifestyle interventions. It is important to acknowledge that a modest financial reward was given to adolescents for weight loss and the effect of this intervention is unknown. This study highlights that there are many unpleasant GIT side-effects associated with orlistat use

Ozkan 2004

Methods	**Random allocation:** Yes. Allocation not concealed. Randomisation was done by alternation of successive patients, who met the inclusion criteria, to receive conventional treatment alone or orlistat in addition to conventional treatment. This study was a prospective, open-label, randomised, controlled pilot trial. However, it is also specified in the methods that the control group consisted of 20 obese patients matched for age, sex, pubertal stage and the degree of obesity?? **Blinding:** · **Children:** No. This was an open-label trial. · **Providers:** No. This was an open-label trial. · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** The duration of treatment is not exactly clear. The intervention group was followed for 5-15 months (average duration of treatment 11.7± 3.7 months). In the control group, duration of follow-up was 6-17 months; mean ± SD 10.2±3.7 months. **Unit of allocation:** Individuals **Unit of analysis:** Individuals **Protection against contamination:** Not done, also open label trial **Drop outs:** 29% [12/42] (intervention group 7, control group 5)
Participants	**n=** 42 **randomised**, 30 **completed** **Age range (mean):** 10 to 16 years (intervention group 12.9±2.4, control group 12.5±2.2) **% Male:** 33,3% (excludes dropouts) **Weight entry criteria:** Severe exogenous obesity, described as weight for height index >140% in otherwise healthy subjects, not associated with endocrinopathy, genetic syndromes or medications. **Weight on entry (mean):** Initial median BMI (kg/m^2) in intervention group: 32.5, in control group: 31.2 **Setting:** Outpatient clinic **Geographic Region:** Erzurum & Istanbul, Turkey
Interventions	**Intervention:** Conventional treatment (nutritional and lifestyle modification programmes) + 120 mg three times a day of orlistat **Target of intervention:** Not specified **Behavioural or psychological component:** No. A behavioural or psychological component was not specifically mentioned but it is possible this was part of the lifestyle modification program. **Physical activity:** The lifestyle modification programme promoted an increase in activity level throughout the study period (at least 30 minutes of moderate exercise per day). Lifestyle modification was reinforced at each visit. **Nutritional advice:** The lifestyle modification programme promoted a 20% reduction in daily calories calculated for age and sex throughout the study period. The subjects were seen by the dietitian monthly and in the outpatient clinic every 2 months. Lifestyle modification was reinforced at each visit.

	Medication: Orlistat (120 mg three times a day) and a daily multivitamin preparation. **Other:** No. **Usual care/ alternative intervention:** Conventional treatment: nutritional and lifestyle modification programmes **Target of intervention:** Not specified **Behavioural or psychological component:** As above. **Physical activity:** As above. **Nutritional advice:** As above. **Medication:** None, no placebo was given; this was an open label study. **Other:** No
Outcomes	Height (cm), weight (kg), BMI (kg/m^2), BMI change from baseline (kg/m^2), percentage change in initial weight change since baseline (%), measures of harm (side effects)
Results	There was a significant difference in change in BMI (initial BMI-final BMI) between the two groups. BMI decreased in the orlistat group by 4.09±2.9 kg/m^2 whereas it increased by +0.11±2.49 kg/m^2 in the control group (P<0.001) (Completers only). Approximately a third of participants in the intervention group (7/22) dropped out of intervention group within the first month of treatment due to GIT complaints attributable to orlistat and this calls into question the tolerability of the medication and implications for compliance
Funding and financial disclosure	**Funding/Support:** This work was supported by the Turkish Academy of Sciences within the framework of the Young Scientist Award program (EA/TUBA-GEBIP/2001-1-1)
Notes	When the authors state "The control group consisted of 20 obese patients matched for age, sex, pubertal stage and the degree of obesity" presumably the authors mean that post-randomisation the groups were similar in these characteristics. However, this is not quite true as the control group had a significantly lower median weight for height (%) and BMI at baseline There was scant reporting of participant demographic characteristics Compliance with orlistat was not assessed. Pathology data (including vitamin levels) and measures of dietary intake & physical activity were not reported Individual length of treatment, for non-drop outs, varied substantially from 5 to 17 months. However the mean length of treatment between groups was not significantly different The conventional treatment was of low intensity and parents rated compliance as poor-fair. The authors acknowledge in the discussion that a more vigorous and frequently monitored lifestyle intervention program could have resulted in better outcomes for both groups

Berkowitz 2003

Methods	**Random allocation:** No description of randomisation process **Blinding:** · **Children:** Yes · **Providers:** Yes · **Outcome assessors:** Unclear **Length of intervention and follow up:** 52 Weeks and 12 Months **Unit of allocation:** Individual adolescent **Unit of analysis:** Individual adolescent **Protection against contamination:** Done **Drop outs:** 10% [8/82] at 6 months (end of double-blind phase; n = 5 in Behavior therapy + placebo group and n = 3 in Behavior therapy + sibutramine group). At 12 months 15% [12/82] (n = 5 in Behavior therapy + placebo group and n = 7 in Behavior therapy + sibutramine group)
Participants	**n=** 82 **randomised**, 62 **completed** **Age range (mean)** 13-17 years (mean±SD 14.1±1.2 year) **% Male:** 33% **Weight entry criteria:** BMI of 32-44 **Weight on entry (mean):** mean (SD) 103.6 (15.4), BMI mean (SD) 37.8 (3.8) **Setting:** Conducted at the Weight and Eating Disorders Program at the University of Pennsylvania School of Medicine **Geographic Region:** Philadelphia, Pennsylvania, USA
Interventions	**Intervention:** Behavioral program + sibutramine **- Target of intervention:** family **- Behavioural or psychological component:** Comprehensive family-based behavioral weight loss (also described as a "therapeutic lifestyle change") program delivered following detailed treatment manuals. In phase 1 (first 6 months): 13 weekly group sessions followed by 6 biweekly group sessions. In phase 2 (second 6 months): group sessions held biweekly from months 7 to 9 and monthly from months 10 to 12. Parent group sessions held separately, but simultaneously, and on the same schedule as the adolescent group sessions. Parent sessions paralleled adolescents' session and used a companion protocol that was intended to promote parental behaviour changes and designed to enhance the adolescent's behavior change. ("Weight Reduction and Pride [WRAP] Program Parents' Edition" by Wadden & Berkowitz). Groups were led by dietitians, psychologists or psychiatrists. Diet and activity goals were set (see below). Participants were encouraged to self-monitor, through daily eating and activity logs, which were submitted at each session **- Physical activity:** Adolescents were prescribed an eventual goal of walking or engaging in similar aerobic activity for 120 minutes per week or more **- Nutrional advice:** Instructed to consume a 1200-1500 kcal/day diet of conventional foods, with approximately 30% from fat and 15% from protein, and the remainder from carbohydrate **- Medication:** During Phase 1 (first 6 months), all participants received placebo (single blind) for week 1. From week 2, for the rest of Phase 1, they were randomised to either placebo or 5 mg/day of sibutramine. In medication-treated participants, sibutramine was increased to 10mg/day at week 3, and to 15 mg/day at week 7. Both drug and placebo were supplied by Knoll Pharmaceutical Company and Abbott Laboratories. Placebo capsules looked exactly like sibutramine capsules and were dispensed in the same way. During Phase 2 (second 6 months), all participants were treated with sibutramine following the dose titration scheduled used in Phase 1 Participants whose systolic or diastolic blood pressure increased from baseline by 10 mm Hg or more (or who had increases in pulse rate $\geq$15%) for 2 or more consecutive visits had their medication dose reduced in 5 mg decrements until acceptable BP and pulse rate values were

	obtained. Sibutramine was discontinued if the dose reductions did not reverse the 10 mm Hg or more increase, or in whom systolic or diastolic BP increased 20 mm Hg or more at any single visit. **- Other:** No **Usual care/ alternative intervention:** Behavioural program + placebo **- Target of intervention:** family **- Behavioural or psychological component:** As above. **- Physical activity:** As above. **- Nutrional advice:** As above. **- Medication:** As above, but placebo. **- Other:** No
Outcomes	Height, weight, BMI, waist circumference; fasting blood tests (lipids, lipoproteins, insulin, glucose); systolic and diastolic BP and pulse rate; Eating Inventory (hunger); Maternal level of education; Medication adherence (by pill counts)
Results	Statistically significant differences between groups also were observed in changes in BMI z score at 6 months: −0.2 (0.2) for the Sibutramine group vs −0.1 (0.1) in the placebo group (p=0.003) . 19 of 43 participants experienced elevations in pulse rate and BP that required reductions in the dose of sibutramine, emphasising the need to monitor such patients carefully
Funding and financial disclosure	**Funding/Support**: This study was supported by grant DK054713 from the National Institutes of Health and grant M01-RR00240 from the General Clinical Research Center of The Children's Hospital of Philadelphia. Knoll Pharmaceutical Co and Abbott Laboratories provided an unrestricted educational grant that was used to support a postdoctoral fellow and several student research assistants. In addition, Knoll Pharmaceutical Co and Abbott Laboratories manufactured and provided both sibutramine and placebo for the study. **Financial disclosure**: Drs Berkowitz and Wadden have served as consultants to Knoll Pharmaceutical and Abbott Laboratories. Dr Wadden is on the speaker's bureau and has received honoraria from Abbott Laboratories. Drs Berkowitz, Wadden, and Tershakovec have received funding from Knoll Pharmaceutical and Abbott Laboratories **Role of Sponsor**: Neither Knoll Pharmaceutical Co nor Abbott Laboratories contributed to the design and conduct of the study, in the collection, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.
Notes	The Behavioral Therapy program was reasonably intensive and may not be equivalent to what is offered in usual weight management clinical practice.

Berkowitz 2006

Methods	**Random allocation:** yes, telephone numbered, opaque sealed envelopes **Blinding:** · **Children:** Yes · **Providers:** Yes · **Outcome assessors:** Unclear **Length of intervention and follow up:** 12 month intervention with major assessments performed at 3, 6, 9, and 12 months from baseline. **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Done. **Drop outs:** 28% [137/498] (intervention group: 87, control group: 50)
Participants	**n=** 498 **randomised**, 361 **completed** **Age range (mean):** 12-16 years (intervention group: 13.7 $\pm$ 1.3, control group: 13.6 $\pm$ 1.3) **% Male:** 35.7% (intervention group: 34.2%, control group: 38.5%) **Weight entry criteria:** BMI at least 2 units more than the US weighted mean of the 95^{th} percentile based on age and sex, and not more than 44 kg/m^2 **Weight on entry (mean):** intervention group: 97.9 kg ±14.7, control group: 97.8 kg ±14.6 **Setting:** 33 U.S weight loss clinics , outpatient clinic based in a University School of Medicine. **Geographic Region:** US
Interventions	**Intervention:** Behavioral program + sibutramine **Behavioural or psychological component:** A centre-specific behavior therapy program. Centers implemented flexible lifestyle modification approaches that were specific to the participant's needs. This included self-monitoring of eating habits and physical activity, stress management, stimulus control, problem solving, contingency management, cognitive restructuring and social support. **Physical activity:** Counselling at each visit promoted increased physical activity and reduced sedentary behaviours. **Nutrional advice:** Nutritional counselling encouraged development of healthy eating habits and promoted dietary consumption based on a 500 kcal/day deficit. **Medication:** Participants were randomised at baseline to receive either 10 mg sibutramine or placebo daily. At month 6, doses of all participants who had not lost more than 10% of their initial BMI were uptitrated (blinded) to 15mg sibutramine or placebo. Abbott (previously Knoll Pharmaceuticals) manufactured and provided all capsules. Placebo and sibutramine capsules appeared identical and were dispensed similarly Therapy was discontinued, or closely monitored, in participants whose systolic BP, diastolic BP or pulse rate increased at a single visit to more than 150 mm Hg or by more than 20 mm Hg, to 95 mm Hg or by more than 15 mm Hg, or to 110 beats per min or by more than 20 beats per min, respectively, until acceptable values returned. A protocol-driven algorithm was used for repeating visits or withdrawing participants whose values did not return to specified limits. In the case of intolerance, participants were to be withdrawn from the study **Other:** No **Usual care/ alternative intervention:** Behavioural program + placebo **Behavioural or psychological component:** As above. **Physical activity:** As above. **Nutrional advice:** As above. **Medication:** As above, but placebo. **Other:** No

Berkowitz 2006 (*Continued*)

Outcomes	Height (cm), weight (kg), BMI (%), Adverse events (%), body weight (%), waist circumference (cm), triglyceride level (*mmol/L, mg/dL),* HDL cholesterol level (*mmol/L, mg/dL),* insulin level (*pmol/L,* micro*U/mL).*
Results	At month 12, the estimated mean change in BMI for sibutramine plus behavior therapy was -3.1 kg/m^2 versus -0.3 kg/m^2 for placebo plus behavior therapy (difference, -2.9 kg/m^2 [95% CI, -3.5 to -2.2 kg/m^2]; P<0.001by linear mixed-effects model). The difference was statistically significant between treatment groups at all study visits, that is, week 1 (mean difference, -0.3 kg/m^2 [CI,-0.4 to -0.2 kg/m^2]; P<0.001) through month 12. Analysis based on last observation carried forward gave similar results at month 12; mean change in BMI for sibutramine versus placebo was -2.9 kg/m^2 versus -0.3 kg/m^2 (difference, -2.6 kg/m^2 [CI, -3.1 to -2.0 kg/m^2]; P<0.001). When BMI data were presented as the BMI Z score, a statistically significant treatment difference of 0.22 favored sibutramine (P<0.001)
Funding and financial disclosure	**Funding/Support**: Knoll Pharmaceuticals (BASF Pharma), now Abbott.
Notes	One of the first multi-center RCTs of sibutramine use in adolescents, with detailed safety monitoring. The use of center-specific behavioural programs, and the large number of centers (n=33) , emphasises the applicability of the findings of this study to a range of weight loss clinic settings that treat adolescents. The study findings cannot be extrapolated to less severely obese adolescents, to adolescents treated without the benefit of a behavioral therapy program, and for treatment periods longer than 12 months

Garcia-Morales 2006

Methods	**Random allocation:** Participants were block-randomized by using a computer generated list. All the materials for a patient were identified by the participant number. The placebo and drug capsules were identical in appearance and smell. The trial medications were prepared by one author (A.B.), who did not know the identity of the patients. Another author (L.M.G.-M.) received the trial materials without any knowledge of the procedures or order in the random number list. **Blinding:** · **Children:** Yes · **Providers:** Yes · **Outcome assessors:** Not clear, not specified. It is not clear which author collected the outcome measures. Note: The trial medications were prepared by one author (A.B.), who did not know the identity of the participants. Another author (L.M.G.-M.) received the trial materials without any knowledge of the procedures or order in the random number list. **Length of intervention and follow up:** 6 months with a run in period (duration not reported). The first patient entered the trial in August 2001 and the last participant finished the trial in August 2003. Monthly individual consultations with dietitian (nutrition advice) and endocrinologist (monitoring). Follow-up 6 months. Note: there was a run-in period **Unit of allocation:** Individuals **Unit of analysis:** Individuals **Protection against contamination:** N/A **Drop outs:** 22% [11/51] (intervention group 5, control group 6)

Participants	**n=** 51 **randomised**, 40 **completed** **Age range (mean): 14 to 18 years** (intervention group 15.2 (1.3) , control group 14.7 (1.1)) **% Male:** 43.48% (20/46, total not reported) **Weight entry criteria:** Sex-specific BMI for age and sex >95th percentile (obesity) **Weight on entry (mean):** Intervention group 92.6 (14.6) , control group 98.9 (22.7) **Setting:** Outpatients attending the Endocrinology Department of the Federico Gomez Children's Hospital of Mexico. **Geographic Region:** Mexico City, Mexico.
Interventions	**Intervention:** Sibutramine + diet + exercise **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** All participants were advised to perform at least 30 minutes of aerobic physical activity per day. Exercise advice was individually tailored for each patient. **Nutritional advice:** participants were advised to adopt a diet supplying 30 kcal/kg of the current body weight; 50% of the diet's energy was derived from carbohydrates, 30% from lipids, and 20% from proteins. All participants received a list of recommended food portions and possible combinations. Diet advice was individually tailored for each patient. participants received the dietetic advice 15 days before the beginning of the medications and dietetic supervision during the treatment phase of the trial each month. Each participant attended individual consultation sessions with a registered paediatric nutritionist. **Medication:** Sibutramine 10 mg QD **Other:** No **Usual care/ alternative intervention:** Placebo + diet + exercise **Target of intervention:** Child **Behavioural or psychological component:** No **Physical activity:** As above **Nutritional advice:** As above. **Medication:** Placebo 10 mg QD **Other:** No
Outcomes	Height (cm), weight (kg), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness, BMI (kg/$m^{2)}$, %BMI (% kg/$m^{2)}$, waist circumference (cm), % waist (% cm), behaviour changes (diet, exercise), measures of self esteem, health status, QOL (quality of life, 36-Item Short-Form Health Survey (SF-36) questionnaire), measures of harm (blood pressure, heart rate, and electrocardiograms), blood cytology, blood chemistry, and urinalysis, adverse events
Results	Mean change in BMI for sibutramine versus placebo was -3.4 (0.43) kg/m^2 versus -1.8 (0.43) kg/m^2 at 6 months follow up ($p<0.05$ intragroup for both, however, not significant between groups) (LOCF). Both treatments were effective to the same content
Funding and financial disclosure	**Funding/ support**: This trial was supported by Abbott Laboratories de Mexico, S.A. de C.V., Mexico City, D.E, Mexico. Dr. Berber was the medical manager of sibutramine in Mexico from 1995 to April 2004. The protocol was designed by all the authors; the study was conducted by the non-industry authors; and analysis and publication formalities were performed by Drs. Garcia-Morales, Del-Rio-Navarro, and Berber. The non-industry authors had access to all the data generated

Garcia-Morales 2006 (*Continued*)

Notes	Few demographic details are given about the participants and it is not known to what extent parents were involved in the lifestyle intervention The study has collected detailed data relating to the safety of sibutramine There was no follow up after the intervention ceased.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	Patients were block-randomized by using a computer generated list. All the materials for a patient were identified by the patient number. The placebo and drug capsules were identical in appearance and smell. The trial medications were prepared by one author (A.B.), who did not know the identity of the patients. Another author (L.M.G.-M.) received the trial materials without any knowledge of the procedures or order in the random number list

Godoy-Matos 2005

Methods	**Random allocation:** Yes. No description of randomisation process. This was the only information given on randomisation: "Subjects who completed the run-in period and returned less than 25% of the prescribed capsules were randomised to receive sibutramine (10 mg/d) or matching placebo capsules without regard to weight loss during the run-in period." **Blinding:** · **Children:** Yes. · **Providers:** Yes. · **Outcome assessors:** Not clear, not specified. The paper reports that a baseline echocardiogram was performed at visits 2 (week 0) and 8 (week 24) by an examiner who was blinded to group assignment. It is not clear whether the person collecting the primary and secondary outcomes was blinded to group allocation. **Length of intervention and follow up:** In the first month, all patients received placebo and a hypocaloric diet plus exercise orientation. For the next 6 months, participants received either sibutramine + diet + exercise or placebo + diet + exercise. Visits were scheduled for every 4 week; total 8 visits. These visits appeared to be for monitoring adverse events, drug compliance and conducting measurements. Follow-up 7 months (includes 1 month run-in period). **Unit of allocation:** Not specified **Unit of analysis:** Not specified **Protection against contamination:** Done. **Drop outs:** 17% [10/60] end of intervention and 6 months follow up.
Participants	**n=** 60 **randomised**, 50 **completed** **Age range (mean):** 14 to 17 years (Intervention group: females: 15.0 $\pm$ 1.1, males: 16.7 $\pm$ 0.6 control group: females: 16.3 $\pm$ 1.16, males: 16.7 $\pm$ 0.6) **% Male:** approximately 20% **Weight entry criteria:** BMI of 30-45

	Weight on entry (mean): Intervention group: females: 100.5 ± 14.2, males: 94.0 ± 13.6 control group: females: 117.1 ± 11.7, males: 113.4 ± 10.0 **Setting:** Regular clinical setting **Geographic Region:** Rio De Janeiro, Brazil
Interventions	**Intervention:** Sibutramine + hypocaloric diet + exercise **Target of intervention:** Not specified **Behavioural or psychological component:** No. Because this study was designed to reproduce a regular clinical setting practice, we did not use structured behavioral counselling. **Physical activity:** Physical activity instructions were delivered by the attendant doctor in a brief written protocol aimed to obtain mainly aerobic moderate exercises for at least 30 min/d. **Nutritional advice:** All patients received dietary counselling to achieve an energy deficit of 500 kcal/d at the start of the run-in phase. No additional visits to the dietitian were allowed. The recommended diet composition was approximately 30% from fat, 20% from protein, and 50% from carbohydrates. **Medication:** 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/d) or matching placebo capsules without regard to weight loss during the run-in period. Subjects were instructed to take their capsule in the morning. Knoll Pharmaceutical, subsequently Abbott Laboratories (Chicago, IL), provided and manufactured both placebo and sibutramine capsules. Visits were scheduled for every 4 weeks; subjects were attended by the same doctor throughout the study whenever possible. **Other:** No **Usual care/ alternative intervention:** Placebo + hypocaloric diet + exercise **Target of intervention:** Not specified **Behavioural or psychological component:** As above. **Physical activity:** As above. **Nutritional advice:** As above. **Medication:** As above, but placebo. **Other:** No
Outcomes	Height (m), weight & Weight Change (kg), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness: BMI (kg/m$^{2)}$, waist (cm), hip (cm), waist to hip ratio (ratio), measures of harm, adverse events, echocardiogram (cm or %), routine blood test (lipids, total Chol, HDL , LDL, TG, serum glucose, insulin), pregnancy test in females
Results	Mean change in BMI for sibutramine versus placebo was -3.6 (2.5) kg/m^2 versus -0.9 (0.9) kg/m ^{2} at 6 months follow up (P<0.001). Safety and tolerance of sibutramine was examined. There was no difference in the rate of adverse events examined between groups except constipation which was more prevalent in the sibutramine intervention group. No participants in either group withdrew because of an adverse event. No significant event (e.g. a serious adverse event or a rare event) was reported during the study
Funding and financial disclosure	**Funding/Support:** This work was supported by a grant from Abbott Laboratories
Notes	This work was supported by a grant from Abbott Laboratories. The role of the company in reviewing the results was not explained Few details were given about participant demographic characteristics, recruitment, randomisation process and sample size calculations

	It is not known to what extent parents were involved in the interventions Approximately 80% of participants were females. The reason for this is not explained and no comment is made about differences in outcomes by gender Mean weight loss in the 4 week run-in period in both groups was 2-3 kg, although it appears that the reported changes in parameters are those from 0-24 weeks only

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	No description of randomisation process.

Van Mil 2007

Methods	**Random allocation:** Knoll Pharmaceuticals BV[currently Abbott Laboratories (Hoofddorp, The Netherlands)], manufactured and provided code-numbered placebo and sibutramine capsules. Subjects received their trial and medication code according to order of entrance into the study, without stratification. **Blinding:** · **Children:** Yes. · **Providers:** Yes. · **Outcome assessors:** Not clear, not specified **Length of intervention and follow up:** 12 weeks treatment with sibutramine or placebo, and diet + exercise. Then 12 weeks follow up including continuation of diet + exercise but no medication. Follow-up 24 weeks. **Unit of allocation:** Child. The only details given about parental involvement was: the subjects with parent(s) were seen by the study dietician for dietary evaluation. The dietician reviewed the record with the parent(s) and subject and calculated the energy intake and macronutrients. **Unit of analysis:** Child. **Protection against contamination:** Done. **Drop outs:** 4% [1/24] end of intervention and 17% [4/24] at 6 months follow up (intervention group 1, control group 3)
Participants	**n=** 24 **randomised**, 20 **completed** **Age range (mean):** 12 to 18 years (intervention group 14.1, control group 13.8) **% Male:** 45.83% **Weight entry criteria:** BMI greater than or equal to the 97th percentile, and further selected for triceps skinfold thickness greater than or equal to the 97th. **Weight on entry (mean):** intervention group 80.8 (SD 15.6), control group 89.2 (SD 16.4) **Setting:** Out-patient clinic **Geographic Region:** Maastricht, The Netherlands
Interventions	**Intervention:** sibutramine (Meridia) in combination with an energy-restricted diet and exercise plan for 12 weeks, followed by an identical, but medication-free, treatment period (follow-up). **Target of intervention:** Child. The only details given about parental involvement was: the subjects with parent(s) were seen by the study dietician for dietary evaluation. The dietician reviewed the record with the parent(s) and subject and calculated the energy intake and macronutrients. **Behavioural or psychological component:** No

	Physical activity: Exercise Plan: In the first phase (12 weeks), physical activity was prescribed, based on individual preferences as well as information obtained by the activity questionnaire. The prescription contained a daily bout of exercise of at least 30 minutes of moderate to vigorous levels of exertions; however, the participants were encouraged to do more. Furthermore, emphasis was put on the implementation of additional physical activities, regardless of intensity, in the daily routine (14). The second phase consisted of a follow-up period of 12 week with continuation of the exercise plan. Throughout the study, the emphasis was put on lifestyle modification. **Nutritional advice:** Energy-restricted diet: In the first phase (12 weeks), dietary advice was based on energy requirements. The energy prescription was calculated from measured basal metabolic rate (BMR) multiplied by an estimated physical activity level (PAL) minus 500 kcal. The dietary intake could not be lower than 18-20 kcal per kilogram of ideal body weight with a minimum of 25% of calories provided by fat. The estimated PAL was determined using an activity questionnaire (13). The second phase consisted of a follow-up period of 12 week with continuation of the diet plan. Throughout the study, the emphasis was put on lifestyle modification. **Medication:** Study phase 1 (12 weeks): 5 mg sibutramine, taken once daily in the morning. After 2 weeks, the dose was increased to 10mg daily. Knoll Pharmaceuticals BV [currently Abbott Laboratories (Hoofddorp, The Netherlands)], manufactured and provided code-numbered placebo and sibutramine capsules. In the second study phase (12 weeks): consisted of a follow-up period of 12 week with continuation of the diet and exercise plan, however, without the study medication. Throughout the study, the emphasis was put on lifestyle modification. **Other:** No **Usual care/ alternative intervention:** placebo in combination with an energy-restricted diet and exercise plan for 12 week, followed by an identical, but medication-free, treatment period (follow-up). **Target of intervention:** As above. **Behavioural or psychological component:** No **Physical activity:** As above. **Nutritional advice:** As above. **Medication:** As above, but placebo. **Other:** No
Outcomes	Height (cm), weight (kg), estimates of % fat content e.g. BMI, ponderal index, skin-fold thickness (change in: BMI (kg/m^2), BMI-SDS, FFM (kg), FM (%), measures of harm (safety (blood pressure, heart rate, electrocardiographical changes)/adverse events), energy expenditure (change MJ/day: SMR, BMR, TEE, $BMR_{adj,}$ TEE $_{Res,}$ PAL was a ratio (i.e. TEE/BMR))
Results	After intervention, at three months, none of the changes in body composition were significantly different between the placebo and the sibutramine group; the decrease in BMI-SDS was comparable in both groups. During follow-up, BMI-SDS decreased in the placebo group and increased insignificantly in the sibutramine group, however the difference in change in BMI-SDS between both groups was not significant in intention-to-treat analysis. The cumulative change in BMI-SDS from baseline to end of follow up at 6 months was not reported. It is important to note that one participant dropped out of the sibutramine group because of symptoms of clinical depression. The sibutramine also had a significantly higher score of abdominal complaints. The authors did not specifically mention this but the table shows that 3 / 6 girls in the sibutramine group reported dysmenorrhoea
Funding and financial disclosure	**Funding/Support:** The primary author was previously employed on a research grant from Knoll (currently Abbott Pharmaceuticals)

	Financial disclosure: Disclosure Statement: K.R.W., A.D.M.K., H.A.D.-v.d.W., W.J.M.G., and W.H.M.S. have nothing to declare. E.G.A.H.V.M. was previously employed by Maastricht University, partly on a research grant from Knoll, currently Abbott Pharmaceuticals, The Netherlands
Notes	Compliance with the medication, diet and exercise regimes were not reported It is important to note that all participants had persisting obesity despite previous professionally supervised weight loss attempts. Therefore this group may have been particularly difficult to treat Duration of the medication intervention was relatively short (i.e. 2 weeks at 5 mg/day and 10 weeks at 10 mg/day) The cumulative change in BMI-SDS from baseline to end of follow up at 6 months was not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	Knoll Pharmaceuticals BV [currently Abbott Laboratories (Hoofddorp, The Netherlands)], manufactured and provided code-numbered placebo and sibutramine capsules. Subjects received their trial and medication code according to order of entrance into the study, without stratification

d: day; h: hour; sd: standard deviation; kcal: kilocalories; kj: kilojoules.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abu-Abeid 2003	Not a randomised controlled trial. Note: surgical intervention
Adamson 2004	Aim of the study was to prevent childhood obesity
Al-Qahtani 2007	Not a randomised controlled trial. Note: surgical intervention
Alexy 2006	Not a randomised controlled trial.
Allen 2005	Not relevant to question: aim to treat polycistic ovary syndrome
Ames 2005	Included participants other than children
Anand 2007	Aim of the study was to prevent childhood obesity

(*Continued*)

Anderson 1991	Not a randomised controlled trial. Included participants other than children. Aim of the study was other than to treat childhood obesity
Angrisani 2005	Not a randomised controlled trial. Note: surgical intervention
Annesi 2007	Aim of the study was to prevent childhood obesity
Balagopal 2005	Intervention plus follow up less than 6 months. Note: meeting abstracts to the same study are listed under this study as well
Ball 2000	Meeting abstract. Study not published.
Ball 2002	Not relevant for question; no intervention
Barnett 2005	Not a randomised controlled trial. Note: surgical intervention
Barnow 2003	Not a randomised controlled trial.
Bauer 2006	Included participants other than children
Becque 1988	Intervention plus follow up less than 6 months Aim of the study was other than to treat childhood obesity
Bialokoz-Kalinowska 2005	Not a randomised controlled trial.
Bonet 2007	Not a randomised controlled trial.
Braet 1997	Not a randomised controlled trial. Included participants other than children.
Braet 2003	Not a randomised controlled trial.
Brown 2007	Aim of the study was to prevent childhood obesity
Brownell 1983	This paper is pre- the 1985 search strategy criteria and so is not included. It is included in systematic review by Glenny 1997
Bustos 1997	Not a randomised controlled trial. Included participants other than children.
Cairella 1991	Not a randomised controlled trial. Included participants other than children. Aim of the study was other than to treat childhood obesity
Capella 2003	Not a randomised controlled trial. Note: surgical intervention

(*Continued*)

Carrasco 2007	Review type paper
Carrel 2007	Not relevant to question: aim to identify predictors of weightloss, succes, maintenance
Casado-Martinez 1993	Included participants other than children. Intervention plus follow up less than 6 months Aim of the study was other than to treat childhood obesity
Celio 2005	Intervention plus follow up less than 6 months.
Ceratti 1990	Not a randomised controlled trial.
Chang 2008	Not a randomised controlled trial. By their own choice, a considerate proportion (16%; 5/32) of participants were moved from control to intervention group
Chen 2001	Not a randomised controlled trial.
Coates 1982	This paper is pre- the 1985 search strategy criteria and so is not included. Not a randomised controlled trial
Collins 2007	Not a randomised controlled trial. Note: surgical intervention
Danielzik 2007	Aim of the study was to prevent childhood obesity
Davis 2006	Aim of the study was other than to treat childhood obesity
Davis 2007	Aim of the study was other than to treat childhood obesity
Deforche 2001	Not a randomised controlled trial.
Deforche 2005	Post-treatment maintenance.
DeJongh 2006	Aim of the study was to prevent childhood obesity
DeWolfe 1984	Included participants other than children Aim of the study was other than to treat childhood obesity This paper is pre- the 1985 search strategy criteria and so is not included. It is included in systematic review by Glenny 1997
Dillard 2007	Not a randomised controlled trial. Note: surgical intervention
Dolan 2003	Not a randomised controlled trial. Note: surgical intervention
Dolan 2004	Not a randomised controlled trial. Note: surgical intervention
Dreimane 2007	Not a randomised controlled trial.
Du 2002	Not relevant to question; alternative therapy

(*Continued*)

Dupuis 2000	Intervention plus follow up less than 6 months
Dämon 2005	Aim of the study was to prevent childhood obesity
Ebbeling 2006	Aim of the study was to prevent childhood obesity
Eliakim 2002	Not a randomised controlled trial.
Eliakim 2004	Not relevant to question: aim to identify predictors of weightloss, succes, maintenance. Not a randomsied controlled trial
Epstein 1984	This paper is pre- the 1985 search strategy criteria and so is not included. It is included in systematic review by Glenny 1997
Epstein 1990a	Intervention plus follow up less than 6 months Note in text as the paper is over 1 year follow up but does not present any 1 year data and the data would be pre search criteria
Epstein 1990b	Over 1 year follow up but does not present any 1 year data and the data would be pre search criteria anyway
Epstein 1994b	Not a randomised controlled trial. The paper is over 1 year follow up but does not present any 1 year data and the data were collected pre the 1985 search criteria anyway. This Paper is included in the Glenny 1997 systematic review
Epstein 1996	Not a randomised controlled trial.
Epstein 1997	Intervention plus follow up less than 6 months
Epstein 2001a	Not relevant to question; aim to treat eating disorders
Epstein 2001b	Review type paper
Epstein 2007	Review type paper
Epstein 2008b	Aim of the study was to prevent childhood obesity
Ezendam 2007	Aim of the study was to prevent childhood obesity
Faden 2004	Meeting abstract
Faith 2001	Intervention plus follow up less than 6 months
Fernandez-Paredes 1986	Not clear if study is a randomised controlled trial.
Fielding 2005	Not a randomised controlled trial. Note: surgical intervention

(*Continued*)

Figueroa-Colon 1993	Not a randomised controlled trial. Included participants other than children.
Figueroa-Colon 1996	Not a randomised controlled trial. Included participants other than children.
Foger 1993	Not a randomised controlled trial. Duration of follow up not clear
Foreyt 1991	Not clear if studiy is a randomised controlled trial. Included participants other than children. Aim of the study was other than to treat childhood obesity.
Foster 1985	Aim of the study was other than to treat childhood obesity.
Freemark 2000	Meeting abstract. Note: drug intervention.
Frenn 2005	Aim of the study was to prevent childhood obesity
Fu 2007	Not a randomised controlled trial.
Fullerton 2007	Dissertation abstract
Gale 2004	Review type paper
Gately 2007	Intervention plus follow up less than 6 months.
Germann 2006	Not a randomised controlled trial.
Gidding 2006	Aim of the study was to prevent childhood obesity
Goldfield 2000	Intervention plus follow up less than 6 months.
Goldfield 2006	Not relevant to question: aim to identify predictors of weightloss, succes, maintenance
Gottschalk 2007	Not relevant to question: aim to treat type 2 diabetes.
Graf 2005b	Not a randomised controlled trial.
Gutin 1995	Not a randomised controlled trial. Included participants other than children. Intervention plus follow up less than 6 months. Aim of the study was other than to treat childhood obesity.
Gutin 1996	Not a randomised controlled trial. Included participants other than children. Intervention plus follow up less than 6 months. Aim of the study was other than to treat childhood obesity.

(*Continued*)

Gutin 1999	Intervention plus follow up less than 6 months. NOTE: 7 papers are cited for this study, although a number of others (at least 5) were identified as also, probably, from the same study - n randomised varied slightly between studies
Hardin 1997	Not a randomised controlled trial. Included participants other than children. Intervention plus follow up less than 6 months. Aim of the study was other than to treat childhood obesity.
Harrell 1998	Intervention plus follow up less than 6 months
Haymond 2007	Not relevant to question: aim to treat type 2 diabetes
Herrera 2004	Not a randomised controlled trial.
Hoeger 2004	Not relevant to question: aim to treat polycistic ovary syndrome
Holterman 2007	Not a randomised controlled trial. Note: surgical intervention
Hope 2002	Dissertation abstract
Huang 2007	Aim of the study was to prevent childhood obesity
Ildik¢ 2007	Not a randomised controlled trial.
Inge 2004	Not a randomised controlled trial. Note: surgical intervention
Ippisch 2008	Not a randomised controlled trial. Note: surgical intervention
Jiang 1997	Not a randomised controlled trial. Included participants other than children.
Johnson 1997	Follow up data at 5 years was self reported.
Johnston 2004	Aim of the study was other than to treat childhood obesity
Jones 2002	Not relevant to question: aim to treat type 2 diabetes.
Kalarchian 2004	Meeting abstract
Kay 2001	Intervention plus follow up less than 6 months. Note: drug intervention
Lake 2007	Not a randomised controlled trial.
Lavine 2006	Not relevant to question: aim to treat fatty liver
Lawson 2006	Not a randomised controlled trial. Note: surgical intervention

(*Continued*)

Lazaar 2007	Aim of the study was to prevent childhood obesity
Le 2002	Not relevant to question: aim to identify predictors of weightloss, succes, maintenance
Libman 2006	Meeting abstract
Madan 2007	Not a randomised controlled trial. Note: surgical intervention
Maffeis 2007	Review type paper
Malecka-Tendera 1996	Intervention plus follow up less than 6 months.
McDuffie 2004	Not a randomised controlled trial. Note: drug intervention.
McGarvey 2004	Aim of the study was to prevent childhood obesity
Mo-suwan 1993	Not a randomised controlled trial. Included participants other than children.
Mohn 2005	Not a randomised controlled trial.
Mulkens 2007	Intervention plus follow up less than 6 months.
Munguba 2008	Not a randomised controlled trial.
Nadler 2007	Not a randomised controlled trial. Note: surgical intervention
Nuutinen 1992	Not a randomised controlled trial. Included participants other than children.
Ong 2007	Not relevant to question: aim to treat precocious pubarche
Pangrazi 2003	Aim of the study was to prevent childhood obesity
Papadia 2007	Not a randomised controlled trial. Note: surgical intervention
Patrick 2006	Aim of the study was to prevent childhood obesity
Peneau 2008	Not relevant to question: aim to identify predictors of weightloss, succes, maintenance
Rand 1994	Not a randomised controlled trial. Included participants other than children. Aim of the study was other than to treat childhood obesity.
Reinehr 2003	Not a randomised controlled trial.
Reinehr 2006	Not a randomised controlled trial.

(*Continued*)

Reybrouck 1990	Not a randomised controlled trial. Included participants other than children. Intervention plus follow up less than 6 months.
Roemmich 2004	Not a randomised controlled trial. Note: surgical intervention
Rudolf 2006	Not a randomised controlled trial.
Ryttig 1989	Included participants other than children. Aim of the study was other than to treat childhood obesity.
Savoye 2005	Not a randomised controlled trial.
Schwimmer 2005	Not a randomised controlled trial. Note: drug intervention.
Silberhumer 2006	Not a randomised controlled trial. Note: surgical intervention
Sothern 1993	Not a randomised controlled trial. Included participants other than children.
Stanford 2003	Not a randomised controlled trial. Note: surgical intervention
Stauber 2004	Intervention plus follow up less than 6 months.
Stein 2006	Not a randomised controlled trial.
Sternberg 2006	Not a randomised controlled trial.
Strauss 2001	Not a randomised controlled trial. Note: surgical intervention
Sugerman 2003	Not a randomised controlled trial. Note: surgical intervention
Sung 2002	Intervention plus follow up less than 6 months.
Suttapreyasri 1990	Not a randomised controlled trial. Included participants other than children.
Taitano 1998	Aim of the study was to prevent childhood obesity. Dissertation abstract
Tanas 2007	Not a randomised controlled trial.
Till 2008	Not relevant to question: technique description
Tsai 2007	Not a randomised controlled trial. Note: surgical intervention
Tsiros 2008	Intervention plus follow up less than 6 months.

(*Continued*)

Turabian 1989	Included participants other than children. Intervention plus follow up less than 6 months. Aim of the study was other than to treat childhood obesity.
Umbehr 2008	Aim of the study was to prevent childhood obesity
Van Dongen 1995	Aim of the study was other than to treat childhood obesity.
Van Egmond-Frohlich 2006	Posttreatment maintenance.
Vicente-Rodriguez 2007	Aim of the study was to prevent childhood obesity
Vido 1993	Intervention plus follow up less than 6 months.
Walker 2008	Dissertation abstract
Webb 2006	Review type paper
Weigel 2005	Meeting abstract
Widhalm 2004	Not a randomised controlled trial. Note: surgical intervention
Wilfley 2007	Posttreatment maintenance.
Willi 2004	Not relevant to question: aim to treat type 2 diabetes
Williamson 2007	Aim of the study was to prevent childhood obesity
Wrotniak 2004	Not relevant to question: aim to identify predictors of weightloss, succes, maintenance
Wunsch 2006	Not a randomised controlled trial.
Yitzhak 2006	Not a randomised controlled trial. Note: surgical intervention
Yoshinaga 2004	Not a randomised controlled trial.
Young-Hyman 2002	Aim of the study was to prevent childhood obesity
Yu 2005	Aim of the study was other than to treat childhood obesity

Criteria for study inclusion:
1) Is it an RCT?
2) Is it an RCT in children only?
3) Is the intervention plus follow-up 1 year or more? if not, 6 months or more?
4) Is the aim of the trial to TREAT childhood obesity?
Papers were excluded if pre 1985. This is because these papers were included in a systematic review by Glenny 1997.

Characteristics of ongoing studies *[ordered by study ID]*

Brennan 2008

Trial name or title	Motivational interviewing and cognitive behaviour therapy in the treatment of adolescent overweight and obesity: Study design and methodology
Methods	**Random allocation:** Participants were asked to select a number and this was used to randomly allocate all participants to the treatment or wait-list control condition **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Yes **Length of intervention and follow up:** The treatment phase consisted of 12 one-hour face-to-face sessions and one phone call session. The first ten treatment sessions were conducted weekly. The remaining sessions were conducted every second week.The maintenance phase consisted of two 1-hour maintenance clinic sessions and seven 15-minutes maintenance phone call sessions. Following the last treatment session, phone call sessions were completed every second week and a face-to-face session was scheduled three months after the last treatment session. This was followed by monthly phone call session and a final face-to-face session conducted six months after the last treatment sessions. Assessments were completed after the assessment interview and prior to randomisation, after the completion of the treatment phase of the intervention (or the end of wait-list), and after completion of the maintenance phase of the intervention (for those in the treatment condition) **Unit of allocation:** Child **Unit of analysis:** Child **Protection against contamination:** Unclear
Participants	**Participants** **n=** 63 **randomised** **Age range (mean):** 11.5 to 18.9 years (Mean(SD) = 14.3(SD)) **% Male:** 46% **Weight entry criteria:** Overweight or obese according to the international cut-off points for body mass index in children **Weight on entry (mean):** not reported **Setting:** Intervention and assessment sessions were conducted in the Psychology Clinics at RMIT University, Melbourne and Bundoora campuses. Physical assessments were conducted in the Exercise Physiology and Body Composition laboratories at RMIT University, Bundoora campus **Geographic Region:** Australia
Interventions	**Interventions:** Cognitive behavioural intervention vs wait-list control condition **Intervention:** Cognitive behavioural intervention **- Target of intervention:** child and parent **- Behavioural or psychological component:** The cognitive behavioural intervention, the CHOOSE HEALTH Program, consisted of 13 individual treatment sessions (12 face-to-face, 1 phone call) followed by 9 maintenance sessions (7 phone calls, 2 face-to-face). Each treatment session commenced with a review of the previous session and a discussion of homework, goal achievement and monitoring. The session material was then introduced with the opportunity for discussion, questions and practice of the strategies. Adolescents were encouraged to complete the exercises (e.g. identifying opportunities for physical activity, reading nutritional labels, problem solving) within the session and were then assisted to set their own goals (e.g. walk part of the way to school, read nutritional labels and select a low energy snack, use problem solving if exercise goals not

	achieved) regarding use of the strategies prior to the next session. Both parents and adolescents were required to attend the first six treatment sessions. Adolescents were then given the choice of attending the remaining sessions alone, or with the support of a parent. Sessios topics: Psycho-education, Eating behaviour, Physical Activity, Healthy food choices, Exercise, Behaviour charts and barriers, Recognising thoughts and emotions, Helpful thoughts and emotions, Assertive communication, Problem solving and planning, Staying on track, Maintaining change, Maintenance and closure **- Physical activity:** The physical activity component of the intervention aimed to promote physical activity habits consistent with the Australian physical activity guidelines for children and young people which recommends adolescents achieve at least 60 minutes of moderate to vigorous physical activity per day and spend no more than two hours per day in noneducational screen activities **- Nutrional advice:** The nutritional component of the intervention aimed to promote eating habits consistent with the Australian Guide to Healthy Eating which recommends the consumption of a variety of foods from each of the five food groups (cereals, vegetables, fruit, diary and meat products and alternatives), the selection of low-fat alternatives, and the consumption of water. **- Other:** No. **Usual care/ alternative intervention:** Wait-list control condition **- Target of intervention:** child and parent **- Overall:** Participants in the wait-list control did not receive any intervention
Outcomes	Improvement in body composition was the primary outcome; secondary outcomes included improved cardiovascular fitness, eating and physical activity habits, family and psychosocial functioning
Starting date	Not reported.
Contact information	Corresponding author: L. Brennan. Discipline of Exercise Sciences, RMIT University, PO Box 71, Bundoora Vic 3083, Australia. Tel.: +61 3 9925 6572;fax: +61 3 9467 8181. E-mail address: leah.brennan@rmit.edu.au
Notes	The first author was funded by a RMIT University Postgraduate Award and a VicHealth Postgraduate Scholarship. Supplementary funding was provided by the ATN Centre for Metabolic Fitness and the Parenting Research Centre

Janicke 2008

Trial name or title	Sensible Treatment of Obesity in Rural Youth (STORY): Design and methods
Methods	**Random allocation:** Method not described **Blinding:** · **Children:** No · **Providers:** No · **Outcome assessors:** Unclear **Length of intervention and follow up:** Intervention: 4 month. Follow-up: 10 month. **Unit of allocation:** Family **Unit of analysis:** Child and parent **Protection against contamination:** Unclear

Participants	**Participants** **n=** 90 **randomised** (sample size estimation) **Age range (mean):** 8-13 years **% Male:** not reported **Weight entry criteria:** Body mass index equal to or above the 85th percentile for age and gender **Weight on entry (mean):** not reported **Setting:** Assessment and intervention sessions will be held at Cooperative Extension offices within each local participating county **Geographic Region:** Four medically underserved rural counties in North Central Florida
Interventions	**Interventions:** Family-Based Behavioral Group Intervention vs Parent-Only Behavioral Group Intervention vs Waitlist control condition **Intervention:** Family-Based Behavioral Group Intervention **- Target of intervention:** family **- Behavioural or psychological component:** Parent-child dyads in the Family-Based intervention and parents in the Parent-Only intervention will participate in weekly sessions for the first 8 weeks, then 4 biweekly sessions over the next 8 weeks for a total of 12 sessions across 16 weeks. Each parent and child dyad will participate in simultaneous, but separate, parent and child groups. As both children and parents will be targeted as "active agents of change", the emphasis will be on modeling and providing support to work together to establish healthier eating and physical activity patterns. Each session will last 90 minutes. Both children and parents will be weighed every other group session to monitor weight status. During the parent group, the first portion of the meeting will involve a review of parent and child progress implementing the strategies developed for changing their eating or exercise habits during the previous session. Difficulties reported by the parents will be dealt with through group support and discussion. The second segment will focus on knowledge and skill training related to benefits of weight loss, basics of nutrition and the Stop-Light program, appropriate methods for increasing physical activity, behavior management, and positive parenting skills (e.g. goal setting, self-monitoring, stimulus control etc.). At the end of each session, children and parents will be brought together to develop specific goals, as well as plans to achieve these goals. The child group sessions will include four segments. Each session will begin with a review of the children's progress in completing their monitoring forms and achieving their dietary and physical activity goals. The second segment will use fun and educational activities to teach children about nutrition (e.g. recognizing calorie and fat content of foods via "signals" of the Stop-Light program), strategies to increase physical activity, behavioral management skills (selfmonitoring and goal settings), and strategies to cope with psychosocial concerns (i.e. building self-esteem). Third, all sessions will include a physical activity component to demonstrate strategies to help children keep physically active. This will include activities such as jumping rope, playing Frisbee, relay races, and participating in a mini-scavenger hunt. Finally, children will help prepare a healthy snack for taste testing during each session **- Physical activity:** Increased physical activity will be encouraged through a pedometer-based step program. Children and parents will be encouraged to monitor their physical activity and gradually increase their steps per day. Program goals will be based on their baseline level of steps and will target an increase of at least 3000 steps per day by the end of the program for both children and parents. Goals will be set for gradually decreasing sedentary activities so that children will spend no more than 2 h per day watching television or playing video games **- Nutrional advice:** Changes in dietary habits will be addressed via a modified version of the Stop-Light program. Child and parent participants will monitor everything they eat using a daily habit log. Daily dietary goals will be set each week, and will include limiting the consumption of high-fat/high-sugar "Red Foods" (with an absolute minimum goal of 2 red foods per day), and increasing fruit and vegetable intake. Children and adults will also be encouraged to eat a well-balanced diet based on the food guide pyramid **- Other:** No.

	Usual care/ alternative intervention: Parent-Only Behavioral Group Intervention **- Target of intervention:** parent **- Behavioural or psychological component:** As above. Only the participating parent(s) will attend weekly group meetings. Each session will last 90 minutes and will include three segments, similar to the parent group previously described in the Family-Based intervention. Each week group interventionists will model the goal setting process with parents and suggest a general range of dietary and physical activity targets that might be appropriate for each child and parent. Parents will then be instructed to meet with their child at home and work together to set individual, achievable goals based on the previous weeks' progress. Parents will participate in role-play activities to practice negotiation of goals with their child. As children will not attend group sessions, an emphasis will be placed on teaching parents how to work with their children to set goals together. Parents will be encouraged to utilize praise, incentives, and modeling to encourage participation and goal achievement. Parents will be provided handouts to guide them in discussing program material and setting weekly goals with their children. Parents will be weighed every other group session to monitor their weight status **- Physical activity:** Increased physical activity will be encouraged through a pedometer-based step program. Children and parents will be encouraged to monitor their physical activity and gradually increase their steps per day. Program goals will be based on their baseline level of steps and will target an increase of at least 3000 steps per day by the end of the program for both children and parents. Goals will be set for gradually decreasing sedentary activities so that children will spend no more than 2 h per day watching television or playing video games **- Nutrional advice:** Changes in dietary habits will be addressed via a modified version of the Stop-Light program. Child and parent participants will monitor everything they eat using a daily habit log. Daily dietary goals will be set each week, and will include limiting the consumption of high-fat/high-sugar "Red Foods" (with an absolute minimum goal of 2 red foods per day), and increasing fruit and vegetable intake. Children and adults will also be encouraged to eat a well-balanced diet based on the food guide pyramid **- Other:** No. **Usual care/ alternative intervention:** Waitlist control condition **- Target of intervention:** No intervention **- Overall:** Families assigned to the WLC condition will complete the assessment protocol at baseline, and at 4 and 10 months. After the follow-up period (month 10) families will be invited to participate in a 12-session behavioral-based intervention. No treatment will be delivered until after the final, 6-month follow-up assessment
Outcomes	Primary outcome measure is change in child body mass index (BMI) z-score. Additional key outcome measures include child dietary intake, physical activity, self-esteem, body image, and parent BMI
Starting date	Not reported
Contact information	Corresponding author: D.M. Janicke. Tel.: +1 352 273 6046; fax: +1 352 273 6156. E-mail address: djanicke@phhp.ufl.edu
Notes	The study is supported by a grant from the National Institute for Diabetes and Digestive and Kidney Diseases R34 DK071555-01. Additional supplemental funding for the preliminary pilot work for this study was supplied by the Institute for Child and Adolescent Research and Evaluation at the University of Florida

DATA AND ANALYSES

Comparison 1. Lifestyle interventions in children younger than 12 years

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in BMI-SDS at six months follow up	4	301	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.12, -0.01]
2 Change in BMI-SDS at twelve months follow up	3	264	Mean Difference (IV, Fixed, 95% CI)	-0.04 [-0.12, 0.04]

Comparison 2. Lifestyle interventions in children 12 years and older

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in BMI-SDS at six months follow up	3	291	Mean Difference (IV, Fixed, 95% CI)	-0.14 [-0.17, -0.12]
2 Change in BMI at six months follow up	4	362	Mean Difference (IV, Fixed, 95% CI)	-3.04 [-3.14, -2.94]
3 Change in BMI-SDS at twelve months follow up	2	231	Mean Difference (IV, Fixed, 95% CI)	-0.14 [-0.18, -0.10]
4 Change in BMI at twelve months follow up	2	231	Mean Difference (IV, Fixed, 95% CI)	-3.27 [-3.38, -3.17]

Comparison 3. Drug interventions with Orlistat in children 12 years and older

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in absolute BMI at six months follow up	2	579	Mean Difference (IV, Fixed, 95% CI)	-0.76 [-1.07, -0.44]

Comparison 4. Drug interventions with Sibutramine in children 12 years and older

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in absolute BMI at six months follow up	2	111	Mean Difference (IV, Fixed, 95% CI)	-1.66 [-1.89, -1.43]

Analysis 1.1. Comparison 1 Lifestyle interventions in children younger than 12 years, Outcome 1 Change in BMI-SDS at six months follow up.

Review: Interventions for treating obesity in children

Comparison: 1 Lifestyle interventions in children younger than 12 years

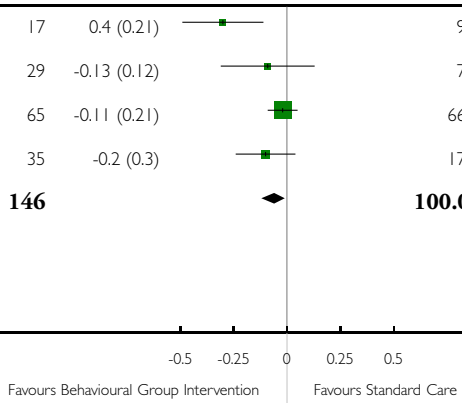
Outcome: 1 Change in BMI-SDS at six months follow up

Study or subgroup	Behavioural Group Intervention N	Mean(SD)	Standard Care N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Golan 2006	20	0.1 (0.37)	17	0.4 (0.21)		9.3 %	-0.30 [-0.49, -0.11]
Golley 2007	31	-0.22 (0.61)	29	-0.13 (0.12)		7.0 %	-0.09 [-0.31, 0.13]
Hughes 2008	69	-0.13 (0.21)	65	-0.11 (0.21)		66.6 %	-0.02 [-0.09, 0.05]
Kalavainen 2007	35	-0.3 (0.3)	35	-0.2 (0.3)		17.1 %	-0.10 [-0.24, 0.04]
Total (95% CI)	**155**		**146**			**100.0 %**	**-0.06 [-0.12, -0.01]**

Heterogeneity: Chi^2 = 7.68, df = 3 (P = 0.05); I^2 =61%

Test for overall effect: Z = 2.18 (P = 0.029)

Test for subgroup differences: Not applicable



Analysis 1.2. Comparison 1 Lifestyle interventions in children younger than 12 years, Outcome 2 Change in BMI-SDS at twelve months follow up.

Review: Interventions for treating obesity in children

Comparison: 1 Lifestyle interventions in children younger than 12 years

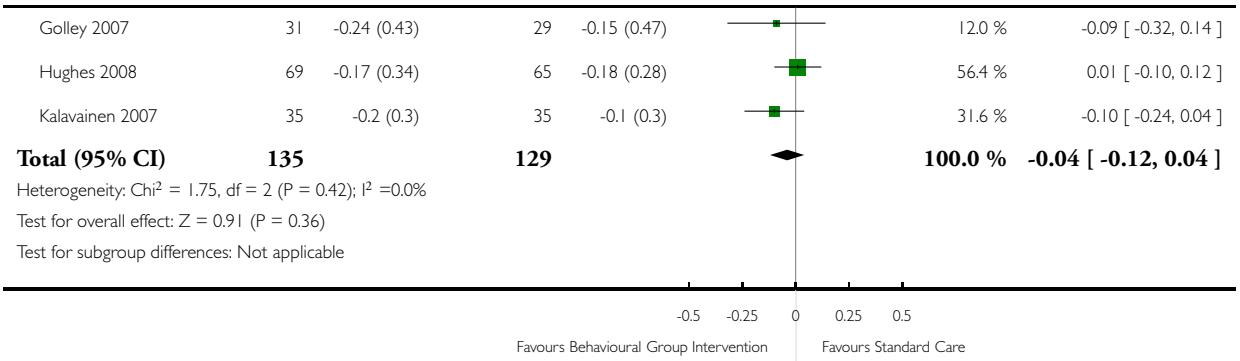
Outcome: 2 Change in BMI-SDS at twelve months follow up

Study or subgroup	Behavioural Group Intervention N	Mean(SD)	Standard Care N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Golley 2007	31	-0.24 (0.43)	29	-0.15 (0.47)		12.0 %	-0.09 [-0.32, 0.14]
Hughes 2008	69	-0.17 (0.34)	65	-0.18 (0.28)		56.4 %	0.01 [-0.10, 0.12]
Kalavainen 2007	35	-0.2 (0.3)	35	-0.1 (0.3)		31.6 %	-0.10 [-0.24, 0.04]
Total (95% CI)	**135**		**129**			**100.0 %**	**-0.04 [-0.12, 0.04]**

Heterogeneity: Chi^2 = 1.75, df = 2 (P = 0.42); I^2 =0.0%

Test for overall effect: Z = 0.91 (P = 0.36)

Test for subgroup differences: Not applicable



Analysis 2.1. Comparison 2 Lifestyle interventions in children 12 years and older, Outcome 1 Change in BMI-SDS at six months follow up.

Review: Interventions for treating obesity in children

Comparison: 2 Lifestyle interventions in children 12 years and older

Outcome: 1 Change in BMI-SDS at six months follow up

Study or subgroup	Behavioural Group Intervention N	Mean(SD)	Self Help or Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Johnston 2007b	40	-0.16 (0.14)	20	0.05 (0.06)		23.5 %	-0.21 [-0.26, -0.16]
Savoye 2007	105	-0.16 (0.18)	69	0.02 (0.06)		43.7 %	-0.18 [-0.22, -0.14]
Williamson 2005	28	-0.06 (0.1)	29	-0.01 (0.06)		32.8 %	-0.05 [-0.09, -0.01]
Total (95% CI)	**173**		**118**			**100.0 %**	**-0.14 [-0.17, -0.12]**

Heterogeneity: Chi^2 = 28.45, df = 2 (P<0.00001); I^2 =93%

Test for overall effect: Z = 11.51 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 2.2. Comparison 2 Lifestyle interventions in children 12 years and older, Outcome 2 Change in BMI at six months follow up.

Review: Interventions for treating obesity in children

Comparison: 2 Lifestyle interventions in children 12 years and older

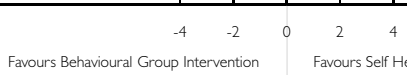
Outcome: 2 Change in BMI at six months follow up

Study or subgroup	Behavioural Group Intervention N	Mean(SD)	Self Help or Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Johnston 2007a	46	-0.16 (1.05)	25	0.64 (0.9)		4.3 %	-0.80 [-1.27, -0.33]
Johnston 2007b	40	-0.99 (3.79)	20	1.08 (1)		0.6 %	-2.07 [-3.32, -0.82]
Savoye 2007	105	-2.1 (0.28)	69	1.1 (0.36)		93.0 %	-3.20 [-3.30, -3.10]
Williamson 2005	28	-0.22 (1.36)	29	0.71 (1.19)		2.1 %	-0.93 [-1.59, -0.27]
Total (95% CI)	**219**		**143**			**100.0 %**	**-3.04 [-3.14, -2.94]**

Heterogeneity: Chi^2 = 139.82, df = 3 (P<0.00001); I^2 =98%

Test for overall effect: Z = 61.57 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 2.3. Comparison 2 Lifestyle interventions in children 12 years and older, Outcome 3 Change in BMI-SDS at twelve months follow up.

Review: Interventions for treating obesity in children

Comparison: 2 Lifestyle interventions in children 12 years and older

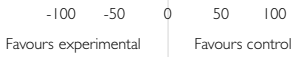
Outcome: 3 Change in BMI-SDS at twelve months follow up

Study or subgroup	Behavioural Group Intervention N	Mean(SD)	Self Help or Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Savoye 2007	105	-0.21 (0.24)	69	0 (0.11)		51.8 %	-0.21 [-0.26, -0.16]
Williamson 2005	28	-0.08 (0.11)	29	-0.02 (0.1)		48.2 %	-0.06 [-0.11, -0.01]
Total (95% CI)	**133**		**98**			**100.0 %**	**-0.14 [-0.18, -0.10]**

Heterogeneity: Chi² = 14.99, df = 1 (P = 0.00011); I² =93%

Test for overall effect: Z = 7.11 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 2.4. Comparison 2 Lifestyle interventions in children 12 years and older, Outcome 4 Change in BMI at twelve months follow up.

Review: Interventions for treating obesity in children

Comparison: 2 Lifestyle interventions in children 12 years and older

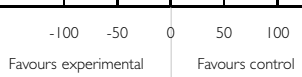
Outcome: 4 Change in BMI at twelve months follow up

Study or subgroup	Behavioural Group Intervention N	Mean(SD)	Self Help or Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Savoye 2007	105	-1.7 (0.31)	69	1.6 (0.38)		98.7 %	-3.30 [-3.41, -3.19]
Williamson 2005	28	0.11 (1.6)	29	1.47 (1.95)		1.3 %	-1.36 [-2.28, -0.44]
Total (95% CI)	**133**		**98**			**100.0 %**	**-3.27 [-3.38, -3.17]**

Heterogeneity: Chi² = 16.69, df = 1 (P = 0.00004); I² =94%

Test for overall effect: Z = 60.10 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 3.1. Comparison 3 Drug interventions with Orlistat in children 12 years and older, Outcome 1 Change in absolute BMI at six months follow up.

Review: Interventions for treating obesity in children

Comparison: 3 Drug interventions with Orlistat in children 12 years and older

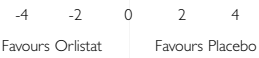
Outcome: 1 Change in absolute BMI at six months follow up

Study or subgroup	Orlistat N	Mean(SD)	Placebo N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Chanoine 2005	357	-1.08 (2.05)	182	-0.31 (1.68)		95.5 %	-0.77 [-1.09, -0.45]
Maahs 2006	20	-1.3 (1.6)	20	-0.8 (3)		4.5 %	-0.50 [-1.99, 0.99]
Total (95% CI)	**377**		**202**			**100.0 %**	**-0.76 [-1.07, -0.44]**

Heterogeneity: Chi^2 = 0.12, df = 1 (P = 0.73); I^2 =0.0%

Test for overall effect: Z = 4.70 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 4.1. Comparison 4 Drug interventions with Sibutramine in children 12 years and older, Outcome 1 Change in absolute BMI at six months follow up.

Review: Interventions for treating obesity in children

Comparison: 4 Drug interventions with Sibutramine in children 12 years and older

Outcome: 1 Change in absolute BMI at six months follow up

Study or subgroup	Sibutramine N	Mean(SD)	Placebo N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Garcia-Morales 2006	26	-3.4 (0.43)	25	-1.8 (0.43)		94.2 %	-1.60 [-1.84, -1.36]
Godoy-Matos 2005	30	-3.6 (2.5)	30	-0.9 (0.9)		5.8 %	-2.70 [-3.65, -1.75]
Total (95% CI)	**56**		**55**			**100.0 %**	**-1.66 [-1.89, -1.43]**

Heterogeneity: Chi² = 4.84, df = 1 (P = 0.03); I² =79%

Test for overall effect: Z = 14.23 (P < 0.00001)

Test for subgroup differences: Not applicable

APPENDICES

Appendix 1. 1999 search strategies

CENTRAL on The Cochrane Library (Issue 4, 1999)

#1 OBESITY*:ME
#2 OBESE
#3 OBESITY
#4 OVERWEIGHT
#5 ADIPOSITY
#6 OVEREATING
#7 OVERNUTRITION
#8 ADIPOSE-TISSUE*:ME
#9 ADIPOSE
#10 BODY-WEIGHT*:ME
#11 (WEIGHT near GAIN)
#12 (LEAN near WEIGHT)
#13 ((INCREASED or EXCESSIVE) near WEIGHT)
#14 (BODY next FAT)
#15 HYPERPHAGIA*:ME
#16 HYPERPHAGIA

#17 (EATING next HABIT)
#18 (BINGE next EATING)
#19 (EATING next DISORDER*)
#20 EATING-DISORDERS:ME
#21 APPETITE:ME
#22 APPETITE
#23 FEEDING-BEHAVIOR:ME
#24 (FEEDING next BEHAVIO*)
#25 (METABOLIC next SYNDROME)
#26 (((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10)
#27 (((((((((#11 or #12) or #13) or #14) or #15) or #16) or #17) or #18) or #19) or #20)
#28 ((((#21 or #22) or #23) or #24) or #25)
#29 ((#26 or #27) or #28)
#30 CHILD*:ME
#31 CHILD
#32 CHILDREN
#33 PAEDIATRIC*
#34 PEDIATRIC*
#35 ADOLESCEN*
#36 (((((#30 or #31) or #32) or #33) or #34) or #35)
#37 PONDERAL
#38 SKINFOLD-THICKNESS:ME
#39 SKINFOLD
#40 ((SKIN near FOLD) near THICKNESS)
#41 BODY-WEIGHT*:ME
#42 WEIGHT-LOSS*:ME
#43 BODY-MASS-INDEX:ME
#44 (WEIGHT next REDUCTION)
#45 (BODY next MASS)
#46 (BODY next WEIGHT)
#47 (BODY next (COMPOSITION or WEIGHT))
#48 ((WEIGHT or FAT) next (((LOSS or MAINENANCE) or CONTROL) or REDUCTION))
#49 (WEIGHT next (GAIN or CHANGE))
#50 ((FAT next FREE) next MASS)
#51 (WAIST near HIP)
#52 (WAIST next SIZE)
#53 (ABDOMEN near HIP)
#54 ((((((((((#37 or #38) or #39) or #40) or #41) or #42) or #43) or #44) or #45) or #46) or #47)
#55 (((((#48 or #49) or #50) or #51) or #52) or #53)
#56 (#54 or #55)
#57 FAMILY-THERAPY:ME
#58 BEHAVIOR-THERAPY*:ME
#59 (GROUP next THERAPY)
#60 (MEDICAL next SUPERVISION)
#61 (FAMILY next THERAPY)
#62 (BEHAVIOUR next THERAPY)
#63 (COGNITIVE next THERAPY)
#64 (BEHAVIOUR next MODIFICATION)
#65 (BEHAVIOR next MODIFICATION)
#66 (BEHAVIOR next THERAPY)
#67 (BEHAVIOUR next MODIFYING)
#68 (GROUP next INTERVENTION*)
#69 (GROUP next PROGRAM*)

#70 (INDIVIDUAL next INTERVENTION*)
#71 (INDIVIDUAL next PROGRAM*)
#72 (INDIVIDUAL next THERAP*)
#73 (POPULATION next INTERVENTION*)
#74 (POPULATION next PROGRAM*)
#75 (POPULATION next THERAP*)
#76 (COMMUNITY next INTERVENTION*)
#77 (COMMUNITY next PROGRAM*)
#78 (COMMUNITY next THERAP*)
#79 ((WEIGHT near REDUCING) near DIET)
#80 (DIETARY near COMPOSITION)
#81 (LOW next CALOR*)
#82 (LOW next FAT)
#83 (CALOR* next RESTRICT*)
#84 (FOOD next DEPRIVAT*)
#85 (DIET near RESTRICT*)
#86 (FAT near RESTRICT*)
#87 (DIET next THERAP*)
#88 (HIGH next (FIBER next DIET))
#89 (HIGH next (FIBRE next DIET))
#90 DIET-THERAPY*:ME
#91 (DIABETIC next DIET)
#92 SLIMMING
#93 (WEIGHT next WATCHERS)
#94 (CORRESPONDENCE next PROGRAMME)
#95 EXERCISE*:ME
#96 (PHYSICAL next ACTIVITY)
#97 FASTING
#98 EXERCISE
#99 (PRIMARY next PREVENTION)
#100 (SECONDARY next PREVENTION)
#101 HEALTH-EDUCATION*:ME
#102 (HEALTH next EDUCATION)
#103 (FOOD next POLIC*)
#104 (NUTRITION* next POLIC*)
#105 (SCHOOL next (HEALTH next SERVICE))
#106 (HEALTH next PROTECTION)
#107 (HEALTH next PROMOTION)
#108 PROPHYLAXIS
#109 (SCHOOL next PROGRAM*)
#110 ALTERNATIVE-MEDICINE*:ME
#111 (COMPLEMENTARY next MEDICINE)
#112 (ALTERNATIVE next MEDICINE)
#113 (COMPLEMENTARY next THERAP*)
#114 ACUPUNCTURE
#115 HOMEOPATHY
#116 HYPNOSIS
#117 (HERBAL next MEDICINE)
#118 (CHINESE next DRUG)
#119 ANOREXIGENIC
#120 (SEROTONIN next AGONIST)
#121 (APPETITE next SUPPRESSANT*)
#122 (APPETITE next DEPRESSANT*)

#123 (BULKING next AGENT)
#124 FLUOXETINE
#125 (((((((#57 or #58) or #59) or #60) or #61) or #62) or #63) or #64) or #65)
#126 (((((((((#66 or #67) or #68) or #69) or #70) or #71) or #72) or #73) or #74) or #75)
#127 (((((((((#76 or #77) or #78) or #79) or #80) or #81) or #82) or #83) or #84) or #85)
#128 (((((((((#86 or #87) or #88) or #89) or #90) or #91) or #92) or #93) or #94) or #95)
#129 (((((((((#96 or #97) or #98) or #99) or #100) or #101) or #102) or #103) or #104) or #105)
#130 (((((((((#106 or #107) or #108) or #109) or #110) or #111) or #112) or #113) or #114) or #115)
#131 (((((((#116 or #117) or #118) or #119) or #120) or #121) or #122) or #123) or #124)
#132 ((((((#125 or #126) or #127) or #128) or #129) or #130) or #131)
#133 (ANOREXIA or BULIMIA)
#134 (#29 and #56)
#135 (#134 and #132)
#136 (#135 and #36)
#137 (#136 not #133)

MEDLINE

1 randomized controlled trial.pt.
2 randomized controlled trials/
3 random allocation/
4 double-blind method/
5 single-blind method/
6 clinical trial.pt.
7 exp clinical trials/
8 (clinical$ adj5 trial$).tw.
9 ((singl$ or doubl$ or trebl or tripl$) adj5 (blind$ or mask)).mp. [mp=title, abstract, registry number word, mesh subject heading]
10 placebos/
11 (placebo$ or random$).tw.
12 research design/
13 comparative study/
14 exp evaluation studies/
15 follow-up studies/
16 prospective studies/
17 (animal not (human and animal)).ti,ab,sh.
18 *obesity/
19 *obesity,morbid/
20 *pickwickian syndrome/
21 *prader-willi syndrome/
22 *weight gain/
23 obesity.ti.
24 obese.ti.
25 overweight.ti.
26 hyperphagia/
27 *bulimia/
28 or/18-27
29 or/1-16
30 29 and 28
31 30 not 17
32 exp behavior therapy/
33 (behavior adj (therapy or modification)).tw.
34 exp appetite depressants/
35 (appetite adj (suppressant? or depressant)).tw.

36 diet, fat-restricted/
37 diet, reducing/
38 (dieting or (low adj calorie) or diet?).tw.
39 food deprivation/
40 (food adj3 (deprivation or depriving)).tw.
41 exercise/
42 exercise therapy/
43 exertion/
44 (exercise or (physical adj therapy) or fitness).tw.
45 fasting/
46 fasting.tw.
47 (jaw adj3 (wiring or wired)).tw.
48 surgical staplers/
49 surgical stapling/
50 (stomach adj2 (stapling or banding or bypass)).ti,ab,sh.
51 gastric bypass/
52 (gastric adj bypass).tw.
53 health promotion/
54 health education/
55 (prevent or prevention of preventing).tw.
56 nutrition policy/
57 (food adj policy).tw.
58 food habits/ and health policy/
59 (program or programs or programme$ or intervention$).tw.
60 lipectomy/
61 liposuction.tw.
62 (guar adj gum).ti,ab,sh.
63 exp alternative medicine/
64 (acupuncture or hypnotism).tw.
65 advertising/
66 ((diet or dieting or slimming) adj club?).tw.
67 weightwatcher?.tw.
68 or/32-67
69 31 and 68
70 limit 69 to (newborn infant < birth to 1 month > or infant< 1 to 23 months > or preschool child < 2 to 5 years > or child < 6 to 12 years > or adolescence < 13 to 18 years >)

EMBASE

1 exp Obesity/
2 Overnutrition/
3 (obese or obesity or overweight or adiposity or
overeating).tw.
4 exp adipose tissue/
5 "weight gain".tw.
6 Lean body weight/
7 ((increased or excessive) adj weight).tw.
8 Body weight/
9 Body fat/
10 Hyperphagia/
11 hyperphagia.tw.
12 Eating habit/
13 (binge adj eating).tw.

14 (eating adj disorder$).tw.
15 Appetite/
16 Feeding behavior/
17 (metabolic adj syndrome).tw.
18 1 or 2 or 3 or 4 or 5 or 6
19 7 or 8 or 9 or 10 or 11 or 12
20 13 or 14 or 15 or 16 or 17
21 18 or 19 or 20
22 Randomized controlled trial/
23 Double blind procedure/
24 Single blind procedure/
25 Crossover procedure/
26 Multicenter study/
27 Clinical trial/
28 Meta analysis/
29 Controlled study/
30 ((intervention or clinical) adj (trial$ or stud$)).tw.
31 (random$ or placebo$).tw.
32 (control$ adj (trial$ or stud$ or group$)).tw.
33 22 or 23 or 24 or 25 or 26
34 27 or 28 or 29 or 30 or 31 or 32
35 33 or 34
36 Group therapy/
37 (medical adj supervision).tw.
38 ((group or individual or population or community) adj (intervention$ or program$ or therap$)).tw.
39 (unsupervised adj (intervention$ or program$)).tw.
40 Family therapy/
41 (family adj (therap$ or program$ or intervention$)).tw.
42 Behavior modification/
43 ((behaviour or behavior) adj (modification or modify)).tw.
44 Behavior therapy/
45 Cognitive therapy/
46 "weight reducing diet".tw.
47 "dietary composition".tw.
48 Low calory diet/
49 "low fat diet".tw.
50 Caloric restriction/
51 Food deprivation/
52 (food adj (deprivation or depriving)).tw.
53 Diet/
54 Diet restriction/
55 "fat restrict$".tw.
56 Diet therapy/
57 High fiber diet/
58 Diabetic diet/
59 ((slim or slimming) adj (plan$ or organisation$ or regimen$ or program$)).tw.
60 (weight adj watchers).tw.
61 (correspondence adj program$).tw.
62 Exercise/
63 Physical activity/
64 "fasting".tw.
65 Primary prevention/
66 Secondary prevention/

67 ((primary or secondary) adj prevention).tw.
68 exp health education/
69 ((food or nutrition$) adj polic$).tw.
70 School health service/
71 (health adj (protection or promotion or education)).tw.
72 Prophylaxis/
73 (school adj program$).tw.
74 exp alternative medicine/
75 (acupuncture or hypnotherapy or homeopathy or hypnotism or hypnosis).tw.
76 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45
77 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 55
78 56 or 57 or 58 or 59 60.mp. or 61 or 62 or 63 or 64 or 65 [mp=title, abstract, heading word, trade name, manufacturer name]
79 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75
80 76 or 77 or 78 or 79
81 Child/
82 School child/
83 child$.tw.
84 Adolescence/
85 adolescen$.tw.
86 81 or 82 or 83 or 84 or 85
87 21 and 35
88 87 and 86
89 88 and 80

CINAHL

1 randomised controlled trial.pt.
2 randomised controlled trials/
3 random allocation/
4 double-blind method/
5 single-blind method/
6 clinical trial.pt.
7 exp clinical trials/
8 (clinical$ adj5 trial$).tw.
9 ((singl$ or doubl$ or trebl or tripl$) adj5 (blind$ or mask)).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
10 placebos/
11 (placebo$ or random$).tw.
12 research design/
13 comparative study/
14 exp evaluation studies/
15 follow-up studies/
16 prospective studies/
17 (animal not (human and animal)).ti,ab,sh.
18 *obesity/
19 *obesity, morbid/
20 *pickwickian syndrome/
21 *prader-willi syndrome/
22 *weight gain/
23 obesity.ti.
24 obese.ti.
25 overweight.ti.
26 hyperphagia/
27 *bulimia/

28 or/18-27
29 or/1-16
30 29 and 28
31 30 not 17
32 exp behavior therapy/
33 (behavior adj (therapy or modification)).tw.
34 exp appetite depressants/
35 (appetite adj (suppressant? or depressant)).tw.
36 diet, fat-restricted/
37 diet, reducing/
38 (dieting or (low adj calorie) or diet?).tw.
39 food deprivation/
40 (food adj3 (deprivation or depriving)).tw.
41 exercise/
42 exercise therapy/
43 exertion/
44 (exercise or (physical adj therapy) or fitness).tw.
45 fasting/
46 fasting.tw.
47 (jaw adj3 (wiring or wired)).tw.
48 surgical staplers/
49 surgical stapling/
50 (stomach adj2 (stapling or banding or bypass)).ti,ab,sh.
51 gastric bypass/
52 (gastric adj bypass).tw.
53 health promotion/
54 health education/
55 (prevent or prevention of preventing).tw.
56 nutrition policy/
57 (food adj policy).tw.
58 food habits/ and health policy/
59 (program or programs or programme$ or intervention$).tw.
60 lipectomy/
61 liposuction.tw.
62 (guar adj gum).ti,ab,sh
63 exp alternative medicine/
64 (acupuncture or hypnotism).tw.
65 advertising/
66 ((diet or dieting or slimming) adj club?).tw.
67 weightwatcher?.tw.
68 or/32-67
69 31 and 68
70 limit 69 to (newborn infant < birth to 1 month > or infant < 1 to 23 months > or preschool child < 2 to 5 years > or child < 6 to 12 years > or adolescence < 13 to 18 years >)

PsycLit

1 explode ”Obesity“
2 overweight*
3 hyperphagia
4 weight
5 loss
6 reduc*

7 weight near (loss or reduc*)
8 adipos*
9 "Hyperphagia-" in DE
10 appetite
11 disorder*
12 appetite near disorder*
13 #1 or #2 or #3 or #7 or #8 or #9 or #12
14 explode "Food-Intake"
15 "Dietary-Restraint" in DE
16 dietary
17 dieting
18 weight
19 loss
20 reduc*
21 weight with (loss or reduc*)
22 weight
23 control
24 maintenance
25 weight with (control or maintenance)
26 fat
27 reduced
28 fat with reduced
29 "Weight-Control" in DE
30 weight
31 management
32 managing
33 manage
34 weight with (management or managing or manage)
35 explode "Behavior-Therapy"
36 "Behavior-Change" in DE
37 explode "Family-Therapy"
38 "Physical-Fitness" in DE
39 explode "Exercise"
40 explode "Self-Management"
41 "Individual-Psychotherapy" in DE
42 "Group-Psychotherapy" in DE
43 #14 or #15 or #16 or #17 or #21 or #25 or #28 or #29 or #34
44 #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42
45 #43 or #44
46 "Followup-Studies" in DE
47 "Random-Sampling" in DE
48 random*
49 trial
50 random* near trial
51 crossover
52 "Experiment-Controls" in DE
53 followups
54 trial
55 trials
56 #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55
57 #13 and #56
58 explode "Children"
59 "Adolescents-" in DE

60 #58 or #59
61 #57 and #60
62 adolescence
63 #60 or #62
64 children
65 #63 or #64

Science and Social Science Citation Indexes

1 (obesity,obese,overweight,adiposity,overeating,overnutrition)
2 (adipose//tissue,weight//gain,body//weight)
3 (increased//weight,excessive//weight,body//fat,hyperphagia)
4 (binge//eating,eating//disorder*,appetite,metabolic//syndrome)
5 #1 or #2 or #3 or #4
6 (child,children,adolescen*)
7 (intervention,interventions,program*,therap*)
8 (medical//supervision)
9 ((behaviour,behavior) +modification)
10 (diet,diets,dieting,low//calorie,food/2/depriv*,slimming,fat//restrict*)
11 (high//fibre,high//fiber,weight//watchers,correspondence,exercise,physical//activit)
12 (fasting,prevention,preventative,health//education,food//policy,nutritional//policy)
13 (schools,school,health//promotion,prophylaxis)
14 (alternative//medicine,alternative//therap*,acupuncture)
15 (hypnotherapy,hypnosis,homeopath*,hypnotism)
16 #7 or #8 or #9 or #10 or #11 or # 12 or #13 or #14 or #15
17 (rats,rat,mice,mouse,hamster*,porcine,murine)
18 (ponderal//index,skinfold//thickness,skin//fold,weight)
19 (weight//reduction,body//mass,body//weight,body//composition)
20 (weight//loss,weight//maintenance,weight//control,weight//reduction)
21 (fat//loss,fat//control,fat//reduction,weight//change,weight//gain)
22 (fat//free,waist//hip,waist//size,abdomen//hip)
23 #18 or #19 or #20 or #21 or #22
24(random*,trial*,double//blind,single//blind,study,control,control//group*,controls,controlled,placaebo*)
25 (#5 and #6) not #17
26 (anorexia,bulemia)
27 (#25 and #16 and #23 and #24) not #26

Appendix 2. 2001 search strategies

CCTR

1 obesity*:me
2 weight-gain:me
3 weight-loss:me
4 obese or obesity
5 weight next gain or weight next loss
6 overweight or over next weight or overeat* or over next eat*
7 weight next change*
8 (bmi or body next mass next index) near (gain or loss or change)
9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
10 child:me

11 adolescence:me
12 child-preschool:me
13 infant:me
14 child* or adolescen* or infant*
15 teenage* or young next people or young next adult* or young next person
16 schoolchildren or school next children
17 paediatr* or pediatr*
18 boys or girls or youth or youths
19 #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
20 #9 and #19

MEDLINE

2explode "Obesity"/ all subheadings
3"Weight-Gain"/ all subheadings "Weight-Loss"/ all subheadings
4obesity or obese
5weight gain or weight loss
6overweight or over weight or overeat* or over eat*
7weight change*
8(bmi or body mass index) near2 (gain or loss or change)
9#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
10"Child-" in MIME,MJME
11"Adolescence"/ all subheadings
12"Child-Preschool"/ all subheadings
13"Infant-" in MIME,MJME
14child* or adolescen* or infant*
15teenage* or young people or young person or young adult*
16schoolchildren or school children
17p?ediatr* in ti,ab
18boys or girls or youth or youths
19#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
20explode "Behavior-Therapy"/ all subheadings
21"Social-Support" in MIME,MJME
22"Family-Therapy"/ all subheadings
23explode "Psychotherapy-Group"/ all subheadings
24(psychological or behavio?r*) adj (therapy or modif* or strateg* or intervention*)
25group therapy or family therapy or cognitive therapy
26(lifestyle or life style) adj (chang* or intervention*)
27counsel?ing
28social support
29peer near2 support
30(children near3 parent?) near therapy
31#20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30
32explode "Obesity"/ drug-therapy
33explode "Anti-Obesity-Agents"/ all subheadings
34lipase inhibitor*
35orlistat or xenical or tetrahydrolipstatin
36appetite adj (suppressant* or depressant*)
37sibutramine or (meridia in ti,ab)
38dexfenfluramine or fenfluramine or phentermine
39bulking agent*
40methylcellulose or celevac
41(antiobesity or anti obesity) adj (drug* or agent*)

42guar gum
43#32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42
44explode "Obesity"/ diet-therapy
45"Diet-Fat-Restricted"/ all subheadings
46"Diet-Reducing"/ all subheadings
47"Diet-Therapy"/ all subheadings
48"Fasting"/ all subheadings
49diet or diets or dieting
50diet* adj (modif* or therapy or intervention* or strateg*)
51low calorie or calorie control* or healthy eating
52fasting or modified fast*
53explode "Dietary-Fats"/ all subheadings
54fruit or vegetable*
55high fat* or low fat* or fatty food*
56formula diet*
57#44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56
58"Exercise"/ all subheadings
59"Exercise-Therapy"/ all subheadings
60exercis*
61aerobics or physical therapy or physical activity or physical inactivity
62fitness adj (class* or regime* or program*)
63aerobics or physical therapy or physical training or physical education
64dance therapy
65sedentary behavio?r reduction
66#58 or #59 or #60 or #61 or #62 or #63 or #64 or #65
67explode "Obesity"/ surgery
68"Surgical-Staplers"/ all subheadings
69"Surgical-Stapling"/ all subheadings
70"Lipectomy"/ all subheadings
71"Gastric-Bypass"/ all subheadings
72"Gastroplasty"/ all subheadings
73dental splinting or jaw wiring
74gastroplasty or gastric band* or gastric bypass
75intragastric balloon* or vertical band*
76stomach adj (stapl* or band* or bypass)
77liposuction
78#67 or #68 or #69 or #70 or #71 or #72 or #73 or #74 or #75 or #76 or #77
79explode "Alternative-Medicine"/ all subheadings
80alternative medicine or complementary therap* or complementary medicine
81hypnotism or hypnosis or hypnotherapy
82acupuncture or homeopathy or homoeopathy
83chinese medicine or indian medicine or herbal medicine or ayurvedic
84#79 or #80 or #81 or #82 or #83
85(diet or dieting or slim*) adj (club* or organi?ation*)
86weightwatcher* or weight watcher*
87correspondence adj (course* or program*)
88fat camp* or diet* camp*
89#85 or #86 or #87 or #88
90"Health-Promotion"/ all subheadings
91"Health-Education"/ all subheadings
92health promotion or health education
93media intervention* or community intervention*
94health promoting school*

95(school* near2 program*) or (community near2 program*)
96family intervention* or parent* intervention*
97parent* near2 (behavio?r or involve* or control* or attitude* or educat*)
98#90 or #91 or #92 or #93 or #94 or #95 or #96 or #97
99"Health-Policy"/ all subheadings
100"Nutrition-Policy"/ all subheadings
101health polic* or school polic* or food polic* or nutrition polic*
102#99 or #100 or #101
103explode "Obesity"/ prevention-and-control
104"Primary-Prevention"/ all subheadings
105primary prevention or secondary prevention
106preventive measure* or preventative measure*
107preventive care or preventative care
108obesity near2 (prevent* or treat*)
109#103 or #104 or #105 or #106 or #107 or #108
110explode "Controlled-Clinical-Trials"/ all subheadings
111"Random-Allocation" in MIME,MJME
112"Double-Blind-Method" in MIME,MJME
113"Single-Blind-Method" in MIME,MJME
114"Placebos"/ all subheadings
115explode "Research-Design"/ all subheadings
116(singl* or doubl* or trebl* or tripl*) near5 (blind* or mask*)
117exact{CONTROLLED-CLINICAL-TRIAL} in PT
118placebo*
119matched communities or matched schools or matched populations
120control* near (trial* or stud* or evaluation* or experiment*)
121comparison group* or control group*
122matched pairs
123outcome study or outcome studies
124quasiexperimental or quasi experimental or pseudo experimental
125nonrandomi?ed or non randomi?ed or pseudo randomi?ed
126#110 or #111 or #112 or #113 or #114 or #115 or #116 or #117 or #118 or #119 or #120 or #121 or #122 or #123 or #124 or #125
127#9 and #19
128#31 or #43 or #57 or #66 or #78 or #84 or #89 or #98 or #102 or #109
129#126 and #127 and #128
130animal in tg
131human in tg
132#130 not (#130 and #131)
133#129 not #132
134#133 and (PY >= "1997")

EMBASE

1 explode "obesity"/ all subheadings
2 "weight-gain"/ all subheadings
3 "weight-reduction"/ all subheadings
4 obesity or obese
5 weight gain or weight loss
6 overweight or over weight or overeat* or over eat*
7 weight change*
8 (bmi or body mass index) near2 (gain or loss or change)
9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8

10 "child"/ all subheadings
11 "adolescence"/ all subheadings
12 "preschool-child"/ all subheadings
13 "infant"/ all subheadings
14 "school-child"/ all subheadings
15 child* or adolescen* or infant*
16 teenage* or young people or young person or young adult*
17 schoolchildren or school children
18 p?ediatr* in ti,ab
19 boys or girls or youth or youths
20 #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
21 "behavior-therapy"/ all subheadings
22 "social-support"/ all subheadings
23 "family-therapy"/ all subheadings
24 "group-therapy"/ all subheadings
25 "behavior-modification"/ all subheadings
26 "cognitive-therapy"/ all subheadings
27 (psychological or behavio?r*) adj (therapy or modif* or strateg* or intervention*)
28 group therapy or family therapy or cognitive therapy
29 (lifestyle or life style) adj (chang* or intervention*)
30 counsel?ing
31 social support
32 peer near2 support
33 (children near3 parent?) near therapy
34 #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33
35 explode "obesity"/ drug-therapy
36 "antiobesity-agent"/ all subheadings
37 lipase inhibitor*
38 orlistat or xenical or tetrahydrolipstatin
39 appetite adj (suppressant* or depressant*)
40 sibutramine or (meridia in ti,ab)
41 dexfenfluramine or fenfluramine or phentermine
42 bulking agent*
43 methylcellulose or celevac
44 (antiobesity or anti obesity) adj (drug* or agent*)
45 guar gum
46 #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45
47 "low-fat-diet"/ all subheadings
48 "low-calory-diet"/ all subheadings
49 "caloric-restriction"/ all subheadings
50 "diet-therapy"/ all subheadings
51 explode "fat-intake"/ all subheadings
52 diet or diets or dieting
53 diet* adj (modif* or therapy or intervention* or strateg*)
54 low calorie or calorie control* or healthy eating
55 fasting or modified fast*
56 fruit or vegetable*
57 high fat* or low fat* or fatty food*
58 formula diet*
59 #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58
60 "exercise"/ all subheadings
61 "kinesiotherapy"/ all subheadings
62 exercis*

63 aerobics or physical therapy
64 fitness adj (class* or regime* or program*)
65 aerobics or physical therapy or physical training or physical education
66 dance therapy
67 sedentary behavio?r reduction
68 #60 or #61 or #62 or #63 or #64 or #65 or #66 or #67
69 explode "obesity"/ surgery
70 "stapler"/ all subheadings
71 "surgical-stapling"/ all subheadings
72 "lipectomy"/ all subheadings
73 "liposuction"/ all subheadings
74 "stomach-bypass"/ all subheadings
75 "gastroplasty"/ all subheadings
76 dental splinting or jaw wiring
77 gastroplasty or gastric band* or gastric bypass
78 intragastric balloon* or vertical band*
79 stomach adj (stapl* or band* or bypass)
80 liposuction
81 #69 or #70 or #71 or #72 or #73 or #74 or #75 or #76 or #77 or #78 or #79 or #80
82 "alternative-medicine"/ all subheadings
83 alternative medicine or complementary therap*
84 hypnotism or hypnosis or hypnotherapy
85 acupuncture or homeopathy or homoeopathy
86 chinese medicine or indian medicine or herbal medicine or ayurvedic
87 #82 or #83 or #84 or #85 or #86
88 (diet or dieting or slim*) adj (club* or organi?ation*)
89 weightwatcher* or weight watcher*
90 correspondence adj (course* or program*)
91 fat camp* or diet* camp*
92 #88 or #89 or #90 or #91
93 "health-promotion"/ all subheadings
94 "health-education"/ all subheadings
95 health promotion or health education
96 media intervention* or community intervention*
97 health promoting school*
98 (school* near2 program*) or (community near2 program*)
99 family intervention* or parent* intervention*
100 parent* near2 (behavio?r or involve* or control* or attitude* or educat*)
101 #93 or #94 or #95 or #96 or #97 or #98 or #99 or #100
102 "health-care-policy"/ all subheadings
103 health polic* or school polic* or food polic* or nutrition polic*
104 #102 or #103
105 explode "obesity"/ prevention
106 "primary-prevention"/ all subheadings
107 primary prevention or secondary prevention
108 preventive measure* or preventative measure*
109 preventive care or preventative care
110 obesity near2 (prevent* or treat*)
111 #105 or #106 or #107 or #108 or #109 or #110
112 explode "controlled-study"/ all subheadings
113 "randomisation"/ all subheadings
114 "double-blind-procedure"/ all subheadings
115 "single-blind-procedure"/ all subheadings

116 ”placebo“/ all subheadings
117 (singl* or doubl* or trebl* or tripl*) near5 (blind* or mask*)
118 placebo*
119 matched communities or matched schools or matched populations
120 control* near (trial* or stud* or evaluation* or experiment*)
121 comparison group* or control group*
122 matched pairs
123 outcome study or outcome studies
124 quasiexperimental or quasi experimental or pseudo experimental
125 nonrandomi?ed or non randomi?ed or pseudo randomi?ed
126 #112 or #113 or #114 or #115 or #116 or #117 or #118 or #119 or #120 or #121 or #122 or #123 or #124 or #125
127 #9 and #20
128 #34 or #46 or #59 or #68 or #81 or #87 or #92 or #101 or #104 or #111
129 #126 and #127 and #128
130 explode ”animal“/ all subheadings
131 ”nonhuman“/ all subheadings
132 #130 or #131
133 explode ”human“/ all subheadings
134 #132 not (#132 and #133)
135 #129 not #134
136 #135 and (PY >= ”1998“)

CINAHL

1 explode ”Obesity“/ all topical subheadings / all age subheadings
2 ”Weight-Control“/ all topical subheadings / all age subheadings
3 ”Weight-Gain“/ all topical subheadings / all age subheadings
4 ”Weight-Loss“/ all topical subheadings / all age subheadings
5 obesity or obese
6 weight gain or weight loss
7 overweight or over weight or overeat* or over eat*
8 weight change*
9 (bmi or body mass index) near2 (gain or loss or change)
10 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9
11 #10 in ti,ab,de
12 explode ”Child“/ all topical subheadings / all age subheadings
13 ”Infant“/ all topical subheadings / all age subheadings
14 ”Child-Preschool“/ all topical subheadings / all age subheadings
15 ”Adolescence“/ all topical subheadings / all age subheadings
16 child* or adolescen* or infant*
17 teenage* or young people or young person or young adult*
18 schoolchildren or school children
19 p?ediatr* in ti,ab
20 boys or girls or youth or youths
21 #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20
22#21 in ti,ab,de
23explode ”Behavior-Therapy“/ all topical subheadings / all age subheadings
24explode ”Support-Psychosocial“/ all topical subheadings / all age subheadings
25”Family-Therapy“/ all topical subheadings / all age subheadings
26”Psychotherapy-Group“/ all topical subheadings / all age subheadings
27”Support-Groups“/ all topical subheadings / all age subheadings
28(psychological or behavio?r*) adj (therapy or modif* or strateg* or intervention*)
29group therapy or family therapy or cognitive therapy

30(lifestyle or life style) adj (chang* or intervention*)
31counsel?ing
32social support
33peer near2 support
34(children near3 parent?) near therapy
35#23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34
36#35 in ti,ab,de
37explode "Obesity"/ drug-therapy / all age subheadings
38explode "Antiobesity-Agents"/ all topical subheadings / all age subheadings
39lipase inhibitor*
40orlistat or xenical or tetrahydrolipstatin
41appetite adj (suppressant* or depressant*)
42sibutramine or (meridia in ti,ab)
43dexfenfluramine or fenfluramine or phentermine
44bulking agent*
45methylcellulose or celevac
46(antiobesity or anti obesity) adj (drug* or agent*)
47guar gum
48#37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47
49#48 in ti,ab,de
50"Diet-Fat-Restricted"/ all topical subheadings / all age subheadings
51"Diet-Reducing"/ all topical subheadings / all age subheadings
52"Diet-Therapy"/ all topical subheadings / all age subheadings
53"Fasting"/ all topical subheadings / all age subheadings
54diet or diets or dieting
55diet* adj (modif* or therapy or intervention* or strateg*)
56low calorie or calorie control* or healthy eating
57fasting or modified fast*
58fruit or vegetable*
59high fat* or low fat* or fatty food*
60formula diet*
61explode "Dietary-Fats"/ all topical subheadings / all age subheadings
62explode "Obesity"/ diet-therapy / all age subheadings
63#50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58 or #59 or #60 or #61 or #62
64#63 in ti,ab,de
65explode "Exercise"/ all topical subheadings / all age subheadings
66explode "Therapeutic-Exercise"/ all topical subheadings / all age subheadings
67exercis*
68aerobics or physical therapy
69fitness adj (class* or regime* or program*)
70aerobics or physical therapy or physical training or physical education
71dance therapy
72sedentary behavio?r reduction
73#65 or #66 or #67 or #68 or #69 or #70 or #71 or #72
74#73 in ti,ab,de
75explode "Obesity"/ surgery / all age subheadings
76"Surgical-Stapling"/ all topical subheadings / all age subheadings
77"Lipectomy"/ all topical subheadings / all age subheadings
78"Gastric-Bypass"/ all topical subheadings / all age subheadings
79"Gastroplasty"/ all topical subheadings / all age subheadings
80dental splinting or jaw wiring
81gastroplasty or gastric band* or gastric bypass
82intragastric balloon* or vertical band*

83stomach adj (stapl* or band* or bypass)
84liposuction
85#75 or #76 or #77 or #78 or #79 or #80 or #81 or #82 or #83 or #84
86#85 in ti,ab,de
87explode "Alternative-Therapies"/ all topical subheadings / all age subheadings
88hypnotism or hypnosis or hypnotherapy
89acupuncture or homeopathy or homoeopathy
90chinese medicine or indian medicine or herbal medicine or ayurvedic
91alternative medicine or complementary therap* or complementary medicine
92#87 or #88 or #89 or #90 or #91
93#92 in ti,ab,de
94(diet or dieting or slim*) adj (club* or organi?ation*)
95weightwatcher* or weight watcher*
96correspondence adj (course* or program*)
97fat camp* or diet* camp*
98#94 or #95 or #96 or #97
99#98 in ti,ab,de
100"Health-Promotion"/ all topical subheadings / all age subheadings
101"Health-Education"/ all topical subheadings / all age subheadings
102"Nutrition-Education"/ all topical subheadings / all age subheadings
103"School-Health-Education"/ all topical subheadings / all age subheadings
104health promotion or health education
105media intervention* or community intervention*
106health promoting school*
107(school* near2 program*) or (community near2 program*)
108family intervention* or parent* intervention*
109parent* near2 (behavio?r or involve* or control* or attitude* or educat*)
110#100 or #101 or #102 or #103 or #104 or #105 or #106 or #107 or #108 or #111
111#110 in ti,ab,de
112"Health-Policy"/ all topical subheadings / all age subheadings
113"Nutrition-Policy"/ all topical subheadings / all age subheadings
114health polic* or school polic* or food polic* or nutrition polic*
115#112 or #113 or #114
116#115 in ti,ab,de
117explode "Obesity"/ prevention-and-control / all age subheadings
118primary prevention or secondary prevention
119preventive measure* or preventative measure*
120preventive care or preventative care
121obesity near2 (prevent* or treat*)
122#117 or #118 or #119 or #120 or #121
123#122 in ti,ab,de
124explode "Clinical-Trials"/ all topical subheadings / all age subheadings
125"Random-Assignment"/ all topical subheadings / all age subheadings
126"Placebos"/ all topical subheadings / all age subheadings
127explode "Quasi-Experimental-Studies"/ all topical subheadings / all age subheadings
128(singl* or doubl* or trebl* or tripl*) near5 (blind* or mask*)
129placebo*
130matched communities or matched schools or matched populations
131control* near (trial* or stud* or evaluation* or experiment*)
132comparison group* or control group*
133matched pairs
134outcome study or outcome studies
135quasiexperimental or quasi experimental or pseudo experimental

136randomi?ed or non randomi?ed or pseudo randomi?ed
137 or #125 or #126 or #127 or #128 or #129 or #130 or #131 or #132 or #133 or #134 or #135 or #136
138 in ti,ab,de
#137 in ti,ab,de
#11 and #22
#36 or #49 or #64 or #74 or #86 or #93 or #99 or #111 or #116 or #123
#138 and #139 and #140
#141 and (PY >= "1997")

PsycINFO

#1 (obesity or obese) and (po=human)
#2 (weight gain or weight loss) and (po=human)
#3 (overweight or over weight or overeat* or over eat*) and (po=human)
#4 weight change* and (po=human)
#5 (bmi or body mass index) and (gain or loss or change) and (po=human)
#6 #1 or #2 or #3 or #4 or #5
#7 (child* or adolescen* or infant*) and (po=human)
#8 (teenage* or young people or young person or young adult*) and (po=human)
#9 (schoolchildren or school children) and (po=human)
#10 p?ediatr* and (po=human)
#11 (boys or girls or youth or youths) and (po=human)
#12 #7 or #8 or #9 or #10 or #11
#13 #6 and #12
#14 (singl* or doubl* or trebl* or tripl*) and (blind* or mask*) and (po=human)
#15 placebo* and (po=human)
#16 (matched communities or matched schools or matched populations) and
(po=human)
#17 control* and (trial* or stud* or evaluation* or experiment*) and (po=human)
#18 (comparison group* or control group*) and (po=human)
#19 matched pairs and (po=human)
#20 (outcome study or outcome studies) and (po=human)
#21 (quasiexperimental or quasi experimental or pseudo experimental) and (po=human)
#22 (nonrandomi?ed or non randomi?ed or pseudo randomi?ed) and (po=human)
#23 #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22
#24 #13 and #23
#25 #6 and #12 and (po=human) and (pt=clinical-trial)
#26#24 or #25

DARE, NHS EED and HTA database

s1 obesity/kwo
s2 weight(w)gain/kwo
s3 weight(w)loss/kwo
s4 obese or obesity
s5 weight(w)gain or weight(w)loss
s6 overweight or over(w)weight or overeat$ or over(w)eat$
s7 weight(w)change$
s8 (bmi or body(w)mass(w)index) and (gain or loss or change)
s9 s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8
s10 child/kwo
s11 adolescence/kwo
s12 child(w)preschool/kwo

s13 infant/kwo
s14 child$ or adolescen$ or infant$
s15 teenage$ or young(w)people or young(w)adult$ or young(w)person
s16 schoolchildren or school(w)children
s17 paediatr$ or pediatr$
s18 boys or girls or youth or youths
s19 s10 or s11 or s12 or s13 or s14 or s15 or s16 or s17 or s18
s20 s9 and s19
s21 (1997 or 1998 or 1999 or 2000 or 2001)/dat
s22 s20 and s21

Kings Fund database, HELM, DH-Data

1 obesity or obese
2 weight gain or weight loss
3 overweight or over weight or overeat* or over eat*
4 weight change*
5 (bmi or body mass index) near2 (gain or loss or change)
6 #1 or #2 or #3 or #4 or #5
7 child* or adolescen* or infant*
8 teenage* or young people or young person or young adult*
9 schoolchildren or school children
10 p?ediatr* in ti,ab
11 boys or girls or youth or youths
12 #7 or #8 or #9 or #10 or #11
13 (singl* or doubl* or trebl* or tripl*) near5 (blind* or mask*)
14 placebo*
15 matched communities or matched schools or matched populations
16 control* near (trial* or stud* or evaluation* or experiment*)
17 comparison group* or control group*
18 matched pairs
19 outcome study or outcome studies
20 quasiexperimental or quasi experimental or pseudo experimental
21 nonrandomi?ed or non randomi?ed or pseudo randomi?ed
22 #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21
23 #6 and #12 and #22
24 #23 and (PY >= ”1997“)

Science and Social Science Citation Indexes

NB. Took out phrases 'over weight'/'over eat' because 'over' is a stop word, and so would not be searched by the search engine
(obesity or obese or weight gain or weight loss or overweight or overeat* or weight change or bmi gain or bmi change or bmi loss) and (child* or adolescen* or infant* or teenage* or young people or young person or young adult* or schoolchildren or school children or pediatr* or paediatr* or boys or girls or youth or youths) and (((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)) or control* group* or control* trial* or control* stud* or comparison group* or placebo* or matched communit* or matched school* or matched population* or nonrandomised or nonrandomized or non-randomized or non-randomised or quasiexperimental or quasi experimental or pseudo experimental)

Appendix 3. 2008 search strategies

The Cochrane Library, including CENTRAL (Issue 2, 2008)

#1 MeSH descriptor obesity explode all trees 3809
#2 MeSH descriptor weight gain this term only 878
#3 MeSH descriptor weight loss this term only 1556
#4 (obese or obesity) 6534
#5 (weight next gain or weight next loss) 6571
#6 (overweight or over next weight or overeat* or over next eat*) 1602
#7 weight next chang* 755
#8 (bmi near/6 gain) 43
#9 (bmi near/6 loss) 84
#10 (bmi near/6 change) 268
#11 (body next mass next index near/6 gain) 65
#12 (body next mass next index near/6 loss) 111
#13 (body next mass next index near/6 change) 308
#14 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13) 11637
#15 MeSH check word Child 31551
#16 MeSH descriptor Adolescent this term only 55746
#17 MeSH descriptor Infant explode all trees 9595
#18 (child* or adolescen* or infant*) 108446
#19 (teenage* or young next people or young next adult* or young next person) 2711
#20 schoolchildren 594
#21 (paediatr* or pediatr*) 24946
#22 (boys or girls or youth or youths) 4303
#23 (#15 or #16 or #17 or #18 or #19 or #20 or #21 or #22) 112769
#24 (#14 and #23) 3379

MEDLINE (on Ovid)

#1 exp Obesity/ (86668)
#2 Weight Gain/ (15116)
#3 Weight Loss/ (14429)
#4 obes$.tw. (91066)
#5 (weight gain or weight loss).tw. (56570)
#6 (overweight or over weight or overeat$ or over eat$).tw. (17401)
#7 weight change$.tw. (4450)
#8 ((bmi or body mass index) adj2 (gain or loss or change)).tw. (1005)
#9 or/1-8 (176730)
#10 exp Behavior Therapy/ (36740)
#11 Support Groups/ (6306)
#12 Family Therapy/ (6495)
#13 exp Psychotherapy, Group/ (19285)
#14 Behavior Modification/ (19393)
#15 Social support/ (32589)
#16 ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).tw. (13054)
#17 (group therapy or family therapy or cognitive therapy).tw. (5630)
#18 ((lifestyle or life style) adj (chang$ or intervention$)).tw. (3268)
#19 Counseling/ (21741)
#20 Directive counselling/ (303)
#21 counsel?ing.tw. (36645)
#22 social support.tw. (12238)

#23 (peer adj2 support).tw. (745)
#24 Motivation/ (35253)
#25 (children adj3 parent$ adj3 therap$).tw. (100)
#26 or/10-25 (179755)
#27 exp Obesity/dh [Diet Therapy] (4156)
#28 Diet Therapy/ (8812)
#29 Diet, Fat-Restricted/ (1901)
#30 Diet reducing/ (7687)
#31 Caloric restriction/ (1351)
#32 Fasting/ (23430)
#33 (diet or diets or dieting).tw. (164473)
#34 (low calorie or calorie control$ or healthy eating).tw. (2489)
#35 (fasting or modified fast$).tw. (47535)
#36 exp Dietary Fats/ (55935)
#37 exp Fruit/ (34339)
#38 exp Vegetables/ (58744)
#39 (fruit or vegetable$).tw. (30052)
#40 (high fat$ or low fat$ or fatty food$).tw. (13421)
#41 formula diet$.tw. (559)
#42 or/27-41 (347981)
#43 exp Exercise/ (59991)
#44 exercis$.tw. (134831)
#45 (aerobics or physical therapy or physical activity or physical inactivity).tw. (33786)
#46 (fitness adj3 (class$ or regime$ or program$)).tw. (744)
#47 exp "Physical Education and Training"/ (11468)
#48 physical education.tw. (1797)
#49 Dance Therapy/ (119)
#50 (dance or dancing).tw. (1626)
#51 Physical Activity/ (51407)
#52 sedentary behavio?r.tw. (318)
#53 ((slim$ or diet or dieting) adj2 (club$ or organi?ation$)).tw. (34)
#54 (weightwatcher$ or weight watcher$).tw. (47)
#55 (correspondence adj (course$ or program$)).tw. (79)
#56 (camp or camps).tw. (60053)
#57 or/43-56 (292790)
#58 exp Health Promotion/ (33804)
#59 exp Health Education/ (106002)
#60 (health adj2 (educat$ or promot$)).tw. (35865)
#61 ((media or community) adj2 intervention$).tw. (2160)
#62 School health services/ (11404)
#63 School nursing/ (3492)
#64 ((school$ or communit$) adj2 (program$ or intervention$)).tw. (9235)
#65 (family intervention$ or parent$ intervention).tw. (685)
#66 (parent$ adj2 (behavio?r or involve$ or control$ or attitude$ or educat$)).tw. (8280)
#67 or/58-66 (173931)
#68 exp Health Policy/ (55105)
#69 ((health or school$ or food or nutrition) adj2 (policy or policies)).tw. (12292)
#70 exp Obesity/pc [Prevention and Control] (5921)
#71 Primary prevention/ (9988)
#72 Preventive health services/ (8470)
#73 (primary prevention or secondary prevention).tw. (13545)
#74 ((preventive or preventative) adj2 (measure$ or care)).tw. (14655)
#75 (obesity adj2 (prevent$ or treat$)).tw. (5380)

#76 or/68-75 (113310)
#77 26 or 42 or 57 or 67 or 76 (1019691)
#78 Child/ (1104915)
#79 exp Infant/ (778916)
#80 Child, Preschool/ (612111)
#81 Adolescence/ (1259668)
#82 (child$ or adolescen$ or infant$).tw. (923147)
#83 (teenage$ or young people or young person or young adult$).tw. (53160)
#84 schoolchildren.tw. (7479)
#85 (boys or girls or youth or youths).tw. (72664)
#86 (paediatric$ or paediatric$).tw. (133744)
#87 or/78-86 (2474848)
#88 9 and 77 and 87 (14431)
#89 exp Anti-Obesity Agents/ (6755)
#90 Metformin/ (3454)
#91 ((anti-obes$ or antiobes$) adj2 (agent$ or drug$ or medicine$)).tw. (478)
#92 ((anti-obes$ or antiobes$) adj2 (agent$ or drug$)).tw. (475)
#93 sibutramine.tw. (558)
#94 rimonabant.tw. (388)
#95 metformin.tw. (3743)
#96 reductil.tw. (13)
#97 lipstatin.tw. (14)
#98 orlistat.tw. (621)
#99 xenical.tw. (57)
#100 acomplia.tw. (17)
#101 glucophage.tw. (67)
#102 (appetite adj2 (suppressant$ or depressant$)).tw. (518)
#103 (weight loss adj2 agent$).tw. (48)
#104 Anorexigenic Agent$.tw. (74)
#105 or/89-104 (12178)
#106 exp Bariatric Surgery/ (8328)
#107 gastroplast$.tw. (1501)
#108 bariatric surgery.tw. (2422)
#109 gastric bypass$.tw. (3092)
#110 (gastric adj2 band$).tw. (1612)
#111 (surgery adj2 obes$).tw. (769)
#112 exp Obesity/su [Surgery] (6220)
#113 Lap-band system.tw. (52)
#114 or/106-113 (11508)
#115 exp Obesity/th [Therapy] (8751)
#116 105 or 114 or 115 (30841)
#117 9 and 87 and 116 (3652)
#118 117 or 88 (16100)
#119 randomised controlled trial.pt. (257171)
#120 controlled clinical trial.pt. (78507)
#121 Randomized controlled trials/ (54762)
#122 random allocation/ (61472)
#123 double blind method/ (98005)
#124 single-blind method/ (12139)
#125 or/119-124 (434227)
#126 exp animal/ not humans/ (3314999)
#127 125 not 126 (406668)
#128 clinical trial.pt. (451614)

#129 exp Clinical Trials as Topic/ (205487)
#130 (clin$ adj25 trial$).ti,ab. (146475)
#131 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).ti,ab. (94704)
#132 placebos/ (27373)
#133 placebo$.ti,ab. (110676)
#134 random$.ti,ab. (411848)
#135 research design/ (52826)
#136 or/128-135 (918397)
#137 136 not 126 (852755)
#138 127 or 137 (876380)
#139 118 and 138 (2518)
#140 limit 139 to yr="2001 - 2008" (1550)

EMBASE (on Ovid)

1 exp Obesity/ (89174)
2 Weight Gain/ (24911)
3 Weight reduction/ (35560)
4 obes$.tw. (73716)
5 (weight gain or weight loss).tw. (47379)
6 (overweight or over weight or overeat$ or over eat$).tw. (14658)
7 weight change$.tw. (3562)
8 ((bmi or body mass index) adj2 (gain or loss or change)).tw. (845)
9 or/1-8 (167541)
10 Behavior Therapy/ (20228)
11 Support Group/ (3704)
12 Family Therapy/ (4536)
13 Group Therapy/ (7151)
14 Behavior Modification/ (5063)
15 Social support/ (15422)
16 ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).tw. (13198)
17 (group therapy or family therapy or cognitive therapy).tw. (5179)
18 ((lifestyle or life style) adj (chang$ or intervention$)).tw. (2971)
19 exp Counseling/ (44293)
20 counsel?ing.tw. (30056)
21 social support.tw. (9726)
22 (peer adj2 support).tw. (511)
23 Motivation/ (17068)
24 (children adj3 parent$ adj3 therap$).tw. (85)
25 or/10-24 (128533)
26 exp Obesity/th [Therapy] (5608)
27 Diet Therapy/ (13785)
28 low fat diet/ (2907)
29 Low calory diet/ (1640)
30 Diet restriction/ (20425)
31 (diet or diets or dieting).tw. (121149)
32 (low calorie or calorie control$ or healthy eating).tw. (1950)
33 (fasting or modified fast$).tw. (41403)
34 exp Fat intake/ (16563)
35 dietary intake/ (30097)
36 exp Fruit/ (20920)
37 exp Vegetables/ (45258)
38 (fruit or vegetable$).tw. (22531)

39 (high fat$ or low fat$ or fatty food$).tw. (11804)
40 formula diet$.tw. (445)
41 or/26-40 (256022)
42 exp Exercise/ (82313)
43 exercis$.tw. (113167)
44 (aerobics or physical therapy or physical activity or physical inactivity).tw. (29641)
45 (fitness adj3 (class$ or regime$ or program$)).tw. (584)
46 exp Physical Education/ (1862)
47 physical education.tw. (1198)
48 (dance or dancing).tw. (1382)
49 exp Physical Activity/ (93042)
50 sedentary behavio?r.tw. (279)
51 ((slim$ or diet or dieting) adj2 (club$ or organi?ation$)).tw. (27)
52 (weightwatcher$ or weight watcher$).tw. (33)
53 (correspondence adj (course$ or program$)).tw. (23)
54 (camp or camps).tw. (51815)
55 or/42-54 (270711)
56 Health Promotion/ (24020)
57 Health Education/ (26626)
58 Nutrition education/ (549)
59 School health education/ (90)
60 (health adj2 (educat$ or promot$)).tw. (19243)
61 ((media or community) adj2 intervention$).tw. (1645)
62 School health service/ (1997)
63 School health nursing/ (45)
64 ((school$ or communit$) adj2 (program$ or intervention$)).tw. (5984)
65 (family intervention$ or parent$ intervention).tw. (643)
66 (parent$ adj2 (behavio?r or involve$ or control$ or attitude$ or educat$)).tw. (6061)
67 or/56-66 (66676)
68 exp Health Care Policy/ (54465)
69 Health program/ (50929)
70 ((health or school$ or food or nutrition) adj2 (policy or policies)).tw. (8327)
71 exp Obesity/pc, dm, rh [Prevention, Disease Management, Rehabilitation] (3675)
72 Primary prevention/ (9281)
73 Preventive health service/ (4334)
74 (primary prevention or secondary prevention).tw. (12960)
75 ((preventive or preventative) adj2 (measure$ or care)).tw. (10695)
76 (obesity adj2 (prevent$ or treat$)).tw. (4336)
77 or/68-76 (137986)
78 25 or 41 or 55 or 67 or 77 (774543)
79 exp Child/ (607372)
80 (child$ or adolescen$ or infant$).tw. (616520)
81 (teenage$ or young people or young person or young adult$).tw. (42974)
82 schoolchildren.tw. (4394)
83 (boys or girls or youth or youths).tw. (54357)
84 (paediatric$ or paediatric$).tw. (111854)
85 or/79-84 (925434)
86 9 and 78 and 85 (8999)
87 Antiobesity Agent/ (1180)
88 Sibutramine/ (2034)
89 exp Anorexigenic Agent/ (25367)
90 Rimonabant/ (2888)
91 Metformin/ (12294)

92 ((anti-obes$ or antiobes$) adj2 (agent$ or drug$ or medicine$)).tw. (506)
93 ((anti-obes$ or antiobes$) adj2 (agent$ or drug$)).tw. (501)
94 sibutramine.tw. (602)
95 rimonabant.tw. (499)
96 metformin.tw. (3979)
97 reductil.tw. (215)
98 lipstatin.tw. (17)
99 orlistat.tw. (931)
100 xenical.tw. (648)
101 acomplia.tw. (227)
102 glucophage.tw. (990)
103 (appetite adj2 (suppressant$ or depressant$)).tw. (372)
104 (weight loss adj2 agent$).tw. (42)
105 Anorexigenic Agent$.tw. (33)
106 or/87-105 (40391)
107 exp Bariatric Surgery/ (3885)
108 gastroplast$.tw. (1187)
109 bariatric surgery.tw. (1972)
110 gastric bypass$.tw. (2328)
111 (gastric adj2 band$).tw. (1127)
112 (surgery adj2 obes$).tw. (625)
113 exp Obesity/su [Surgery] (4982)
114 Lap-band system.tw. (30)
115 or/107-114 (7602)
116 exp Obesity/th [Therapy] (5608)
117 106 or 115 or 116 (50739)
118 9 and 85 and 117 (2167)
119 118 or 86 (9717)
120 controlled clinical trial/ (45910)
121 random$.tw. (369899)
122 randomised controlled trial/ (157804)
123 follow-up.tw. (333189)
124 double blind procedure/ (69280)
125 placebo$.tw. (105339)
126 placebo/ (113348)
127 factorial$.ti,ab. (7623)
128 (crossover$ or cross-over$).ti,ab. (37985)
129 (double$ adj blind$).ti,ab. (81997)
130 (singl$ adj blind$).ti,ab. (7143)
131 assign$.ti,ab. (102901)
132 allocat$.ti,ab. (32311)
133 volunteer$.ti,ab. (95107)
134 Crossover Procedure/ (20276)
135 Single Blind Procedure/ (7545)
136 or/120-135 (963194)
137 (exp animals/ or nonhuman/) not human/ (2588469)
138 136 not 137 (880257)
139 119 and 138 (1797)
140 limit 139 to yr="2001 - 2008" (1264)

CINAHL

1 "randomised controlled trial".pt. (0)

2 randomised controlled trials/ (42740)
3 random allocation/ (0)
4 double-blind method/ (0)
5 single-blind method/ (0)
6 clinical trial.pt. (28635)
7 exp clinical trials/ (55623)
8 (clinical$ adj5 trial$).tw. (13599)
9 ((singl$ or doubl$ or trebl or tripl$) adj5 (blind$ or mask)).mp. [mp=title, subject heading word, abstract, instrumentation] (15015)
10 placebos/ (4101)
11 (placebo$ or random$).tw. (53031)
12 research design/ (3536)
13 comparative study/ (43421)
14 exp evaluation studies/ (11780)
15 follow-up studies/ (68863)
16 prospective studies/ (68863)
17 (animal not (human and animal)).ti,ab,sh. (2971)
18 *obesity/ (7889)
19 *obesity, morbid/ (490)
20 *pickwickian syndrome/ (21)
21 *prader-willi syndrome/ (117)
22 *weight gain/ (928)
23 obesity.ti. (4229)
24 obese.ti. (1358)
25 overweight.ti. (1093)
26 hyperphagia/ (63)
27 *bulimia/ (828)
28 or/18-27 (10809)
29 or/1-16 (185254)
30 29 and 28 (2387)
31 30 not 17 (2379)
32 exp behavior therapy/ (5454)
33 (behavior adj (therapy or modification)).tw. (491)
34 exp appetite depressants/ (1449)
35 (appetite adj (suppressant? or depressant)).tw. (31)
36 diet, fat-restricted/ (966)
37 diet, reducing/ (1461)
38 (dieting or (low adj calorie) or diet?).tw. (12530)
39 food deprivation/ (0)
40 (food adj3 (deprivation or depriving)).tw. (23)
41 exercise/ (10978)
42 exercise therapy/ (6592)
43 exertion/ (1876)
44 (exercise or (physical adj therapy) or fitness).tw. (30895)
45 fasting/ (724)
46 fasting.tw. (2897)
47 (jaw adj3 (wiring or wired)).tw. (1)
48 surgical staplers/ (0)
49 surgical stapling/ (107)
50 (stomach adj2 (stapling or banding or bypass)).ti,ab,sh. (5)
51 gastric bypass/ (298)
52 (gastric adj bypass).tw. (160)
53 health promotion/ (14074)

54 health education/ (7717)
55 (prevent or prevention of preventing).tw. (17081)
56 nutrition policy/ (619)
57 (food adj policy).tw. (22)
58 food habits/ and health policy/ (12)
59 (program or programs or programme$ or intervention$).tw. (139125)
60 lipectomy/ (147)
61 liposuction.tw. (90)
62 (guar adj gum).ti,ab,sh. (24)
63 exp alternative medicine/ (52458)
64 (acupuncture or hypnotism).tw. (2977)
65 advertising/ (3012)
66 ((diet or dieting or slimming) adj club?).tw. (5)
67 weightwatcher?.tw. (0)
68 or/32-67 (257022)
69 31 and 68 (1183)
70 limit 69 to (newborn infant <birth to 1 month> or infant <1 to 23 months> or preschool child <2 to 5 years> or child <6 to 12 years> or adolescence <13 to 18 years>) (399)
71 limit 70 to yr="2001 - 2008" (323)
72 from 71 keep 1-323 (323)

PsychINFO

#32 #31 and (PY=2001-2008)(657 records)
#31 #17 and #30(972 records)
#30 #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 (225896 records)
#29 TREATMENT-OUTCOME-CLINICAL-TRIAL in MD(12341 records)
#28 "Clinical-Trials" in MJ,MN(1861 records)
Searches and results below from saved search history RCT filter terms
#27 "Placebo-" in MJ,MN(1922 records)
Searches and results below from saved search history 9911 obesity 2 1 2008
#26 volunteer*(19028 records)
#25 prospectiv*(21076 records)
#24 (control or comparison) near group(45367 records)
#23 PROSPECTIVE-STUDY in MD(6986 records)
#22 LONGITUDINAL-STUDY in MD(48788 records)
#21 FOLLOWUP-STUDY in MD(28411 records)
#20 (clinical* stud*) or (single-blind) or (single blind) or (triple-blind) or (triple blind)(7553 records)
#19 (random*) or (clinical trial*) or (controlled study) or ((double-blind)or (double blind))(86179 records)
#18 TREATMENT-OUTCOME-CLINICAL-TRIAL in MD(12341 records)
#17 #10 and #16(4743 records)
#16 #11 or #12 or #13 or #14 or #15(601897 records)
#15 boys or girls or youth or youths(84169 records)
#14 pediatr* or paediatr*(27296 records)
#13 child* or adololescen* or infant*(471482 records)
#12 child* or adolescen*(507086 records)
#11 CHILDHOOD in AG(294367 records)
#10 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9(19171 records)
#9 (bmi or body mass) near (gain* or loss* or change*)(739 records)
#8 weight change*(864 records)
#7 overeat* or over eat*(997 records)
#6 overweight or over weight(3414 records)
#5 weight loss*(4492 records)

#4 weight gain*(4267 records)
#3 obes*(11040 records)
#2 "Weight-Control" in MJ,MN(2454 records)
#1 explode "Overweight-" in MJ,MN(7031 records)

Science and Social Science Citation Indexes on ISI Web of Science

#5 (#1 or #2 or #3 or #4)*; Timespan=2001-2008*
#4 ts=((appetite adj2 (suppressant$ or depressant$)) or (rimonabant or metformin or reductil or lipstatin or orlistat or xenical or acomplia or glugophage) or ((anti-obes* or antiobes* or "weight loss") same (agent* or drug* or medicine*))) and ts=((child* or adolescen* or infant* or teenage* or "young people" or "young person" or "young adult*" or schoolchildren or pediatr* or paediatr* or boys or girls or youth or youths) and (Random* or trial* or placebo* or control* or ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)) or (comparison same group*) or (clinical same trial*)))
#3 ts=((bariatric same surgery) or gastroplas* or (gastric same (bypass* or band*)) or (lap same band same system) or (obes* same (surgery or surgical))) and ts=((child* or adolescen* or infant* or teenage* or "young people" or "young person" or "young adult*" or schoolchildren or pediatr* or paediatr* or boys or girls or youth or youths) and (Random* or trial* or placebo* or control* or ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)) or (comparison same group*) or (clinical same trial*)))
#2 TS=(((obesity or obese or "weight gain" or "weight loss" or overweight or overeat* or (weight same change) or (bmi same gain) or (bmi same change) or (bmi same loss)) and (child* or adolescen* or infant* or teenage* or "young people" or "young person" or "young adult*" or schoolchildren or pediatr* or paediatr* or boys or girls or youth or youths)) and (Random* or trial* or placebo* or control* or ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)) or (comparison same group*) or (clinical same trial*))) and TS=(therap* or support or modif* or training)
#1 TS=(((obesity or obese or "weight gain" or "weight loss" or overweight or overeat* or (weight same change) or (bmi same gain) or (bmi same change) or (bmi same loss)) and (child* or adolescen* or infant* or teenage* or "young people" or "young person" or "young adult*" or schoolchildren or pediatr* or paediatr* or boys or girls or youth or youths)) and (Random* or trial* or placebo* or control* or ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)) or (comparison same group*) or (clinical same trial*))) and TS=(Program* or manage* or intervention* or diet* or activity or counsel* or educat* or promot*)

WHAT'S NEW

Last assessed as up-to-date: 10 October 2008.

Date	Event	Description
11 October 2008	New citation required and conclusions have changed	This review concludes that combined behavioural lifestyle interventions compared to standard care or self-help can produce a significant and clinically meaningful reduction in overweight in children and adolescents The search was updated to May 2008. Some amendments were made to update the search strategies. No changes have been made to other aspects of the methodology. Forty-six new studies have been included. These included information on drug interventions for treating obesity in adolescents. The added evidence suggests that lifestyle interventions appear to have positive effects in the treatment of child and adolescent obesity. Furthermore, orlistat and sibutramine were found to have beneficial effects on adiposity in obese adolescents. However, a range of adverse effects was noted

(*Continued*)

3 July 2008	Amended	Converted to new review format. Authorship changed with new authors and new contact person

CONTRIBUTIONS OF AUTHORS

HOL: Co-ordinated the update of the review; Extracted and checked information from all included/excluded papers; Performed meta-analysis; Wrote the update of the review; Assisted in final editing of 2008 review.

LAB: Reviewed papers for inclusion/exclusion; Extracted and checked information from all included/excluded papers; Helped write text of review; Assisted in final editing of review.

HJ: Reviewed papers for inclusion/exclusion; Extracted and checked information from all included/excluded papers; Helped write text of review; Assisted in final editing of review.

VS: Reviewed papers for inclusion/exclusion; Extracted and checked information from all included/excluded papers; Helped write text of review; Assisted in final editing of review.

CO: Reviewed papers for inclusion/exclusion; Extracted and checked information from all included/excluded papers; Helped write text of review; Assisted in final editing of review.

RS: Reviewed papers for inclusion/exclusion; Checked information from all included/excluded papers; Performed meta-analysis; Helped write text of review; Assisted in final editing of review.

CS: Reviewed papers for inclusion/exclusion; Extracted and checked information from all included/excluded papers; Helped write text of review. Assisted in final editing of review.

DECLARATIONS OF INTEREST

Louise Baur is a co-author on three of the papers included in the Cochrane Review (Srinivasan 2006; Golley 2007; McCallum 2007).

Hiltje Oude Luttikhuis and Ronald Stolk are involved in the design and conduct of a potentially eligible study for this review. The clinical trial registration number for this ongoing trial is ISRCTN47185691.

SOURCES OF SUPPORT

Internal sources

- University Medical Center, Groningen, Netherlands.
- The Children's Hospital at Westmead, Sydney, Australia.
- Centre for Food Physical Activity and Obesity Research, University of Teesside, UK.
- The Wolfson Research Institute, University of Durham, UK.
- Australian National Health & Medical Research Council, Australia.

Postgraduate Research Scholarship for Ms Shrewsbury

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

Anti-Obesity Agents [therapeutic use]; Diet, Reducing; Life Style; Motor Activity; Obesity [*therapy]; Randomized Controlled Trials as Topic

MeSH check words

Child; Humans