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Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years (Review)

Mead E, Brown T, Rees K, Azevedo LB, Whittaker V, Jones D, Olajide J, Mainardi GM, Corpeleijn E, O'Malley C, Beardsmore E, Al-Khudairy L, Baur L, Metzendorf MI, Demaio A, Ells LJ

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[Intervention Review]

Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years

Emma Mead¹, Tamara Brown^{1,2}, Karen Rees³, Liane B Azevedo¹, Victoria Whittaker¹, Dan Jones¹, Joan Olajide¹, Giulia M Mainardi⁴, Eva Corpeleijn⁵, Claire O'Malley², Elizabeth Beardsmore¹, Lena Al-Khudairy³, Louise Baur⁶, Maria-Inti Metzendorf⁷, Alessandro Demaio⁸, Louisa J Ells¹

¹Health and Social Care Institute, Teesside University, Middlesbrough, UK. ²School of Medicine, Pharmacy and Health, Durham University Queen's Campus, Durham, UK. ³Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry, UK. ⁴Department of Preventive Medicine, School of Medicine, University of São Paulo, São Paulo, Brazil. ⁵Department of Epidemiology, University Medical Centre Groningen, Groningen, Netherlands. ⁶Department of Paediatrics and Child Health, The University of Sydney, Westmead, Australia. ⁷Cochrane Metabolic and Endocrine Disorders Group, Institute of General Practice, Medical Faculty of the Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany. ⁸The World Health Organization, Geneva, Switzerland

Contact address: Louisa J Ells, Health and Social Care Institute, Teesside University, Middlesbrough, TS1 3BA, UK. L.Ells@tees.ac.uk.

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ABSTRACT

Background

Child and adolescent overweight and obesity has increased globally, and can be associated with significant short- and long-term health consequences. This is an update of a Cochrane review published first in 2003, and updated previously in 2009. However, the update has now been split into six reviews addressing different childhood obesity treatments at different ages.

Objectives

To assess the effects of diet, physical activity and behavioural interventions (behaviour-changing interventions) for the treatment of overweight or obese children aged 6 to 11 years.

Search methods

We searched CENTRAL, MEDLINE, Embase, PsycINFO, CINAHL, LILACS as well as trial registers ClinicalTrials.gov and ICTRP Search Portal. We checked references of studies and systematic reviews. We did not apply any language restrictions. The date of the last search was July 2016 for all databases.

Selection criteria

We selected randomised controlled trials (RCTs) of diet, physical activity, and behavioural interventions (behaviour-changing interventions) for treating overweight or obese children aged 6 to 11 years, with a minimum of six months' follow-up. We excluded 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.

Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years (Review)

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Data collection and analysis

Two review authors independently screened references, extracted data, assessed risk of bias, and evaluated the quality of the evidence using the GRADE instrument. We contacted study authors for additional information. We carried out meta-analyses according to the statistical guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions*.

Main results

We included 70 RCTs with a total of 8461 participants randomised to either the intervention or control groups. The number of participants per trial ranged from 16 to 686. Fifty-five trials compared a behaviour-changing intervention with no treatment/usual care control and 15 evaluated the effectiveness of adding an additional component to a behaviour-changing intervention. Sixty-four trials were parallel RCTs, and four were cluster RCTs. Sixty-four trials were multicomponent, two were diet only and four were physical activity only interventions. Ten trials had more than two arms. The overall quality of the evidence was low or very low and 62 trials had a high risk of bias for at least one criterion. Total duration of trials ranged from six months to three years. The median age of participants was 10 years old and the median BMI z score was 2.2.

Primary analyses demonstrated that behaviour-changing interventions compared to no treatment/usual care control at longest follow-up reduced BMI, BMI z score and weight. Mean difference (MD) in BMI was -0.53 kg/m^2 (95% confidence interval (CI) -0.82 to -0.24); $P < 0.00001$; 24 trials; 2785 participants; low-quality evidence. MD in BMI z score was -0.06 units (95% CI -0.10 to -0.02); $P = 0.001$; 37 trials; 4019 participants; low-quality evidence and MD in weight was -1.45 kg (95% CI -1.88 to -1.02); $P < 0.00001$; 17 trials; 1774 participants; low-quality evidence.

Thirty-one trials reported on serious adverse events, with 29 trials reporting zero occurrences RR 0.57 (95% CI 0.17 to 1.93); $P = 0.37$; 4/2105 participants in the behaviour-changing intervention groups compared with 7/1991 participants in the comparator groups). Few trials reported health-related quality of life or behaviour change outcomes, and none of the analyses demonstrated a substantial difference in these outcomes between intervention and control. In two trials reporting on minutes per day of TV viewing, a small reduction of 6.6 minutes per day (95% CI -12.88 to -0.31), $P = 0.04$; 2 trials; 55 participants) was found in favour of the intervention. No trials reported on all-cause mortality, morbidity or socioeconomic effects, and few trials reported on participant views; none of which could be meta-analysed.

As the meta-analyses revealed substantial heterogeneity, we conducted subgroup analyses to examine the impact of type of comparator, type of intervention, risk of attrition bias, setting, duration of post-intervention follow-up period, parental involvement and baseline BMI z score. No subgroup effects were shown for any of the subgroups on any of the outcomes. Some data indicated that a reduction in BMI immediately post-intervention was no longer evident at follow-up at less than six months, which has to be investigated in further trials.

Authors' conclusions

Multi-component behaviour-changing interventions that incorporate diet, physical activity and behaviour change may be beneficial in achieving small, short-term reductions in BMI, BMI z score and weight in children aged 6 to 11 years. The evidence suggests a very low occurrence of adverse events. The quality of the evidence was low or very low. The heterogeneity observed across all outcomes was not explained by subgrouping. Further research is required of behaviour-changing interventions in lower income countries and in children from different ethnic groups; also on the impact of behaviour-changing interventions on health-related quality of life and comorbidities. The sustainability of reduction in BMI/BMI z score and weight is a key consideration and there is a need for longer-term follow-up and further research on the most appropriate forms of post-intervention maintenance in order to ensure intervention benefits are sustained over the longer term.

PLAIN LANGUAGE SUMMARY

Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years

Review question

How effective are diet, physical activity and behavioural interventions in reducing the weight of overweight or obese children aged 6 to 11 years?

Background

Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years (Review)

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Across the world more children are becoming overweight and obese. These children are more likely to suffer from health problems, both while as children and in later life. More information is needed about what works best for treating this problem.

Study characteristics

We found 70 randomised controlled trials (clinical trials where people are randomly put into one of two or more treatment groups) comparing diet, physical activity, and behavioural (where habits are changed or improved) treatments to a variety of control groups delivered to 8461 overweight or obese children aged 6 to 11 years. We reported on the effects of 64 multicomponent interventions (different combinations of diet and physical activity and behaviour change), four physical activity interventions and two dietary interventions compared with no intervention, 'usual care' or some other therapy if it was also delivered in the intervention arm. The children in the included studies were followed up between six months and three years.

Key results

The average age of the children was 10 years. Most studies reported the body mass index (BMI) z score: BMI is a measure of body fat and is calculated by dividing weight (in kilograms) by the square of the body height measured in metres (kg/m^2). In children, BMI is often measured in a way that takes into account sex and age, weight, and height changes as children grow older (BMI z score).

We summarised the results of 37 trials in 4019 children reporting the BMI z score, which on average was 0.06 units lower in the intervention groups compared with the control groups. We summarised the results of 24 trials in 2785 children reporting BMI, which on average was $0.53 \text{ kg}/\text{m}^2$ lower in the intervention groups compared with the control groups. We summarised the results of 17 trials in 1774 children reporting weight, which on average was 1.45 kg lower in the intervention groups compared with the control groups.

Other effects of the interventions, such as improvements in health-related quality of life were less clear. No study investigated death from any cause, morbidity or socioeconomic effects. Serious adverse events were rare: only two of 31 trials with data reported any serious adverse events (4/2105 participants in the behaviour-changing intervention groups compared with 7/1991 participants in the comparator groups). This evidence is up to date as of July 2016.

Quality of the evidence

The overall quality of the evidence was low or very low, mainly because of limited confidence in how studies were performed, and the results were inconsistent between the studies. Also there were just a few studies for some outcomes, with small numbers of included children.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in children aged 6 to 11 years

Population: children (aged 6 to 11 years) being overweight or obese

Settings: various

Intervention: behaviour-changing interventions (behavioural, diet and/or physical activity components)

Comparison: no treatment or usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments				
	Assumed risk	Corresponding risk								
	No treatment or usual care	Behaviour-changing intervention								
Change in BMI (kg/m²) Follow-up: 6 to 36 months	The mean change in BMI ranged across control groups from -0.3 to 2.8 kg/m ²	The mean change in BMI in the intervention groups was 0.53 kg/m² lower (0.82 lower to 0.24 lower)	-	2785 (24) 4019 (37)	⊕⊕○○ low^a ⊕⊕○○ low^a	Lower units indicate weight loss Lower units indicate weight loss Lower units indicate weight loss				
	Change in BMI z score^b (units) Follow-up: 6 to 36 months	BMI z score ranged across control groups from -1.1 to 0.26 units The mean change in weight ranged across control groups from 1.95 to 17.1 kg					The mean change in BMI z score in the intervention groups was 0.06 units lower (0.10 lower to 0.02 lower) The mean change in weight in the intervention group was 1.45 kg lower (1.88 lower to 1.02 lower)	1774 (17)	⊕⊕○○ low^a	Lower units indicate weight loss
	Change in weight (kg) Follow-up: 6 to 36 months									
Adverse events (serious adverse events) Follow-up: 0 to 36 months	4 per 1000	2 per 1000 (1 to 7)	RR 0.57 (0.17 to 1.93)	4096 (31)	⊕⊕○○ low^c	No adverse events occurred in 29 trials. Only two of 31 trials with data reported the oc-				

						currence of serious adverse events
Change in health-related quality of life (SMD) Parent-reported measures Instruments: PedsQL parent proxy: 23 items that yield total, physical summary, and psychosocial summary scores, each with a possible range of 0-100 (100 = best possible health); Child Health Questionnaire, parent version (CHQ-PF50), physical and psychosocial concepts Follow-up: 6 to 15 months Child-reported measures Instrument: PedsQLchild self-report: 23 items that yield total, physical summary, and psychosocial summary scores, each with a possible range of 0-100 (100 = best possible health); KINDL-R questionnaire: total score includes domains of well-being, emotional well-being, self-esteem,	The mean in caregiver PedsQL ranged across control groups from -4.2 units to 3.6 units	The SMD in caregiver PedsQL in the intervention groups was 0.13 units higher (0.06 lower to 0.32 higher) The mean change in child PedsQL in the intervention group was 0.15 units higher (0.34 lower to 0.64 higher)	-	718 (5)	⊕⊕○○ low^d	Higher units indicate improvements. The minimal clinically important difference (MCID) for a PedsQL parents' proxy report is 4.50 raw units. When converting the SMD back to raw units, the MCID was not met in either meta-analysis
	The mean in child PedsQL ranged across control groups from -1.4 units to 4.01 units				164 (3)	⊕○○○ very low^e

family, friends, school. 5-point Likert scale Follow-up: 6 months						
All-cause mortality	See comment	No deaths were reported in any of the trials				
Morbidity	See comment	No trials reported morbidity				
Socioeconomic effects	See comment	No trials reported socioeconomic effects				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) was derived from the event rates in the comparator groups. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
BMI: body mass index; **CI**: confidence interval; **PedsQL**: Pediatric Quality of Life Inventory; **RR**: risk ratio; **SMD**: standardised mean difference

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

^aDowngraded by two levels because of risk of performance and detection bias and inconsistency - see Appendix 12.

^b“A BMI z score or standard deviation score indicates how many units (of the standard deviation) a child’s BMI is above or below the average BMI value for their age group and sex. For instance, a z score of 1.5 indicates that a child is 1.5 standard deviations above the average value, and a z score of -1.5 indicates a child is 1.5 standard deviations below the average value” (NOO NHS 2011).

^cDowngraded by two levels because of risk of performance and detection bias, and imprecision (low event rate) - see Appendix 12

^dDowngraded by two levels due to risk of bias (performance bias and a subjective measure used) and inconsistency (inconsistent direction of effect) - see Appendix 12

^eDowngraded by three levels due to risk of bias (performance bias and a subjective measure used), inconsistency (inconsistent direction of effect) and imprecision (small sample size and number of studies) - see Appendix 12

BACKGROUND

The prevalence of overweight and obese children and adolescents has increased throughout the world, presenting a global public health crisis (Ng 2014; WHO 2015). Although once considered to be a condition affecting only high-income countries, rates of paediatric overweight and obesity have recently started to rise dramatically in some low- and middle-income countries (Wang 2012). Using the International Obesity Task Force (IOTF) standard definition, the age-standardised prevalence of overweight and obesity in children and adolescents has increased in low-, middle-, and high-income countries over the last 30 years (Cole 2000). In 2013, the prevalence of overweight and obese children and adolescents in high-income countries was estimated at 23.8% (95% confidence interval (CI) 22.9 to 24.7) for boys and 22.6% (95% CI 21.7 to 23.6) for girls. In low- and middle-income countries, the prevalence was estimated as 12.9% (95% CI 12.3 to 13.5) for boys and 13.4% (95% CI 13 to 13.9) for girls (Ng 2014).

Inequalities in overweight and obesity prevalence have also been documented. Generally, socioeconomically disadvantaged children in high-income countries (Knai 2012; NCB 2015; Shrewsbury 2008), and children of higher socioeconomic status in low- and middle-income countries (Lobstein 2004; Wang 2012), are at greater risk of becoming overweight. However, this relationship may vary by population demographics (for example age, gender, ethnicity), and environment (for example country, urbanisation) (Wang 2012). The prevalence of obesity has been shown to vary by ethnicity, with large data sets showing substantial ethnic variation in English (HSCIC 2013), American (Freedman 2006; Skinner 2014), and New Zealand (Rajput 2014) child populations.

Whilst there is some evidence that the rate of increase in paediatric obesity may be slowing in some high-income countries, current levels remain too high, and continue to rise in many low- and middle-income countries (Olds 2011; Rokholm 2010). However, an additional concern in some high-income countries such as the USA, in Kelly 2013 and Skinner 2014, and the UK, in CMO 2015 and Ells 2015a, is the rise in severe paediatric obesity. Whilst the IOTF published an international definition for severe paediatric (morbid) obesity in 2012 (Cole 2012), often severe obesity prevalence is reported using country-specific cut points, making international comparisons difficult. However, data from the USA, in Skinner 2014, and England, in Ells 2015a, have shown that the prevalence of severe paediatric obesity varies by socioeconomic status and ethnicity, and may result in a greater risk of adverse cardiometabolic events and severe obesity in adulthood (Kelly 2013).

Description of the condition

Childhood overweight and obesity results from an accumulation of excess body fat, and can increase the risk of both short- and longer-

term health consequences. Numerous obesity-related comorbidities can develop during childhood, which include muscular skeletal complaints (Paulis 2014); cardiovascular risk factors such as hypertension, insulin resistance, and hyperlipidaemia (Reilly 2003), even in very young children (Bocca 2013); motor and developmental delays (Cataldo 2016); and conditions such as sleep apnoea (Narang 2012), asthma (Egan 2013), liver disease, and type 2 diabetes (Daniels 2009b; Lobstein 2004). The condition can also affect psychosocial well-being, with obese young people being susceptible to reduced self esteem and quality of life (Griffiths 2010), as well as stigmatisation (Puhl 2007; Tang-Peronard 2008). Evidence also shows that childhood obesity can track into adulthood (Parsons 1999; Singh 2008; Whitaker 1997), and is therefore associated with an increased risk of ill health later in life (Reilly 2011).

Description of the intervention

Given the serious implications associated with childhood and adolescent obesity, effective treatment is imperative. Whilst the fundamental principles of weight management in children and adolescents are the same as in adults (that is, reduced energy intake and increased energy expenditure), the primary aim of treatment (that is, weight reduction or deceleration of weight gain) and the most suitable intervention approach vary, and are dependent on the child's age and degree of excess weight, among other considerations. Family-based interventions combining dietary, physical activity, and behavioural components have been shown to be effective and are considered the current best practice in the treatment of childhood obesity in children under 12 years of age (Oude Luttikhuis 2009).

Adverse effects of the intervention

It is not anticipated that diet, physical activity, and behavioural interventions will lead to adverse outcomes. However, as with all obesity treatment interventions in children and young people, potential adverse effects should be considered, including effects on linear growth, eating disorders and psychological well-being.

How the intervention might work

Obesity is a complex multifactorial condition with numerous possible biological, behavioural and environmental determinants (Butland 2007). Many children now grow up in an obesogenic environment that promotes energy imbalance through the marketing, affordability and availability of energy dense foods, coupled with decreases in physical activity and increases in screen-based sedentary pursuits (Kremers 2006). Therefore, behaviour-changing interventions that aim to improve dietary intake, increase physical activity levels and reduce sedentary behaviours are often prescribed, and were recommended as a treatment option

for childhood obesity in the preceding Cochrane Review on the treatment of child and adolescent obesity (Oude Luttikhuis 2009). Behaviour-changing interventions may target just one behavioural component (e.g. diet, physical activity or sedentary behaviour) or combine several components, and are often supported by theory-based behaviour-change techniques to help sustain positive changes and prevent relapse. As the family environment (e.g. home activities, meal times and availability of unhealthy food) plays an important role in the aetiology of obesity, parents can be defined as the 'agents for change' particularly in children under 12 years of age (Golan 2004). Given the number of interacting components, difficulty of the target behaviours and variability in possible outcomes, behaviour-changing interventions are regarded as 'complex interventions' (Craig 2008).

Why it is important to do this review

The first version of this systematic review was published in 2003 and included analysis of childhood obesity treatment trials published up until July 2001 (Summerbell 2003). The second version was published in 2009, updating the 2003 review (Oude Luttikhuis 2009).

To reflect the rapid growth in this field, the third update to this review has been split across six reviews focusing on the following treatment approaches: surgery (Ells 2015b); drugs (Mead 2016a); parent-only interventions (Loveman 2015); diet, physical activity, and behavioural interventions for young children up to the age of six years (Colquitt 2016); schoolchildren aged 6 to 11 years; and adolescents aged 12 to 17 years.

The current review examines the effects of interventions for school-aged children aged from 6 years to 11 years. The results of this current review and other systematic reviews in this series will provide information on which to underpin clinical guidelines and health policy on the treatment of childhood obesity.

OBJECTIVES

To assess the effects of diet, physical activity and behavioural interventions (behaviour-changing interventions) for the treatment of overweight or obese children aged 6 to 11 years.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) or cluster RCTs. Included studies observed participants for a minimum of six months (this time frame refers to the intervention itself or to a combination of the intervention with a follow-up phase).

Types of participants

Overweight or obese participants, with a mean age of six years and over, and under 12 years at the commencement of the intervention. Trials involving participants with comorbid disorders were eligible for inclusion as long as the primary focus of the intervention was to treat overweight and obese children. Parents could be involved in the intervention; however, interventions focused solely on the parents (with no child involvement) were excluded from this review as they are evaluated in another Cochrane Review: 'Parent-only interventions for childhood overweight or obesity' (Loveman 2015).

Types of interventions

Any behaviour-changing intervention (with any one or any combination of behavioural, nutritional and physical activity component) delivered as a single or multicomponent intervention, in any setting, using any delivery method, which aimed to treat paediatric obesity using any of the following intervention versus control sequences.

Intervention

- Behaviour-changing intervention (any forms of dietary, physical activity and/or behavioural therapy delivered as single- or multicomponent interventions)

Comparator

- No treatment (including wait-list control)
- Usual care
- Concomitant intervention (another behaviour-changing intervention, which was also delivered in the intervention group).

Minimum duration of intervention

No restriction on the length of intervention

Minimum duration of follow-up

Minimal duration of follow-up was six months from baseline.

Specific exclusion criteria

- Studies with pregnant participants
- Studies that included critically ill participants
- Interventions that specifically dealt with the treatment of eating disorders or type 2 diabetes
- Studies that included participants with a secondary or syndromic cause of obesity

Types of outcome measures

We did not exclude trials if one or several of the review primary or secondary outcomes were not reported.

Primary outcomes

- Changes in measured (not self-reported) body mass index (BMI), BMI z score and weight
- Adverse events

Secondary outcomes

- Health-related quality of life
- Self-esteem
- All-cause mortality
- Morbidity
- Anthropometric measures other than change in BMI, BMI z score and weight
- Behaviour change
- Participants' views of the intervention
- Socioeconomic effects

Method and timing of outcome measurement

- Changes in BMI (kg/m²) and body weight (kg): measured at baseline and any time-point from six months' follow-up.
- Adverse events: defined as adverse outcome that occurs during or after the intervention but is not necessarily caused by it and measured at any time-point after the start of the intervention.
- Health-related quality of life: evaluated by a validated instrument such as Paediatric Quality of Life Inventory and measured at baseline and any time point from six months.
- Self-esteem: evaluated by a validated instrument and measured at baseline and any time point from six months.
- All-cause mortality: measured at any time-point after the start of the intervention.
- Morbidity: defined as illness or harm associated with the intervention and measured at baseline and any time point from six months' follow-up.
- Anthropometric measures other than change in BMI: defined by the use of validated tools (such as waist circumference, skin fold thickness, waist-to-hip ratio, dual X-ray absorptiometry or bioelectrical impedance analysis) and measured at baseline and any time point from six months' follow-up.
- Behaviour change: defined as validated measures of diet or physical activity and measured at baseline and any time point from six months' follow-up.
- Participants' views of the intervention: defined as documented or accounts from participant feedback and measured at baseline and any time point from six months' follow-up.
- Socioeconomic effects: defined as a validated measure of socioeconomic status such as parental income or educational status and measured at baseline and at least at six months.

Summary of findings

We have presented a 'Summary of findings' table to report the following outcomes, listed according to priority.

- Changes in BMI, BMI z score and weight
- Adverse events
- Health-related quality of life
- All-cause mortality
- Morbidity
- Socioeconomic effects

Search methods for identification of studies

Electronic searches

On 14 July 2016 we searched the following sources from inception of each database and placed no restrictions on the language of publication.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2016, issue 6,) in the Cochrane Library
- Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (from 1946 to Present)
- Embase Ovid (1974 to 2016 Week 28)
- PsycINFO (1806 to July Week 1 2016)
- CINAHL
- LILACS (Latin American and Caribbean Health Science Information database) (last update 08/07/2016)
- ClinicalTrials.gov (www.clinicaltrials.gov)
- World Health Organization International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch/)

For details on search strategies and search platforms see Appendix 1.

Searching other resources

We tried to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, (systematic) reviews, meta-analyses and health technology assessment reports. We also contacted study authors of included trials to identify any further studies that we may have missed.

Data collection and analysis

Selection of studies

Two review authors (two of CO, EC, EM, KR, LA, LA-K, LE) independently scanned the abstract, title, or both, of every record we retrieved in the literature searches, to determine which trials we should assess further. We obtained the full texts of all potentially-relevant records. We resolved any discrepancies through consensus or by recourse to a third review author (EM, LE, TB). We have presented a PRISMA flow-chart showing the process of trial selection (Liberati 2009).

Data extraction and management

For trials that fulfilled our inclusion criteria, two review authors (two of CO, DJ, EB, EC, EM, GM, JO, KR, LA, LA-K, LB, LE, TB) independently abstracted key participant and intervention characteristics. We reported data on efficacy outcomes and adverse events using standard data extraction sheets from Cochrane Metabolic and Endocrine Disorders. We resolved any disagreements by discussion or, if required, by consultation with a third review author (EM, KR, LE, TB) for details, see [Characteristics of included studies](#); Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8; Appendix 9; Appendix 10; Appendix 11).

We have provided information including trial identifier about potentially relevant ongoing studies in the [Characteristics of ongoing studies](#) table. We attempted to locate the protocol of each included study and reported primary, secondary and other outcomes in comparison with data in publications in Appendix 6.

We attempted to email all authors of included trials to enquire whether they were willing to answer questions regarding their trials; Appendix 11 shows the results of this survey. Thereafter, we sought relevant missing information on the trial from the primary author(s) of the article, if required.

Dealing with duplicate and companion publications

In the event of duplicate publications, companion documents or multiple reports of a primary trial, we tried to maximise yield of information by collating all available data, and used the most complete dataset aggregated across all known publications.

We listed duplicate publications, companion documents, multiple reports of a primary trial and trial documents of included trials (such as trial registry information) as secondary references under the study ID of the included trial. Furthermore, we also listed duplicate publications, companion documents, multiple reports of a trial and trial documents of excluded trials (such as trial registry information) as secondary references under the study ID of the excluded trial.

Data from clinical trial registers

In case data from included trials were available as study results in clinical trials registers such as [ClinicalTrials.gov](#) or similar sources, we made full use of this information and extracted data. If there was also a full publication of the trial, we collated and critically appraised all available data. If an included trial was marked as a completed study in a clinical trials register but no additional information (study results, publication or both) was available, we added this trial to the table [Characteristics of studies awaiting classification](#).

Assessment of risk of bias in included studies

Two review authors (two of EM, TB, LE, KR, DJ, JO, GM, EC, CO, EB, LA, LA-K, LB) independently assessed the risk of bias of each included trial. We resolved any disagreements by consensus or by consultation with a third review author (EM, TB, LE, KR).

In case of disagreement, we consulted the rest of the group and made a judgement based on consensus. If adequate information was not available from trial authors, trial protocols, or both we contacted trial authors for missing data on 'Risk of bias' items.

We used the Cochrane 'Risk of bias' assessment tool ([Higgins 2011a](#)) and judged 'Risk of bias' criteria as having low, high, or unclear risk. We evaluated individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* according to the criteria and associated categorisations contained therein ([Higgins 2011b](#)).

Random sequence generation (selection bias due to inadequate generation of a randomised sequence) - assessment at trial level

For each included trial we described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

- Low risk of bias: the trial authors achieved sequence generation using computer-generated random numbers or a random numbers table. Drawing of lots, tossing a coin, shuffling cards or envelopes, and throwing dice are adequate if an independent person performed this who was not otherwise involved in the trial. We considered the use of the minimisation technique as equivalent to being random.
- Unclear risk of bias: insufficient information about the sequence generation process.
- High risk of bias: the sequence generation method was non-random or quasi-random (e.g. sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number; allocation by judgement of the clinician; allocation by preference of the participant; allocation based on the results of a laboratory test or a series of tests; or allocation by availability of the intervention).

Allocation concealment (selection bias due to inadequate concealment of allocation prior to assignment) - assessment at trial level

We described for each included trial the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment.

- Low risk of bias: central allocation (including telephone, interactive voice-recorder, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.
- Unclear risk of bias: insufficient information about the allocation concealment.
- High risk of bias: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used

without appropriate safeguards; alternation or rotation; date of birth; case record number; any other explicitly un concealed procedure.

Blinding of participants and study personnel (performance bias due to knowledge of the allocated interventions by participants and personnel during the trial) - assessment at outcome level

We evaluated the risk of detection bias separately for self-reported ('subjective outcomes') versus investigator-assessed ('objective outcomes') outcomes (Hróbjartsson 2013). We noted whether endpoints were self-reported, investigator-assessed or adjudicated outcome measures (see below).

- Low risk of bias: blinding of participants and key study personnel is ensured, and it was unlikely that the blinding could have been broken; no blinding or incomplete blinding, but we judge that the outcome is unlikely to have been influenced by lack of blinding.
- Unclear risk of bias: insufficient information about the blinding of participants and study personnel; the trial does not address this outcome.
- High risk of bias: no blinding or incomplete blinding, and the outcome is likely to have been influenced by lack of blinding; blinding of trial participants and key personnel attempted, but likely that the blinding could have been broken, and the outcome was likely to be influenced by lack of blinding.

Blinding of outcome assessment (detection bias due to knowledge of the allocated interventions by outcome assessment) - assessment at outcome level

We evaluated the risk of detection bias separately for self-reported ('subjective outcomes') versus investigator-assessed ('objective outcomes') outcomes (Hróbjartsson 2013). We noted whether endpoints were self reported, investigator-assessed or adjudicated outcome measures (see below).

- Low risk of bias: blinding of outcome assessment is ensured, and it was unlikely that the blinding could have been broken; no blinding of outcome assessment, but we judge that the outcome measurement was unlikely to have been influenced by lack of blinding.
- Unclear risk of bias: insufficient information about the blinding of outcome assessors; the trial did not address this outcome.
- High risk of bias: no blinding of outcome assessment, and the outcome measurement was likely to have been influenced by lack of blinding; blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement was likely to be influenced by lack of blinding.

Incomplete outcome data (attrition bias due to amount, nature or handling of incomplete outcome data) - assessment at outcome level

For each included trial and for self-reported ('subjective outcomes') versus investigator-assessed ('objective outcomes') outcomes, we described the completeness of data, including attrition and exclusions from the analyses. We stated whether the trial reported attrition and exclusions, and the number of participants included in the analysis at each stage (compared with the number of randomised participants per intervention/comparator groups). We also noted if the trial reported the reasons for attrition or exclusion and whether missing data were balanced across groups or were related to outcomes. We considered the implications of missing outcome data per outcome such as high dropout rates (e.g. above 15%) or disparate attrition rates (e.g. difference of 10% or more between trial arms).

- Low risk of bias: no missing outcome data; reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to introduce bias); missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk was not enough to have a clinically-relevant impact on the intervention effect estimate; for continuous outcome data, plausible effect size (mean difference or standardised mean difference) among missing outcomes is not enough to have a clinically relevant impact on observed effect size; appropriate methods, such as multiple imputation, were used to handle missing data.
- Unclear risk of bias: insufficient information to assess whether missing data in combination with the method used to handle missing data were likely to induce bias; the trial did not address this outcome.
- High risk of bias: reason for missing outcome data was likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically-relevant bias in intervention effect estimate; for continuous outcome data, plausible effect size (mean difference or standardised mean difference) among missing outcomes enough to induce clinically-relevant bias in observed effect size; 'as-treated' or similar analysis done with substantial departure of the intervention received from that assigned at randomisation; potentially inappropriate application of simple imputation.

Selective reporting (reporting bias due to selective outcome reporting) - assessment at trial level

We assessed outcome reporting bias by integrating the results of Appendix 5, 'Matrix of trial endpoints (publications and trial documents)' (Boutron 2014; Jones 2015b; Mathieu 2009), with those

of Appendix 6, 'High risk of outcome reporting bias according to ORBIT classification' (Kirkham 2010). This analysis formed the basis for the judgement of selective reporting.

- Low risk of bias: the trial protocol was available and all of the trial's pre-specified (primary and secondary) outcomes that were of interest in the review had been reported in the pre-specified way; the study protocol was unavailable, but it was clear that the published reports included all expected outcomes (ORBIT classification).

- Unclear risk of bias: insufficient information about selective reporting.

- High risk of bias: not all of the trial's pre-specified primary outcomes review were reported incompletely so that we could not enter them in a meta-analysis; the trial report failed to include results for a key outcome that we would expected to have been reported for such a trial (ORBIT classification).

Other bias (bias due to problems not covered elsewhere) - assessment at trial level

- Low risk of bias: the trial appears to be free of other sources of bias.

- Unclear risk of bias: there was insufficient information to assess whether an important risk of bias existed; insufficient rationale or evidence that an identified problem introduced bias.

- High risk of bias: the trial has a potential source of bias related to the specific trial design used; the trial has been claimed to have been fraudulent; or the trial had some other serious problem.

We have presented a 'Risk of bias' graph and a 'Risk of bias' summary figure.

We distinguished between self-reported, investigator-assessed and adjudicated outcome measures.

We defined the following endpoints as potentially self-reported outcomes.

- Adverse events, if reported by participants
- Health-related quality of life
- Self-esteem
- Participants views of the intervention
- Behaviour change, if reported by participants

We defined the following outcomes as potentially investigator-assessed outcomes.

- Changes in BMI and weight, if measured by trial personnel
- Adverse events, if measured by trial personnel
- All-cause mortality
- Morbidity
- Behaviour change, if measured by trial personnel

Summary assessment of risk of bias

Risk of bias for a trial across outcomes: some 'Risk of bias' domains such as selection bias (sequence generation and allocation

sequence concealment), affect the risk of bias across all outcome measures in a trial. In case of high risk of selection bias, we marked all endpoints investigated in the associated trial as high risk. Otherwise, we did not perform a summary assessment of the risk of bias across all outcomes for a trial.

Risk of bias for an outcome within a trial and across domains: we assessed the risk of bias for an outcome measure by including all entries relevant to that outcome (i.e. both trial-level entries and outcome-specific entries). We considered low risk of bias to denote a low risk of bias for all key domains, unclear risk to denote an unclear risk of bias for one or more key domains and high risk to denote a high risk of bias for one or more key domains.

Risk of bias for an outcome across trials and across domains: these were our main summary assessments that we incorporated into our judgements about the quality of evidence in the 'Summary of finding' tables. We defined outcomes as at low risk of bias when most information came from trials at low risk of bias, unclear risk when most information came from trials at low or unclear risk of bias, and high risk when a sufficient proportion of information came from trials at high risk of bias.

Measures of treatment effect

When at least two included trials were available for a comparison and a given outcome, we expressed dichotomous data as a risk ratio (RR) or odds ratio (OR) with 95% confidence interval (CI). For continuous outcomes measured on the same scale (e.g. weight loss in kg) we estimated the intervention effect using the mean difference with 95% CI. For continuous outcomes measuring the same underlying concept (e.g. health-related quality of life) but using different measurement scales, we calculated the standardised mean difference (SMD). We expressed time-to-event data as hazard ratio with 95% CI.

Unit of analysis issues

We took into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials and multiple observations for the same outcome. If more than one comparison from the same trial was eligible for inclusion in the same meta-analysis, we either combined groups to create a single pair-wise comparison (if the groups were suitably similar interventions) or appropriately reduced the sample size so that the same participants did not contribute multiple times (splitting the 'shared' group into two or more groups). While the latter approach offers some solution to adjusting the precision of the comparison, it does not account for correlation arising from the same set of participants being in multiple comparisons (Deeks 2011).

We analysed cluster RCTs separately from individually randomised trials.

Dealing with missing data

If possible, we obtained missing data from the authors of the included trials. We carefully evaluated important numerical data such as screened, eligible, randomly-assigned participants as well as intention-to-treat, as-treated and per-protocol populations. We investigated attrition rates (e.g. dropouts, losses to follow-up, withdrawals), and we critically appraised issues concerning missing data and use of imputation methods (e.g. last observation carried forward).

Where standard deviations for outcomes were not reported, and we did not receive information from trial authors, we calculated these following the methods presented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c). Where papers did not report results as change from baseline, we calculated this and for the standard deviation differences followed the methods presented in the *Cochrane Handbook for Systematic Reviews of Interventions* for imputing these (Section 16.1.3.2 Imputing standard deviations for changes from baseline; Higgins 2011c), and assumed a correlation of 0.5 between baseline and follow-up measures as suggested by Follmann 1992.

Assessment of heterogeneity

In the event of substantial clinical, methodological or statistical heterogeneity, we did not report trial results as the pooled effect estimate in a meta-analysis.

We identified heterogeneity (inconsistency) by visually inspecting the forest plots and by using a standard χ^2 test with a significance level of $\alpha = 0.1$ (Higgins 2002). In view of the low power of this test, we also considered the I^2 statistic (Higgins 2003), which quantifies inconsistency across trials to assess the impact of heterogeneity on the meta-analysis, where an I^2 statistic of 75% or more indicates a considerable level of inconsistency (Deeks 2011).

When we found heterogeneity, we attempted to determine potential reasons for it by examining individual study and subgroup characteristics.

Assessment of reporting biases

If we included 10 studies or more for a given outcome, we used funnel plots to assess small study effects. Due to several explanations for funnel plot asymmetry we interpreted results carefully (Sterne 2011).

Data synthesis

We undertook a meta-analysis only if we judged participants, interventions, comparisons and outcomes to be sufficiently similar. We included all relevant trials regardless of risk of bias assessments using random-effect models; subgrouping was undertaken according to risk of bias (high, low, unclear risk). We performed statistical analyses according to the statistical guidelines presented in the

Cochrane Handbook for Systematic Reviews of Interventions (Deeks 2011).

Quality of evidence

We have presented the overall quality of the evidence for each outcome specified under 'Types of outcome measures: Summary of findings' according to the GRADE approach (gradeworkinggroup.org), which takes into account issues related to internal validity (risk of bias, inconsistency, imprecision, publication bias) and also to external validity, such as directness of results. Two review authors (EM, TB) independently rated the quality of the evidence for each outcome. We have presented a summary of the evidence in a 'Summary of findings' table. This provides key information about the best estimate of the magnitude of the effect, in relative terms and as absolute differences, for each relevant comparison of alternative management strategies, numbers of participants and trials that address each important outcome and a rating of overall confidence in effect estimates for each outcome. We created the 'Summary of findings' table based on the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011) using Review Manager 5 (RevMan 5) table editor (RevMan 2014). We have included an appendix titled 'Checklist to aid consistency and reproducibility of GRADE assessments' (Meader 2014), to help with standardisation of the 'Summary of findings' tables. Alternatively, we planned to use the GRADEpro Guideline Development Tool (GDT) software (GRADEproGDT 2015) and would have presented evidence profile tables as an appendix. We have presented results for the outcomes as described in the 'Types of outcome measures' section. If meta-analysis was not possible, we presented the results narratively in the 'Summary of findings' table. We justified all decisions to downgrade the quality of trials using footnotes and we made comments to aid the reader's understanding of the Cochrane Review where necessary.

Subgroup analysis and investigation of heterogeneity

We expected the following characteristics to introduce clinical heterogeneity, and we planned to carry out the following subgroup analyses including investigation of interactions (Altman 2003).

- Type of control (no treatment, usual care or another intervention with the same components)
- Type of intervention (diet, physical activity and/or behavioural therapy)
- Attrition bias (low, high, unclear)
- Setting
- Duration of post-intervention follow-up
- Parental involvement
- Baseline BMI z score

There is no single accepted classification for severe obesity in school children; we used the 2.67 BMI z score which equates to the 99.6th centile for severe obesity (Ells 2015a). We put studies into

subgroups based on a whether their mean baseline BMI z score was less than 2.67 units, or 2.67 units or over.

Sensitivity analysis

We investigated the impact of imputation on meta-analyses by performing sensitivity analyses, and we reported per outcome which trials were included with imputed SDs.

RESULTS

Description of studies

For an overview of study populations please see [Table 1](#); for a detailed description of trials, see '[Characteristics of included studies](#)', '[Characteristics of excluded studies](#)', and '[Characteristics of ongoing studies](#)' sections.

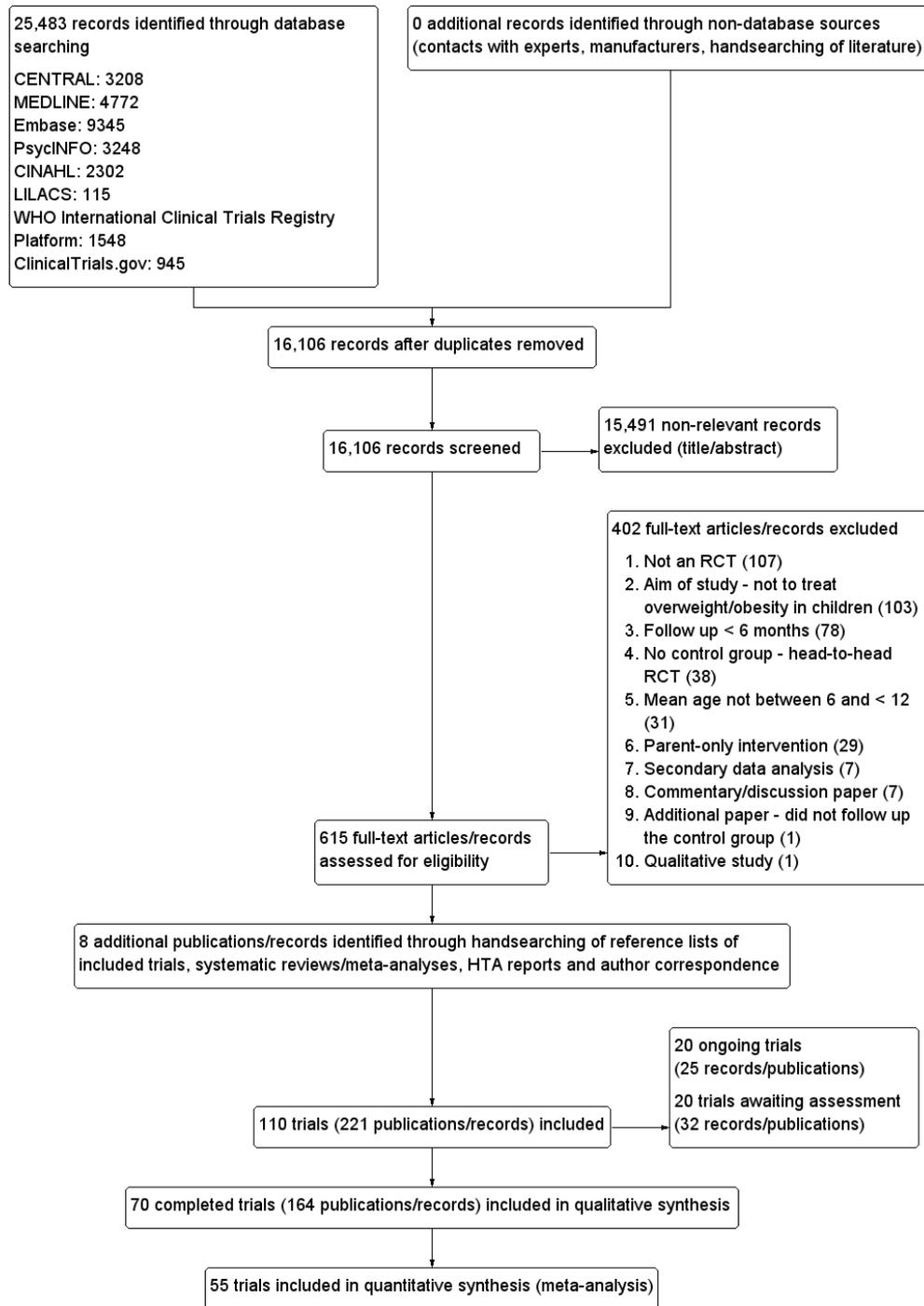
Results of the search

One overarching search was conducted for all the behaviour-changing reviews:

- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years.
- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in schoolchildren from the age of 6 to 11 years.
- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years.
- Parent-only interventions for childhood overweight or obesity.

Our comprehensive literature searches identified 25,483 records, after duplicates were removed this left 16,106 records. From these 15,491 records were excluded based on the title/abstract. We obtained 615 records as full-text articles and screened them for inclusion or exclusion (see [Figure 1](#) for the PRISMA flow diagram) ([Liberati 2009](#)). We included 70 trials (164 articles) in the review and 55 trials in the meta-analyses. Twenty trials are awaiting classification ([Characteristics of studies awaiting classification](#)) and 20 trials are ongoing ([Characteristics of ongoing studies](#)).

Figure I. Trial flow diagram



Ongoing studies

We found 20 ongoing RCTs, see [Characteristics of ongoing studies](#). All but one are parallel RCTs. Five of the 20 ongoing studies only include participants within the age range of this review (between six years and less than 12 years). This includes: [ChiCTR-IQB-15005874](#); [NCT01642836](#); [NCT02258126](#); [NCT02343367](#); [RBR-8ttw64](#). Eleven studies have age ranges which include children 12 years or older. This includes: [DRKS00007879](#) (8 years to 16 years old), [Moore 2013](#) (11 years to 12 years old), [NCT01221220](#) (8 years to 15 years old), [NCT01574352](#) (10 years to 13 years old), [NCT01736748](#) (6 years to 18 years old), [ACTRN12613001037796](#) (7 years to 16 years old), [NCT02082080](#) (9 years to 14 years old), [NCT02560493](#) (10 years to 12 years old), [NCT02711488](#) (9 years to 15 years old), [NCT02720302](#) (9 years to 12 years old), and [NCT02773823](#) (8 years to 12 years old). Three studies include children younger than six years old: [ISRCTN81798055](#) (4 years to 11 years old), [NCT02573142](#) (5 years to 11 years old), and [NCT02684214](#) (4 years to 10 years old). In addition, one study has an age range that include children both younger and older than six years to less than 12 years old: [NCT02124460](#) (2 years to 12.9 years old). Many studies include both overweight and obese participants, while eight studies only include obese participants. In one ongoing trial ([NCT02720302](#)) only overweight children are included. The majority of interventions (N = 14) have a behavioural, diet and physical activity component. The remaining studies are diet and exercise component only ([ChiCTR-IQB-15005874](#); [NCT02082080](#); [RBR-8ttw64](#)), physical activity and behavioural only ([NCT01736748](#)), physical activity only ([ACTRN12613001037796](#)) and behavioural only ([DRKS00007879](#); no mention of a diet or physical activity component). Eleven studies have a usual care/standard treatment control group while four studies include a no-treatment control group ([NCT02082080](#); [NCT02560493](#); [NCT02711488](#); [NCT02773823](#)). The remaining five trials compare a behaviour-changing intervention plus component with the same behaviour-changing intervention without the additional component ([DRKS00007879](#); [NCT01221220](#); [NCT02560493](#); [NCT02684214](#); [NCT02720302](#)). The most common primary outcome is BMI/BMI z score (N = 17 trials). No trial reported adverse events as a primary outcome.

Studies awaiting classification

Twenty studies are awaiting classification. Seventeen trials were identified on a clinical trial register website as completed; however, no results are available. For the remaining three studies we were unable to obtain a full publication; therefore, we are unable to assess whether the trial met the inclusion of this review.

Included studies

We have presented a detailed description of the characteristics of the 70 included trials in [Characteristics of included studies](#), and in Appendix 2; Appendix 3; Appendix 4. The following is a succinct overview.

Source of data

We obtained the majority of data presented in the review from published literature, including supplementary published data and trials registers where available. Some data were requested from study authors (see Appendix 11 for an overview). Only one study did not have data published in a journal article and all data were obtained from the clinical trial record ([NCT02436330](#)).

Comparisons

Of the 70 studies included in this review, only 21 studies included a true control; hence, the control groups received no treatment throughout the duration of the study ([Arauz Boudreau 2013](#); [Boutelle 2014](#); [Bryant 2011](#); [Coppins 2011](#); [Croker 2012](#); [de Niet 2012](#); [Eddy Ives 2012](#); [Epstein 1984a](#); [Maddison 2011](#); [Maddison 2014](#); [Markert 2014](#); [McCallum 2007](#); [Nowicka 2009](#); [Reinehr 2010](#); [Sacher 2010](#); [Satoh 2007](#); [Siwik 2013](#); [Vann 2013](#); [Wafa 2011](#); [Wake 2009](#); [Wake 2013](#)).

Control group participants in 34 studies were given usual/standard care, either as defined by the study authors or assessed by the review authors ([Alves 2008](#); [Barkin 2011](#); [Berry 2014](#); [Davis 2013](#); [Davoli 2013](#); [Diaz 2010](#); [Epstein 2000a](#); [Faude 2010](#); [Gillis 2007](#); [Gunnarsdottir 2011a](#); [Hamilton-Shield 2014](#); [Ho 2016](#); [Hughes 2008](#); [Kalarchian 2009](#); [Kalavainen 2007](#); [Kirk 2012](#); [Lison 2012](#); [Lochrie 2013](#); [Looney 2014](#); [Mirza 2013](#); [Nemet 2005](#); [Nova 2001](#); [O'Connor 2013](#); [Rodearmel 2007](#); [Saelens 2013](#); [Serra-Paya 2015](#); [Taveras 2015](#); [Taylor 2015](#); [Waling 2012](#); [Warschburger 2016](#); [Weigel 2008](#); [Weintraub 2008](#); [Wilfley 2007](#); [Wright 2012](#)).

The remaining 15 studies ([Bathrellou 2010](#); [Berry 2007](#); [Duffy 1993](#); [Duggins 2010](#); [Epstein 1985a](#); [Epstein 1985b](#); [Epstein 1985c](#); [Epstein 2001](#); [Epstein 2005](#); [Epstein 2015](#); [Flodmark 1993](#); [Larsen 2015](#); [NCT02436330](#); [Schwingshandl 1999](#); [Woo 2004](#)) included a control condition in which the participants received an intervention that was also provided in the intervention group, with the intervention group also receiving an additional component (for example, diet plus physical activity plus behavioural therapy versus diet plus physical activity). Five of these trials had multiple comparator arms and could also be evaluated as intervention versus control (either usual care or no treatment) ([Epstein 1984a](#); [Epstein 2000a](#); [Looney 2014](#); [Taveras 2015](#); [Vann](#)

2013); hence, both comparator types were evaluated where appropriate.

Overview of trial populations

Individual study sample size at randomisation ranged from 16 (eight in the intervention group, eight in the control group) (Gunnarsdottir 2011a) to 686 (336 in the intervention group, 350 in the control group) (Warschburger 2016). Twenty-one studies had a sample size less than 50 at baseline, 21 studies had between 50 and 100 participants, 17 studies had between 100 and 200 participants, four studies had between 200 and 300 participants, and finally, seven studies had more than 300 participants at baseline; these included Berry 2014; Davoli 2013; Maddison 2011; Markert 2014; Taveras 2015; Warschburger 2016 and Wright 2012. Only 39 studies clearly reported using a power calculation in their methods; only 10 of these studies actually achieved their target sample size at follow-up, after dropout (Croker 2012; Davis 2013; Davoli 2013; Hughes 2008; Lison 2012; McCallum 2007; Nemet 2005; Wafa 2011; Wilfley 2007; Wright 2012).

A total of 8461 participants were randomised to either the intervention or control groups. In three studies, it was unclear how many participants were measured at the endpoint (i.e. completed the whole study) (Berry 2014, Epstein 2015, Woo 2004). Therefore, in the remaining 67 studies, 5960 participants out of the 7997 randomised were measured at the study's endpoint (74.5%). The endpoints varied across studies with the shortest follow-up time from baseline being 24 weeks and the longest being three years. The number and proportions of participants completing the study, where reported, ranged from 2899 participants (71.9%) in the intervention groups and 2737 participants (76.9%) in the control groups.

Trial design

All 70 studies had a superiority design. All but six studies were parallel RCTs; four studies (Berry 2007; Berry 2014; Taveras 2015; Wright 2012) were cluster RCTs. Coppins 2011 and Siwik 2013 were presented as cross-over trials; these were treated as parallel RCTs where only the first phase was analysed before crossover and the control groups were treated as waiting-list controls.

Twenty trials were multi-centre (Barkin 2011; Berry 2014; Davis 2013; Davoli 2013; de Niet 2012; Duggins 2010; Eddy Ives 2012; Gillis 2007; Hamilton-Shield 2014; Larsen 2015; McCallum 2007; O'Connor 2013; Reinehr 2010; Sacher 2010; Satoh 2007; Serra-Paya 2015; Taveras 2015; Wake 2009; Wake 2013; Wright 2012), ranging from 2 to 69 centres.

Trials were published between 1984 and 2016.

One study (Hamilton-Shield 2014) was terminated before the endpoint due to recruitment issues and technical problems with the intervention equipment.

The length of the interventions ranged from 10 days to two years. Just over half (N = 37) trials had a period of post intervention fol-

low-up (defined as the period after the active intervention and up to the final measurement) with a median duration of 10 months; follow-up from end of the intervention period ranged from one month to two years. We did not extract any information on whether the post-intervention period was passive (i.e. just measurement) or active (i.e. a maintenance intervention period with the aim of helping children to sustain the weight status they had achieved).

Settings

Thirty of the included studies were conducted in the USA, six in the UK, five in Germany, four in Australia, three each in Sweden, New Zealand and Spain, and two each in Israel and in Italy. The remaining studies were conducted in Austria, Brazil, Canada, Denmark, Finland, Greece, Hong Kong, Iceland, Japan, Malaysia, Mexico and the Netherlands. Twenty-five studies were conducted in secondary care, eleven in primary care, seven in university research clinics, seven in the community, four in homes and four in schools. Ten studies were based in more than one setting and in two studies the setting was unclear (Duffy 1993, NCT02436330).

Participants

All participants included in this review were overweight, obese or severely obese at baseline; various diagnostic criteria were applied across the trials. Thirty-two studies included children who were overweight or obese (including morbidly obese) while 26 studies only included children who were obese (including morbidly obese). Overweight children only (not obese) were included in five studies (Davoli 2013; Duffy 1993; Faude 2010; Larsen 2015; Reinehr 2010). Six studies included both overweight and obese children but did not include morbidly/severely obese children (Eddy Ives 2012; Epstein 2001; McCallum 2007; O'Connor 2013; Saelens 2013; Wake 2009). Only one study included just severely obese children (Kalarchian 2009).

All but three studies were conducted in upper-income countries (defined using the World Bank classification). Alves 2008; Diaz 2010 and Wafa 2011 included participants from upper middle-income countries.

Of the 38 studies that clearly reported the ethnic group(s) of their participants, six studies reported that all of their participants were white (Coppins 2011; Epstein 1985a; Epstein 1985b; Epstein 1985c; Lison 2012; Warschburger 2016). In 23 studies participants were of mixed ethnic groups, but the majority ethnic group was white (Alves 2008; Boutelle 2014; Bryant 2011; Croker 2012; Davis 2013; Epstein 2000; Epstein 2001; Epstein 2005; Hamilton-Shield 2014; Kalarchian 2009; Kirk 2012; Lochrie 2013; Looney 2014; NCT02436330; Reinehr 2010; Rodearmel 2007; Sacher 2010; Saelens 2013; Siwik 2013; Taveras 2015; Wake 2009; Wake 2013; Wilfley 2007). Berry 2007 had a similar number of white and black participants, and also some Hispanic

participants. [Berry 2014](#) and [Vann 2013](#) had a higher percentage of African American children in their studies while [O'Connor 2013](#) had a higher percentage of Hispanic/Latino/Mexican American participants. In [Mirza 2013](#), [Weintraub 2008](#) and [Wright 2012](#), the majority of participants were Hispanic/Latino. [Woo 2004](#) included participants who were all Hong Kong Chinese and [Wafa 2011](#) included participants who were of Malay ethnicity. The mean age (SD) of participants at baseline ranged from 6.2 (1.2) years ([Larsen 2015](#)) to 11.9 (2.4) years ([Berry 2007](#)), with the majority of studies including participants with a mean age over nine years but under 12 years of age; only 17 studies included participants with a mean age under nine years old ([Alves 2008](#); [Bryant 2011](#); [Coppins 2011](#); [Davis 2013](#); [Davoli 2013](#); [Epstein 1985c](#); [Hughes 2008](#); [Kalavainen 2007](#); [Larsen 2015](#); [Looney 2014](#); [McCallum 2007](#); [Nova 2001](#); [O'Connor 2013](#); [Taylor 2015](#); [Wake 2009](#); [Wake 2013](#); [Wright 2012](#)). One study ([Lison 2012](#)) had three groups with one group having a mean age of 12.3 years; however, the average age across all three groups fell under the cut-off of 12 years.

Twenty-six studies had roughly an equal number of boys and girls at baseline, while in 27 studies, 55% to 69% of participants were female at baseline. In six studies, there were 70% or more girls at baseline; this included two studies that only recruited girls ([Epstein 1985b](#); [Epstein 1985c](#)). Seven studies had more boys than girls at baseline but only two of these had more than 70% boys ([Davis 2013](#); [Maddison 2011](#)). No study included boys only. In five studies it was unclear how many boys and girls were included at baseline ([Epstein 1984a](#); [Gunnarsdottir 2011a](#); [Nowicka 2009](#); [Weintraub 2008](#)). Socioeconomic status was recorded in 32 studies at baseline (no studies reported on socioeconomic effects as an outcome); however, the variables and tools used varied greatly between the studies.

Mean BMI or BMI z score, or both, at baseline were reported in 63 studies. Mean BMI (kg/m^2) value at baseline ranged from 18.3 kg/m^2 to 41.1 kg/m^2 in the intervention group and 18.2 kg/m^2 to 36.7 kg/m^2 in the control group with a median values of 26.6 kg/m^2 and 26.5 kg/m^2 , respectively. Mean BMI z score at baseline ranged from 1.3 units to 5.6 units in the intervention group and 1.3 units to 5.3 units in the control group with median values of 2.2 units and 2.2 units, respectively. Only one study reported the mean duration at which their participants had been overweight or obese prior to starting the trial. [Davoli 2013](#) reported 63.6% and 64.3% of intervention and control participants, respectively, were overweight before five years old.

Comorbidities at baseline were reported in five studies ([Eddy Ives 2012](#); [Gunnarsdottir 2011a](#); [Kalavainen 2007](#); [Satoh 2007](#); [Waling 2012](#)) and included asthma, type 2 diabetes, metabolic syndrome, depression, anxiety and fatty liver diagnoses. None of the interventions had a pharmacological component; however participants in all three groups in one study were encouraged to take a vitamin/mineral supplement throughout the study ([Kirk 2012](#)).

Diagnosis

A number of different growth chart references/criteria were used to categorise overweight and obesity. The 'United States Centers for Disease Control and Prevention (CDC) 2000 growth reference' (cdc.gov/growthcharts) was used to define overweight and obesity in 31 studies while the 'International Obesity Task Force (IOTF) cut-offs' (worldobesity.org/resources/child-obesity/newchildcutoffs) were used in 12 studies. Four studies based in the UK used the 'British 1990 growth reference (UK90)' (noo.org.uk) to define the weight status categories ([Bryant 2011](#); [Hamilton-Shield 2014](#); [Hughes 2008](#); [Sacher 2010](#)), while only one study used the 'World Health Organization (WHO) Child Growth Standard' (who.int/childgrowth) ([Eddy Ives 2012](#)). The remaining studies used references specific to their country, raw BMI or percentage overweight cut off references - but in four studies it was unclear which growth references were used to define overweight and obesity ([Duffy 1993](#); [Ho 2016](#); [NCT02436330](#); [Schwingshandl 1999](#)).

Interventions

The majority of studies in this review had a behavioural, diet and physical activity component (N = 49). Two studies included both a behavioural and diet component but had no physical activity ([Boutelle 2014](#); [Flodmark 1993](#)). [Barkin 2011](#) and [Maddison 2014](#) were the only studies to have both a behavioural and physical activity intervention without a diet component. Four studies had only a physical activity arm ([Alves 2008](#); [Faude 2010](#); [Maddison 2011](#); [Weintraub 2008](#)). Eleven studies had no behavioural arm ([Duggins 2010](#); [Eddy Ives 2012](#); [Kirk 2012](#); [Larsen 2015](#); [Lison 2012](#); [Nova 2001](#); [Nowicka 2009](#); [Rodearmel 2007](#); [Schwingshandl 1999](#); [Vann 2013](#); [Woo 2004](#)). [Ho 2016](#) and [Satoh 2007](#) were the only studies to include a diet component alone.

The majority of studies (N = 65) included the child and parent/caregiver (or child's family). Four of these 65 studies involved both the child and parent/caregiver; however, the main aim of the intervention was to target the parent ([McCallum 2007](#); [Taveras 2015](#); [Wafa 2011](#); [Warschburger 2016](#)). Five studies only involved the child in the intervention and there was no input from the parent/caregiver ([Alves 2008](#); [Faude 2010](#); [Maddison 2011](#)), [Schwingshandl 1999](#), [Vann 2013](#)). One study directly investigated whether parental involvement or parental control would add benefit to an intervention aimed at the child ([Bathrellou 2010](#)).

Participants in two studies were given treatment before randomisation, this included [de Niet 2012](#) where a behavioural-changing treatment (BFC) programme was given to all participants, then they were randomised to receive a short message service maintenance treatment (via text messages) plus BFC follow-up sessions or BFC follow-up sessions only for an additional nine months. [Wilfley 2007](#) included a weight-loss treatment and then participants were randomised to three different maintenance arms. These two studies were the only two studies that specifically investigated

the impact of a maintenance programme (rather than treatment programme).

Treatments provided to the intervention and comparator groups were mainly led (or co-led) by registered dietitians, therapists or psychologists. Other professionals involved in providing treatment included nutritionists, paediatricians, nurses, physical activity teachers/coaches, exercise consultants/specialists, undergraduates/postgraduates studying nutrition or physical activity-related or medical degrees, GPs, physicians, physiotherapists, exercise psychologists, health educators/trainers, research assistants, trained study members and community workers.

Outcomes

Fifty-one trials explicitly stated a primary/secondary endpoint in their publications (Appendix 5). The most commonly defined primary outcome was BMI or BMI z score (SDS). A median of seven outcomes was collected by the 70 studies, ranging between two and 27 outcomes. All 70 studies measured at least one outcome defined in this review - for a detailed description of how each outcome was measured in each study see Appendix 7. A total of 67 studies reported measuring BMI or BMI z scores in their publications. Only six studies reported adverse events occurring (it was unclear whether any adverse events occurred in 29 studies). Forty-seven studies measured additional body fat distribution measures such as waist circumference, body fat percentage and percent overweight. Fifty-six studies measured behaviour-change outcomes us-

ing validated tools, such as physical activity via accelerometry data, and dietary behaviours via food frequency questionnaires. Health-related quality of life or self-esteem was measured by 21 studies, while participants' views of the intervention was reported by nine studies. Only two studies reported morbidity data such as number of participants with metabolic syndrome. No studies reported socioeconomic effects or all-cause mortality.

We found differences between defined primary outcomes in publication and trials registers/protocols eight studies (Boutelle 2014; de Niet 2012; Epstein 2015; Kalarchian 2009; Kirk 2012; Lochrie 2013; Looney 2014; Taveras 2015) - see Appendix 5 and Appendix 6 for more details on outcome reporting bias.

Excluded studies

We excluded 402 full-text articles after evaluation, see [Characteristics of excluded studies](#). The main reasons for exclusions was the trial not being an RCT, mean age was not six years to less than 12 years old, the aim of the study was preventing overweight/obesity, and length of follow-up was less than six months from baseline.

Risk of bias in included studies

For details on the risk of bias of the included trials see [Characteristics of included studies](#). For an overview of review authors' judgements about each risk of bias item for individual trials and across all trials see [Figure 2](#) and [Figure 3](#).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies (blank cells indicate that the particular outcome was not investigated in some studies)

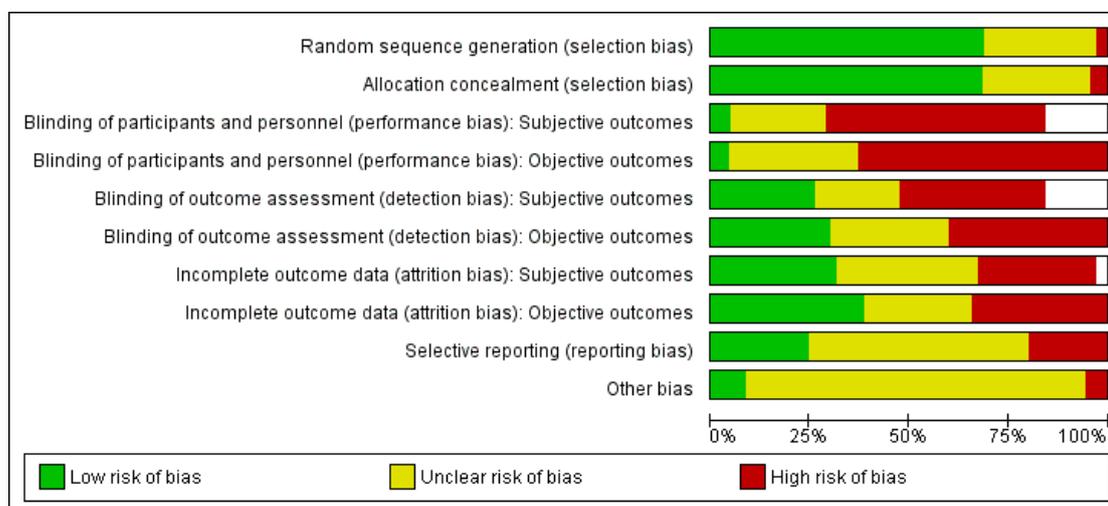


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study (blank cells indicate that the study did not report that particular outcome)

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias) - Subjective outcomes	Blinding of outcome assessment (detection bias) - Subjective outcomes	Blinding of outcome assessment (detection bias) - Objective outcomes	Incomplete outcome data (attrition bias) - Subjective outcomes	Incomplete outcome data (attrition bias) - Objective outcomes	Selective reporting (reporting bias)	Other bias
Ahns 2008	●	●	●	●	●	●	●	●	●
Arazi-Boudreau 2013	●	●	●	●	●	●	●	●	●
Barlin 2011	●	●	●	●	●	●	●	●	●
Battirelou 2010	●	●	●	●	●	●	●	●	●
Berry 2007	●	●	●	●	●	●	●	●	●
Berry 2014	●	●	●	●	●	●	●	●	●
Boutefte 2014	●	●	●	●	●	●	●	●	●
Bryant 2011	●	●	●	●	●	●	●	●	●
Coppins 2011	●	●	●	●	●	●	●	●	●
Crozier 2012	●	●	●	●	●	●	●	●	●
Davis 2013	●	●	●	●	●	●	●	●	●
Davoli 2013	●	●	●	●	●	●	●	●	●
de Nêl 2012	●	●	●	●	●	●	●	●	●
Diaz 2010	●	●	●	●	●	●	●	●	●
Duffy 1993	●	●	●	●	●	●	●	●	●
Duggins 2010	●	●	●	●	●	●	●	●	●
Eddihis 2012	●	●	●	●	●	●	●	●	●
Epstein 1984a	●	●	●	●	●	●	●	●	●
Epstein 1985a	●	●	●	●	●	●	●	●	●
Epstein 1985b	●	●	●	●	●	●	●	●	●
Epstein 1985c	●	●	●	●	●	●	●	●	●
Epstein 2000a	●	●	●	●	●	●	●	●	●
Epstein 2001	●	●	●	●	●	●	●	●	●
Epstein 2005	●	●	●	●	●	●	●	●	●
Epstein 2015	●	●	●	●	●	●	●	●	●
Faulstich 2010	●	●	●	●	●	●	●	●	●
Fiedmark 1993	●	●	●	●	●	●	●	●	●
Osik 2007	●	●	●	●	●	●	●	●	●
Gunnarsdottir 2011a	●	●	●	●	●	●	●	●	●
Hamilton-Shield 2014	●	●	●	●	●	●	●	●	●
Ho 2016	●	●	●	●	●	●	●	●	●
Hughes 2008	●	●	●	●	●	●	●	●	●
Kabernon 2009	●	●	●	●	●	●	●	●	●
Kalishman 2007	●	●	●	●	●	●	●	●	●
Kim 2012	●	●	●	●	●	●	●	●	●
Larsen 2015	●	●	●	●	●	●	●	●	●
Lison 2012	●	●	●	●	●	●	●	●	●
Lochte 2013	●	●	●	●	●	●	●	●	●
Looney 2014	●	●	●	●	●	●	●	●	●
Maddison 2011	●	●	●	●	●	●	●	●	●
Maddison 2014	●	●	●	●	●	●	●	●	●
Marlet 2014	●	●	●	●	●	●	●	●	●
McCaffery 2007	●	●	●	●	●	●	●	●	●
Mizu 2013	●	●	●	●	●	●	●	●	●
NCT02436338	●	●	●	●	●	●	●	●	●
Nemet 2005	●	●	●	●	●	●	●	●	●
Nowa 2001	●	●	●	●	●	●	●	●	●
Nowicka 2009	●	●	●	●	●	●	●	●	●
O'Connor 2013	●	●	●	●	●	●	●	●	●
Reinahr 2010	●	●	●	●	●	●	●	●	●
Robaume 2007	●	●	●	●	●	●	●	●	●
Saxler 2010	●	●	●	●	●	●	●	●	●
Saekel 2013	●	●	●	●	●	●	●	●	●
Sahn 2007	●	●	●	●	●	●	●	●	●
Schwingshendl 1998	●	●	●	●	●	●	●	●	●
Beta-Paya 2015	●	●	●	●	●	●	●	●	●
Smek 2013	●	●	●	●	●	●	●	●	●
Taveras 2015	●	●	●	●	●	●	●	●	●
Taylor 2015	●	●	●	●	●	●	●	●	●
Vaini 2013	●	●	●	●	●	●	●	●	●
Wafa 2011	●	●	●	●	●	●	●	●	●
Wake 2009	●	●	●	●	●	●	●	●	●
Wake 2013	●	●	●	●	●	●	●	●	●
Walling 2012	●	●	●	●	●	●	●	●	●
Warschburger 2016	●	●	●	●	●	●	●	●	●
Weigel 2008	●	●	●	●	●	●	●	●	●
Weiraub 2008	●	●	●	●	●	●	●	●	●
Withey 2007	●	●	●	●	●	●	●	●	●
Woo 2004	●	●	●	●	●	●	●	●	●
Wright 2012	●	●	●	●	●	●	●	●	●

Allocation

Forty-eight studies reported adequate sequence generation (i.e. low risk), 20 were unclear, and two were high risk due to the randomisation method they used. We rated 49 studies low risk (i.e. adequate allocation concealment), 18 were unclear and three were high risk of allocation concealment. Overall, the risk of selection bias was low for 42 studies, unclear for 26 studies and high for two studies (Gillis 2007; Lison 2012).

Blinding

Forty-four studies did not blind their participants or study personnel to study group allocation with regards to objective measures and we assessed them as high risk. We rated 23 studies as unclear and three studies as low risk for performance bias because participants and study personnel were both blinded to study group allocation. With regards to subjective measures, we judged all bias assessments to be at the same level of risk as the objective measures unless a study did not have any subjective outcomes, then the risk was left blank in the risk of bias table and figures (this also applied to detection and attrition bias).

Outcome assessors collecting objective outcomes were blinded to the study group in 21 studies and we assessed them as low risk, while in 21 studies it was unclear whether outcome assessment was blinded; we rated 28 studies as high risk of detection bias because outcome assessment was not blinded. If a study had subjective outcomes, then we gave the detection bias assessment the same classification as for objective measures.

Incomplete outcome data

Dropout rates were classed as low if less than 15%; high if more than 25% in studies with follow-up from baseline of six to 12 months or more than 30% in studies with over 12 months' follow-up; unclear if more than 15% but less than 25% in studies with follow-up from six to 12 months, or less than 30% in studies with follow-up more than 12 months. We also took into consideration whether a study used intention-to-treat and also what method it used to impute missing data. For objective outcomes, we rated 27 studies as low risk; 24 studies at high risk; and 19 studies at unclear risk.

Selective reporting

To assess selective outcome reporting we checked whether publications reported outcomes described in the publication itself and in a protocol/clinical trials register entry. We rated 17 studies as low risk because they provided results for all outcomes described. Studies could only be rated as low risk if they had published a protocol or registered the trial on a clinical trials website because there

was no other way to determine if the publication had reported all outcomes intended to be measured.

We classified 14 studies as having a high risk of selective outcome reporting. In Kalarchian 2009 the clinical trials register stated BMI and cardiovascular risk factors as the primary outcome; however, in the publication it was percentage overweight. In Barkin 2011 they did not report BMI outcome results for the intervention and control groups separately, only for the group combined. Epstein 2000a also combined all three groups together in the additional publication (Epstein 2001), likely due to non-significant results. Lochrie 2013 did not report raw data at baseline and follow-up (or mean change) for each group, while Gunnarsdottir 2011a failed to compare intervention and control outcomes and did not present raw results for many of its intended measured outcomes, including health-related quality of life. Reinehr 2010 did not provide quality-of-life measures separately for each group. Mirza 2013 also failed to present the results for many of its outcomes, including outcomes described on a clinical trials website. Croker 2012 also did not provide the results for all outcomes reported on the clinical trials website. Nova 2001 did not provide behavioural outcome results at follow-up, or results at 24 months' follow-up (endpoint) while Schwingshandl 1999 did not provide any BMI data at the study's endpoint (12 months). Hamilton-Shield 2014 terminated the trial before its endpoint; however, it failed to provide any data on outcomes collected before termination.

The remaining 39 studies we rated as unclear risk of selective outcome reporting bias primarily because the trial protocol was not published in advance of the study or registered on a clinical trials website. There were however, additional reasons why we classified risk of bias as unclear: Boutelle 2014 had a clinical trials entry but we rated it as unclear because the entry stated that there were three intervention groups and one control group; however, in the publication there was only one intervention and one control group. In addition, Bryant 2011; Coppins 2011; Eddy Ives 2012; Markert 2014; Wake 2009 and Warschburger 2016 had clinical trials entries but they were retrospectively entered, while O'Connor 2013 only provided one outcome measure (family attendance) on its clinical trials register entry. Potential bias may also occur in Coppins 2011 due to only reporting some outcomes as significant or non-significant (no raw results). Looney 2014 reported measuring cost-effectiveness on the clinical trials entry; however, this is not reported in the publication. In addition Sacher 2010; Serra-Paya 2015 and Taveras 2015 reported a number of outcomes in their clinical trials register entries that were not reported in the main publications.

Other potential sources of bias

We rated 60 studies as unclear, mainly because of a lack of detail in the publication or an unclear risk of bias for the other domains resulting in uncertainty of the presence of other biases. Six studies were low risk because the trials were generally well-conducted and well-reported (Ho 2016; McCallum 2007; Serra-Paya 2015; Taveras 2015; Wake 2009; Wake 2013). Four studies were high risk - Berry 2007 and Wright 2012 were cluster RCTs but did not adjust for clustering in their analyses, Woo 2004 non-randomly split their intervention group into two groups at six weeks, and Hamilton-Shield 2014 was terminated before the study's endpoint because of problems with recruitment and equipment.

Effects of interventions

See: [Summary of findings for the main comparison Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in children aged 6 to 11 years](#)

Baseline characteristics

For details of baseline characteristics, see Appendix 3 and Appendix 4.

Behaviour-changing interventions versus no treatment or usual care

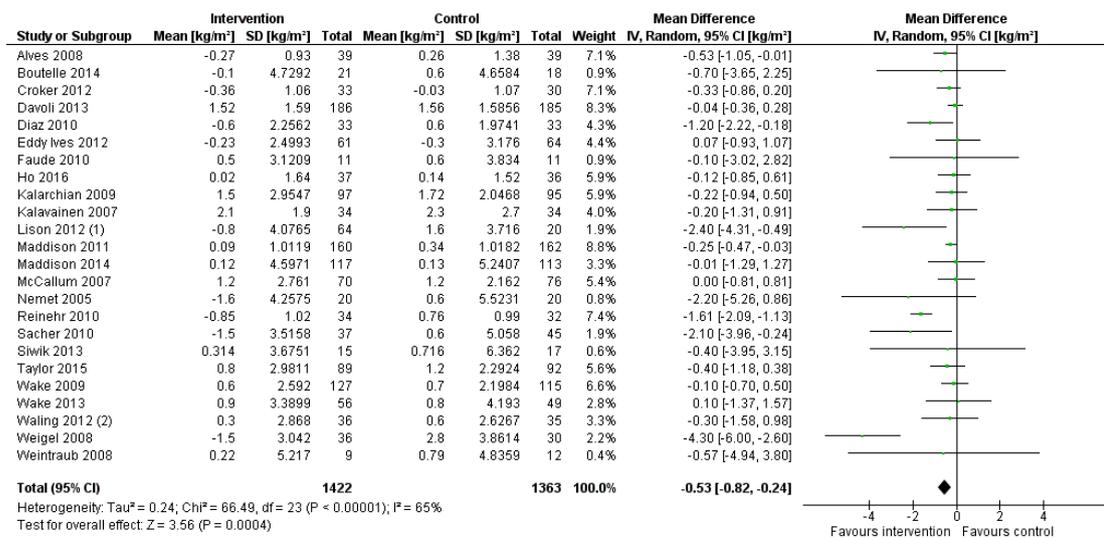
Fifty-five trials compared behaviour-changing (diet and/or physical activity and/or behavioural therapy) interventions, usual care, enhanced usual care, information control, or wait-list control. Excluding cluster RCTs and weight maintenance trials (N = 5) there were 20 trials in which the control groups received no treatment throughout the duration of the study and 30 trials in which the control group participants were given usual care, either defined by the trial author or assessed by the review authors. We considered outcomes here at the longest follow-up point reported for each trial.

Primary outcomes

Changes in body mass index (BMI), BMI z score and body weight

Twenty-four trials reported BMI change data that could be meta-analysed. Pooling the effects in a random-effects meta-analysis (Analysis 1.1; Figure 4) demonstrated a reduction in BMI in the intervention groups compared with controls at the final follow-up: MD -0.53 kg/m² (95% CI -0.82 to -0.24); P = 0.0004; 24 trials; 2785 participants; low-quality evidence.

Figure 4. Forest plot of comparison: I Lifestyle intervention versus no treatment/usual care, outcome: I.1 Change in BMI (all trials) (kg/m²)

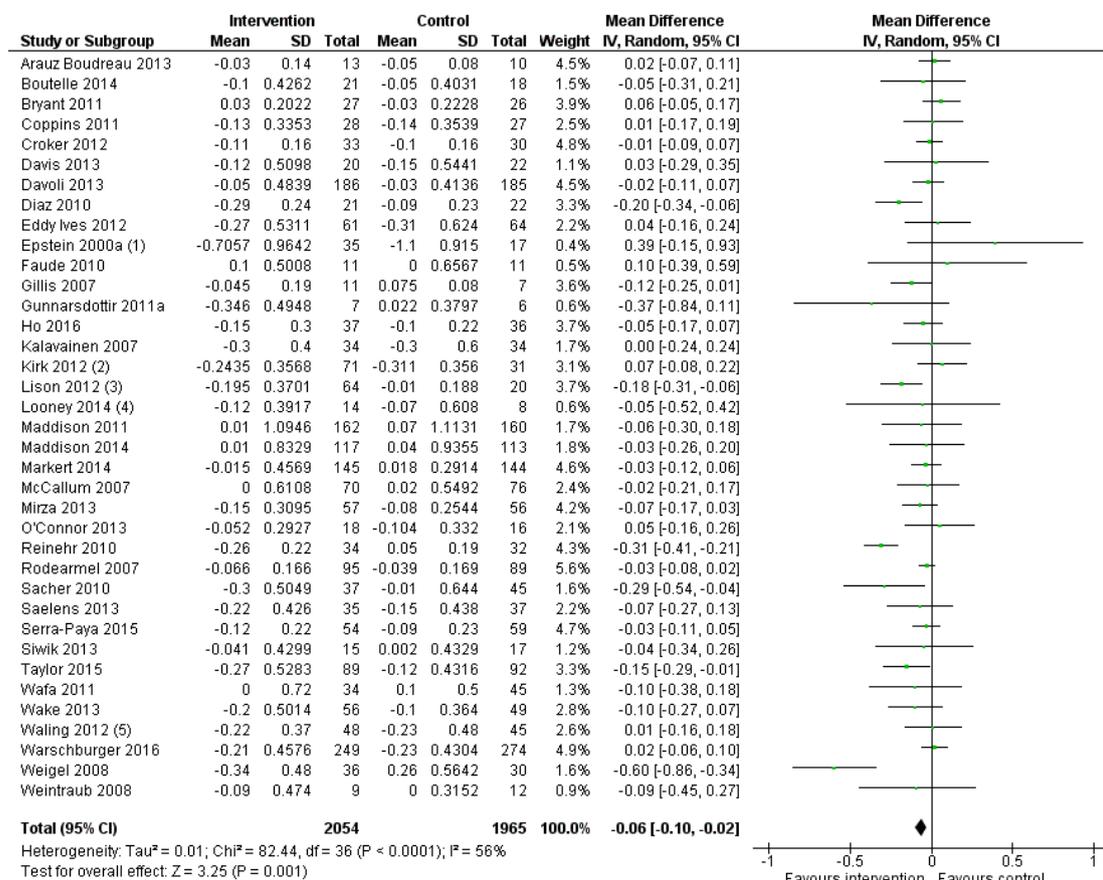


Footnotes

- (1) Pairwise
(2) Data at 2 years

Thirty-seven trials reported BMI z score change data that could be meta-analysed. Pooling the effects in a random-effects meta-analysis (Analysis 1.2; Figure 5) demonstrated a reduction in BMI z score in the intervention groups compared with controls at the final follow-up: MD -0.06 units (95% CI -0.10 to -0.02); P = 0.001; 37 trials; 4019 participants; low-quality evidence.

Figure 5. Forest plot of comparison: I Lifestyle intervention versus no treatment/usual care, outcome: I.2 Change in BMI z score (all trials)

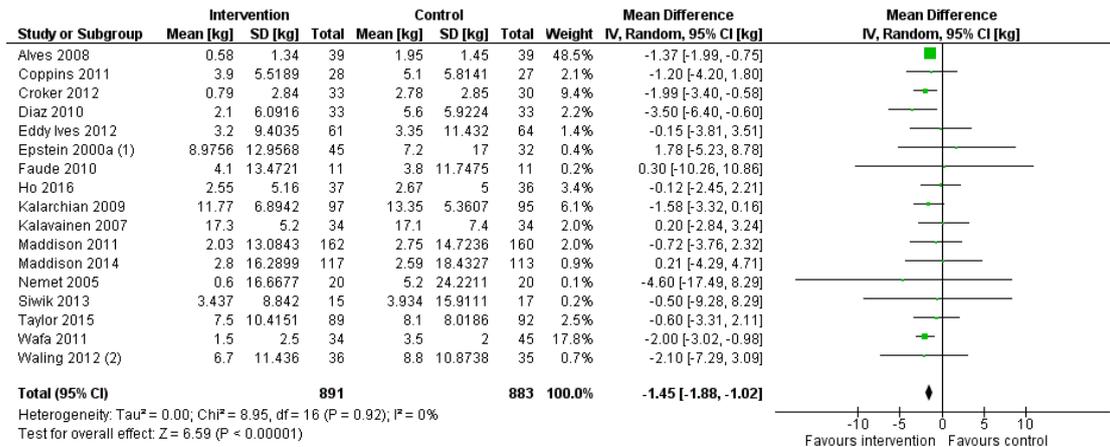


Footnotes

- (1) pairwise
- (2) Pairwise (diet)
- (3) Pairwise
- (4) Pairwise
- (5) Data at 1 year

Seventeen trials reported data on change in body weight that could be meta-analysed. Pooling the effects in a random-effects meta-analysis (Analysis 1.3; Figure 6) demonstrated a reduction in body weight in the intervention groups compared with controls at the final follow-up: MD -1.45 kg (95% CI -1.88 to -1.02); P < 0.00001; 17 trials; 1774 participants; low-quality evidence.

Figure 6. Forest plot of comparison: I Lifestyle intervention versus no treatment/usual care, outcome: I.3 Change in weight (all trials)



Some meta-analyses revealed substantial heterogeneity which we explored by subgroup analysis by type of control, type of intervention, risk of attrition bias, setting of intervention and period of post-intervention follow-up. The heterogeneity was not fully explained by any of these factors (see “Subgroup analyses” section below).

We were unable to include nine trials with no treatment or usual care control groups in the BMI and BMI z score meta-analyses and so they are narratively reported: [Satoh 2007](#), [Epstein 1984a](#) and [Nova 2001](#) only presented data for percent overweight. [Nowicka 2009](#) reported no differences in follow-up outcome measures between the intervention and control groups. We could not include [Vann 2013](#) in the meta-analyses because they did not provide SDs for BMI values at baseline and follow-up (or effect sizes and P values). A small decrease of 0.1 kg/m² was seen in the pedometer plus DVD group; however, an increase in BMI was observed in the two other intervention groups and the control group. [Barkin 2011](#) only provided BMI data for the intervention and control groups combined - in a linear regression model they observed that parent-child dyads in the control group were more likely to decrease their BMI over the six-month study. [Lochrie 2013](#) only provided means and standard errors at follow-up - the SD at baseline was unclear. The study found a larger reduction in BMI z score at 12 months’ follow-up in the intervention group. Finally, [Hughes 2008](#) only presented change in BMI z score as median and IQR, which cannot be converted into mean and SD (or 95% CI). At six months and 12 months the median difference between groups was not substantially different (P = 0.4 and P = 0.5, respectively). No BMI/BMI z score data were available in [Hamilton-Shield 2014](#) because the study was terminated.

In the weight meta-analyses, we were unable to include [Hughes 2008](#) as this study only presented weight data as median and IQR - a non-substantial difference between groups was found at both six months’ and 12 months’ follow-up (P = 0.1 and P = 0.9, respectively). In addition, [Lison 2012](#) did not provide any SD values for weight at follow-up so could not be included in the analyses. The control group increased their weight over the six-month period while a smaller increase in weight was seen in the hospital clinic group along with a small reduction in weight in the home-based group. [Epstein 1984a](#) provided weight data in an additional secondary analysis paper; however, they only presented data for the two intervention groups. Hence, we decided not to include these data in the weight meta-analyses because data were not reported for the control group. The authors found a reduction in weight in the two treatment groups combined. We were unable to include the remaining studies in the weight meta-analysis because no weight data were provided in the publications.

Adverse events

The majority of publications did not report whether or not any adverse events occurred; hence, we had to contact most study authors to obtain this information. As a result, it was confirmed that no adverse events occurred in 28 trials with a no-treatment/usual-care control group. In 16 trials it was unclear whether any adverse events had occurred. The remaining six studies reported adverse events occurring: [Maddison 2011](#) and [Maddison 2014](#) provided data on serious adverse events, as described below. [Croker 2012](#) reported that one participant in the control group had a very high reduction in BMI and standardised BMI (BMI SDS). [Kirk](#)

2012 reported that some participants in both groups developed elevated triglycerides (12.2%), elevated blood pressure (3.6%), elevated LDL cholesterol (3.5%) and/or elevated fasting glucose (3.5%); however, there were no substantial differences by group. Weintraub 2008 reported that three adverse events occurred in the intervention group (skin rash, diagnosis of hypothyroidism, car collision) and six events in the control group (foot injury, eye pain and headaches, ingrown toenail, ear infection, knee pain, skin rash); however, none of these were considered to be related to the study, and it was unclear if any of these were considered serious adverse events. Mirza 2013 reported that no serious adverse events occurred; however, one child in the control group reported feeling faint during the three-month blood taking. Adverse events and the level of severity were author-assessed, often using pre-defined criteria; however, these criteria varied between the studies leading to potential inconsistency between the studies and this should be borne in mind when evaluating the adverse events outcomes.

Thirty-one trials reported serious adverse event data that could be meta-analysed. Pooling the effects in a random-effects meta-analysis (Analysis 1.4) demonstrated a RR of 0.57 (95% CI 0.17 to 1.93); $P = 0.37$; 31 trials; 4096 participants; low-quality evidence), in favour of the intervention group. Only two of the 31 trials reported any serious adverse events; the other 29 reported zero serious adverse events. Serious adverse events were reported by Maddison 2011 and these included seasonal influenza that required hospitalisation ($N = 3$), hip surgery due to a chronic condition ($N = 1$), an ankle injury ($N = 1$), diagnosis of type 1 diabetes ($N = 1$), a blood clot ($N = 1$) and observation after a fall ($N = 1$); none of these were seen as related to the study. Maddison 2014 also reported a small number of serious adverse events but none of these were considered as related to the study; they included two events in the intervention group (bowel replacement surgery and a dislocated hip) and three events in the control group (an operation to remove a cyst, a broken ankle, and two broken fingers).

These data were based on the total number of participants who suffered at least one serious adverse event (4/2105 participants in the behaviour-changing intervention groups compared with 7/1991 participants in the comparator groups). We were unable to include studies where they reported adverse events but did not define if they were serious or if they did not provide the number of participants in each group who had at least one adverse event. We aimed to provide a meta-analysis showing the number of participants in each group who discontinued due to adverse events. However, of those studies that reported adverse events occurring, only three actually reported if any participants discontinued (Croker 2012; Mirza 2013; Weintraub 2008) and they all reported that no participants dropped out due to adverse events.

Secondary outcomes

Health-related quality of life and self-esteem

Appendix 13 details the instruments that were used for analysis of health-related quality of life in the included trials. However, we were unable to meta-analyse all of the studies for the following reasons: unable to calculate mean change from data provided (Wake 2013, Warschburger 2016); no raw data were provided (Bryant 2011; Hamilton-Shield 2014; Lochrie 2013; Markert 2014; Reinehr 2010), no SDs given (Arauz Boudreau 2013), the study only presented results via domains, not overall score (Taylor 2015), and data were presented as median and interquartile ranges (IQR) (Hughes 2008). Four trials (Croker 2012, McCallum 2007; Wafa 2011; Wake 2009) reported the Pediatric Quality of Life Inventory (PedsQL) generic core scales, using the total score, either via parental or child report (Analysis 1.5; Analysis 1.6). An additional study measured health-related quality of life using the CHQ-PF50 global score (parental-report) (Kalarchian 2009) and Faude 2010 used the KINDL-R questionnaire (child-report). Using standardised mean differences (SMD), there were no substantial differences between intervention and control (higher scores indicate better quality of life) in the change in health-related quality of life at the final follow-up for parent/caregiver-reported data, demonstrating a SMD of 0.13 units (95% CI -0.06 to 0.32); $P = 0.17$; 5 trials; 718 participants; low-quality evidence. There were no substantial differences between intervention and control (higher scores indicate better quality of life) in the change in health-related quality of life at the final follow-up for child-reported data, demonstrating a SMD of 0.15 units (95% CI -0.34 to 0.64); $P = 0.55$; 3 trials; 164 participants; very low-quality evidence. The minimal clinically important difference (MCID) for a PedsQL child's self-report is 4.36 units and for PedsQL parents' (proxy) report 4.50 units (Varni 2007); when converting the SMD back to raw units, the MCID was not met in either meta-analysis.

Two trials reported a measure of self-esteem using the Harter global score that could be meta-analysed (Analysis 1.7). There were no substantial differences between intervention and control (higher scores indicate better self-esteem) in the change in self-esteem found at the final follow-up, demonstrating a MD of 0.19 units (95% CI -0.04 to 0.42); $P = 0.11$; 2 trials; 144 participants; very low-quality evidence.

All-cause mortality

No deaths were reported in any of the trials.

Morbidity

No trials measured morbidities.

However, metabolic syndrome (which is a composite of risk indicators such as elevated blood lipids, insulin resistance, obesity and high blood pressure) was mentioned in Mirza 2013 using the National Cholesterol Education Program (Adult treatment panel III). Approximately 40% of the low glycaemic index dietary group (intervention) and 30% of the low fat dietary group (comparator) had

the metabolic syndrome at baseline; at 24 months there was slight reduction in the percentage of participants with metabolic syndrome in both groups. However, there were no substantial differences between groups. [Waling 2012](#) also measured the metabolic syndrome prevalence at baseline and follow-up using the International Diabetes Federation (IDF) definition. At baseline one participant in the intervention group and two participants in the control group had the metabolic syndrome; at one year's follow-up the number of participants with the metabolic syndrome was three in the intervention group and two in the control group.

Anthropometric measures other than change in BMI

Eleven trials reported waist circumference data that could be meta-analysed (Analysis 1.8). Meta-analysis demonstrated a reduction in waist circumference in the intervention groups compared with controls at the final follow-up: MD -2.41 cm (95% CI -3.59 to -1.23); $P < 0.0001$; 11 trials; 1325 participants.

Three trials reported percentage overweight data that could be meta-analysed (Analysis 1.9). Meta-analysis demonstrated no substantial difference in percentage overweight in the intervention groups compared with controls at the final follow-up: MD -3.27% (95% CI -7.47 to 0.92); $P = 0.13$; 3 trials; 347 participants).

Eleven trials reported percentage body fat data that could be meta-analysed (Analysis 1.10). Meta-analysis demonstrated no substantial difference in percentage body fat in the intervention groups compared with controls at the final follow-up using (1) bioelectrical impedance analysis: MD -1.25% (95% CI -2.62 to 0.12); $P = 0.07$; 5 trials; 1004 participants; and (2) using dual energy X-ray absorptiometry (DEXA): MD -1.04% (95% CI -2.88 to 0.80); $P = 0.27$; 5 trials; 443 participants.

Behaviour change

Two trials reported total kcals per day data that could be meta-analysed (Analysis 1.11). Meta-analysis demonstrated no substantial difference in total kcals per day in the intervention groups compared with controls at the final follow-up: MD -161.53 total kcals/day (95% CI -583.79 to 260.73); $P = 0.45$; 2 trials; 168 participants.

Two trials reported total minutes per day for television viewing data that could be meta-analysed (Analysis 1.12). Meta-analysis demonstrated a reduction in total minutes per day in the intervention groups compared with controls at the final follow-up: MD -6.60 minutes per day (95% CI -12.88 to -0.31); $P = 0.04$; 2 trials; 55 participants.

Six trials reported physical activity using accelerometers and total minutes per day data that could be meta-analysed (Analysis 1.13). Meta-analysis demonstrated no substantial difference in total minutes per day of physical activity in the intervention groups compared with controls at the final follow-up: MD -0.76 minutes per day (95% CI -5.30 to 3.78); $P = 0.74$; 6 trials; 744 participants.

Participants' views of the intervention

Eight studies asked parents, the children or both for their views on the intervention (or comparator) given. [Gunnarsdottir 2011a](#) used an acceptability questionnaire to rate how satisfied families were with the intervention; the majority gave ratings of 1 to 3 (Likert scale, 1 = very satisfied, 5 = not satisfied). The most liked components were the individual sessions and the traffic light diet food guide, and the least liked was a behavioural change technique called "token economies" which were defined as establishing goals, determining preferred rewards and providing them contingently upon achieving behavioural goals) and self-monitoring diet and physical activity.

[Boutelle 2014](#) also asked all children and parents in the intervention group whether they liked the intervention: 50% of children liked the intervention a lot or loved it and 85% of them believed other children would like the intervention; 67% of parents in the intervention group liked it a lot or loved it, while 47% believed their child liked it a lot. Participants in [Looney 2014](#) also undertook a process evaluation at the end of the study. There were no substantial differences in ratings between the three groups and 90% of families rated the programme as very good or excellent; 90% also said it was easy to understand. [O'Connor 2013](#) also reported that 85% of the intervention group were positive about the treatment given.

[Satoh 2007](#) interviewed 17 out of 21 children who completed the one-month intervention. Sixteen children said the intervention was easy to understand; however 14 children said completing the meal chart was a burden. [Wake 2013](#) reported that the majority of parents thought the clinicians and GPs providing the intervention understood the challenges faced by the family and were confident that the intervention would make a difference.

[Bryant 2011](#) randomly selected 10% of their sample to answer feedback about the study. The majority of parents and children reported positive experiences; however, those in the waiting list control group were disappointed that they had to wait for the intervention. Children were generally positive about the assessment but thought the worst part was the blood taking.

[Hamilton-Shield 2014](#) collected qualitative data on treatment acceptance. The study involved an electrical device which included a weighing scale to measure food and provided feedback on satiety. Even though some parents gave some positive comments on the intervention, there were many technical problems with the device and some found it confusing to use. This may have contributed to the early termination of the study.

Socioeconomic effects

No trials measured socioeconomic effects.

Behaviour-changing intervention plus additional component versus behaviour-changing intervention alone

These interventions had the same components in the intervention and comparator groups to establish fair comparisons, and an additive component in the intervention arm. For example, diet plus physical activity plus behaviour therapy versus diet plus physical activity (with behaviour therapy being the additive component). We identified 15 trials in this category.

Of these studies, five studies also had a no-treatment or usual-care-condition group as they were at least three-arm studies (Epstein 1984a; Epstein 2000a; Looney 2014; Taveras 2015; Vann 2013). Davis 2013 compared the addition of telemedicine to standard physician visits and Duggins 2010 investigated adding a YMCA membership (physical activity) to nutrition classes led by dietitians. Epstein 2015 investigated whether adding a different nutritional component to a multi-component intervention was more beneficial. One study compared whether increasing physical activity or decreasing sedentary behaviours was more beneficial (Epstein 2001), while Epstein 1985a investigated adding a physical activity component (aerobic or behaviour-changing activity) to diet and behaviour therapy (with calisthenic exercise as a placebo).

Five studies investigated whether adding a physical activity component to a nutritional intervention improved weight-related outcomes (Duggins 2010; Epstein 1984a; Epstein 1985b; Schwingshandl 1999; Woo 2004). NCT02436330 added an exergaming component (classed as physical activity) to a didactic health teaching intervention. Vann 2013 also included two trial arms adding a physical activity component (fitness DVD or pedometers).

Bathrellou 2010 investigated whether adding a parental involvement to a diet and physical activity intervention would be beneficial. Duffy 1993 added cognitive self-management to a behavioural intervention and Epstein 2005 added a behavioural element with regards to alternative behaviours to eating. Behavioural therapy was also an additional component in Epstein 1985c and Flodmark 1993. Larsen 2015 added an educational consultation to a diet and physical activity intervention, and Epstein 2000a assessed adding problem solving with or without parental involvement. Looney 2014 added a behavioural therapy component to a growth-monitoring intervention. Taveras 2015 (cluster RCT) also looked at adding individual family coaching to a clinical-support intervention.

Primary outcomes

Changes in body mass index (BMI), BMI z score and weight

Four trials reported BMI data that could be meta-analysed (Analysis 2.1). Meta-analysis demonstrated a reduction in BMI in the intervention groups compared with controls at the final follow-up: MD -0.75 kg/m² (95% CI -1.42 to -0.09); P = 0.03; 4 trials; 195 participants.

Five trials reported BMI z score data that could be meta-analysed (Analysis 2.2). Meta-analysis demonstrated no substantial differ-

ence in BMI z score in the intervention groups compared with controls at the final follow-up: MD -0.03 units (95% CI -0.10 to 0.04); P = 0.37; 5 trials; 212 participants.

Four trials reported data for change in body weight that could be meta-analysed (Analysis 2.3). Meta-analysis demonstrated no difference in body weight in the intervention groups compared with controls at the final follow-up: MD 1.59 kg (95% CI -4.58 to 7.77); P = 0.61; 4 trials; 106 participants.

We were unable to include seven trials in the BMI/BMI z score meta-analyses. Bathrellou 2010 and Epstein 2015 only presented BMI values at baseline but did not present them at follow-up (only gave percent overweight). Epstein 1985a measured BMI but did not provide any data (only provided data for weight and percent overweight). Duffy 1993 and Epstein 1985b did not measure or present BMI values. Duggins 2010 presented mean change in BMI at the end of the study but did not provide any SDs. Hence, we could not use these data in the meta-analyses. At 12 months, a mean change of +10.2 units in the treatment group versus +6.5 units in the control group was reported (no P value was given). Schwingshandl 1999 found a change in BMI SDS of -0.53 units in the intervention group versus -0.51 units in the control group after the 12-week intervention. The participants were followed up one year after baseline; however, the publication only provides results for fat free mass at one year, no BMI results were given.

Adverse events

In two trials, no adverse events occurred in either group (Woo 2004 - confirmed through author correspondence, and NCT02436330 - data given in clinical trials register). In 12 trials it was unclear whether adverse events occurred. This included six Epstein studies (Epstein 1985a; Epstein 1985b; Epstein 1985c; Epstein 2001; Epstein 2005; Epstein 2015) where it was unclear from the publications whether any adverse events occurred; however, after correspondence with the studies' author they highlighted that no adverse events were related to study participation but it was still unclear which studies had adverse events and what they were.

Secondary outcomes

The additive components across the studies varied greatly, therefore we analysed these comparisons in a separate meta-analysis from the usual-care and no-treatment controls for the primary analyses (see above) and have not used these comparisons in subgrouping. We have narratively described the secondary outcomes, as meta-analyses were not possible because the additive components that were investigated varied greatly between the studies.

Health-related quality of life and self-esteem

No trials measured health-related quality of life. However, NCT02436330 measured physical self-worth and global self-worth using the Children and Youth Physical Self-Perception

Profile; no substantial differences between groups were found in changes from baseline to six months' follow-up.

All-cause mortality

No deaths were reported in any of the trials.

Morbidity

No trials measured morbidity.

Anthropometric measures other than change in BMI

Fourteen studies reported measuring other anthropometric measures; three of the eight studies that reported percent overweight found a significant difference in favour of the intervention group at the longest follow-up (Epstein 1985a; Epstein 1985c; Epstein 2015).

Waist circumference was measured in two studies (Larsen 2015; NCT02436330) but only Larsen 2015 found a difference in favour of the intervention group at the study's two-year endpoint (a similar finding was also seen for waist-to-height ratio). Woo 2004 measured waist-to-hip ratio, but found no substantial differences between groups.

Skinfold thickness was measured in Flodmark 1993 and found differences in reduction of all three skinfold measurements (triceps, subscapular and suprailiac) in favour of the intervention. Woo 2004 was the only study to measure body fat via DEXA - they found no substantial differences between groups.

Behaviour change

No studies used accelerometry to measure physical activity but NCT02436330 used pedometers to measure weekly steps - no substantial differences between groups were observed. Epstein 2005 used a three-day physical activity recall method to measure MVPA but found no substantial differences between groups. Three studies measured physical work capacity/physical fitness using a bicycle ergometry test and two of these studies found a treatment difference (Epstein 1985b; Flodmark 1993) while the remaining study found no substantial difference between groups (Epstein 1985a). NCT02436330 measured after school and Saturday screen time but found no substantial differences between groups at six months. NCT02436330 measured dietary intake using "The Block Alive food frequency questionnaire (FFQ)". An increase in carbohydrates was seen in the treatment group compared to the control; however, the number of fruit servings was higher in the control group after six months. No substantial differences were found between groups in the other dietary domains (total calorie intake, percent fat, number of vegetable servings, sugar-sweetened beverage intake). Dietary intake was also measured by two studies (Duffy 1993; Epstein 2015) using a Traffic Light Diet questionnaire but only Epstein 2015 found a treatment effect for the reduction in red foods (unhealthy foods) and also fat intake, but they did not observe a substantial difference between groups in total calorie intake. Epstein 2005 measured dietary intake through

a habit book and found a treatment effect at six and 12 months in alternatives to eating (activities that did not involve eating) but did not see a substantial difference between groups in eating periods. Two studies used the O'Neil 1979 questionnaire (Epstein 1985a; Epstein 1985c) to assess eating behaviours but only differences in favour of the intervention group were observed in Epstein 1985c.

Participant views

No studies measured participants' views of the intervention

Socioeconomic effects

No trials measured socioeconomic effects.

Cluster RCTs

All cluster RCTs had a usual care or no treatment control group except Berry 2007 which added a coping skills training element to a family behavioural therapy intervention.

Primary outcomes

Changes in body mass index (BMI), BMI z score and weight

We meta-analysed two cluster RCTs (Berry 2007; Taveras 2015) (Analysis 3.1) and demonstrated no substantial difference in BMI in the intervention groups compared with controls at the final follow-up: mean difference (MD) -0.49 kg/m² (95% CI -1.24 to 0.27); P = 0.20; 2 trials; 629 participants. Taveras 2015 also reported the BMI z score - compared with the usual care group, children in the two intervention arms (clinical decision support and clinical decision support plus individual family coaching) showed a small mean change in BMI z score: -0.06 (95% CI -0.11 to -0.02) and -0.05 (95% CI -0.09 to 0.00), respectively. No substantial differences were found between the two treatment groups.

Wright 2012 presented changes in BMI and BMI z score at 12 months' follow-up; however, there were concerns over the 95% CIs presented which we suspected were ranges rather than CIs. We tried to contact the study author to clarify but did not receive a response. Therefore, we did not include this study in the meta-analysis. The publication reports that there were between-group differences in BMI and BMI z score, in favour of the intervention group. We did not include Berry 2014 in the meta-analyses for BMI/BMI z score because it was not clear from the publication how many children were included in the follow-up analysis. The publication reported that there were no substantial differences between groups for BMI percentile at both 12 and 18 months' follow-up.

There were no cluster trials that reported data on weight.

Adverse events

In the four cluster trials in this review, [Berry 2007](#), [Berry 2014](#) and [Taveras 2015](#) had no adverse events in either group (confirmed through study author correspondence). It was unclear if any adverse events occurred in [Wright 2012](#).

Secondary outcomes

Health-related quality of life and self-esteem

No trials measured health-related quality of life or self-esteem.

All-cause mortality

No deaths were reported in any of the trials.

Morbidity

No trials measured morbidity.

Anthropometric measures other than change in BMI

[Berry 2007](#) measured body fat percentage using bioelectrical impedance analysis (BIA) but found no substantial differences between groups at the study's endpoint. [Berry 2014](#) measured waist circumference and found a treatment effect at 12 months' follow-up but not at 18 months. Triceps and subscapular skinfolds were also measured and a treatment effect was found at 18 months' follow-up.

Behaviour change

Activity was measured using pedometers (number of steps) in [Berry 2007](#) but no substantial differences between groups were observed at follow-up.

[Berry 2014](#) used the Child and Adolescent (CATCH) questionnaire to measure diet and physical activity changes, but only dietary knowledge was improved in the intervention group at 18 months compared to the control. [Berry 2014](#) also used the Child Health behaviour survey by the Department of Health and Human Services 2004 to measure dietary habits and only found a treatment effect for reduced soda consumption at 18 months. [Wright 2012](#) used the Child and Adolescent Trial for Cardiovascular Health After-School Student Questionnaire (ASSQ) to assess dietary intake and eating behaviours and found treatment effects for some outcomes (e.g. fruit and vegetable intake, food intentions); however, others showed no substantial differences (e.g. sweets intake, always reading food labels).

Participants' views

Participants' views were measured in one cluster trial ([Taveras 2015](#)) that involved two clinical-led interventions compared against a usual-care group; the most intensive intervention was highly rated by parents (81.3% were satisfied) while only 46.9% of the parents in the less intensive intervention were satisfied.

Socioeconomic effects

No trials measured socioeconomic effects.

Maintenance intervention following weight reduction

Primary outcomes

Changes in body mass index (BMI), BMI z score and weight

Two trials reported BMI z score data ([de Niet 2012](#); [Wilfley 2007](#)) that could be meta-analysed (Analysis 4.1) and demonstrated no difference in BMI z score in the intervention groups compared with controls at the final follow-up: mean difference (MD) -0.07 units (95% CI -0.19 to 0.04); $P = 0.22$; 2 trials; 263 participants). There were no maintenance trials that reported data for BMI or for body weight suitable for meta-analysis.

Adverse events

Both trials had no adverse events ([de Niet 2012](#) confirmed through study author correspondence, and [Wilfley 2007](#) through information in the publication).

Secondary outcomes

Health-related quality of life and self-esteem

[de Niet 2012](#) used The Child Health Questionnaire-PF50 (CHQ-PF50) to measure health-related quality of life. A treatment effect was found at three and six months' follow-up in the physical domain but this was lost at nine months' follow-up. [de Niet 2012](#) also measured self-esteem using the Self-Perception Profile for Children (SPPC)/Harter global score but found no substantial differences between groups at nine months.

All-cause mortality

No deaths were reported in any of the trials.

Morbidity

No trials measured morbidity.

Anthropometric measures other than change in BMI

[Wilfley 2007](#) measured percentage overweight at two years' follow-up but found no substantial differences between the treatment and control groups. The BMI z score meta-analysis for maintenance trials (Analysis 4.1) showed no substantial differences between groups.

Behaviour change

The Dutch Eating Behaviour Questionnaire (DEBQ) was used to measure behaviour change in [de Niet 2012](#). A treatment effect was seen for external eating at three months from baseline, but not at six or 15 months. No substantial differences were observed in emotional eating or restrained eating.

[Wilfley 2007](#) used a Child Dietary Self-efficacy scale and found a treatment effect at two-year follow-up for the social facilitation maintenance intervention group when compared against the control group; the behavioural-skills maintenance intervention group showed a treatment effect compared with control but only at one-year follow-up. There were no substantial differences between the two treatment groups. [Wilfley 2007](#) also used a Self-efficacy Scale for Children's Physical Activity but only found a difference in favour of the social facilitation maintenance for 'positive alternatives to unhealthy habits' (increasing healthy foods and decreasing sedentary behaviour) at two years; no substantial differences were found for barriers between treatment groups.

Participants' views

No studies measured participants' views of the intervention.

Socioeconomic effects

No trials measured socioeconomic effects.

Subgroup analyses

We performed a number of subgroup analyses to test the effects of different types of comparators, the type of intervention, the setting, risk of attrition bias, duration of post-intervention follow-up, the involvement of parents, and mean baseline BMI z score on outcomes of BMI, BMI-z score and weight.

We did not perform subgroup analyses on the different durations of follow-up from baseline, combining those studies reporting six months' follow-up, those reporting 12 months' follow-up and those reporting 18 months' follow-up or more. Neither did we perform subgroup analyses based on the length of the interventions, combining studies with a duration of intervention of six months or less and studies with duration of intervention of greater than six months. This would have resulted in some studies being included in more than one subgroup for the duration of follow-up because some studies reported follow-up at multiple time points. Also, grouping studies according to whether they were six months or less or greater than six months would not assess all studies immediately post-intervention and would not evaluate the actual length of active intervention for all studies. We were most interested in the longer-term effects of weight-management interventions and the sustainability of weight reduction. Due to the relatively large number of included studies in this review we were able to subgroup according to duration of post-intervention follow-up, that is, we could assess whether follow-up after the active intervention, and the duration of that follow-up period, impacted on BMI, BMI z score and weight outcomes.

Type of control

We did not see any subgroup differences for change in BMI, BMI z score and weight when comparing studies with controls described as 'no intervention' and studies with controls described as 'usual care' (Analysis 1.14; Analysis 1.15; Analysis 1.16).

Type of intervention

The majority of studies were multi-disciplinary interventions, however, some studies were single or dual interventions. We did not see any subgroup differences for change in BMI (Analysis 1.17), change in BMI z score (Analysis 1.18) or change in weight (Analysis 1.19).

Risk of attrition bias

We did not see any subgroup differences when combining studies according to high, low or unclear risk of attrition bias for change in BMI (Analysis 1.20), change in BMI z score (Analysis 1.21) or change in weight (Analysis 1.22).

Setting of intervention

For setting, the studies were divided into eight subgroups, school, community, home, primary care, secondary care, university research clinics, hospital inpatient and mixed settings. We did not see any subgroup differences for change in BMI (Analysis 1.25), change in BMI z score (Analysis 1.24) or change in weight (Analysis 1.23).

Duration of post-intervention follow-up

We put studies into subgroups based on whether they had a period of post-intervention follow-up (defined as the period after the active intervention and up to the final measurement) and the duration of that period: no post-intervention follow-up (N = 15), less than six months (N = 3), six months to less than 12 months (N = 2) and post-intervention follow-up lasting 12 months or longer (N = 4). We calculated the duration of no post-intervention follow-up by subtracting the active intervention period from the total duration of the study (i.e. intervention and all follow-up duration).

For change in BMI (Analysis 1.26), combining studies by post-intervention follow-up indicated a statistically significant subgroup difference (P = 0.03), however this is not reliable because all the CIs overlap (to a small degree, regarding the CI for studies with post-intervention follow-up 12 months or more versus no post-intervention follow-up). There were no subgroup differences for BMI z score change (Analysis 1.27) or change in weight (Analysis 1.28).

Parental involvement

We put studies into subgroups based on whether the intervention involved the parent and child, whether only the child was treated without any parental involvement and whether the parent was specifically targeted (but the child was included in the intervention). There was no subgroup difference on change in BMI (Analysis 1.29), change in BMI z score (Analysis 1.30) or change in weight (Analysis 1.31).

Mean baseline BMI z score

We put studies into subgroups based on whether the mean baseline BMI z score was less than 2.67 units or 2.67 units or greater (which equates to the 99.6th centile for severe obesity). There was no subgroup difference on change in BMI z score (Analysis 1.32).

Sensitivity analyses

We performed sensitivity analyses restricting the main BMI, BMI z score and weight meta-analyses (Analysis 1.1; Analysis 1.2; Analysis 1.3) to those studies that provided change score data (along with an SD, SE and 95% CI). Hence, we excluded studies where the mean change score SD was not provided but was imputed following the guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions* (Section 16.1.3.2 Imputing standard deviations for changes from baseline; Higgins 2011c) and assumed a correlation of 0.5 between baseline and follow-up measures as suggested by Follmann 1992. All three sensitivity analyses were very similar to the original analyses; which showed that our original analyses were robust (see Table 2).

Assessment of reporting bias

We generated funnel plots for the primary outcomes of BMI, BMI z score and weight, as these analyses included the highest number of studies on which to assess publication bias. Inspection of the funnel plots for BMI and weight (but not BMI z score) showed an uneven distribution of studies and suggested a possibility of small study bias (data not shown).

DISCUSSION

Summary of main results

We included 70 trials in this review, with 55 comparing a behaviour-changing intervention with no treatment or usual-care control and 15 testing an additional component added to a behaviour-changing intervention. The vast majority of trials were multicomponent (N = 64) and individual trial sample sizes ranged from 16 to 686 participants. Total duration of trials ranged from

six months to three years; duration of active intervention ranged from 10 days to two years. Just over half (37) of the trials had a period of post-intervention follow-up with a median duration of 10 months.

A total of 8461 participants were randomised to either the intervention or control groups; approximately 69.5% of participants were measured at the study's endpoint. Primary analyses demonstrated that behaviour-changing interventions compared to no treatment or usual-care control reduced BMI, BMI z score and body weight. We could pool data from 24 trials reporting BMI for analysis, which demonstrated a reduction in BMI in favour of the intervention (measured at the last available point of follow-up) of -0.53 (95% CI -0.82 to -0.24); 24 trials; 2785 participants; low-quality evidence). Thirty-seven trials reported BMI z score data suitable for meta-analysis, which resulted in a reduction in favour of intervention (measured at last available point of follow-up) of -0.06 units (95% CI -0.10 to -0.02); 37 trials; 4019 participants; low-quality evidence). Seventeen trials reported change in body weight that could be meta-analysed, and demonstrated a reduction in body weight in the intervention groups compared with controls at the final follow-up: MD -1.45 kg (95% CI -1.88 to -1.02); P < 0.00001; 17 trials; 1774 participants; low-quality evidence).

We excluded from the main analysis the 15 trials that evaluated an additional component to a behaviour-changing intervention, as the additive elements under investigation were extremely diverse and not comparable to the other interventions.

Thirty-five trials had no adverse events, 29 trials were unclear as to whether adverse events occurred and six trials reported a range of adverse events in a small percentage of participants. Thirty one trials documented serious adverse events, although the vast majority (N = 29) reported zero occurrence.

Six trials (718 participants) reported paediatric quality of life inventory, two trials (144 participants) reported a measure of self-esteem, two trials (168 participants) reported change in caloric intake and six (744 participants) reported accelerometry-measured physical activity; however, none of these analyses demonstrated a significant difference between intervention and control. In the two trials reporting on minutes per day of TV viewing, a small reduction of 6.6 minutes per day (95% CI -12.88 to -0.31), P = 0.04; 2 trials; 55 participants) was found in favour of the intervention.

No trials reported on all-cause mortality, morbidity or socioeconomic effects, and few trials reported on participant views; none of which could be meta-analysed.

As the meta-analyses revealed significant heterogeneity, we conducted subgroup analyses to examine the impact of type of comparator, type of intervention, risk of attrition bias, setting of intervention, duration of post-intervention follow-up period, type of parental involvement and mean baseline BMI z score. No substantial subgroup effects were shown for any of the subgroups on any of the outcomes (BMI, BMI z score or weight). There was an indication of an effect for duration of post-intervention fol-

low-up for BMI only, which demonstrated that intervention effects between groups differed only immediately post intervention (heterogeneity increased) and for post-intervention follow-up of less than six months (heterogeneity reduced to zero), however this hypothetical finding has to be further investigated in independent studies. These findings align with data from the two trials (263 participants) identified in this review that specifically examined the impact of a maintenance period following weight loss on BMI z score and found no substantial difference between intervention and control.

Overall completeness and applicability of evidence

This review contains the largest number of trials and participants, compared to the other systematic reviews in this series (surgery; drugs; parent-only interventions; diet, physical activity and behavioural interventions for young children aged 0 to 6 years, and adolescents aged 12 to 17 years).

The bulk of the evidence was derived from multicomponent interventions that involved the parent and child. The interventions varied in duration including longer-term interventions (up to three years) and follow-up after a period of no active intervention in half of the trials. The majority of evidence relates to trials published from 2000 onwards; however, there was no evidence included from trials conducted in lower middle-income countries. The review included evidence from a wide variety of settings. There was less evidence relating to younger children (median age was 10 across the trials) and for non-white children; however, both girls and boys were equally represented. These limitations call into question the transferability of the findings to cultural and geographic settings other than upper- and upper middle-income countries. Therefore, the results should be interpreted carefully within the context of local population needs (i.e. age, sex, socioeconomic status, ethnicity, religion, culture, disabilities/complex needs, severity of obesity) and local political and health systems.

All participants included in this review were overweight, obese or severely obese at baseline. Whilst any reduction in body mass in overweight or obese children may be of benefit, the small reduction observed in the studies included in this review may not be sufficient to improve or prevent obesity-related comorbidities. Indeed there was a lack of data reported on obesity-related comorbidities. The authors of a recent study in England (in older school aged children - median age 12.4 years) reported that a reduction of 0.25 BMI z score units was required to improve adiposity and metabolic health (Ford 2010). This is a reduction much higher than that observed in this review.

Very few studies measured any of the review's secondary outcomes other than anthropometric outcomes, the results of those that did were inconsistent and used a variety of measurement tools. Outcome results were also inconsistent depending on the timing of measurements within the studies. In summary, the data were too

limited and heterogeneous to enable any meaningful synthesis of secondary outcomes for those studies that investigated adding a component to a behaviour-changing intervention, maintenance trials and cluster RCTs. Meta-analyses of secondary outcomes for usual care/no treatment comparators showed no substantial differences between groups or wide 95% CIs, or both.

Quality of the evidence

We rated over half (N = 48) of the 70 included studies as having a low risk of selection bias based on the randomisation method they used. We rated 49 studies as low risk of bias for allocation concealment. However, we rated a majority of trials as high risk of bias for blinding (for both performance and detection bias). Forty-five studies did not blind their participants or study personnel to study group allocation with regards to objective measures. Only eight trials did not have a high risk of bias on at least one criterion. GRADE assessments of the outcomes in this review led to trials being downgraded for risk of bias, inconsistency and also imprecision. This made overall interpretation of the data difficult. Overall the quality of included trials was low for BMI, BMI z score, weight, adverse events and parent-reported health-related quality of life, and very low for child-reported health-related quality of life.

Potential biases in the review process

The review identified all relevant trials with searches from inception of databases to July 2016 and all efforts were made to include studies published up until the start of November 2016 and to obtain any additional data.

There is a potential bias in terms of the wider applicability of the findings, with the vast majority of included studies conducted in high-income countries, with a heavy reliance on data from the USA. It is also unclear as to applicability of the findings in populations of different socioeconomic status and ethnicity, due to lack of reporting of ethnicity data in the majority of trials.

The impact of the comparator group should also be considered, given that a significant proportion of studies used a 'usual care' condition which varied greatly in terms of content and intensity; there was an element of subjectivity introduced in that review authors had to sometimes assess whether the comparator was 'usual care' if not reported by the study authors as such.

We attempted to contact all study authors whenever there were missing data or clarification was needed. The majority of studies did not report if adverse events occurred; hence, we contacted study authors for this information. Some study authors did not reply and this may have introduced bias. However, we felt it was important to contact study authors about adverse events because reporting was so poor. Furthermore, we had concerns that some

studies never measured or documented adverse events, so if any did occur, they would not have been captured.

Agreements and disagreements with other studies or reviews

This review is a partial update to a previous Cochrane Review: the original review 'Interventions for treating obesity in children and adolescents' (Oude Luttikhuis 2009) was split into six separate reviews, with a specific intervention and age focus.

- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years
 - Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in children from the age of 6 to 11 years
 - Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years (Colquitt 2016)
 - Drug interventions for the treatment of obesity in children and adolescents (Mead 2016a)
 - Parent-only interventions for childhood overweight or obesity (Loveman 2015)
 - Surgery for the treatment of obesity in children and adolescents (Ells 2015b)

This review is now a stand-alone review of all the RCT evidence relating to the treatment of overweight or obesity in children aged 6 to 11 years. The evidence base contained in this review has increased substantially; the majority of these new trials have focused on multi-component interventions with a mix of diet, physical activity and behaviour-change elements. However, despite the substantial increase in available evidence, the overall effects in terms of BMI/BMI z score and weight reductions in favour of interventions remain similar to the previous Cochrane Review of interventions to treat childhood obesity (Oude Luttikhuis 2009), with continued heterogeneity in terms of comparators, intervention content and delivery. The previous Cochrane Review (Oude Luttikhuis 2009) found very similar reductions in BMI z scores, in favour of the intervention for children under 12 years old, at 6 and 12 months' follow-up: -0.06 (95% CI -0.12 to -0.01) and -0.04 (95% CI -0.12 to 0.04), respectively.

When comparing the findings of this review to the other behaviour-changing intervention reviews in this series (preschool, adolescent and parent-only), our findings are very similar. The preschool review (Colquitt 2016) found slightly larger reduction in BMI z score in favour of the intervention group than in this review: -0.3 units (95% CI -0.4 to -0.2) for 6 to 12 months' follow-up, and -0.4 units (95% CI -0.6 to -0.2) for 12 to 18 months' follow-up. However, very similar reductions in BMI z score were found when comparing parent-only interventions to parent-child interventions (-0.04 units, 95% CI -0.15 to 0.08) and parent-only

interventions with a waiting list control (-0.10, 95% CI -0.19 to -0.01) (Loveman 2015). Therefore, the other two reviews support the findings found in this review - small reductions in BMI and BMI z score occur when comparing behaviour-changing interventions to control groups.

The effects of behaviour-changing interventions for overweight/obese children were assessed in another recent systematic review and meta-analysis (Ho 2012). When comparing behaviour-changing treatments to no care or waiting list controls they saw a reduction of -1.00 kg/m² (95% CI -1.91 to -0.08) in favour of the intervention group for children 12 years old or less. A similar reduction was found when they compared the treatment group to a usual-care/minimal-intervention control group. A recent review assessing the effects of educational interventions to treat obesity in 6- to 12-year-old children (Sbruzzi 2013) found very similar reductions in BMI and BMI z scores to this review: -0.86 kg/m² (95% CI -1.59 to -0.14) and -0.06 units (95% CI -0.16 to 0.03), respectively.

An overview of reviews for childhood obesity is underway that examines interventions for the treatment of obesity in children using Cochrane methodology (Ells 2016 [pers comm]). This overview will bring together all the evidence for any type of intervention to treat childhood obesity and highlight any evidence gaps that remain.

All types of treatment interventions should also be viewed within the context of prevention interventions. It is interesting that the effect size for BMI z score reduction (measured at longest follow-up) observed in this treatment review of behaviour-changing interventions (MD -0.06 units (95% CI -0.10 to -0.02); P = 0.001; 37 trials; 4019 participants; low-quality evidence) is very similar to the BMI z score reduction (measured at first available point of follow-up after 12-weeks) observed in the recently updated (Brown 2016 [pers comm]) obesity prevention review (Waters 2011) of children aged up to 18 years (-0.05 units (95% CI -0.07 to -0.03); P < 0.00001; 58 studies; 53,777 participants; low-quality evidence).

AUTHORS' CONCLUSIONS

Implications for practice

Multi-component behaviour-changing interventions that incorporate diet, physical activity and behaviour-change components may be beneficial in achieving small, short-term reductions in body mass index (BMI), BMI z score and weight in children aged 6 to 11 years. The evidence was low quality for BMI, BMI z score and weight; and there was a limited number of trials reporting low- to very low-quality evidence for health-related quality of life including self-esteem. Although data on adverse events were not well reported and of low quality, where provided, the evidence suggests a very low occurrence of adverse events. The heterogeneity

observed across all outcomes was not explained by subgrouping based on the type of intervention, type of comparator, setting, risk of bias, parental involvement or severity of obesity at baseline. The sustainability of any observed reduction in BMI/BMI z score and body weight is a key consideration and there is a need for longer-term follow-up of these children. The evidence highlights a focus in paediatric obesity on initial weight reduction interventions rather than longer term maintenance interventions. This review demonstrates that interventions show effects at the end of the intervention and up to six months post-intervention; the fact that these intervention effects might not persist is not a failure of the initial intervention, but due to a lack of maintenance interventions. Obesity is a severe chronic relapsing disease becoming manifest in an obesity-conducive environment, therefore it is unsurprising that short-term effects do not persist. Continued support through obesity maintenance interventions are required to build upon behaviour changes which increase resilience to obesity-conducive environments.

Implications for research

The systematic review identified 20 ongoing trials of behaviour-changing interventions, which will contribute data to the results of an updated review. Further research is required of interventions in lower income countries and in children from ethnic minority groups. We still do not understand what the key components of multicomponent interventions are that contribute to success, and for which children. Study designs other than randomised controlled trials may be helpful in improving our understanding.

Children aged 6 to 11 years are likely to require the support of families (hence only five of the 70 included interventions targeted the child and did not involve parents) which adds another layer of complexity, particularly given that we know parents are also likely to be suffering from excess weight; further research into the optimal ways of involving parents in paediatric obesity interventions is required. Despite this review including many more studies compared with the original review (Oude Luttikhuis 2009), the effect size on BMI z score is almost identical. Although the evidence is of low or very low quality according to GRADE, the review authors believe that it is unlikely that any subsequent update would dramatically alter the effects on BMI, BMI z score or weight. Perhaps a change of focus is required, for example, qualitative research to further our understanding of what works for who, when and why, in the context of the family, in order to tailor and target future obesity interventions. Future research could examine family-based approaches that treat both obese parents and children simultaneously, similar to two studies included within this review (Berry 2007; Berry 2014).

Further research is required on the impacts of these interventions for health-related quality of life, long term diet and activity behaviour change and obesity-related comorbidities. There is a need for standardised reporting of key outcomes and moderators (e.g.

ethnicity, health-related quality of life, diet and physical activity changes and socioeconomic status). Cost data were not considered within the remit of this review; nine of the 70 (13%) included studies measured costs associated with resource use or cost effectiveness of the intervention (Bryant 2011; Coppins 2011; Hughes 2008; Kalavainen 2007; Lison 2012; McCallum 2007; Reinehr 2010; Wake 2009; Wake 2013). Nine studies reported on cost data using a variety of different reporting methods. Whilst Wake 2013 planned a full economic evaluation, this was not conducted, as the programme did not prove to be effective, and Lison 2012 simply reported that the hospital-based intervention was more expensive when compared to the home-based approach. Kalavainen 2007 reported a cost per 0.1 decrease in BMI SDS of EUR 168 for the intervention group, whilst Reinehr 2010 reported a cost per family of EUR 652. The remaining five studies provided an estimated cost of the intervention per person ranging from GBP 108 (Hughes 2008), GBP 403 (Coppins 2011), GBP 858 (Bryant 2011), AUD 873 (McCallum 2007) and AUD 1317 (Wake 2009). However, not all of these studies conducted formal cost-effectiveness analyses. As these outcomes are vitally important for practice implications and decision-makers, it is important that these outcomes are systematically reviewed.

A UK tracking study (Mead 2016b) using data from the Millenium cohort showed that overweight and obese children at 4/5 years old are very likely to remain overweight and obese at 11/12 years old. In addition, obese deprived boys at age 4/5 were more likely to remain obese at age 11/12 compared with non-deprived obese boys (trend not seen in girls). Therefore, interventions targeted at children aged 6 to 11 years are capturing an important timeframe, however there is a complete lack of data reporting on the potential moderating effect of socioeconomic status on obesity.

Further work is required to determine the most appropriate and effective forms of post intervention maintenance, including the level of intensity and different modes of maintenance intervention, in order to ensure intervention benefits are sustained over the longer term.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Alves 2008

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: BMI \geq 85th percentile (CDC growth charts), absence of clinical evidence of heart disease (congenital or acquired), respiratory failure or type 1 diabetes, do not use drugs which interfere with cardiac response during exercise (e.g. beta blockers) Exclusion criteria: - Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: none Intervention: exercise group Comparator: no-care control	
Outcomes	Outcome measures reported in abstract: weight, BMI	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: Portuguese Funding: non-commercial funding (Cnpq, Brazilian Government) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "To verify the effectiveness of an exercise intervention to control excess of body weight without the incorporation of diet guidelines in children who lives in a deprived area in a developing country"	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Patients were listed consecutively and after randomly selected, without spare, to compose the group intervention" Comment: adequate randomisation method
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed allocation was concealed

Alves 2008 (Continued)

Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed study was not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed study was not blinded
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Comment: dropout rates fairly low
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Arauz Boudreau 2013

Methods	Parallel RCT Randomisation ratio: 3:2 during the first half of the study, and then 2:2 during the second half of the study to adequately fill the group classes Superiority design
Participants	Inclusion criteria: Latino children aged 9-12 years, overweight or obese (\geq 85th percentile or \geq 95th percentile, CDC growth charts. Had received primary care at a single community health centre Exclusion criteria: children who had chronic diseases (other than asthma) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: lifestyle intervention and coaching on lifestyle behaviours Comparator: waiting-list control
Outcomes	Outcome measures reported in abstract: attendance, barriers to changing lifestyles to control obesity, HRQoL, obesity markers, BMI, physical activity
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: Robert Wood Johnson Foundation; Massachusetts General Hospital Multicultural Affairs Career Development Award; Massachusetts General Hospital Disparities Solution Center; Harvard Catalyst Clinical Research Center (Grant no. UL1 RR025758-01); NIH; National Center for Research Resources; and General Clinical Research Centers Program (non-commercial)

	Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “To assess the feasibility and effectiveness of a family-centred, primary care-based approach to control childhood obesity through lifestyle choices”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of the randomisation method
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: no subjective outcomes measured
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “Although participants were randomized, because of the waitlist study design, neither participants nor study team members were blinded to group allocation” Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “Although participants were randomized, because of the waitlist study design, neither participants nor study team members were blinded to group allocation” Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “Although participants were randomized, because of the waitlist study design, neither participants nor study team members were blinded to group allocation” Comment: outcome assessors were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “A total of 67% (12/18) control and 61% (14/23) intervention participants took part in first and second visits”

Arauz Boudreau 2013 (Continued)

		Comment: attrition rates were high
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “A total of 67% (12/18) control and 61% (14/23) intervention participants took part in first and second visits” Comment: attrition rates were high
Selective reporting (reporting bias)	Unclear risk	Comment: unable to find clinical trial record/protocol
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Barkin 2011

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: Latino children who were 8-11 years, BMI \geq 85% adjusted for age and gender (CDC growth charts), parent > 18 years and committed to participating in the intervention Exclusion criteria: - Diagnostic criteria: see above
Interventions	Number of study centres: 2 Run-in period: no Extension period: no Intervention: group physical activity and goal setting Comparator: standard care counselling and health education session
Outcomes	Outcome measures reported in abstract: BMI (parents and children)
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: National Institutes of Health (NICHD Grant No. R21 HD050990-02) and 'The Collaborative to Strengthen Families and Neighborhoods' - part funded by The Duke Endowment (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “To assess whether body mass index (BMI) change in preadolescents reflected that of their participating parent.”
Notes	-

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of randomisation method
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed. No mention in text
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participant and study personnel were blinded. No mention in text
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if outcome assessors were blinded. No mention in text
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: "For this community-based randomized controlled trial, we had a 68% retention rate, consistent with other studies of this kind." "The completers (those who completed both baseline and 6-month data) did not differ significantly on the variables of interest compared with those who did not complete the study (refer to Table 3)." Comment: attrition rates were high and bias assessed as high even with multiple imputation method used. Only 45% of participants were followed up
Selective reporting (reporting bias)	High risk	Comment: they only report baseline and change from baseline BMI measurements for both groups combined, don't report them individually for intervention and control groups. No clinical trial register or protocol to assess reporting of outcomes
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Bathrellou 2010

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: overweight or obese children (IOTF growth references), aged 7-12 years Exclusion criteria: chronic physical or mental illness Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: behavioural intervention with parental involvement Comparator: behavioural intervention without parental involvement
Outcomes	Outcome measures reported in abstract: percent overweight
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: part funded by the Department of Nutrition and Dietetics Graduate programme (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: "In this context, the aim of the present study was to evaluate the effectiveness of involving parents in an intense childhood obesity programme involving lifestyle intervention based on cognitive behavioral therapy (CBT) principles and assigning high self-management to the children"
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of randomisation method
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participant and study personnel were blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if outcome assessors were blinded

Bathrellou 2010 (Continued)

Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Although most children attended the intensive phase of the intervention (88%), only three quarters of the children completed all stages of the 18-month follow-up assessment.” Comment: relatively high dropout rates at the end of the follow-up
Selective reporting (reporting bias)	Unclear risk	Comment: methods paper lists a number of outcomes they plan to measure including diet, physical activity, biochemical & metabolic and psychological measures. However, in the results of the publication only BMI and percent overweight are mentioned - and only percent overweight results are given (in graph), not BMI - potential reporting bias
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Berry 2007

Methods	Cluster RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: children aged 7-17 years who assented, children whose BMI > 85th percentile (CDC growth charts), parents who consented and had a BMI > 25, English or Spanish speaking parents and children, any ethnic group (white, black or Hispanic), no major diagnosis that would affect participation Exclusion criteria: - Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: nutrition and exercise education programme (NEEP) plus coping skills training (CPT) Comparator: nutrition and exercise education programme (NEEP) only
Outcomes	Outcome measures reported in abstract: BMI, body fat percentage, pedometer steps, parental behaviour outcomes
Study details	Trial terminated early: no Trial ID: -

Berry 2007 (Continued)

Publication details	Language of publication: English Funding: research grants (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The purpose of this pilot study was to determine the effects of the addition of coping skills training for obese multiethnic parents whose overweight children were attending a weight management program.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “After participants consented and children assented to join the study, they were randomized by class, using the “sealed envelope technique” in blocks of 8-10 parent-child dyads to either the experimental group or the control group” Comment: adequate randomisation method
Allocation concealment (selection bias)	Low risk	Quote from publication: “sealed envelope technique” Comments: it’s likely allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Low risk	Comment: study author confirmed via email that participants and personnel were blinded
Blinding of participants and personnel (performance bias) Objective outcomes	Low risk	Comment: study author confirmed via email that participants and personnel were blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Trained research assistants blinded to the study group collected clinical and psychosocial data” Comment: outcome assessors were blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Trained research assistants blinded to the study group collected clinical and psychosocial data” Comments: outcome assessors were blinded

Berry 2007 (Continued)

Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “dropout rates and loss to follow up were moderate” Comments: potential attrition bias
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “dropout rates and loss to follow up were moderate” Comments: potential attrition bias
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trial register entry available
Other bias	High risk	Comment: was a cluster-RCT and did not adjust for clustering in their analyses

Berry 2014

Methods	Cluster-RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: children and parents able to speak, read and write in English, children in the 2nd-4th grade (age 7-11 years), children with a BMI \geq 85th percentile (CDC growth charts), at least 1 biological parent with a BMI \geq 25 kg/m ² and parent must live with the child, child self-consent and parental consent to participate Exclusion criteria: if parent or child had congenital heart disease, a heart murmur, family history of sudden death or claustrophobia, if parent or child were participating in other weight management programme, Asian descent (due to lower BMI cut-offs for overweight and obesity) Diagnostic criteria: see above
Interventions	Number of study centres: 8 Run-in period: no Extension period: no Intervention: nutrition and exercise education and coping skills intervention Comparator: waiting list control, usual care
Outcomes	Outcome measures reported in abstract: BMI percentile children, triceps growth rate, subscapular skinfolds growth rate, dietary knowledge, glasses of soda/d, eating, exercise self-efficacy parental BMI, parental triceps growth, parental subscapular skinfolds growth, parental nutrition knowledge, parental exercise knowledge, parental water and unsweetened drinks consumption, parental eating self-efficacy, parental emotional eating self-efficacy, parental exercise self-efficacy
Study details	Trial terminated early: no Trial ID: NCT01378806

Berry 2014 (Continued)

Publication details	<p>Language of publication: English Funding: National Institute of Health and the National Institute of Nursing Research (1R01NR010254-05) (non-commercial) Publication status: peer-reviewed journal</p>	
Stated aim for study	<p>Quote from publication: “The purpose of this study was to test a 2-phased nutrition and exercise education, coping skills training, and exercise intervention programme for overweight or obese low-income ethnic minority 2nd to 4th grade children and their parents in rural North Carolina, USA”</p>	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote from publication: “Schools were randomized to either the experimental or the control group for the first enrollment and exchanged conditions for the second enrolment. The sequence of each school was randomized before the start of the study and was stratified by county. A total of 18 months had passed and the first group had completed their time in the study prior to the second enrollment in each school. This design preserved a balance of treatment groups within each site to avoid confounding site effects with intervention effects”</p> <p>Comment: randomisation process described but there were baseline differences likely due to the cluster randomisation - potential bias</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from publication: “Participants and staff were blinded to group assignment from enrolment until implementation.”</p> <p>Comment: allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	Low risk	<p>Comment: study author confirmed via email that participants and personnel were blinded</p>
Blinding of participants and personnel (performance bias) Objective outcomes	Low risk	<p>Comment: study author confirmed via email that participants and personnel were blinded</p>

Berry 2014 (Continued)

Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Comment: study author confirmed via email that outcome assessment was blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Comment: study author confirmed via email that outcome assessment was blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “To assess the extent of selection bias owing to attrition, the mean values for parent BMI and for child BMI percentiles were compared between those participants who did not contribute data beyond the Phase I intervention and those who did. There were no significant differences between these groups, either overall or by experimental group (P= 0.35).” Comment: sensitivity analysis performed between completers and dropouts - low dropout overall
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “To assess the extent of selection bias owing to attrition, the mean values for parent BMI and for child BMI percentiles were compared between those participants who did not contribute data beyond the Phase I intervention and those who did. There were no significant differences between these groups, either overall or by experimental group (P= 0.35).” Comment: sensitivity analysis performed between completers and dropouts - low dropout overall
Selective reporting (reporting bias)	Low risk	Comment: no differences found between publication and protocol/clinical trial register entry
Other bias	Unclear risk	Comment: was a cluster-RCT and adjusted for clustering in their analyses

Boutelle 2014

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: overweight children (\geq 85th percentile, CDC growth charts), age 8-12 years, the children ate > 10% of their daily caloric intake in the free access paradigm, children must also like cheese pizza (the dinner provided) Exclusion criteria: non-English speakers/readers, already participating in a formal weight loss programme, have a medical condition or taking medication which could influence growth or weight, and eating, food allergies or dietary restrictions, having a disability which would prevent them from participating Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: regulation of cues (ROC) programme Comparator: usual care control group
Outcomes	Outcome measures reported in abstract: acceptability ratings, child food responsiveness, eating in the absence of hunger, body weight measures
Study details	Trial terminated early: no Trial ID: NCT01442142
Publication details	Language of publication: English Funding: University of Minnesota, Faculty Development Grant (R01DK094475 and K02HL112042) (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “This study evaluated the feasibility, acceptability, and initial efficacy of an intervention based on Schachter’s externality theory; the Regulation of Cues (ROC) program.”
Notes	-

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “the project coordinator used a computer-generated randomization table to assign participants to 1 of 2 possible treatment condition (ROC or control) by sex” Comment: randomisation method well described

Boutelle 2014 (Continued)

Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants were not blinded
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants were not blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Comment: study author confirmed via email that outcome assessment was blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Comment: study author confirmed via email that outcome assessment was blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “As can be seen in Figure 1, treatment completion rate was high for the ROC intervention” Comment: 95% and 82% of intervention and control group completed the follow-up - relatively low dropout rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “As can be seen in Figure 1, treatment completion rate was high for the ROC intervention” Comment: 95% and 82% of intervention and control group completed the follow-up - relatively low dropout rates
Selective reporting (reporting bias)	Unclear risk	Comment: clinical trial entry reports that there were three intervention groups and 1 control group; however, there is only 1 intervention group in the publication
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Bryant 2011

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 8-16 years, BMI > 98th percentile (UK 1990 growth references) , parent or carer who spoke fluent English Exclusion criteria: a medical cause for obesity, severe learning difficulties, significant medical or psychiatric problems, siblings already enrolled in the study Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: WATCH IT intervention Comparator: waiting-list control
Outcomes	Outcome measures reported in abstract: recruitment, blinding success, sample size, costs
Study details	Trial terminated early: no Trial ID: ISRCTN95431788
Publication details	Language of publication: English Funding: the Wellcome Trust Ltd. (078174/Z05/Z) (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “Our aim was to conduct a feasibility trial of the evaluation of WATCH IT, a community obesity intervention for children and adolescents”
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “After informed consent (parental consent and child assent) and baseline assessment, participants were randomised to either WATCH IT or a waiting list control for 12 months using a remote automated telephone randomisation system. Randomisation was stratified by BMI standard deviation score (SDS; ≤3.0 vs. >3.0), age (≤12 years vs. >12 years) , gender, and maternal level of education (less than General Certificate of Secondary Education (GCSE) or equivalent (attainment reached at the age of 16 years) vs. higher).”

Bryant 2011 (Continued)

		Comment: randomisation method well described
Allocation concealment (selection bias)	Low risk	Comment: allocation was concealed (as confirmed by study author)
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “An assessor-blinded randomised controlled feasibility trial” Comment: participants and study personnel were not blinded
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “An assessor-blinded randomised controlled feasibility trial” Comment: participants and study personnel were not blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Follow-up assessments performed after randomisation were conducted by assessors who were blinded to the treatment allocation for each family.” Comment: outcome assessment was blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Follow-up assessments performed after randomisation were conducted by assessors who were blinded to the treatment allocation for each family.” Comment: outcome assessment was blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Retention strategies were not formalised within the protocol, but we had an acceptable level of dropout (24% withdrawal overall).” Comment: 75.7% follow-up - some losses to follow-up
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Retention strategies were not formalised within the protocol, but we had an acceptable level of dropout (24% withdrawal overall).” Comment: 75.7% follow-up - some losses to follow-up

Bryant 2011 (Continued)

Selective reporting (reporting bias)	Unclear risk	Comment: clinical trial entry retrospectively entered. Also, publication specifies this study was a feasibility study - hence, it doesn't report results of some of the outcome measures, e.g. HRQoL
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Coppins 2011

Methods	<p>Cross-over RCT (however, analysed as a parallel RCT) Randomisation ratio: 1:1 Superiority design Non-inferiority design: (specify 1- or 2-sided confidence interval) Equivalence design: (specify 1- or 2-sided confidence interval) Controlled clinical trial (CCT)</p>
Participants	<p>Inclusion criteria: BMI > 91st centile (SIGN 2010 guidelines), children with intellectual disability were included if they were judged to be able to participate in the intervention, age 6-14 years Exclusion criteria: medical conditions which might impede physical activity - GPs were asked to notify the dietitian of such conditions (none were disclosed) Diagnostic criteria: see above</p>
Interventions	<p>Number of study centres: 1 Run-in period: no Extension period: no Intervention: multi-component family-focused education package Comparator: waiting-list control</p>
Outcomes	<p>Composite outcome measures reported: BMI z scores, weight, attendance</p>
Study details	<p>Trial terminated early: no Trial ID: ISRCTN55734850</p>
Publication details	<p>Language of publication: English Funding: Wessex Medical Research and The Public Health Department in States of Jersey funded the project. Department of Education, Sports and Culture, States of Jersey funded all the activities. The Channel Islands Co-op funded the food for all the healthy eating workshops; and Jersey Bowl sponsored the Family Project Xmas party (non-commercial) Publication status: peer-reviewed journal</p>
Stated aim for study	<p>Quote from publication: "To determine if a multi-component family focused education package is more effective than a waiting list control group in treating overweight and obese children"</p>

Notes	Participants in the intervention and control groups crossed over into the other condition after 12 months - however, in the publication results are presented as if the trial was a parallel RCT. Hence, results are presented up to 12 months before the crossover	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote from publication: from author (via email): "Simple random test/control each time a patient came forward." Comment: unclear if this method would have introduced bias
Allocation concealment (selection bias)	Low risk	Comment: allocation was concealed (as confirmed by study author)
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "A waiting list control group may also not have been the best comparison, as enrolment into the study may have had a placebo effect." "The lead investigator was also not blind to treatment allocation" Comment: participants and study personnel were not blinded
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: "A waiting list control group may also not have been the best comparison, as enrolment into the study may have had a placebo effect." "The lead investigator was also not blind to treatment allocation" Comment: participants and study personnel were not blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: "A waiting list control group may also not have been the best comparison, as enrolment into the study may have had a placebo effect." "The lead investigator was also not blind to treatment allocation" Comment: assume assessors were not blinded either
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: "A waiting list control group may also not have been the best comparison, as enrolment into the study may have had a placebo effect." "The lead investigator was also not blind to treat-

Coppins 2011 (Continued)

		ment allocation” Comment: assume assessors were not blinded either
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “After the study was completed, we calculated the actual power of the study for an effect size of 0.3 for BMI SDS and it was about 60%.” Comment: dropout rates were low
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “After the study was completed, we calculated the actual power of the study for an effect size of 0.3 for BMI SDS and it was about 60%.” Comment: dropout rates were low
Selective reporting (reporting bias)	Unclear risk	Comment: potential selective reporting as lifestyle outcomes only briefly reported with significant or not significant P values
Other bias	Unclear risk	Comment: study was presented as if it was a crossover trial where each participant was given the intervention and control condition. However, the results are only analysed comparing the 2 groups (I/C and C/I) - no individual analyses performed

Croker 2012

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: 8-12 years, overweight or obese (IOTF definition), at least 1 parent/guardian willing to participate in the intervention, parent and child could speak English well enough to take part in the groups and understand the materials Exclusion criteria: had an identified medical cause for obesity (e.g. hypothyroidism, Prada Willi syndrome), had type 2 diabetes, taking obesity medication, undergoing obesity treatment, had significant learning difficulties, the parent or child had significant mental health problems, were currently receiving psychological or psychiatric treatment including psychotropic medication Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: family-based behavioural treatment (FBBT) Comparator: waiting-list control

Outcomes	Outcome measures reported in abstract: BMI SDS, BMI, systolic blood pressure, QoL, eating attitudes, body composition, psychosocial outcomes, adverse events	
Study details	Trial terminated early: no Trial ID: ISRCTN51382628	
Publication details	Language of publication: English Funding: Cancer Research UK, Great Ormond Street Hospital and Weight Concern (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "To examine the acceptability and effectiveness of 'family-based behavioural treatment' (FBBT) for childhood obesity in an ethnically and socially diverse sample of families in a UK National Health Service (NHS) setting"	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Randomisation was carried out by a statistician; each child was given an ID code, and computer-generated random numbers were used to allocate them to a treatment condition." Comment: low risk of selection bias from randomisation method described
Allocation concealment (selection bias)	Low risk	Quote from publication: (from author via email): "allocation was not known until they were randomised. This was a group programme and we randomised in waves, so waited until we had recruited enough families to run a treatment group. Families were informed of their group allocation as soon as they had been randomised." Comment: allocation was concealed (as confirmed by author)
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "It was not possible to blind families or clinicians to treatment allocation because of the nature of the intervention" Comment: participants and study personnel were not blinded

Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “It was not possible to blind families or clinicians to treatment allocation because of the nature of the intervention” Comment: participants and study personnel were not blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Quote from publication: “the researcher collecting anthropometric data was blinded to group allocation unless families disclosed this information” Comment: unclear if subjective outcomes were measured by a researcher who was blinded to the study group (only mentions anthropometric data which was an objective outcome)
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “the researcher collecting anthropometric data was blinded to group allocation unless families disclosed this information” Comment: outcome assessors measuring objective measures (anthropometric data) were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “22 of the children randomised to the treatment group completed the 6 month intervention (59% of those randomised and 73% of those starting treatment)” Comment: high dropout in the intervention group. Missing data replaced by baseline carried forward which is a highly criticised method
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “22 of the children randomised to the treatment group completed the 6 month intervention (59% of those randomised and 73% of those starting treatment)” Comment: high dropout in the intervention group. Missing data replaced by baseline carried forward which is a highly criticised method
Selective reporting (reporting bias)	High risk	Comment: potential reporting bias as study trial register states they aimed to measure additional outcomes not reported in this publication

Croker 2012 (Continued)

Other bias	Unclear risk	Comment: unable to assess if any other biases present
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Davis 2013

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: criteria for school participation included having rural designation (in a town or county with a population < 20,000) and telemedicine capabilities (common in rural districts for distance learning), child living in rural Kansas and attending elementary school, child being overweight/obese for age/gender (\geq 85th percentile, CDC growth charts), parent able to speak English Exclusion criteria: developmental disability preventing child from participating, being immobile and preventing the child from increasing exercise Diagnostic criteria: see above	
Interventions	Number of study centres: 1 for each study Run-in period: no Extension period: no Intervention: telemedicine intervention Comparator: physician-visit intervention	
Outcomes	Composite outcome measures reported: BMI z, dietary behaviours, physical activity behaviours	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: National Institutes of Health (DK068221) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The objective of the current study was to examine the effectiveness of a multidisciplinary weekly family-based behavioral group delivered via telemedicine to rural areas, compared with a standard physician visit intervention”	
Notes	-	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Children within each school were ranked based on an obesity factor (child BMI percentile plus primary parent BMI and strat-

		<p>ified based on a household factor (single or dual parent household), and gender, according to previous research, which indicates these factors are closely linked to obesity and to treatment outcome. One child from each stratification was then randomly assigned (via a random numbers table) to the telemedicine intervention (TM) with the other half of the pair being assigned to the physician visits (PV) intervention.”</p> <p>Comment: low risk of selection bias from randomisation method described</p>
Allocation concealment (selection bias)	Low risk	Comment: author confirmed allocation was concealed via email contact
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	<p>Quote from publication: (from study author via email) “participants were blinded, and assessment personnel were blinded. Intervention personnel were not blinded.”</p> <p>Comment: participants were blinded but study personnel were not</p>
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	<p>Quote from publication: (from study author via email) “participants were blinded, and assessment personnel were blinded. Intervention personnel were not blinded.”</p> <p>Comment: participants were blinded but study personnel were not</p>
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	<p>Quote from publication: (from author via email): “Yes, the assessment staff were blinded.”</p> <p>Comment: assessment staff were blinded to study group</p>
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	<p>Quote from publication: (from study author via email): “Yes, the assessment staff were blinded.”</p> <p>Comment: participants were blinded but study personnel were not</p>
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	<p>Quote from publication: · “In terms of other outcome measures, attrition was not significantly different by group, but there was a trend for slightly higher attrition in the TM group compared with the PV group.”</p> <p>Comment: potential attrition bias due to</p>

Davis 2013 (Continued)

		moderate dropout rates in intervention group
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “In terms of other outcome measures, attrition was not significantly different by group, but there was a trend for slightly higher attrition in the TM group compared with the PV group.” Comment: potential attrition bias due to moderate dropout rates in intervention group
Selective reporting (reporting bias)	Low risk	Comment: no differences between protocol and publication found
Other bias	Unclear risk	Comment: unable to assess if any other biases present

Davoli 2013

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: overweight children (\geq 85th BMI percentile but \leq 95th - CDC growth charts), age 4-7 years, live in the Reggio Emilia Province and assisted by that paediatrician for at least 12 months Exclusion criteria: metabolic pathologic conditions and all pathologic conditions related to overweight and obesity, families who did not consider childhood overweight/obesity being a problem and were not interested in advice to lose weight Diagnostic criteria: see above
Interventions	Number of study centres: 69 (paediatricians working from their own centres in Reggio Emilia) Run-in period: no Extension period: no Intervention: family paediatrician-led motivational interviewing Comparator: usual care plus a booklet on obesity prevention
Outcomes	Outcome measures reported in abstract: attendance, BMI, parent-reported lifestyle behaviours
Study details	Trial terminated early: no Trial ID: NCT01822626
Publication details	Language of publication: English Funding: no external funding (non-commercial)

	Publication status: peer-reviewed journal	
Stated aim for study	<p>Quote from publication: “The aim of this study was to evaluate the effect of family pediatrician-led motivational interviews (MIs) on BMI of overweight (85th \geq BMI percentile \leq 95th) children aged 4 to 7 years”</p> <p>“The objective of the current study was to examine the effectiveness of a multidisciplinary weekly family-based behavioral group delivered via telemedicine to rural areas, compared with a standard physician visit intervention”</p>	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: “Eligible children whose parents signed the informed consent form were centrally allocated to intervention or control groups according to a randomization list created by the Epidemiology Unit by using the package RALLOC (Stata version 11.0; Stata Corp, College Station, TX)” “Due to the practical constraints of a maximum of 3 treated children per pediatrician, different allocation rules were used according to the number of eligible children. To balance allocation within strata, observations were opportunely weighted”</p> <p>Comment: low risk of selection bias from randomisation method described</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from publication: “Each paediatrician was informed of the group allocation by means of a corporate Intranet Web form customized for the trial (Supplemental Tutorial).”</p> <p>Comment: allocation likely concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	<p>Quote from publication: “The primary outcome was the individual variation of BMI, assessed by paediatricians unblinded to treatment groups.”</p> <p>Comment: unlikely that participants and study personnel were blinded</p>
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	<p>Quote from publication: “The primary outcome was the individual variation of BMI, assessed by paediatricians unblinded</p>

Davoli 2013 (Continued)

		to treatment groups.” Comment: unlikely that participants and study personnel were blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “Both primary and secondary outcomes were assessed by the pediatricians without any blinding.” Comment: assessment staff were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “Both primary and secondary outcomes were assessed by the pediatricians without any blinding.” Comment: assessment staff were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Compliance to the 1- year intervention was high, even for a population-based study involving almost all the pediatricians in the RE Province and a relevant sample of their overweight patients” Comment: 95% of participants completed the 1-year intervention - dropout low
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Compliance to the 1- year intervention was high, even for a population-based study involving almost all the pediatricians in the RE Province and a relevant sample of their overweight patients” Comment: 95% of participants completed the 1 year intervention - dropout low
Selective reporting (reporting bias)	Low risk	Comment: no differences between protocol and publication found
Other bias	Unclear risk	Comment: unable to assess if any other biases present

de Niet 2012

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
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Participants	<p>Inclusion criteria: overweight or obese (defined by Cole 2000 international survey), parent participation in the BFC (behavioural lifestyle treatment), sufficient knowledge of the Dutch language, parent and child fluent in Dutch language and show motivation to the programme (assessed by motivational interviewing)</p> <p>Exclusion criteria: behavioural programmes (score > 70 on Child Behaviour Checklist (CBCL), any disease causing overweight that can be treated with drugs, mental retardation</p> <p>Diagnostic criteria: see above</p>	
Interventions	<p>Number of study centres: 8</p> <p>Run-in period: no</p> <p>Extension period: no</p> <p>Treatment before study: all participants took part in 3 months of behavioural lifestyle treatment</p> <p>Intervention: short message service maintenance treatment and behavioural lifestyle treatment</p> <p>Comparator: behavioural lifestyle treatment only</p>	
Outcomes	<p>Composite outcome measures reported: physical health scores, number of SMS sent, weight loss, BMI, dropout rates</p>	
Study details	<p>Trial terminated early: no</p> <p>Trial ID: ISRCTN33476574</p>	
Publication details	<p>Language of publication: English</p> <p>Funding: Vodafone (the Netherlands), and grants were received from the Erasmus University Medical Centre Rotterdam - MRACE (Medical Research Advice Committee) grant no. 2006-26 and Innovation Fund Insurances (Innovatiefonds Verzekeringen) grant no. 06-334 (commercial and non-commercial)</p> <p>Publication status: peer-reviewed journal</p>	
Stated aim for study	<p>Quote from publication: “The effect of a short message service maintenance treatment on body mass index and psychological well-being in overweight and obese children: a randomized controlled trial”</p>	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: “Randomization allocation in a 1:1 ratio was applied in a randomized block design. The blocks were formed by the treatment groups”</p> <p>Comment: randomisation method described</p>

Allocation concealment (selection bias)	Low risk	Quote from publication: “The randomization allocation was printed on paper in a sealed envelope. An equal number of SMSMT and control notes were put in the envelopes. The researcher randomized the children to the SMSMT or control group by picking an envelope from a basket” Comment: allocation likely concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed nobody was blinded to the study group in the trial
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed nobody was blinded to the study group in the trial
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed nobody was blinded to the study group in the trial
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed nobody was blinded to the study group in the trial
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Only 10 children in the intervention group dropped out of the BFC treatment (14%) in the period between 3 and 12 months compared to 21 children in the control group (31%).” Comment: potential attrition bias as more dropped out in control group
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Only 10 children in the intervention group dropped out of the BFC treatment (14%) in the period between 3 and 12 months compared to 21 children in the control group (31%).” Comment: potential attrition bias as more dropped out in control group
Selective reporting (reporting bias)	Unclear risk	Comment: raw data for many outcomes not reported in tables or text but given in graphs or reported as either significant or non-significant

de Niet 2012 (Continued)

Other bias	Unclear risk	Comment: unable to assess if any other biases were present
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Diaz 2010

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: age 9-17 years, BMI > 95th percentile (CDC growth charts) or BMI > 90th percentile + WC > 90th percentile, willingness to attend the group sessions, caregivers showing an interest in weight control Exclusion criteria: glucose intolerance of type 2 diabetes, psychiatric disorders, medical condition that would preclude participating in the study, medication that affects weight or involvement in another weight loss programme, participants who had lost weight during the 4 months before the study Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Treatment before study: 5% of volunteers took part in a previous cross-sectional study Intervention: behavioural curriculum plus registered dietitians and physician consultations Comparator: physician consultations only	
Outcomes	Outcome measures reported in abstract: completion rates, body weight, BMI, insulin sensitivity	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: grant from the International Atomic Energy Agency (ARCAL 6/059) and CONACyT (R/182996) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The main objective of this study was to compare a lifestyle intervention-primary care physician supported by a registered dietitian (RD) and a behavioral curriculum- to a brief primary care physician intervention for treating pediatric obesity in the primary care setting"	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	<p>Quote from publication: “Once measurements were completed, the study statistician randomly assigned participants 1:1 to the lifestyle intervention or the control group by simple randomization, stratified according to sex. The randomization sequence was generated by a computer”</p> <p>Comment: randomisation method described</p>
Allocation concealment (selection bias)	Low risk	<p>Comment: study author confirmed via email that allocation was concealed</p>
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	<p>Quote from publication: (from author via email) “Only study personnel who measured the primary outcomes were blinded to group assignments, as were personnel who measured body composition by dual-energy x-ray absorptiometry and performed blood work.”</p> <p>Comment: study author confirmed participants were not blinded</p>
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	<p>Quote from publication: (from author via email): “Study personnel who measured the primary outcomes were blinded to group assignments, as were personnel who measured body composition by dual-energy x-ray absorptiometry and performed blood work.”</p> <p>Comment: those who measured objective outcome were blinded to study group</p>
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	<p>Quote from publication: “A limitation of this study was the high attrition rates” “We also applied an intention-to-treat analysis at 12 months in the primary outcomes of the study. Considering the risk of bias of procedures for analyzing incomplete data, we made an effort to obtain the primary outcomes (weight and BMI) of all participants who dropped out of the study (n=33) measuring children at their homes. However, we were able to measure the primary outcomes only in 23 drop outs. Thus, intention-to-treat analysis included 66 (87%) of the original 76 randomized participants (lifestyle group, n=33; control group, n=</p>

Diaz 2010 (Continued)

		33).” Comment: high risk of bias due to high attrition rates; however, the study authors measured 23/33 dropouts in their own homes and presented this presented this for weight and raw BMI; therefore, rated as unclear due to disparity
Selective reporting (reporting bias)	Unclear risk	Comment: no clinical trial register entry or protocol available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Duffy 1993

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: age 7-13 years, exceeding 15% of ideal weight for age, height and sex (reference used unclear), 1 parent willing to attend sessions Exclusion criteria: none Diagnostic criteria: unclear
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: cognitive self-management training plus behaviour therapy Comparator: behaviour therapy plus attention placebo control methods
Outcomes	Outcome measures reported in abstract: percentage overweight, number of red foods/d
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: unclear Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “The present study was therefore designed to evaluate the benefits of cognitive self-management techniques in enhancing the effectiveness of a traditional behavioural approach.”
Notes	-
Risk of bias	

Duffy 1993 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of the randomisation process
Allocation concealment (selection bias)	Unclear risk	Comment: not clear whether allocation was concealed
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants/study personnel were blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: "Of the 27 children who commenced treatment, 21 completed therapy and were available for post-treatment and 3-month follow-up". "At the 6-month follow-up, four children who had completed the programme were not available, leaving eight in the BT + APC condition and nine in the CBT group" Comment: dropout rate high at 6 months' follow up (37%) and no ITT analysis
Selective reporting (reporting bias)	Unclear risk	Comment: no clinical trial register entry or protocol available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Duggins 2010

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: age 5-17 years, BMI above the 85th percentile for age and sex (CDC growth charts) Exclusion criteria: no criteria for exclusion Diagnostic criteria: see above
Interventions	Number of study centres: 2 family medicine clinics and a specialty Pediatrics Clinic and 6 YMCAs Run-in period: no

Duggins 2010 (Continued)

	Extension period: no Intervention: nutrition classes and family YMCA membership Comparator: nutrition classes only	
Outcomes	Composite outcome measures reported: adherence, BMI percentile	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: KT Wiedemann Foundation, Children's Miracle Network, Medical Society of Sedgwick County, and the Greater Wichita YMCA (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "We sought to test the effectiveness of an evidence- based intervention that feasibly could be incorporated into the routine primary care of a diverse population."	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "The study physician enrolled participants using a computer-generated randomization list" Comment: randomisation process adequately described
Allocation concealment (selection bias)	Low risk	Quote from publication: "The allocation sequence was concealed before randomization by using sequentially numbered envelopes containing the group-appropriate materials" Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "Given the nature of the intervention neither clinicians nor participants were blind to the treatment allocation once randomization occurred." Comment: participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: "Given the nature of the intervention neither clinicians nor participants were blind to the treatment allocation once randomization occurred." Comment: participants and study person-

		nel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: "Participants' height and weight were collected and entered into the medical record at baseline and at 2 months, 4 months, 6 months, 9 months, and 12 months after enrollment by the nonblinded nursing staff." Comment: assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: "Participants' height and weight were collected and entered into the medical record at baseline and at 2 months, 4 months, 6 months, 9 months, and 12 months after enrollment by the nonblinded nursing staff." Comment: assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "17 children were excluded from analysis, leaving evaluable data from 30 children in the control group and 36 in the treatment group." "Overall attendance at scheduled study-related visits was poor" Comment: 80% of participants were included in the ITT analysis however the publication does not specify how many completed the study. Furthermore attendance at sessions very low
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: "17 children were excluded from analysis, leaving evaluable data from 30 children in the control group and 36 in the treatment group." "Overall attendance at scheduled study-related visits was poor" Comment: 80% of participants were included in the ITT analysis however the publication does not specify how many completed the study. Furthermore attendance at sessions very low
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register available. However, publication only reports dietary outcomes for whole group, does not split them by group or comment on statistical significance. Also

Duggins 2010 (Continued)

		do not report standard deviations for change in BMI or BMI percentile. Risk of selective reporting bias therefore unclear
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Eddy Ives 2012

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: age 10-14 years of both sexes, overweight or obese (BMI 85th-95th or > 95th percentiles, depending on age and sex, WHO classification) Exclusion criteria: morbid obesity, secondary obesity, bulimia nervosa, mental retardation, difficulties understanding the recommendations, current or recent participation in another clinical trial Diagnostic criteria: see above	
Interventions	Number of study centres: 48 Run-in period: no Extension period: no Intervention: dietary and physical exercise recommendations during 6 sessions Comparator: dietary and physical exercise recommendations in 2 sessions only (waiting list control)	
Outcomes	Outcome measures reported in abstract: completion rates, BMI z scores, WC z score, food habits, physical activities	
Study details	Trial terminated early: no Trial ID: ISRCTN35399598 (retrospectively entered)	
Publication details	Language of publication: English Funding: IX Research Award Nutribén 2007 (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “to assess the efficiency of an educational intervention on lifestyle habits to reduce the body mass index in adolescents.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Quote from publication: “We obtained the informed consent of those who chose to participate, and randomly allocated each adolescent to one of the study groups based on a sequence of random numbers generated in a centralised manner from the Research Unit that participated in the study.” Comment: randomisation process adequately described
Allocation concealment (selection bias)	Low risk	Comment: allocation likely concealed due to randomisation method (as described above)
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Thus, 174 participants were randomised, and 125 (71.8%) completed the follow up” Comment: relatively moderate dropout rates - may have introduced bias
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Thus, 174 participants were randomised, and 125 (71.8%) completed the follow up” Comment: relatively moderate dropout rates - may have introduced bias
Selective reporting (reporting bias)	Unclear risk	Comment: clinical trial entry registered retrospectively
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Epstein 1984a

Methods	Parallel RCT Randomisation ratio: 1:1:1 Superiority design	
Participants	Inclusion criteria: children age 8-12 years, child and parent between 20%-80% of their ideal weight for height, age and sex (Jelliffe 1966), parent and child had triceps skinfold thickness > 85th percentile, parent willing to participate in all treatment meetings Exclusion criteria: child had a current psychiatric contact or a learning disability, medical problem that contraindicated exercise (parent or child) Diagnostic criteria: see above	
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention 1: diet-plus-exercise group Intervention 2: diet only Comparator: waiting list control	
Outcomes	Outcome measures reported in abstract: weight, parental weight, lipids, triglycerides, cholesterol, HDL, fitness	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: part by Grant HD12520 from the National Institute of Child Health and Human Behavior (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The present study reports the comparison of diet with diet-plus-life-style exercise in a sample of overweight children and parents enrolled in the family-based obesity treatment program previously developed in this laboratory"	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of randomisation process
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group

Epstein 1984a (Continued)

Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “At 6 months, results were available for 47 (89%) of the original 53 families, with 15, 18, and 14 families measured per group.” Comment: attrition rates were low
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “At 6 months, results were available for 47 (89%) of the original 53 families, with 15, 18, and 14 families measured per group.” Comment: attrition rates were low
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Epstein 1985a

Methods	Parallel RCT Randomisation ratio: 1:1:1 Superiority design
Participants	Inclusion criteria: children aged 8-12 years, child and parent > 20% over their ideal weight for height (Metropolitan Life Insurance Company 1959 ; Robinson 1968) Exclusion criteria: parent and child with a problem that would interfere with exercise Diagnostic criteria: see above
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention 1: diet plus programmed aerobic exercise programme Intervention 2: diet plus lifestyle exercise programme Comparator: diet plus low intensity callisthenic exercise programme

Epstein 1985a (Continued)

Outcomes	Outcome measures reported in abstract: weight, parental weight	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: GRANT HD12520 from National Institute of Child Health and Human Development (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The present study is designed to assess the reliability of the effects of diet plus lifestyle versus diet plus programmed aerobic exercise over an extended two year observation interval.”	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of randomisation process
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Complete data were available for 35 families, which represent 85% of the families beginning the study” Comment: attrition rates fairly were low

Epstein 1985a (Continued)

Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Complete data were available for 35 families, which represent 85% of the families beginning the study” Comment: attrition rates fairly were low
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Epstein 1985b

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: girls between 8-12 years, at least 20% over her ideal weight for height and age (Jeliffe 1966), at least 1 parent willing to participate Exclusion criteria: medical problems that would contraindicate weight loss, exercise or fitness testing Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: diet and exercise education Comparator: diet education only
Outcomes	Outcome measures reported in abstract: weight, percent overweight, fitness
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: Grant HD 16411 from National Institute of child health and human development (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “The present study was designed to re-evaluate the role of exercise plus diet in weight control by having children participate in a structured exercise program during the first 6 weeks of exercise, which may facilitate the development of appropriate exercise behavior.”
Notes	-

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "After acceptance into the program, families were assigned to one of two treatment groups by a stratified random assignment procedure. Children were stratified on the basis of age, percent overweight, and physical work capacity, and were then randomly assigned to either the diet plus exercise group (group 1) or the diet without exercise group (group 2)." Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: "Twenty of the 23 children completing treatment (86.96%) attended the 6-month assessment, and 19 children (82.61%) attended the 1-year assessment. There was no difference in the dropout rate between groups" Comment: even though dropout rates were relatively low, there was no sensitivity analysis or missing data imputation, and furthermore original sample size was small. Hence attrition rate may have led to bias

Epstein 1985b (Continued)

Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Twenty of the 23 children completing treatment (86.96%) attended the 6-month assessment, and 19 children (82.61%) attended the 1-year assessment. There was no difference in the dropout rate between groups” Comment: even though dropout rates were relatively low, there was no sensitivity analysis or missing data imputation, and furthermore original sample size was small. Hence attrition rate may have led to bias
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Epstein 1985c

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: obese female children (obesity defined by Robinson 1968), 5-8 years of age Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: behaviourally-oriented programme that emphasised parent management Comparator: provided equal education and attention but not behavioural principles
Outcomes	Composite outcome measures reported: weight
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: part by Grant HD16411 from the national Institute of child health and human development (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “The purpose of this study was to evaluate the effectiveness of family-based treatment for childhood obesity for 5-to-8 year old children”

Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no description of randomisation method
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: "Five families dropped out after the preliminary meeting because of conflicting obligations" Comment: moderate dropout rates, unclear if attrition bias occurred
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: "Five families dropped out after the preliminary meeting because of conflicting obligations" Comment: moderate dropout rates, unclear if attrition bias occurred
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Epstein 2000a

Methods	Parallel RCT Randomisation ratio: 1:1:1 Superiority design
Participants	Inclusion criteria: child > 20% overweight (Must 1991), 1 parent willing to attend meetings, child reading third-grade level or higher Exclusion criteria: if a either parent was > 100% overweight, a family member on an alternative weight management programme, parent or child having psychiatric problems, parent or child having activity restrictions Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention 1: behavioural weight-control programme plus parent and child problem solving Intervention 2: behavioural weight-control programme plus child problem solving only Comparator: standard treatment with no additional problem solving
Outcomes	Composite outcome measures reported: BMI, child behaviour problems, parental distress, parent problem solving, child problem solving, parental weight, eating disorder symptoms
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: in part by Grant HD20829 (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “This study was designed to determine the effects of adding problem-solving training for parents and children or children alone to a comprehensive family-based behavioral childhood obesity treatment”
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: (from study author via email) “After participants are screened to ensure they met eligibility criteria for the specific study, families are randomized to treatment groups using a random number algorithm which assigned a random number that was limited to the number of groups, for example in a two group study group 1 or 2. Groups are then

Epstein 2000a (Continued)

		checked to make sure they are not different in child and parent relative body weight (BMI, percent overweight, z-BMI), usually SES, and sometimes other study specific baseline values of other measures. If groups are not equal randomization is repeated” Comment: unlikely this randomisation method introduced selection bias
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “Attrition was 3%, 11%, and 15% at 6, 12, and 24 months, respectively” Comment: low attrition rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Attrition was 3%, 11%, and 15% at 6, 12, and 24 months, respectively” Comment: low attrition rates
Selective reporting (reporting bias)	High risk	Comment: no protocol or clinical trials register entry available. Also, in the additional publication all three groups were grouped together for analysis - potential reporting bias due to non-significant results
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Epstein 2001

Methods	<p>Parallel RCT Randomisation ratio: 1:1 Superiority design</p>	
Participants	<p>Inclusion criteria: children aged 8-12-years, child \geq 85th BMI percentile but $<$ 100% over average BMI for age and sex (using standards derived from the National Health and Nutrition Examination Survey III) child at or $>$ 85th, 1 parent willing to attend the weekly treatment meetings Exclusion criteria: either parent over 100% overweight, a parent or child on another weight-control programme, medical restrictions to the parent or child that would prevent exercise, current psychiatric disorders in parents or child, a history of eating disorders in the parents Diagnostic criteria: see above</p>	
Interventions	<p>Number of study centres: 1 Run-in period: no Extension period: no Intervention: a combination of reducing sedentary behaviour and increasing physical activity Comparator: targeting increasing physical activity only</p>	
Outcomes	<p>Outcome measures reported in abstract: percent overweight, adherence</p>	
Study details	<p>Trial terminated early: no Trial ID: -</p>	
Publication details	<p>Language of publication: English Funding: in part by Grant HD34284 (non-commercial) Publication status: peer-reviewed journal</p>	
Stated aim for study	<p>Quote from publication: "The primary goal was to evaluate sex differences in child weight control programs that targeted increasing physical activity (increase) or the combination of reducing sedentary behavior and increasing physical activity (combined). A second goal was to evaluate the benefits of family-based interventions on non-targeted siblings."</p>	
Notes	<p>-</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: (from author via email) "After participants are screened to ensure they met eligibility criteria for the specific study, families are randomized to treatment groups using a random number algorithm which assigned a random number that was limited to the number of

		groups, for example in a two group study group 1 or 2. Groups are then checked to make sure they are not different in child and parent relative body weight (BMI, percent overweight, z-BMI), usually SES, and sometimes other study specific baseline values of other measures. If groups are not equal randomization is repeated" Comment: unlikely this randomisation method introduced selection bias
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessment staff were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: "The final sample with complete data for targeted children at baseline, 6-month, and 12-month measurements was based on 56 of the 67 families that were randomized (84%), which included 245 family members." Comment: low attrition rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: "The final sample with complete data for targeted children at baseline, 6-month, and 12-month measurements was based on 56 of the 67 families that were randomized (84%), which included 245 family members." Comment: low attrition rates
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry

Epstein 2001 (Continued)

Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias
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Epstein 2005

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: children aged 8-12-years, overweight or obese (\geq 85th BMI percentile, CDC growth charts), a parent willing to attend treatment meetings, child reading level at a minimum of third-grade level Exclusion criteria: if any family members are participating in another weight-control programme, parent or child with medical restrictions on diet or physical activity, which could interfere with participation in the study, current psychiatric, addictive or eating disorders in parents or child Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: standardised family-based behavioural weight control programme plus reinforcement for increasing alternatives to eating Comparator: standardised family-based behavioural weight control programme only	
Outcomes	Outcome measures reported in abstract: BMI z score, alternatives to eating, physical activity, energy intake	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: supported in part by grant HD 39792 awarded to the lead study author (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "Two experiments that attempt to increase alternatives to eating in obese youth are presented"	
Notes	-	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "After participants are screened to ensure they met eli-

		<p>gibility criteria for the specific study, families are randomized to treatment groups using a random number algorithm which assigned a random number that was limited to the number of groups, for example in a two group study group 1 or 2. Groups are then checked to make sure they are not different in child and parent relative body weight (BMI, percent overweight, z-BMI), usually SES, and sometimes other study specific baseline values of other measures. If groups are not equal randomization is repeated”</p> <p>Comment: unlikely this randomisation method introduced selection bias</p>
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear if assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	<p>Quote from publication: “Complete height and weight data at 24 months was available for 35 of the 41 families”The intention to treat analysis replaced missing data with return to baseline values.“</p> <p>Comment: dropout rates were moderate and ITT analysis was used - however they replaced missing data with baseline values which is not a robust imputation method. Bias may still have occurred</p>
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: ”Complete height and weight data at 24 months was available for 35 of the 41 families “The in-

Epstein 2005 (Continued)

		<p>tention to treat analysis replaced missing data with return to baseline values.”</p> <p>Comment: dropout rates were moderate and ITT analysis was used - however they replaced missing data with baseline values which is not a robust imputation method. Bias may still have occurred</p>
Selective reporting (reporting bias)	Unclear risk	<p>Comment: unclear as no protocol or clinical trials register. Study found no significant differences between groups - raw data reported either in the text or in graphical format (not presented in a table) hence will be difficult to extract. Potential selective reporting due to non-significant results</p>
Other bias	Unclear risk	<p>Comment: unclear if the study was at risk of any other bias</p>

Epstein 2015

Methods	<p>Parallel RCT</p> <p>Randomisation ratio: 1:1</p> <p>Superiority design</p>
Participants	<p>Inclusion criteria: children aged 8-12-years, > 85th BMI percentile (CDC growth charts), 1 overweight/obese (BMI \geq 25) parent willing to attend treatment meetings, child reading level at a minimum of third-grade level</p> <p>Exclusion criteria: taking weight-altering drugs, if any family members are participating in another weight-control programme, parent or child with diet or physical activity restrictions, which could interfere with participation in the study, psychiatric problems in child or parent</p> <p>Diagnostic criteria: see above</p>
Interventions	<p>Number of study centres: 1</p> <p>Run-in period: prior to initiating the pilot, 21 families were seen to develop treatment methods, and provide therapists experience with the intervention</p> <p>Extension period: no</p> <p>Intervention: family-based treatment + variety of high energy-dense foods</p> <p>Comparator: family-based treatment only</p>
Outcomes	<p>Composite outcome measures reported: percent overweight, BMI z score, RED foods, parent BMI</p>
Study details	<p>Trial terminated early: no</p> <p>Trial ID: NCT01208870</p>

Publication details	Language of publication: English Funding: funded in part by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases UO1 DK088380 awarded to lead author (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The aims of the pilot study were to assess effects of variety of both child and parent weight loss, and to assess whether reduced variety of high energy dense foods was associated with weight loss."	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: (from author via email) "After participants are screened to ensure they met eligibility criteria for the specific study, families are randomized to treatment groups using a random number algorithm which assigned a random number that was limited to the number of groups, for example in a two group study group 1 or 2. Groups are then checked to make sure they are not different in child and parent relative body weight (BMI, percent overweight, z-BMI), usually SES, and sometimes other study specific baseline values of other measures. If groups are not equal randomization is repeated" Comment: randomisation method described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear if subjective outcomes were measured by blinded staff

Epstein 2015 (Continued)

Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Height and weight measurements were taken at 0 and 6 months by staff blind to treatment assignment using a digital weight scale and stadiometer calibrated daily.” Comment: objective anthropometric outcomes were measured by blinded staff
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Comment: attrition rates unknown
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Comment: attrition rates unknown
Selective reporting (reporting bias)	Low risk	Comment: no differences found between clinical trial register entry and the publication
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Faude 2010

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: children aged 8-12 years, overweight (large German reference sample - Kromeyer-Hauschild 2001) Exclusion criteria: children not actively involved in regular sports activities, children not exposed to any nutritional or pharmacological intervention, adverse cardiovascular conditions, and chronic metabolic or orthopaedic disorders Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: football training programme (FB) Comparator: established standard sports programme (STD)
Outcomes	Composite outcome measures reported: maximal performance capacity, submaximal heart rate, motor skills, self-esteem, body composition, psychometric variables
Study details	Trial terminated early: no Trial ID: -

Publication details	<p>Language of publication: English Funding: FIFA/FMARC (Fédération International de Football Associations, FIFA - Medical Assessment and Research Center) (commercial) Publication status: peer-reviewed journal</p>	
Stated aim for study	<p>Quote from publication: “The present study aimed at analyzing the efficacy of a 6-month football training program compared with a standard exercise program on health and fitness parameters in overweight children”</p>	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote from publication: “Children underwent a stratified randomization into two groups (according to age, gender, body mass index (BMI) percentile and maximal performance in cycling ergometry).” Comment: randomisation method not described in enough detail</p>
Allocation concealment (selection bias)	Unclear risk	<p>Comment: unclear if allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	<p>Quote from publication: “The training programs were carried out in two different locations at the same time of the day on the same days of the week (Monday, Tuesday, Thursday, 16:00-17:00 hour). This was decided to blind the groups to the training program of the other group” Comment: participants were likely blinded to study group - unclear if personnel were blinded however</p>
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	<p>Quote from publication: “The training programs were carried out in two different locations at the same time of the day on the same days of the week (Monday, Tuesday, Thursday, 16:00-17:00 hour). This was decided to blind the groups to the training program of the other group” Comment: participants were likely blinded to study group - unclear if personnel were blinded however</p>

<p>Blinding of outcome assessment (detection bias) Subjective outcomes</p>	<p>Unclear risk</p>	<p>Quote from publication: “Cycling ergometry was conducted by a trained institutional investigator who was blinded for group randomization to avoid investigator bias” Comment: unclear if subjective outcomes were measured by blinded staff</p>
<p>Blinding of outcome assessment (detection bias) Objective outcomes</p>	<p>Unclear risk</p>	<p>Quote from publication: “Cycling ergometry was conducted by a trained institutional investigator who was blinded for group randomization to avoid investigator bias” Comment: unclear whether other objective outcomes were measured by blinded staff</p>
<p>Incomplete outcome data (attrition bias) Subjective outcomes</p>	<p>High risk</p>	<p>Quote from publication: “17 children (44%) dropped out during the study period due to insufficient compliance (N=12), private or school problems (N=4) or change of residence (N=1). No significant differences were observed between drop-outs and children who completed the training (P>0.10).” Comment: even though no differences were observed between dropouts and completers, attrition rate was high and would likely have introduced bias. Plus ITT analysis was not used</p>
<p>Incomplete outcome data (attrition bias) Objective outcomes</p>	<p>High risk</p>	<p>Quote from publication: “17 children (44%) dropped out during the study period due to insufficient compliance (N=12), private or school problems (N=4) or change of residence (N=1). No significant differences were observed between drop-outs and children who completed the training (P>0.10).” Comment: even though no differences were observed between dropouts and completers, attrition rate was high and would likely have introduced bias. Plus ITT analysis was not used</p>
<p>Selective reporting (reporting bias)</p>	<p>Unclear risk</p>	<p>Comment: no protocol or clinical trial register entry available</p>

Faude 2010 (Continued)

Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias
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Flodmark 1993

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: children aged 10-11 years, obese (BMI > 23 kg/m ²) Exclusion criteria: none Diagnostic criteria: see above	
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention: family therapy Comparator: conventional treatment	
Outcomes	Outcome measures reported in abstract: BMI, triceps thickness, subscapular thickness, suprailiac skinfold thickness, physical fitness	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: the Golje Foundation, the Swedish Medical Associations, the Albert Pahlsson Foundation, the Swedish Society of Medicine, the Johanna Andersson Foundation, "Forenade Liv" mutual group life insurance company Stockholm, the medical faculty of the University of Lund (commercial and non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "To evaluate the effect of family therapy on childhood obesity"	
Notes	-	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote from publication: "44 obese children were divided into two treatment groups" Comment: in the abstract the study authors do not say that the children were randomised. They do in the main text of the publication but do not describe the process

Flodmark 1993 (Continued)

		and there are also concerns over imbalance of sexes in the two groups. The study also includes a non-randomised control group - unclear why they were not randomised as well
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: "intention to treat analysis were made of the weight and height data for 39 of 44 children in the two treatment groups" Comment: dropout rates relatively low
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Gillis 2007

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 7-16 years, BMI > 90th percentile (CDC growth charts) Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: 2 Run-in period: no Extension period: no Intervention: exercise and diet education with weekly diaries and telephone calls Comparator: exercise and diet education only
Outcomes	Outcome measures reported in abstract: attitude, BMI SDS, LDL

Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: personal funds (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "We aimed to determine whether in a small pilot group, treated over a 6-month period, this intervention strategy could show at least a trend toward improving obesity-related attitudes, reducing weight and decreasing adverse metabolic consequences of obesity"	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote from publication: "Patients were allocated alternately to one of the groups as they enrolled." Comment: potential selection bias introduced through this method
Allocation concealment (selection bias)	High risk	Comment: study author confirmed via email that allocation was not concealed before randomisation
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that the study was not blinded
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that the study was not blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that the study was not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that the study was not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "After 6 months 11/14 (78.6%) intervention and 7/13 (53.8%) control participants remained in the trial"

Gillis 2007 (Continued)

		Comment: high dropout rates in the control group
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “After 6 months 11/14 (78.6%) intervention and 7/13 (53.8%) control participants remained in the trial” Comment: high dropout rates in the control group
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry available to assess reporting bias
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Gunnarsdottir 2011a

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: children 8-12 years, BMI SDS > 2.4 (BMI reference values for Swedish children - Karlberg, Luo & Albertsson-Wikland, 2001), simple obesity (obesity not due to an identifiable medical cause), 1 parent willing to participate fully in the treatment with the child, neither parent nor child receiving other obesity treatment, children with comorbid emotional, behavioural and/or learning-related disorders were not excluded as long as they could comprehend intervention material and self-monitor Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: Epstein’s family-based behavioural treatment (FBBT) Comparator: standard care (waiting-list control)
Outcomes	Composite outcome measures reported: BMI-SDS
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: Landspítali University Hospital Research Fund, The Icelandic Research Fund for Graduate Students, University of Iceland Research Fund, and a grant from Thorvaldsson Society (non-commercial) Publication status: peer-reviewed journal

Gunnarsdottir 2011a (Continued)

Stated aim for study	Quote from publication: “To assess the acceptability and effectiveness of Epstein’s family-based behavioural treatment (FBBT) for childhood obesity in a medical setting in Iceland”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation method not described
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear whether participants or study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear whether participants or study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear whether outcome assessors were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear whether outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Three families dropped out prematurely (Figure 1 shows flow of participants during study process) . The children dropping out all had emotional, behavioural, and/or learning-related comorbidities.” “Of the three families who dropped out before the study ended, two families dropped out for reasons unrelated to the intervention but one family was unable to cope with the high at-home demands of the program” Comment: 3/16 (19%) families dropped out of the study at 4 months. It is unclear whether these 13 participants were followed up until the end of the study. Furthermore all dropouts had comorbidities

Gunnarsdottir 2011a (Continued)

		even though the study stated 2 of the families dropped out for reasons unrelated to the intervention - risk of bias is unclear
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Three families dropped out prematurely (Figure 1 shows flow of participants during study process) . The children dropping out all had emotional, behavioural, and/or learning-related comorbidities.” “Of the three families who dropped out before the study ended, two families dropped out for reasons unrelated to the intervention but one family was unable to cope with the high at-home demands of the program” Comment: 3/16 (19%) families dropped out of the study at 4 months. It is unclear whether these 13 participants were followed up until the end of the study. Furthermore all dropouts had comorbidities even though the study stated 2 of the families dropped out for reasons unrelated to the intervention - risk of bias is unclear
Selective reporting (reporting bias)	High risk	Comment: no clinical trials register entry or protocol. They did not do a comparison of the intervention and control outcomes - did not present raw data for physical activity or fruit and vegetable consumption for each group separately
Other bias	Unclear risk	Comment: unable to assess if any other biases are present

Hamilton-Shield 2014

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: obese (\geq 95th percentile, UK 1990 references) children aged 5-11 years old Exclusion criteria: parents unable to read English; secondary care evaluation was required if: possible genetic cause of obesity, possible endocrine disorder, possible comorbidity, features of an overt eating disorder, iatrogenic causes of obesity Diagnostic criteria: see above

Interventions	Number of study centres: 9 Run-in period: no Extension period: no Intervention: standard care plus Mandolean training Comparator: standard care only	
Outcomes	Outcome measures reported in abstract: progression to the main trial, recruitment numbers, attendance	
Study details	Trial terminated before regular end (for benefit/because of adverse events): yes Trial ID: ISRCTN90561114	
Publication details	Language of publication: English Funding: NIHR Health Technology Assessment programme (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “This pilot study aimed to test recruitment strategies, treatment adherence, clinic attendance and participants’ experiences of using a device [Mandolean® (previously Mandometer®, Mikrodidakt AB, Lund, Sweden)] to slow down speed of eating as an adjunct to dietary and activity advice in treating obesity in primary school-aged children”	
Notes	This trial was terminated due to recruitment issues and technical issues relating to the Mandolean equipment	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Participants were randomised into one of two groups: (1) standard care plus Mandolean therapy or (2) standard care alone. Participants were randomised using the Bristol Randomised Trials Collaboration randomisation service” Comment: randomisation method was well described
Allocation concealment (selection bias)	Low risk	Quote from publication: “Concealment of allocation was ensured by use of an automated web-based randomisation service hosted by the Bristol Randomised Trials Collaboration, a UKCRC (UK Clinical Research Collaboration)-registered clinical trials unit.” Comment: allocation was concealed

Hamilton-Shield 2014 (Continued)

Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear whether participants or study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear whether participants or study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear whether outcome assessors were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear whether outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “None of the criteria for progression to the main trial were reached. Despite numerous pathways being available for referral, only 21 (13 to standard care, eight to intervention arm; 58%) of the target 36 families were recruited in the pilot phase. Less than 20% of those randomised to Mandolean used the device at least five times a week. The > 60% target for slowing down of eating speed by 3 months was unmet. Attendance at the weight management clinic in general practice hubs for both arms of the study at 3 months was 44% against a target of 80%.” Comment: attendance at the sessions was very low and the trial was not completed - high attrition bias
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “None of the criteria for progression to the main trial were reached. Despite numerous pathways being available for referral, only 21 (13 to standard care, eight to intervention arm; 58%) of the target 36 families were recruited in the pilot phase. Less than 20% of those randomised to Mandolean used the device at least five times a week. The > 60% target for slowing down of eating speed by 3 months was unmet. Attendance at the weight management clinic in general practice hubs for both arms of the study at 3 months was 44% against a target of 80%.”

Hamilton-Shield 2014 (Continued)

		Comment: attendance at the sessions was very low and the trial was not completed - high attrition bias
Selective reporting (reporting bias)	High risk	Comment: even though the study was terminated, the report does not provide any outcome data of those who participated
Other bias	High risk	Comment: this study was terminated before its endpoint

Ho 2016

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: 8-16 years, BMI \geq 85 th centile for age and gender Exclusion criteria: currently taking a weight loss medication, enrolled in any organised weight loss programmes or exercise programmes, consumed more than 30% of all meals at restaurants, had a history of gastrointestinal disorder, psychiatric illness under the care of a physician, Cushing's syndrome, hypothalamic or genetic aetiology of obesity, uncontrolled or untreated thyroid disease, a current diagnosis of cancer, history of an eating disorder such as bulimia or anorexia nervosa, any surgery in the past 3 months, any surgery planned in the ensuing 6 months or any other chronic illness that could affect weight change Diagnostic criteria: BMI percentile (population reference not stated)
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: standard nutrition counselling plus portion control equipment Control: standard nutrition counselling only
Outcomes	Outcome measures reported in abstract: BMI z score
Study details	Trial terminated early: no Trial ID: NCT00881478
Publication details	Language of publication: English Funding: non-commercial funding and commercial donation, research grant from the Alberta Children's Hospital Foundation (Calgary, Alberta, Canada). Some of the portion control tools were donated for use in the study by The Diet Plate Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: "to assess the effect of a family intervention using a portion control tool on BMI z score in children."

Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "A computer-based random number sequence generator was used to create the random allocation.." Comment: low risk of selection bias from the randomisation method used
Allocation concealment (selection bias)	Low risk	Quote from publication: "Sequentially numbered sealed envelopes were used to conceal the sequence until participants were assigned. The random allocation sequence was generated by a research assistant, while enrolment and assignment of participants to groups was done by the research coordinator.." Comment: allocation was likely concealed, hence low risk of selection bias
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "Participants and care givers were not blinded to the intervention since they were instructed on use of the portion control tools." Comment: investigator-assessed. Participants weren't blinded due to the nature of the intervention in addition it is currently not stated whether trial personnel were blinded - this presents potentially high risk of bias
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: "Participants and care givers were not blinded to the intervention since they were instructed on use of the portion control tools." Comment: investigator-assessed. Participants weren't blinded due to the nature of the intervention in addition it is currently not stated whether trial personnel were blinded - this presents potentially high risk of bias
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Quote from publication: "Participants and care givers were not blinded to the intervention since they were instructed on use

Ho 2016 (Continued)

		of the portion control tools..” Comment: unclear if outcome assessment was blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Quote from publication: “Participants and care givers were not blinded to the intervention since they were instructed on use of the portion control tools.” Comment: unclear if outcome assessment was blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Comment: reported and ITT analysis conducted
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Comment: reported and ITT analysis conducted
Selective reporting (reporting bias)	Low risk	Comment: study was conducted as described in the trials register
Other bias	Low risk	Comment: no other bias identified - this was a generally well conducted and reported study

Hughes 2008

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: obese children (BMI \geq 98th centile, UK 1990 references) aged 5-11 years, attending a standard elementary school, at least 1 parent who perceived their child’s weight as a problem and willing to make changes to their lifestyle Exclusion criteria: child with an underlying medical cause for their obesity, serious comorbidity requiring urgent treatment, had received treatment for obesity in the past year Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: behavioural programme Comparator: standard care
Outcomes	Outcome measures reported in abstract: BMI z scores, weight, total physical activity, percentage time spent in sedentary behaviour and light intensity physical activity, parental views of the treatment

Hughes 2008 (Continued)

Study details	Trial terminated early: no Trial ID: ISRCTN41383109	
Publication details	Language of publication: English Funding: grant from the Scottish Executive Health Department. The funder's role was limited to peer review of the original grant application (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The objective of this study was to determine whether a generalizable best practice individualized behavioral intervention reduced BMI z score relative to standard dietetic care among overweight children"	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "For ensuring concealment, the study code was sent to a statistician, who produced a computer-generated randomization list and allocated participants to the intervention or control group. Randomization was in blocks of 10 (ratio 1:1) and was stratified by gender and study center (Edinburgh or Glasgow) . The statistician informed the research dietitians, who were delivering the intervention of the group allocation and who then informed participants of their groups." Comment: randomisation method was well described
Allocation concealment (selection bias)	Low risk	Quote from publication: "For ensuring concealment, the study code was sent to a statistician, who produced a computer-generated randomization list and allocated participants to the intervention or control group" Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "The primary aim of this assessor-blinded RCT" Comment: participants or study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: "The primary aim of this assessor-blinded RCT" Comment: participants or study personnel

Hughes 2008 (Continued)

		were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “The primary aim of this assessor-blinded RCT” Comment: outcomes investigators were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “The primary aim of this assessor-blinded RCT” Comment: outcomes investigators were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “Of the 134 children who were randomly assigned, 97 (72.4%) attended the 6 month follow up and 86 (64.2%) attended at 12 months” Comment: dropout rates were quite high
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Of the 134 children who were randomly assigned, 97 (72.4%) attended the 6 month follow up and 86 (64.2%) attended at 12 months” Comment: dropout rates were quite high
Selective reporting (reporting bias)	Low risk	Comment: no differences between protocol and publication
Other bias	Unclear risk	Comment: unable to assess whether any other biases were present

Kalarchian 2009

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: child 8-12 years, BMI \geq 97th percentile (CDC growth charts) - severely obese, adult willing to participate in the programme Exclusion criteria: mental retardation, pervasive development disorder or psychosis, psychiatric symptoms that require alternative treatment, genetic obesity syndrome, currently undertaking obesity treatment, inability to take part in prescribed daily activity, medical conditions which contraindicate usual care, medication which affects body weight (stable doses of stimulant or antidepressant medication allowed) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no

	Intervention: family-based, behavioural weight control group Comparator: usual care	
Outcomes	Composite outcome measures reported: percent overweight, medical outcomes, parental BMI, binge eating, eating disorder symptoms, self-esteem	
Study details	Trial terminated early: no Trial ID: NCT00177229	
Publication details	Language of publication: English Funding: National Institutes of Health grants to Dr Marcus at the University of Pittsburgh (grant R01 HD38425 and minority supplement grant HD38425-02S1), University of Pittsburgh Obesity and Nutrition Research Center (grant P30 DK46204), Children's Hospital of Pittsburgh General Clinical Research Center (grant M01-RR00084), and University of Pittsburgh Clinical and Translational Science Institute (Clinical and Translational Science Award UL1-RR024153) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "We evaluated the efficacy of family-based, behavioural weight control in the management of severe pediatric obesity"	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "After baseline assessments, participants were assigned randomly to study conditions (1:1) through permuted block randomization with stratification according to race, with a block size of 2, 4, or 6." Comment: randomisation method described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed participants and study personnel were not blinded to study group

<p>Blinding of outcome assessment (detection bias) Subjective outcomes</p>	<p>Unclear risk</p>	<p>Quote from publication: “Assessors did not provide the intervention but were not blinded to the treatment condition.” Comment: unclear because even though assessors were not involved in the intervention, they were not blinded to study group</p>
<p>Blinding of outcome assessment (detection bias) Objective outcomes</p>	<p>Unclear risk</p>	<p>Quote from publication: “Assessors did not provide the intervention but were not blinded to the treatment condition.” Comment: unclear because even though assessors were not involved in the intervention, they were not blinded to study group</p>
<p>Incomplete outcome data (attrition bias) Subjective outcomes</p>	<p>Low risk</p>	<p>Quote from publication: “However, 18-month assessment completers differed from noncompleters with respect to baseline child BMI (31.7 vs 34.0 kg/m²; $t = -2.14$; $P = .037$), percent overweight (87.4% vs 101.8%; $t = 2.36$; $P = .023$), and number of people in the household (4.11 vs 3.67 persons; $t = 2.13$; $P = .035$).” “Finally, there was a significant proportion of missing data in the ITT analyses for medical risk factors, which suggests that replication is needed before firm conclusions about medical outcomes can be drawn.” Comment: relatively low amount of missing data</p>
<p>Incomplete outcome data (attrition bias) Objective outcomes</p>	<p>Low risk</p>	<p>Quote from publication: “However, 18-month assessment completers differed from noncompleters with respect to baseline child BMI (31.7 vs 34.0 kg/m²; $t = -2.14$; $P = .037$), percent overweight (87.4% vs 101.8%; $t = 2.36$; $P = .023$), and number of people in the household (4.11 vs 3.67 persons; $t = 2.13$; $P = .035$).” “Finally, there was a significant proportion of missing data in the ITT analyses for medical risk factors, which suggests that replication is needed before firm conclusions about medical outcomes can be drawn.” Comment: relatively low amount of missing data</p>
<p>Selective reporting (reporting bias)</p>	<p>High risk</p>	<p>Comment: primary outcome on clinical trials register was BMI and cardiovascular</p>

Kalarchian 2009 (Continued)

		risk factors, while in publication it was percentage overweight
Other bias	Unclear risk	Comment: unable to assess if any other bias were present

Kalavainen 2007

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: child age 7-9 years, attending primary school, presence of weight for height from 120%-200% (Finnish national growth charts - Tilator Oy Ltd 2004) Exclusion criteria: disease or medication causing obesity, obvious movement disturbance, major mental problems in child or parents, family members participating in another weight-management programme Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: family-centred group programme Comparator: routine treatment	
Outcomes	Outcome measures reported in abstract: weight for height, BMI, BMI SDS, participation rate, attrition rates, cost effectiveness, waist/height, metabolic risk factors, triglycerides, fasting insulin	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: 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, Social Insurance Institution, and the Finnish Cultural Foundation (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The aim of the study was to compare the efficacy of group treatment stressing a health-promoting lifestyle with routine counselling in the treatment of childhood obesity"	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	<p>Quote from publication: "Three children with weight for height $\geq 120\%$ at the individual interview, but 115-117% at the baseline measurement, were included (two allocated into the routine treatment and one to group treatment). The children were then stratified on the basis of their weight for height in four blocks, that is weight for height $< 120\%$, 120-139%, 140-160% and $> 160\%$, and thereafter they were randomly allocated within each block, using closed envelopes, to either routine or group program. The siblings (three pairs in this study) were randomized together, and the stratification was based on the higher weight for height of the siblings."</p> <p>Comment: randomisation method well described</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from publication: "they were randomly allocated within each block, using closed envelopes, to either routine or group program"</p> <p>Comment: used closed envelopes so assume allocation was concealed</p>
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	<p>Comment: Heale 2008 (see Kalavainen 2007 for reference) states study was unblinded</p>
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	<p>Comment: Heale 2008 (see Kalavainen 2007 for reference) states study was unblinded</p>
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	<p>Quote from publication: "The number of children participating in the 2-year follow-up was 69 (35 in routine counselling and 34 in the group program) and in the 3-year follow-up was 68 (34 in both treatment arms)."</p> <p>Comment: 70 children were randomised and 68 were followed up at 3 years - very low dropout rates, unlikely to have attrition bias</p>
Selective reporting (reporting bias)	Unclear risk	<p>Comment: 1 publication reports that they only measured height and weight - however, in a later paper results of additional outcomes were reported (metabolic and</p>

Kalavainen 2007 (Continued)

		body composition) but were compared with a healthy-weight children's group. Results of these outcomes were not significant - potential reporting bias
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Kirk 2012

Methods	<p>Parallel RCT Randomisation ratio: 1:1:1 Superiority design</p>
Participants	<p>Inclusion criteria: age 7-12 years, fasting blood glucose level \leq 100 mg/dL, BMI z score of 1.60-2.65 (CDC growth charts), absence of development or physical disabilities, ability to function independently in group exercise sessions, parent/guardian commitment to the study sessions</p> <p>Exclusion criteria: medical conditions such as: cardiac, pulmonary or liver disease; hyperlipidaemia, diabetes or significant mental illness, taking medications which may alter bone density, lipid or glucose metabolism or appetite (e.g. stimulants)</p> <p>Diagnostic criteria: see above</p>
Interventions	<p>Number of study centres: 1 Run-in period: no Extension period: no Intervention 1: low carbohydrate diet + group exercise/education sessions Intervention 2: reduced glycaemic load diet + group exercise/education sessions Comparator: standard portion-controlled diet + group exercise/education sessions</p>
Outcomes	<p>Outcome measures reported in abstract: completion rates, daily caloric intake, adherence, BMI z score, WC, percent body fat</p>
Study details	<p>Trial terminated early: no Trial ID: NCT00215111</p>
Publication details	<p>Language of publication: English Funding: Thrasher Research Fund and an Institutional Clinical and Translational Science Award (National Institutes of Health (NIH)/National Center for Research Resources grant, 5UL1RR026314-02) (non-commercial) Publication status: peer-reviewed journal</p>
Stated aim for study	<p>Quote from publication: "To compare the effectiveness and safety of carbohydrate (CHO)-modified diets with a standard portion-controlled (PC) diet in obese children"</p>
Notes	-
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "The subjects were stratified by pubertal development (4 categories) and BMI z score (2 categories: ≤ 2.1 SD or > 2.1 SD). Within these 8 strata, randomly permuted block sizes were used to generate the randomized allocation sequence. Subjects were randomly assigned to one of 3 diet groups-LC (n = 35), RGL (n = 36), or PC (n = 31)-and informed of their diet assignment at the initial intervention visit." Comment: randomisation method well described
Allocation concealment (selection bias)	Low risk	Quote from publication: "Within these 8 strata, randomly permuted block sizes were used to generate the randomized allocation sequence" Comment: assume allocation was concealed via the randomisation method used
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "Neither subjects nor study staff members were blinded to diet assignment." Comment: participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: "Neither subjects nor study staff members were blinded to diet assignment." Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: "Neither subjects nor study staff members were blinded to diet assignment." Comment: assessment staff were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: "Neither subjects nor study staff members were blinded to diet assignment." Comment: assessment staff were not blinded to study group

Kirk 2012 (Continued)

Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Retention of subjects for follow-up assessments was 82% at the 12-month follow-up and did not differ significantly among the 3 diet groups at any time point (RGL: 3 months, 92%; 6 months, 89%; 12 months, 89%; PC: 3 months, 94%; 6 months, 87%; 12 months, 90%; LC: 3 months, 69%; 6 months, 69%; 12 months, 69%)” Comment: dropout rates moderate and they used ITT analysis. But was unclear how they replaced missing data
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Retention of subjects for follow-up assessments was 82% at the 12-month follow-up and did not differ significantly among the 3 diet groups at any time point (RGL: 3 months, 92%; 6 months, 89%; 12 months, 89%; PC: 3 months, 94%; 6 months, 87%; 12 months, 90%; LC: 3 months, 69%; 6 months, 69%; 12 months, 69%)” Comment: dropout rates moderate and they used ITT analysis. But was unclear how they replaced missing data
Selective reporting (reporting bias)	Low risk	Comment: the majority of outcomes given in the clinical trials register were measured and reported in the publication
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Larsen 2015

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: overweight (IOTF criteria), children aged 5-9 years, registered with a GP on the island of Fumen Exclusion criteria: families unable to speak Danish, previous or current participation in other overweight/obesity project, mental or physical disabilities, endocrine causes of obesity, signs of precocious puberty Diagnostic criteria: see above

Larsen 2015 (Continued)

Interventions	<p>Number of study centres: 60 Run-in period: no Extension period: no Intervention: an education programme in addition to health consultations Comparator: health consultations only</p>	
Outcomes	<p>Outcome measures reported in abstract: BMI z scores, attendance</p>	
Study details	<p>Trial terminated early: no Trial ID: -</p>	
Publication details	<p>Language of publication: English Funding: Health Insurance Foundation, Rhode's Foundation, the Egmont Foundation, the Tryg Foundation, Institute of Clinical Research, Faculty of Health Sciences, University of Southern Denmark, and Odense University Hospital. (commercial and non-commercial) Publication status: peer-reviewed journal</p>	
Stated aim for study	<p>Quote from publication: "To evaluate the effect of two intervention modalities concerning overweight and obesity among children in general practice."</p>	
Notes	<p>-</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: "Participants were randomized using a random number table prepared before recruitment of participants for the study." Comment: low risk of bias from the method described</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from publication: "In order to ensure concealment of the allocated intervention at the time of enrolment of participants, the participants were randomized in blocks of two for patients enrolled in a single-handed practice, and in blocks of four or six for patients enrolled in a group practice. The size of the blocks and the allocation sequence were unknown to the general practitioners (GPs). Besides information to the patients regarding the study and obtainment of oral and written consent, the GPs did not take part in either the allocation process, or information to the families</p>

Larsen 2015 (Continued)

		on results of the randomization. The GPs informed the study investigator about the patient's acceptance of participation in the study. The study investigator allocated the patient according to the random number table and informed the family by telephone or letter." Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear whether participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear whether assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: "A total of 10 children in Model 1 and 16 children in Model 2 succeeded in a full two-year follow-up." Comment: only 29% of the control group and 36% of the intervention group completed the 2-year follow-up
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trial register entry
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Lison 2012

Methods	Parallel RCT Randomisation ratio: approximately 2:2:1 Superiority design
Participants	Inclusion criteria: white children and adolescents aged 6-16 years, both sexes, overweight or obese (\geq 85th percentile, Cole's LMS method - Cole 2000), recruited at the obesity and cardiovascular risk unit, Consorcio Hospital General Universitario, Valencia, Spain Exclusion criteria: secondary obesity syndromes or acute illnesses, severe obesity (z score $>$ 2.5) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention 1: hospital clinic group exercise-diet programme

Lison 2012 (Continued)

	Intervention 2: home-based combined exercise-diet programme Comparator: usual care control group	
Outcomes	Outcome measures reported in abstract: BMI z score, WC, percentage body fat, attendance	
Study details	Trial terminated early: no Trial ID: NCT01503281	
Publication details	Language of publication: English Funding: grants from the Comunidad Valenciana Government (GV06/227) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The aim of this study was to compare the effect of a hospital clinic group- versus home-based combined exercise- diet program for the treatment of childhood obesity”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote from publication: “Patients were assigned to experimental groups on the basis of the day of the week in which they attended the outpatient clinic. Patients who attended on Mondays and Wednesdays were assigned to the GRX and those on Tuesdays and Thursdays to the HOX. Those who attended on Fridays were assigned to the control group.” Comment: potential bias as participants would have been able to predict which group they would be allocated to
Allocation concealment (selection bias)	High risk	Comment: unlikely that allocation was concealed due to randomisation method used
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “An open study design was used” “The paediatrician who attended these visits was blinded to group allocation criteria.” Comment: only the paediatrician was blinded to study group

Lison 2012 (Continued)

Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “All outcome measures were recorded at baseline and at the end of the program by a trained nurse who was blinded to group allocation.” Comment: the nurse taking the measurements was blinded
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “The number of treatment completers was similar comparing across the GRX and HOX intervention groups (22 of 45; 21 of 41, respectively).” Comment: the number followed up was moderate; however, the number who actually completed the treatment was relatively low
Selective reporting (reporting bias)	Low risk	Comment: outcomes given in the clinical trials register the same as reported in the publication. No other differences found
Other bias	Unclear risk	Comment: unable to assess whether any other biases are present

Lochrie 2013

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 8-11 years, age-and sex-adjusted BMI \geq 85th percentile (CDC growth charts) Exclusion criteria: impaired glucose tolerance, diabetes mellitus type 2, metabolic syndrome, hypertension or significant learning problems Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: family-based intervention Comparator: education session
Outcomes	Outcome measures reported in abstract: BMI z scores, triglycerides, psychosocial data
Study details	Trial terminated early: no Trial ID: NCT01146314

Publication details	Language of publication: English Funding: American Diabetes Association (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "This article examined immediate post-treatment and follow-up results of a randomized controlled trial of a 6-month lifestyle intervention involving diet, education, physical exercise, behavior change, and psychosocial methods for overweight or obese school-age children ages 8 to 11 to decrease risk factors associated with medical complications of obesity."	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Randomization was stratified based on BMI (85th to 95th or >95th percentiles). For both of the lists, participants were randomized using a random sequence of 1s and 2s, such that 75 were assigned to the IG and 75 were assigned to the EG" Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed participants and personnel were not blinded
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed participants and personnel were not blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed outcome assessors were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed outcome assessors were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "We recognize that this study did not achieve adequate retention of participants. Only 68% of par-

Lochrie 2013 (Continued)

		participants completed the baseline and post-treatment evaluation and 55% completed the follow-up evaluation.” Comment: high dropout
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “We recognize that this study did not achieve adequate retention of participants. Only 68% of participants completed the baseline and post-treatment evaluation and 55% completed the follow-up evaluation.” Comment: high dropout
Selective reporting (reporting bias)	High risk	Comment: clinical trial entry similar to publication but publication does not given raw data for any outcomes (only shows BMI z score in a graph but no SDs) - for other outcomes they just say the difference was not statistically significant
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Looney 2014

Methods	Parallel RCT Randomisation ratio: 1:1:1 Superiority design
Participants	Inclusion criteria: aged 4-10 years, overweight or obese, BMI \geq 85th percentile (CDC growth charts) Exclusion criteria: medication condition that affected growth, physical activity or dietary intake, child was participating in another weight loss programme and/or taking weight loss medication, primary caretaker did not want to take part, or did not speak or read English, child did not speak English, family did not have a working telephone number, child spent < 50% at the primary caretaker’s home, family was planning to move out of the East Tennessee area during the study Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention 1: newsletter and growth monitoring plus behavioural counselling Intervention 2: newsletter and growth monitoring Comparator: newsletter only
Outcomes	Outcome measures reported in abstract: BMI z score, servings per/d of sugar-sweetened beverages

Looney 2014 (Continued)

Study details	Trial terminated early: no Trial ID: NCT01358448	
Publication details	Language of publication: English Funding: Amy Joye Memorial Research Award from the Academy of Nutrition and Dietetics Foundation (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “This pilot randomized controlled trial investigated the effect of 3 low-intensity (≤ 25 contact hours over 6 months) pediatric obesity treatments on z-BMI”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Sealed blank envelopes with condition assignments enclosed were used to randomize families in blocks of 3.” Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: (from study author via email) “Study personnel were not blinded. Participants cannot be blinded as in this type of intervention we are asking them to complete specific tasks depending upon what condition there were randomized too” Comment: study author confirmed participants and personnel were not blinded
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: (from study author via email) “Study personnel were not blinded. Participants cannot be blinded as in this type of intervention we are asking them to complete specific tasks depending upon what condition there were randomized too” Comment: study author confirmed participants and personnel were not blinded

Looney 2014 (Continued)

Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed outcome assessors were not blinded
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed outcome assessors were not blinded
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “There were no significant differences between conditions for retention at the 6-month assessments (N, 7/8 completed an assessment vs N+GM, 7/7 completed an assessment vs N + GM + BC, 7/7 completed an assessment).” Comment: only 1 lost to follow-up and 1 with missing data at 6 months (anthropometrics only)
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “There were no significant differences between conditions for retention at the 6-month assessments (N, 7/8 completed an assessment vs N+GM, 7/7 completed an assessment vs N + GM + BC, 7/7 completed an assessment).” Comment: only 1 lost to follow-up and 1 with missing data at 6 months (anthropometrics only)
Selective reporting (reporting bias)	Unclear risk	Comment: study still ongoing in clinical trials register. Cost-effectiveness given as a secondary outcome in trials register but not reported in publication - perhaps will be included in an additional publication
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Maddison 2011

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 10-14 years, overweight or obese (IOTF cut offs), owned a Playstation 2 or 3 gaming console (Sony Computer Entertainment Inc, Tokyo, Japan), but no active video games (including EyeToy (Sony) or NintendoWii, played ≥ 2 h of

	video games per week, only 1 child per household was eligible to take part in the study Exclusion criteria: contraindications to performing physical activity (e.g. medical conditions) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: active video game package Comparator: no-care control group
Outcomes	Outcome measures reported in abstract: BMI, percentage body fat, daily time spent playing active video games and nonactive video games
Study details	Trial terminated early: no Trial ID: ACTRN12607000632493
Publication details	Language of publication: English Funding: Health Research Council of New Zealand (grant 07/077B), a Heart Foundation of New Zealand Fellowship (RM), a Heart Foundation of New Zealand Senior Fellowship (CNM), and a Tertiary Education Commission Bright Futures Doctoral Scholarship (LF). Sony Computer Entertainment Europe provided the gaming software for the study (commercial and non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “The aim of this study was to evaluate the effect of active video games over a 6-mo period on weight, body composition, physical activity, and physical fitness”
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “The randomization is via a computerized central randomization service and stratified by sex and ethnicity.” Comment: randomisation process well described
Allocation concealment (selection bias)	Low risk	Quote from publication: “However allocation concealment (up to the point of randomization) was maintained” Comment: allocation was concealed
Blinding of participants and personnel (performance bias)	High risk	Quote from publication: “It was not possible to blind participants to their experi-

Maddison 2011 (Continued)

Subjective outcomes		mental group allocation.” “It was also not possible to blind study staff administering interventions and assessing outcomes to experimental group allocation for pragmatic reasons.” Comment: participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “It was not possible to blind participants to their experimental group allocation.” “It was also not possible to blind study staff administering interventions and assessing outcomes to experimental group allocation for pragmatic reasons.” Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “It was also not possible to blind study staff administering interventions and assessing outcomes to experimental group allocation for pragmatic reasons.” Comment: staff who assessed outcomes were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “It was also not possible to blind study staff administering interventions and assessing outcomes to experimental group allocation for pragmatic reasons.” Comment: staff who assessed outcomes were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Treatment evaluations were performed on the principle of intention to treat for the primary outcome and by using the approach of the last observation carried forward when data were missing.” Comment: even though they used ITT analysis and included all participants in the analysis, dropout rates were moderate (around 20%) at follow up
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Treatment evaluations were performed on the principle of intention to treat for the primary outcome and by using the approach of the

Maddison 2011 (Continued)

		last observation carried forward when data were missing.” Comment: even though they used ITT analysis and included all participants in the analysis, dropout rates were moderate (around 20%) at follow-up
Selective reporting (reporting bias)	Low risk	Comment: no differences found in publication versus clinical trials register/protocol
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Maddison 2014

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 9-12 years, lived in the greater Auckland metropolitan area, overweight or obese (Cole 2007), used electronic media (e.g. television, video games) for at least 15 h/week, speak and understand English, a primary caregiver participating in the study (aged 18 or above) and could speak and understand English Exclusion criteria: medical condition precluding them from performing regular physical activity, if they lived in more than 1 household and spent equal time at both households Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: SWITCH intervention group Comparator: usual care control group
Outcomes	Outcome measures reported in abstract: BMI z score, moderate-intensity physical activity, percentage body fat
Study details	Trial terminated early: no Trial ID: ACTRN12611000164998
Publication details	Language of publication: English Funding: Health Research Council of New Zealand (10/077). Dr Ralph Maddison supported by a Heart Foundation Research Fellowship (Grant 1211). Professor Cliona Ni Mhurchu supported by the National Heart Foundation Senior Fellowship (Grant 1380). Dr Louise Foley supported by a Heart Foundation of New Zealand Postdoctoral Fellowship (non-commercial) Publication status: peer-reviewed journal

Maddison 2014 (Continued)

Stated aim for study	Quote from publication: “The SWITCH (Screen-Time Weight-loss Intervention Targeting Children at Home) study aimed to determine the effect of a home-based, family-delivered intervention to reduce screen-based sedentary behaviour on body composition, sedentary behaviour, physical activity, and diet over 24 weeks in overweight and obese children.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Eligible participants were randomised at a 1:1 ratio to the intervention or control groups via centralised computer randomisation, using stratified blocked randomisation (with variable block sizes) to maintain balance across important prognostic factors. Two stratification factors were considered: sex (male and female) and ethnicity (Mā ori, Pacific, and non-Mā ori/non-Pacific).” Comment: randomisation process well described
Allocation concealment (selection bias)	Low risk	Quote from publication: “Allocation concealment was maintained up to the point of randomisation” Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “Blinding of participants and research assistants was not possible due to the nature of the intervention.” Comment: participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “Blinding of participants and research assistants was not possible due to the nature of the intervention.” Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “Blinding of participants and research assistants was not possible due to the nature of the intervention.” Comment: staff who assessed outcomes

Maddison 2014 (Continued)

		were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “Blinding of participants and research assistants was not possible due to the nature of the intervention.” Comment: staff who assessed outcomes were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Children were randomly assigned to the intervention (n = 127) and control (n =124) groups, with 121 (95%) and 117 (94%) completing 24 weeks’ follow up.” Comment: low dropout rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Children were randomly assigned to the intervention (n = 127) and control (n =124) groups, with 121 (95%) and 117 (94%) completing 24 weeks’ follow up.” Comment: low dropout rates
Selective reporting (reporting bias)	Low risk	Comment: no differences found between publication and clinical trials register
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Markert 2014

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: BMI SDS over the 90th centile (German reference values, Kromeyer-Hauschild 2001), age 4-17 years Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention: telephone-based adiposity prevention for families (TAFF) Comparator: no-care control
Outcomes	Outcome measures reported in abstract: BMI SDS, HRQoL, eating patterns, physical activity, media consumption, participation rates

Study details	Trial terminated early: no Trial ID: DRKS00000803	
Publication details	Language of publication: English Funding: Federal Ministry of Education and Research, Germany (Integrated Research and Treatment Center IFB “AdiposityDiseases,” FKZ: 01E01001), the Roland-Ernst-Stiftung für Gesundheitsforschung, Dresden, Germany, and the Saxonian Ministry for Social Affairs, Germany (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The aim of this paper is to present one-year results of the T.A. F.F. program, a randomized controlled obesity prevention program based on telephone counseling for families with overweight children or adolescents”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Randomization to the intervention or control group was performed with a 1:1 allocation ratio and stratified according to sex and age group (4-9 years, 10-13 years, 14-17 years) using electronically generated four-block-random-lists.” Comment: randomisation process well described
Allocation concealment (selection bias)	Low risk	Quote from publication: “The lists were generated before the start of the trial and assignment to trial arm was performed consecutively by a member of the team who did not have contact with participants and was not involved in data analysis. Enrolment of participants was carried out by the respective prevention manager.” Comment: it was likely that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear whether participants or study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear whether participants or study personnel were blinded to study group

Markert 2014 (Continued)

Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear whether assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear whether assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “Since the participants were not seen face to face, it was not always easy to encourage them to be weighed and measured and to return study material at the appropriate time. However, the effect of lag-times was analyzed and not found to have a significant impact on the results.” Comment: dropout rate in intervention group was high (62.8%)
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Since the participants were not seen face to face, it was not always easy to encourage them to be weighed and measured and to return study material at the appropriate time. However, the effect of lag-times was analyzed and not found to have a significant impact on the results.” Comment: dropout rate in intervention group was high (62.8%)
Selective reporting (reporting bias)	Unclear risk	Comment: there is a clinical trials register entry but it was retrospectively entered. The protocol was also published after recruitment and baseline measures were taken
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

McCallum 2007

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: overweight or mildly obese (IOTF cut points), not receiving ongoing weight management in a secondary or tertiary care programme and their parents provided contact details

	<p>Exclusion criteria: any chromosomal, endocrine or medical condition/disability/medications which may impact on their weight or growth</p> <p>Diagnostic criteria: see above</p>
Interventions	<p>Number of study centres: 29</p> <p>Run-in period: no</p> <p>Extension period: no</p> <p>Intervention: LEAP Intervention</p> <p>Comparator: no-care control group</p>
Outcomes	<p>Outcome measures reported in abstract: attrition, BMI, nutrition scores, daily physical activity, health status, body image, cost-effectiveness</p>
Study details	<p>Trial terminated early: no</p> <p>Trial ID: ISRCTN45068927</p>
Publication details	<p>Language of publication: English</p> <p>Funding: lead author (McCallum) was funded via Public Health Postgraduate National Health and Medical Research Council Scholarship (ID 216745). The LEAP trial was funded by a grant from the Australian Health Ministers' Advisory Council for Priority Driven Research (AHMAC PDR 2001/15) (non-commercial)</p> <p>Publication status: peer-reviewed journal</p>
Stated aim for study	<p>Quote from publication: "The study aims to reduce incremental gain in body mass index (BMI) of overweight/obese children aged 5-9 years"</p>
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: "Randomization was performed by a third-party biostatistician using a pre-generated computerized sequence."</p> <p>Comment: randomisation process well described</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from publication: "Blinding was maintained throughout allocation and data collection."</p> <p>Comment: allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	<p>Quote from publication: "Blinding was maintained throughout allocation and data collection. Following randomization, intervention families were contacted by a non-blinded member of the research team"</p>

		and the first GP appointment made. Control families were notified of their status via letter and were not identified to the GPs at any time.” Comment: participants were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “Blinding was maintained throughout allocation and data collection. Following randomization, intervention families were contacted by a non-blinded member of the research team and the first GP appointment made. Control families were notified of their status via letter and were not identified to the GPs at any time.” Comment: participants were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Assessors of the 6- and 12-month follow-ups were blinded to randomization status.” Comment: assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Assessors of the 6- and 12-month follow-ups were blinded to randomization status.” Comment: assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “A total of 12 (15%) subjects in the intervention group and five (6%) subjects in the control group were not visited at 15 months.” Comment: dropout rates were low
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “A total of 12 (15%) subjects in the intervention group and five (6%) subjects in the control group were not visited at 15 months.” Comment: dropout rates were low
Selective reporting (reporting bias)	Low risk	Comment: no differences found between publication and protocol
Other bias	Low risk	Comment: no other bias identified - low risk of bias in majority of other domains

Mirza 2013

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: Hispanic children aged 7-15, BMI \geq 95th percentile for age and sex (CDC growth charts) and otherwise healthy Exclusion criteria: any known medical conditions which would interfere with the study's objectives/procedures (e.g. type 2 diabetes, Cushing's syndrome, severe asthma, use of medications known to promote weight gain or loss) Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: low-glycaemic load dietary group Comparator: conventional low-fat dietary group	
Outcomes	Outcome measures reported in abstract: completion rates, glycaemic load, BMI z score, WC, systolic blood pressure, BMI, insulin resistance, components of metabolic syndrome	
Study details	Trial terminated early: no Trial ID: NCT01068197	
Publication details	Language of publication: English Funding: NIH grants K23-RR022227 (NMM), MO1-RR-020359, and UL1RR031988, which were awarded by the National Center for Research Resources to support the General Clinical Research Center and the Children's Research Institute at Children's National Medical Center, and ZIA-HD-00641 and the following foundations and organizations: Consumer Health Foundation, The Jessie Ball DuPont Foundation, and United Way of the National Capital Area. J Yanovski is supported by the Intramural Research Program of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute on Minority Health and Health Disparities of the NIH. D Ludwig is supported in part by career award K24DK082730 from the National Institute of Diabetes and Digestive and Kidney Diseases (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "We compared the effects of an LGD and a low-fat diet (LFD) on body composition and components of metabolic syndrome in obese Hispanic youth"	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Mirza 2013 (Continued)

Random sequence generation (selection bias)	Low risk	<p>Quote from publication: “The order in which groups occurred was determined by random assignment in blocks of 2 within strata determined by the BMI percentile, sex, and pubertal stage”</p> <p>Comment: randomisation process well described</p>
Allocation concealment (selection bias)	Unclear risk	<p>Comment: unclear if allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	<p>Quote from publication: “Because of the nature of the dietary intervention, the study was not a double-blind randomized study. Participants were not informed of their dietary group assignment but could ascertain their group on the basis of the diets offered.”</p> <p>Comment: participants were not blinded to study group</p>
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	<p>Quote from publication: “Because of the nature of the dietary intervention, the study was not a double-blind randomized study. Participants were not informed of their dietary group assignment but could ascertain their group on the basis of the diets offered.”</p> <p>Comment: participants were not blinded to study group</p>
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	<p>Quote from publication: “The staff who obtained primary and secondary outcome measurements did not take part in the interventions and were blinded to subject group assignments</p> <p>Comment: assessment staff were blinded to study group</p>
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	<p>Quote from publication: ”The staff who obtained primary and secondary outcome measurements did not take part in the interventions and were blinded to subject group assignments</p> <p>Comment: assessment staff were blinded to study group</p>

Mirza 2013 (Continued)

Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “Seventy-nine percent of LGD and LFD enrolees completed the 3-mo study, 61% of enrolees completed 1 y of follow-up, and 54.9% enrolees completed 2 y of follow-up (Figure 1).” Comment: dropout rates were quite high
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Seventy-nine percent of LGD and LFD enrolees completed the 3-mo study, 61% of enrolees completed 1 y of follow-up, and 54.9% enrolees completed 2 y of follow-up (Figure 1).” Comment: dropout rates were quite high
Selective reporting (reporting bias)	High risk	Comment: some outcomes not reported - cholesterol, BP, WC, glucose, total body fat mass, fat-free mass - some reported in supplementary data but only as combined groups, not separately. Did report WC and SBP in abstract but could not find in paper. Clinical trial no: NCT01068197 - secondary outcomes hormonal, lipid assay and body fat mass not reported in publication
Other bias	Unclear risk	Comment: unable to assess if any biases were present

NCT02436330

Methods	Parallel RCT Randomisation ratio: 2:1 Superiority design
Participants	Inclusion criteria: child aged 8-16 years, BMI \geq 85th percentile, English speaking, approval by Primary Care Doctor Exclusion criteria: participants with medical, developmental or psychiatric diagnoses which precluded participation in both the physical activity and classroom portions of the curriculum, participants who were taking medications that positively or negatively affected weight Diagnostic criteria: BMI percentile reference unclear
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention: exergaming and didactic healthy teaching Control: didactic healthy teaching only

Outcomes	Outcome measures reported in abstract: no publication	
Study details	Trial terminated early: no Trial ID: NCT02436330	
Publication details	Language of publication: English Funding: unclear Publication status: other (results from ClinicalTrials.gov)	
Stated aim for study	Quote from publication: “Primary objective: to assess impact of the program on BMI z-scores. Secondary objectives: to measure impact on cardiovascular fitness, self-worth, sedentary screen time, and the influence of exergaming component on attendance and participation.”	
Notes	Clinical trials register entry only - no published results	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote from publication: “enrolled sequentially and randomized 2:1 in experimental and control groups.” Comment: no further information about randomisation provided
Allocation concealment (selection bias)	Unclear risk	Quote from publication: “enrolled sequentially and randomized 2:1 in experimental and control groups...” Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “Masking: open label...” Comment: investigator-assessed
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “Masking: open label...” Comment: investigator-assessed
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “Masking: open label...” Comment: investigator-assessed
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “Masking: open label...” Comment: investigator-assessed

Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Comment: in intervention arm 14/60 lost to follow-up and 11/60 withdrew; in the control arm 4/24 lost to follow-up and 7/24 withdrew. Thus over 40% of all intervention participants did not complete
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Comment: in intervention arm 14/60 lost to follow-up and 11/60 withdrew; in the control arm 4/24 lost to follow-up and 7/24 withdrew. Thus over 40% of all intervention participants did not complete
Selective reporting (reporting bias)	High risk	Comment: although all outcomes were reported as stated on the registry, only completers' analyses were presented (and numbers varied for different outcomes). Also the tests used have not undergone peer review as part of formal publication
Other bias	Unclear risk	Comment: results have only been extracted from trials register therefore can only be treated as provisional

Nemet 2005

Methods	Parallel RCT Randomisation ratio: 5:4 Superiority design
Participants	Inclusion criteria: age 6-16, obese children and adolescents (CDC growth charts) Exclusion criteria: organic cause for obesity, receiving medication which may interfere with growth or weight control (e.g. corticosteroids, thyroid hormones) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: combined dietary and exercise programme Comparator: usual care control group
Outcomes	Outcome measures reported in abstract: body weight, BMI, body fat percentage, total cholesterol, LDL, fitness, leisure-time physical activity
Study details	Trial terminated early: no Trial ID: -

Publication details	<p>Language of publication: English Funding: grant from the Israeli Heart Fund (non-commercial) Publication status: peer-reviewed journal</p>
Stated aim for study	Quote from publication: “To examine prospectively the short- and long-term effects of a 3-month, combined dietary-behavioral-physical activity intervention on anthropometric measures, body composition, dietary and leisure-time habits, fitness, and lipid profiles among obese children”
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: “Thirty children and adolescents were assigned randomly, with a computerized, random number generator, to participate in our 3-month, combined dietary and exercise program for the treatment of childhood obesity, at the Child Health and Sports Center, Meir General Hospital, Tel Aviv University” Comment: randomisation process well described</p>
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: not clear if participants and study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: not clear if participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	<p>Quote from publication: “Twenty-four subjects completed the 3-month program, and 20 of them returned for evaluation</p>

Nemet 2005 (Continued)

		1 year later. (intervention)” “Twenty-two control subjects completed the 3-month evaluation, and 20 of them returned for evaluation after 1 year.” Comment: moderate missing data, potential attrition bias
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Twenty-four subjects completed the 3-month program, and 20 of them returned for evaluation 1 year later. (intervention)” “Twenty-two control subjects completed the 3-month evaluation, and 20 of them returned for evaluation after 1 year.” Comment: moderate missing data, potential attrition bias
Selective reporting (reporting bias)	Unclear risk	Comment: no clinical trials register entry or protocol available
Other bias	Unclear risk	Comment: unable to assess if any biases were present

Nova 2001

Methods	Parallel RCT Randomisation ratio: 2:5 Superiority design
Participants	Inclusion criteria: child aged 3-12 years, excess weight, ≥ 20 of ideal body weight, attended a family paediatrician’s office 15 November 1997-31 March 1998 Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention: enhanced approach Comparator: routine approach
Outcomes	Outcome measures reported in abstract: percentage overweight, physical activity, computer or television use, dietary behaviour, attendance
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: NIH (the national institute of nursing research) (non-commercial) Publication status: peer-reviewed journal

Stated aim for study	Quote from publication: “To compare two types of intervention intended to reduce weight in obese children that can be carried out in the family paediatricians (FPs) office”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation process not described
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: not clear if participants and study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: not clear if participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “On average 70% of all children attended their 12 month follow up visit. However, if we consider the population of any single FP, we observe a huge dispersion around this mean value: two fps in A and four in group B maintained all their enrolled children, whereas three FPs in A and two in group B lost >75% of participants” Comment: in some areas attrition rates were high
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “On average 70% of all children attended their 12 month follow up visit. However, if we consider the population of any single FP, we

Nova 2001 (Continued)

		observe a huge dispersion around this mean value: two fps in A and four in group B maintained all their enrolled children, whereas three FPs in A and two in group B lost >75% of participants” Comment: in some areas attrition rates were high
Selective reporting (reporting bias)	High risk	Comment: no protocol or clinical trials register available. Potential reporting bias by not reporting BMI at follow-up. Raw results not given for behavioural measures. No results given for 24-month follow-up
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Nowicka 2009

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: obesity defined by the IOTF cut-points Exclusion criteria: receiving any other obesity treatment, identifiable medical cause for obesity (with the exception of those with elevated blood lipids and asthma) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: summer camp Comparator: no-care control
Outcomes	Outcome measures reported in abstract: BMI z score
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: study was funded by Swedish Savings Bank Foundation, the Swedish Sports Confederation and Östra Göinge municipality. Research related to this paper was supported by the Sven Jerring Foundation, Regional Research Support, and the Faculty of Medicine at Lund University, Sweden (non-commercial) Publication status: peer-reviewed journal

Nowicka 2009 (Continued)

Stated aim for study	Quote from publication: “The general aim of this study was to evaluate the effect of management of childhood obesity by promoting increased physical activity, in comparison with an untreated waiting list control group.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation process not described
Allocation concealment (selection bias)	High risk	Comment: study author confirmed via email that allocation was not concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: study author confirmed via email that participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that outcome assessors were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that outcome assessors were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “13 did not want to be in the control group” Comment: 13 of the control group dropped out - potential attrition bias
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “13 did not want to be in the control group” Comment: 13 of the control group dropped out - potential attrition bias
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: healthy children aged 5-8 years, overweight (BMI \geq 85%) but not morbidly obese (BMI < 99%) (CDC growth charts), attended participating Texas Children's Pediatric Associate (TCPA) clinics, and were Texas Children's Health Plan (TCHP) members, only 1 child per family was eligible Exclusion criteria: medical consequences of obesity (e.g. hypertension) that required intensive treatment, taking medications which could affect a child's weight status, medical problems which would cause difficulties in participating in the programme, if the child was participating in other weight loss programmes, parent was unable to read or write in English or Spanish, parents had participated in formative studies to develop the Helping HAND intervention Diagnostic criteria: see above	
Interventions	Number of study centres: 4 Run-in period: no Extension period: no Intervention: 'Helping HAND' obesity intervention Comparator: waiting-list control	
Outcomes	Outcome measures reported in abstract: attrition, BMI z score, dietary intake, physical activity, hours of TV per week	
Study details	Trial terminated early: no Trial ID: NCT01195012	
Publication details	Language of publication: English Funding: US Department of Agriculture (USDA/ARS) Children's Nutrition Research Center, Department of Pediatrics, BCM funded in part by the USDA/ARS (Cooperative Agreement 6250-51000) and the Gillson Longenbaugh Foundation BCM Seed Funds (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "Test the feasibility of Helping HAND (Healthy Activity and Nutrition Directions), an obesity intervention for 5- to 8-year-old children in primary care clinics"	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Families who met all criteria were enrolled and randomized to immediately starting Helping HAND (intervention group: IG) or wait-

		<p>listed for the programme (control group: CG) via a random number sequence protocol developed by the project statistician”</p> <p>Comment: randomisation process described</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from publication: (from author via email) “Yes, participants were recruited and baseline data obtained prior to them being randomized to the intervention of waitlist control group”</p> <p>Comment: study author confirmed via email that allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	<p>Quote from publication: “No, it was not possible to blind participants to the study group since this was a feasibility study and the control group did not receive an intervention (wait-listed). For the same reasons and due to the budget available for this feasibility study, study staff were not blinded to condition. We did have a different staff team conduct the assessment from those that delivered the program.”</p> <p>Comment: participants and study personnel were not blinded to study group</p>
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	<p>Quote from publication: “No, it was not possible to blind participants to the study group since this was a feasibility study and the control group did not receive an intervention (wait-listed). For the same reasons and due to the budget available for this feasibility study, study staff were not blinded to condition. We did have a different staff team conduct the assessment from those that delivered the program.”</p> <p>Comment: participants and study personnel were not blinded to study group</p>
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	<p>Quote from publication: “Because of limited staffing those who collected data could not be blinded to participant group assignment at post assessment for this pilot study.”</p> <p>Comment: study author confirmed via email that outcome assessors were not blinded to study group</p>

Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: "Because of limited staffing those who collected data could not be blinded to participant group assignment at post assessment for this pilot study." Comment: study author confirmed via email that outcome assessors were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: "There was 20% attrition from Helping HAND (attended 4/6 sessions)." Comment: relatively low attrition rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: "There was 20% attrition from Helping HAND (attended 4/6 sessions)." Comment: relatively low attrition rates
Selective reporting (reporting bias)	Unclear risk	Comment: clinical trials register only states that family attendance was the primary outcome - does not provide any secondary or other outcomes
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Reinehr 2010

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 8-16 years, overweight, BMI > 90th percentile and < 97th percentile using German percentiles (Kromeyer-Hauschild 2001), apparently healthy and not on any medication, attending a regular school Exclusion criteria: obese children Diagnostic criteria: see above
Interventions	Number of study centres: 2 Run-in period: no Extension period: no Intervention: 'Obeldicks Light' lifestyle intervention Comparator: waiting list control
Outcomes	Outcome measures reported in abstract: dropout rates, BMI SDS, WC, blood pressure, skinfold thickness, fat mass (BIA and skinfold thickness), dietary intake (energy, fat, sugar), HRQoL, self-esteem

Study details	Trial terminated early: no Trial ID: NCT00422916	
Publication details	Language of publication: English Funding: German Federal Ministry of Research (grant numbers 01EL619 and 01EL0603) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “Our primary hypothesis was that this lifestyle intervention is effective in reducing the degree of overweight based on standard deviation scores of body mass index”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “The children were randomized in the control group (CG) (waiting period of 6 months) or in the intervention group (IG) (6 months intervention) using a computer” Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “The study was an open randomized controlled trial since blinding was not possible due to the nature of the intervention.” Comment: participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “The study was an open randomized controlled trial since blinding was not possible due to the nature of the intervention.” Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “The study was an open randomized controlled trial since blinding was not possible due to the nature of the intervention.” Comment: outcome assessors were not blinded to study group

Reinehr 2010 (Continued)

Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “The study was an open randomized controlled trial since blinding was not possible due to the nature of the intervention.” Comment: outcome assessors were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Only one child (3%) dropped out of the intervention group, and 5 children (16%) dropped out of the control group” Comment: in addition there were 5 families who withdrew consent prior to baseline measurements. Dropout rates quite low
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Only one child (3%) dropped out of the intervention group, and 5 children (16%) dropped out of the control group” Comment: in addition there were 5 families who withdrew consent prior to baseline measurements. Dropout rates quite low
Selective reporting (reporting bias)	High risk	Comment: in the main publication (Reinehr 2010) there is no mention of them measuring QoL. The clinical trials register entry specifies QoL as a secondary measure and an additional publication (Finne 2013, see Reinehr 2010) but does not present results for intervention and control separately even though they were measured at these time points
Other bias	Unclear risk	Comment: unable to assess whether any other biases are present

Rodearmel 2007

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 7-14 years, overweight or risk for overweight (BMI \geq 85th percentile for age and gender based on CDC growth charts), at least 1 parent/guardian to participate in the study Exclusion criteria: children or parents with medical or physical conditions that prevented them for participating in physical activity (assessed by health history questionnaire), pregnancy or lactation (child or parent)

	Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: 'America on the Move' intervention group Comparator: self-monitoring group
Outcomes	Outcome measures reported in abstract: BMI for age, parental weight, steps/d
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: McNeil Nutritionals, LLC, and National Institutes of Health grant DK42549 (commercial and non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: "The intent of this study was to evaluate whether small changes in diet and physical activity, as promoted by the America on the Move initiative, could prevent excessive weight gain in overweight children"
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote from study author (via email): "During initial telephone contact, families with a child meeting eligibility criteria were randomized to the control or experimental groups using the next assignment provided by a simple randomization schedule" Comment: unclear if this method would have resulted in selection bias
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Quote from study author (via email): "Participants were not aware that there were two study groups. At the point of randomization they were only told about their assigned group. Personnel were not blinded to study group." Comment: participants potentially were blinded to study group but personnel were not - unclear level of bias

Rodearmel 2007 (Continued)

Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Quote from study author (via email): “Participants were not aware that there were two study groups. At the point of randomization they were only told about their assigned group. Personnel were not blinded to study group.” Comment: participants potentially were blinded to study group but personnel were not - unclear level of bias
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: study author confirmed via email that assessors were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Comment: study author confirmed via email that assessors were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Overall, the dropout rate for target children was 16%, with the rate slightly but not statistically significantly higher in AOM than in SM families.” Comment: low dropout rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Overall, the dropout rate for target children was 16%, with the rate slightly but not statistically significantly higher in AOM than in SM families.” Comment: low dropout rates
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Sacher 2010

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 8-12 years, obese (BMI \geq 98th percentile, UK 1990), no apparent clinical problems, comorbidities, physical disabilities or learning difficulties which would interfere with taking part, at least 1 parent/carer who could attend the programme sessions

	<p>Exclusion criteria: none Diagnostic criteria: see above</p>
Interventions	<p>Number of study centres: 5 Run-in period: no Extension period: no Intervention: MEND program Comparator: waiting list control</p>
Outcomes	<p>Outcome measures reported in abstract: BMI z score, WC z score, cardiovascular fitness, physical activity, sedentary activity, self-esteem, attendance</p>
Study details	<p>Trial terminated early: no Trial ID: ISRCTN30238779</p>
Publication details	<p>Language of publication: English Funding: National Institute for Health Research, Sainsbury's Supermarkets Ltd., Bromley Mytime, Bromley Primary Care Trust (PCT), Great Ormond Street Hospital for Children NHS Trust, London Borough of Lewisham, MEND Central Ltd., New Cross Gate New Deal for Communities, Parkwood Leisure, Southwark PCT, The Lewisham Hospital NHS Trust, UCL Institute of Child Health, and Waveney PCT (commercial and non-commercial) Publication status: peer-reviewed journal</p>
Stated aim for study	<p>Quote from publication: "The aim of this study was to evaluate the effectiveness of the Mind, Exercise, Nutrition, Do it (MEND) Program, a multicomponent community-based childhood obesity intervention (www.mendcentral.org)."</p>
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: "randomization was conducted by an independent researcher using a random permuted block design with blocks of size 6. The randomization schedule was computer generated" Comment: randomisation process well described</p>
Allocation concealment (selection bias)	Low risk	<p>Comment: study author confirmed via email that allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	<p>Quote from study author (via email): "As we used a delayed intervention control group, it was not possible to blind participants to the study group. Study personnel</p>

		<p>were not blinded”</p> <p>Comment: participants and study personnel were not blinded to study group</p>
<p>Blinding of participants and personnel (performance bias) Objective outcomes</p>	High risk	<p>Quote from study author (via email): “As we used a delayed intervention control group, it was not possible to blind participants to the study group. Study personnel were not blinded”</p> <p>Comment: participants and study personnel were not blinded to study group</p>
<p>Blinding of outcome assessment (detection bias) Subjective outcomes</p>	Low risk	<p>Quote from study author (via email): “Study personnel were not blinded but all measurements were repeated and double checked by blinded additional research staff.”</p> <p>Comment: even though study personnel were not blinded, measurements were checked by blinded staff</p>
<p>Blinding of outcome assessment (detection bias) Objective outcomes</p>	Low risk	<p>Quote from study author (via email): “Study personnel were not blinded but all measurements were repeated and double checked by blinded additional research staff.”</p> <p>Comment: even though study personnel were not blinded, measurements were checked by blinded staff</p>
<p>Incomplete outcome data (attrition bias) Subjective outcomes</p>	High risk	<p>Quote from publication: “Of the 60 intervention children, 54 started and all 54 completed the intensive phase of the intervention (9-week MEND Program), while 62% of the 60 were seen at 6 months and 83% either at 6 or 12 months”</p> <p>Comment: dropout rates relatively low in control group but moderate in intervention - potential attrition bias</p>
<p>Incomplete outcome data (attrition bias) Objective outcomes</p>	High risk	<p>Quote from publication: “Of the 60 intervention children, 54 started and all 54 completed the intensive phase of the intervention (9-week MEND Program), while 62% of the 60 were seen at 6 months and 83% either at 6 or 12 months”</p> <p>Comment: dropout rates relatively low in control group but moderate in intervention - potential attrition bias</p>

Sacher 2010 (Continued)

Selective reporting (reporting bias)	High risk	Comment: outcomes reported in clinical trials register entry report outcomes not reported in the publication (family functioning, child mental health, dietary intake) - potential reporting bias
Other bias	Unclear risk	Comment: unable to assess if any other biases are present

Saelens 2013

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: children aged 7-11 years, above the 85th percentile for age- and gender-specific BMI but not > 175% above median BMI for age and gender (CDC growth charts), at least 1 overweight parent (BMI \geq 25), no existing thought disorder, suicidality, substance abuse disorder, no disability or illness stopping them from engaging in at least moderate intensity activity, English speaking and at least second grade reading level, no current or prior diagnosed eating disturbance, live < 50 miles from the treatment site, parent/caregiver willing to attend treatment sessions and engage in the behaviour change around eating and physical activity, parents were allowed to participate in other weight programmes if the behavioural changes recommended were consistent with the study's targets Exclusion criteria: conditions known to promote obesity (e.g. Prader-Willi), participating in another weight control programme, recently started taking medications which affect weight (e.g. stimulants) Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: self-directed approach Comparator: prescribed approach
Outcomes	Outcome measures reported in abstract: BMI z score, parental BMI
Study details	Trial terminated early: no Trial ID: NCT00746629
Publication details	Language of publication: English Funding: Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health under award number R21HD054871 and the Seattle Children's Hospital Research Institute (non-commercial) Publication status: peer-reviewed journal

Stated aim for study	Quote from publication: “To examine the efficacy of an adjunct motivational and autonomy-enhancing intervention (self-directed) for behavioral family-based pediatric obesity relative to the standard prescription of uniform behavioural skills use and interventionist goal assignment (prescribed)”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Families were randomly assigned to receive either the prescribed or self-directed approach, with child gender and child level of overweight [$<$ or $>$ 60% above median body mass index (BMI) for age and gender] as stratification variables. Randomization blocks were randomly selected to be either four or six participating families” Comment: randomisation process well described
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Quote from publication: “During consenting, families were provided a brief description of each approach, but were otherwise blind to approach differences during treatment.” Comment: participants blinded to which was the intervention and which was the control group. Unclear if study personnel were
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Quote from publication: “During consenting, families were provided a brief description of each approach, but were otherwise blind to approach differences during treatment.” Comment: participants blinded to which was the intervention and which was the control group. Unclear if study personnel were
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Assessors were not interventionists and were blind to approach differences”

		Comment: outcome assessors were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: "Assessors were not interventionists and were blind to approach differences" Comment: outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "There were 57 assessment completers at posttreatment, 58 at 3-month follow-up, 54 at 6-month follow-up, 52 at 1-year follow-up, and 46 at 2-year follow-up." Comment: dropout rates fairly high (48%) . Did use an imputation method to replace some data but attrition bias likely to still exist
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: "There were 57 assessment completers at posttreatment, 58 at 3-month follow-up, 54 at 6-month follow-up, 52 at 1-year follow-up, and 46 at 2-year follow-up." Comment: dropout rates fairly high (48%) . Did use an imputation method to replace some data but attrition bias likely to still exist
Selective reporting (reporting bias)	Unclear risk	Comment: no clinical trial entry or protocol available
Other bias	Unclear risk	Comment: unable to assess if any other biases are present

Satoh 2007

Methods	Parallel RCT Randomisation ratio: 2:1 Superiority design
Participants	Inclusion criteria: aged 8-14 years, obesity (definition adopted from The Ministry of Health, Labor and Welfare in Japan, body weight exceeded 120% of standard body weight corresponding to height for age and sex obtained from national statistics for Japanese school children 1990) Exclusion criteria: none Diagnostic criteria: see above

Interventions	<p>Number of study centres: 3 Run-in period: no Extension period: no Treatment before study: before starting dietary guidance both intervention and control subjects and their parents received conventional dietary guidance Intervention: dietary guidance using an easily handled model nutritional balance chart (MNBC) Comparator: usual care</p>	
Outcomes	<p>Outcome measures reported in abstract: percentage overweight, nutritional balance (sugar and beans)</p>	
Study details	<p>Trial terminated early: no Trial ID: -</p>	
Publication details	<p>Language of publication: English Funding: unclear Publication status: peer-reviewed journal</p>	
Stated aim for study	<p>Quote from publication: "In the present study, an easily handled model nutritional balance chart (MNBC) for obese children and their families was investigated"</p>	
Notes	<p>-</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation process not described
Allocation concealment (selection bias)	Unclear risk	Comment: not clear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: not clear whether study personnel or participants were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: not clear whether study personnel or participants were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group

Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “Among the 43 obese children, 29 were randomly chosen for the obesity intervention groups and the other 14 children comprised the control group. Three children in the intervention group refused to participate in the study and five children in the intervention group withdrew after 1 month of intervention, leaving 21 remaining children in the intervention group. Among the 14 children in the control group, six children refused to participate in the study, leaving eight remaining children in the control group. These two groups were stable during the entire length of the study.” Comment: dropout high in both groups at 6 months (around 47%) - attrition bias likely
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Among the 43 obese children, 29 were randomly chosen for the obesity intervention groups and the other 14 children comprised the control group. Three children in the intervention group refused to participate in the study and five children in the intervention group withdrew after 1 month of intervention, leaving 21 remaining children in the intervention group. Among the 14 children in the control group, six children refused to participate in the study, leaving eight remaining children in the control group. These two groups were stable during the entire length of the study.” Comment: dropout high in both groups at 6 months (around 47%) - attrition bias likely
Selective reporting (reporting bias)	Unclear risk	Comment: no clinical trial entry or protocol available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Schwingshandl 1999

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: obese children and adolescents (unclear how obesity was defined) Exclusion criteria: none Diagnostic criteria: unclear	
Interventions	Number of study centres: unclear Run-in period: no Extension period: no Intervention: physical activity programme and dietary advice Comparator: dietary advice alone	
Outcomes	Outcome measures reported in abstract: weight, fat-free mass	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: unclear Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "To study the effect of a standardised training programme focusing on maintenance of fat free mass during weight reduction by energy reduction in obese children."	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation process not described
Allocation concealment (selection bias)	Unclear risk	Comment: not clear if allocation was concealed
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: not clear whether study personnel or participants were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group

Schwingshandl 1999 (Continued)

Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Thirty obese children and adolescents (14 group A, 16 group B) participated in the 12 week long programme; 20 children (10 group A, 10 group B) were also reassessed after one year” Comment: dropout rates relatively high
Selective reporting (reporting bias)	High risk	Comment: no clinical trials register entry or protocol available. The authors do not provide data for BMI at 12 months’ follow-up (only provide at 12 weeks)
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Serra-Paya 2015

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 6-12 years, overweight or obese (IOTF), sedentary, < 2 h/week of physical activity outside of school, live in or near the municipality of Lleida (Spain) and their healthcare paediatric unit has been accepted to take part, at least 1 parent/guardian able to participate Exclusion criteria: co-morbidities e.g. Cushing’s disease, or serious chronic illness, use of medication that might affect weight loss or adaptations to exertion, previous enrolment in other obesity treatment interventions, regular participation in physical exercise programmes in the past 6 months Diagnostic criteria: see above
Interventions	Number of study centres: 16 Run-in period: no Extension period: no Intervention: Nereu programme Comparator: counselling group
Outcomes	Outcome measures reported in abstract: BMI SDS, moderate-intense physical activity, daily fruit servings, daily soft drink consumption
Study details	Trial terminated early: no Trial ID: NCT01878994
Publication details	Language of publication: English Funding: partially funded by the Instituto de Salud Carlos III in Spain, from the Ministry of Economy and Competitiveness (Grant PI12/02220) co-funded by FEDER and the Institute of Physical Education of Catalonia (INEFC), University of Lleida, Spain, (Grants: VCP/3570/2010, 29th October, DOGC NÚM. 5753 - 11.11.2010; VCP/28/

	2009, 14th January, DOGC NÚM. 5302 - 22/01/2009) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “To evaluate the effectiveness of the Nereu Program in improving anthropometric parameters, physical activity and sedentary behaviours, and dietary intake.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Each cooperating healthcare paediatric unit was provided a sort list (using a computer-generated random number) of their eligible patients who met the inclusion criteria (age and BMIsd), according to the data contained in clinical records. These eligible children had been randomly assigned to one of the study arms, stratified by age group in each HPU” Comment: randomisation process described in detail
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if randomisation process would introduce selection bias through allocation concealment
Blinding of participants and personnel (performance bias) Subjective outcomes	Low risk	Comment: study author confirmed via email that they were both blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Low risk	Comment: study author confirmed via email that they were both blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “All the measurements and questionnaires were administered by the same expert interviewers, who were blinded to the allocated study group in both sessions (baseline and at the end of the intervention).” Comment: outcome assessors were blinded to study group for subjective outcomes
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: not clear if outcome assessors were blinded to study group

Serra-Paya 2015 (Continued)

Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: “Despite high program adherence, the rate of losses and missing values affected the effect size, depending on the parameter, which limited the statistical power to detect differences between groups in the changes observed” Comment: moderate dropout rates - potential attrition bias
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Quote from publication: “Despite high program adherence, the rate of losses and missing values affected the effect size, depending on the parameter, which limited the statistical power to detect differences between groups in the changes observed” Comment: moderate dropout rates - potential attrition bias
Selective reporting (reporting bias)	Unclear risk	Comment: publication did not report some of the outcomes given in the protocol - e.g. QOL - or endpoint (12 months after intervention). Perhaps will be reported in another publication
Other bias	Low risk	Comment: no other bias identified - study generally low risk of bias in other domains

Siwik 2013

Methods	Cross-over RCT (analysed as a parallel RCT) Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: child age 8-11 years, BMI above the 85th percentile (CDC growth charts), child was in the 3rd-5th grades Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: 'Choices' group office-visit intervention Comparator: lagged control group
Outcomes	Outcome measures reported in abstract: BMI z score, weight for age z score, low and high METs, behaviours and attitudes

Study details	Trial terminated early: no Trial ID: NCT01674920	
Publication details	Language of publication: English Funding: National Institutes of Health grant R21 HD50962 (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “To improve coping skills and increase the likelihood of success in making lifestyle changes, we enhanced the concept of ”choices“ by providing an innovative approach to problem-solving skills designed to strengthen resiliency. We developed a group office curriculum and conducted an early phase trial to test the efficacy of the program using a lagged intervention/control design.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Allocation was done using design-adaptive allocation that minimizes the differences between groups as participants enter the study. Balancing factors were sex, age, and BMI.” Comment: randomisation process described
Allocation concealment (selection bias)	Unclear risk	Comment: not clear whether allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear if participants and study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear if outcome assessors were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if outcome assessors were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Two families were unable to attend sessions, but the chil-

Siwik 2013 (Continued)

		dren received nearly all the measurements and are included in all analyses” Comment: only 3 children were not available for follow-up measurements and missing data were imputed
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Two families were unable to attend sessions, but the children received nearly all the measurements and are included in all analyses” Comment: only 3 children were not available for follow-up measurements and missing data were imputed
Selective reporting (reporting bias)	Low risk	Comment: clinical trials register entry available - no bias
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Taveras 2015

Methods	Cluster RCT Randomisation ratio: 1:1:1 Superiority design
Participants	Inclusion criteria: child aged 6-12.9 years, BMI \geq 90th percentile for age and sex at baseline well child visit (CDC growth charts), child has received well child care at Harvard Vanguard Medical Associates (HVMA) within the past 15 months, at least 1 parent able to communicate in English Exclusion criteria: if child has already enrolled in study, family planning to leave HVMA within the study time frame, their clinician feels the study is not appropriate for them, had chronic medical conditions which impacted on their diet/physical activity Diagnostic criteria: see above
Interventions	Number of study centres: 14 Run-in period: no Extension period: no Intervention 1: computerised point-of-care alerts plus direct to parent outreach and support Intervention 2: computerised point-of-care alerts only Comparator: usual care
Outcomes	Outcome measures reported in abstract: BMI, Healthcare Effectiveness Data and Information Set (HEDIS) performance measures for obesity
Study details	Trial terminated early: no Trial ID: NCT01537510

Publication details	<p>Language of publication: English</p> <p>Funding: this study was supported by award R18 AE000026 from the American Recovery and Reinvestment Act (Dr Taveras) (non-commercial)</p> <p>Publication status: peer-reviewed journal</p>	
Stated aim for study	Quote from publication: “To examine the extent to which computerized clinical decision support (CDS) delivered to pediatric clinicians at the point of care of obese children, with or without individualized family coaching, improved body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) and quality of care”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote from publication: “We used a stratified block randomization scheme to assign practices to one of the 3 study arms. Strata were based on the volume of children aged 6.0 to 12.9 with a BMI 95th percentile seen for well-child visits at each site from April 2010 through March 2011. A biostatistician (KPK) blinded to the names of the practices ordered them on this characteristic, then introduced a false practice at a random spot within the order to make the number of ”practices“ evenly divisible by 3. Strata consisted of consecutive groups of three practices from this ordered list. He then used a pseudo-random number generator in SAS 9.2 (SAS Institute, Cary NC) to assign one practice from each strata to each of the arms, with the exception that the false practice was deterministically assigned to the usual care arm. This resulted in 5 practices in each of the intervention arms and 4 in the usual care arm.”</p> <p>Comment: randomisation process described</p>
Allocation concealment (selection bias)	Low risk	<p>Comment: unlikely that selection bias would have occurred from the randomisation process described above</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	<p>Quote from publication: “Study participants and the pediatricians in each practice are blinded to specific study hypotheses but not to intervention assignment”</p>

		Comment: were not blinded to treatment group, but did not know study hypothesis - unclear if any bias would have occurred
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Quote from publication: “Study participants and the pediatricians in each practice are blinded to specific study hypotheses but not to intervention assignment” Comment: were not blinded to treatment group, but did not know study hypothesis - unclear if any bias would have occurred
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Research staff performing all assessments is blinded to specific study hypotheses and to intervention assignment” Comment: outcomes assessors were blinded to treatment group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Research staff performing all assessments is blinded to specific study hypotheses and to intervention assignment” Comment: outcomes assessors were blinded to treatment group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “we obtained BMI from 518 children (94.4% and HEDIS measurement from 491 visits (89.4%).” Comment: relatively low dropout rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “we obtained BMI from 518 children (94.4% and HEDIS measurement from 491 visits (89.4%).” Comment: relatively low dropout rates
Selective reporting (reporting bias)	Unclear risk	Comment: clinical trial mentions measuring costs and health behaviours- but these are not reported in the publication - may be published in an additional paper
Other bias	Low risk	Comment: was a cluster RCT and adjusted for clustering in their analyses

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: age 4-8 years-, enrolled at several Dunedin general practices, overweight or obese (BMI \geq 85th percentile, CDC growth charts) Exclusion criteria: unable to participate in a behavioural intervention, on medication known to affect body composition or growth, planning on moving out of Dunedin in the next 2 years Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: tailored package family-based intervention Comparator: usual care	
Outcomes	Outcome measures reported in abstract: BMI, BMI z score, WC, fruit and vegetables intake, noncore food intake, noncore food availability, physical activity, parental feeding practices, parenting, QoL, child sleep, behaviours, satisfaction	
Study details	Trial terminated early: no Trial ID: ACTRN12609000749202	
Publication details	Language of publication: English Funding: Health Research Council of New Zealand. Dr Dawson was in receipt of a Freemasons New Zealand Fellowship at the time the data were collected. Dr R.W. Taylor is funded by the KPS Research Fellowship (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "To determine whether a 2-year family-based intervention using frequent contact and limited expert involvement was effective in reducing excessive weight compared with usual care."	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Randomization to intervention condition occurred using random block lengths (Stata 12.0, StataCorp) after stratifying for feedback condition." Comment: randomisation process described

Allocation concealment (selection bias)	Low risk	Quote from publication: “We also met virtually all study quality criteria, including blinding of outcome assessors to treatment, allocation concealment, and appropriate statistical analyses” Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “Participants were not blinded to intervention condition because the 2 conditions differed in the amount of contact.” Comment: participants were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “Participants were not blinded to intervention condition because the 2 conditions differed in the amount of contact.” Comment: participants were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Outcome assessments were undertaken at baseline (including screening), 12 and 24 months by trained assistants blinded to intervention allocation.” Comment: outcomes assessors were blinded to treatment group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Outcome assessments were undertaken at baseline (including screening), 12 and 24 months by trained assistants blinded to intervention allocation.” Comment: outcomes assessors were blinded to treatment group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “A major strength of our study is the high retention, with 88% of children at study end.” Comment: relatively low dropout rates
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “A major strength of our study is the high retention, with 88% of children at study end.” Comment: relatively low dropout rates

Taylor 2015 (Continued)

Selective reporting (reporting bias)	Low risk	Comment: no differences found between publication and online clinical trials register
Other bias	Unclear risk	Comment: unable to assess if any other bias present

Vann 2013

Methods	Parallel RCT Randomisation ratio: 1:1:1:1 Superiority design	
Participants	Inclusion criteria: age 3-18 years (sample were 4-17 years), enrolled at Healthy Lifestyle Clinic at University of South Carolina, overweight or obese (CDC growth charts), had a DVD player Exclusion criteria: none Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention 1: pedometer + DVD group Intervention 2: pedometer group Intervention 3: fitness DVD group Control: usual care	
Outcomes	Outcome measures reported in abstract: adherence, BMI	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: Richland Memorial Hospital Research and Education Foundation (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The primary research aims were as follows: 1) Increase physical activity of obese children and adolescents 2) Encourage at least 10,000 steps per patient daily 3) Increase awareness that physical activity can lead to improved overall health status. The ultimate goal was to determine if the use of pedometers and/or fitness DVDs will improve physical activity parameters in the Healthy Lifestyles patient population."	
Notes	-	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	<p>Quote from study author (via email) : “Study participants were randomly assigned in equal groups to four arms: 1) control group; 2) Pedometer group; 3) Fitness DVD group; 4) Pedometer and fitness DVD”</p> <p>Comment: randomisation process described</p>
Allocation concealment (selection bias)	Low risk	<p>Quote from study author (via email): “Yes. The persons involved in recruitment of subjects were not a part of the allocation process.”</p> <p>Comment: allocation was concealed</p>
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	<p>Quote from study author (via email): “Participants were blinded to group selection. They only knew we were conducting a study which evaluated exercise patterns in their population. So, it is technically a single blinded study.”</p> <p>Comment: participants were blinded to group selection - not study personnel</p>
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	<p>Quote from study author (via email): “Participants were blinded to group selection. They only knew we were conducting a study which evaluated exercise patterns in their population. So, it is technically a single blinded study.”</p> <p>Comment: participants were blinded to group selection - not study personnel</p>
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	<p>Comment: study author confirmed assessors were not blinded</p>
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	<p>Comment: study author confirmed assessors were not blinded</p>
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	<p>Quote from publication: “While the participants seemed eager to participate in this study at its onset, there was a drastic drop in patient follow through as the study proceeded”</p> <p>Comment: a large amount of missing data. Only 14/28 (50%) were followed up at end of the study</p>

Vann 2013 (Continued)

Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “While the participants seemed eager to participate in this study at its onset, there was a drastic drop in patient follow through as the study proceeded” Comment: a large amount of missing data. Only 14/28 (50%) were followed up at end of the study
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Wafa 2011

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 7-11 years, obese (BMI > 95th percentile, CDC growth charts) , at least 1 parent who perceived their child’s weight status as a problem and were willing to participate in the intervention Exclusion criteria: the child had a serious co-morbidity requiring treatment Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: low-intensity intervention Control: waiting list control
Outcomes	Outcome measures reported in abstract: BMI z scores, weight change, HRQoL, objectively-measured physical activity and sedentary behaviour
Study details	Trial terminated early: no Trial ID: ISRCTN14241825
Publication details	Language of publication: English Funding: Scottish Funding Council (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “To test whether a good practice intervention for the treatment of childhood obesity would have a greater impact on weight status and other outcomes than a control condition in Kuala Lumpur, Malaysia”

Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Participating children attended a research clinic where all baseline measures (see below) were taken, then assigned a unique study code prior to random allocation into treatment or control group. To ensure concealment of allocation, codes were sent electronically to a statistician (JHM) who produced a computer generated randomization list which allocated participants to intervention or control group so that groups were balanced in blocks of 20. The statistician informed the researchers responsible for delivering the intervention (HNH, LN) of the allocation, and families were invited to intervention or waiting list control groups as appropriate." Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Comment: allocation was concealed via the randomisation method described above
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from study author (via email): "personnel who measured outcomes were blinded to group allocation, participating families were not (not possible/realistic we thought)" Comment: participants and personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from study author (via email): "personnel who measured outcomes were blinded to group allocation, participating families were not (not possible/realistic we thought)" Comment: participants and personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: "Outcome measures were made at baseline and again at six months (25 - 27 weeks) after the start of the intervention by the same trained researcher

Wafa 2011 (Continued)

		(SWW) who was blinded to group allocation and was not involved in delivery of the treatment program Comment: study author confirmed assessors were blinded
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: "Outcome measures were made at baseline and again at six months (25 - 27 weeks) after the start of the intervention by the same trained researcher (SWW) who was blinded to group allocation and was not involved in delivery of the treatment program Comment: study author confirmed assessors were blinded
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "Of the 107 participants entered at baseline, 80 (75%) attended for outcome measures at the six-month follow-up." Comment: moderate dropout rates that were higher in the intervention group
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: "Of the 107 participants entered at baseline, 80 (75%) attended for outcome measures at the six-month follow-up." Comment: moderate dropout rates that were higher in the intervention group
Selective reporting (reporting bias)	Low risk	Comment: no differences found between online clinical trial entry and publication
Other bias	Unclear risk	Comment: unable to assess if any other biases were present

Wake 2009

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: age 5 years-10th birthday, attending participating practices between May 2005-July 2006, not receiving an ongoing weight management programme, overweight or obese (IOTF cut points) Exclusion criteria: BMI z score was ≥ 3.0 Diagnostic criteria: see above

Interventions	Number of study centres: 45 Run-in period: no Extension period: no Intervention: LEAP2 behavioural intervention Control: no-care control group
Outcomes	Outcome measures reported in abstract: attrition, BMI, BMI z scores, physical activity (accelerometry), nutrition scores (diary), harm, costs
Study details	Trial terminated early: no Trial ID: ISRCTN52511065
Publication details	Language of publication: English Funding: Australian National Health and Medical Research Council (NH&MRC) Project Grant 334309. M Wake is supported by NH&MRC Career Development Award 284556; L Gold by NH&MRC Capacity Building Grant 425855; and OC Ukoumunne by NH&MRC Capacity Building Grant 436914 (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: "To determine whether ascertainment of childhood obesity by surveillance followed by structured secondary prevention in primary care improved outcomes in overweight or mildly obese children."
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Randomisation by child was stratified by GP and by overweight versus obese status; it was performed by an independent biostatistician using computer generated random numbers." Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Quote from publication: "The randomisation sequence was concealed from the study investigators, and the researchers collecting data remained blind to participants' trial status until follow-up was complete." Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from study author (via email): "Randomisation and outcomes measurement, but not participants, were blinded to

		group assignment” Comment: participants were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from study author (via email): “Randomisation and outcomes measurement, but not participants, were blinded to group assignment” Comment: participants were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Randomisation and outcomes measurement, but not participants, were blinded to group assignment” Comment: assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Randomisation and outcomes measurement, but not participants, were blinded to group assignment” Comment: assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “attrition was 3.1% at 6 months and 6.2% at 12 months.” Comment: attrition rates were fairly low for 12 months’ follow-up
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “attrition was 3.1% at 6 months and 6.2% at 12 months.” Comment: attrition rates were fairly low for 12 months’ follow-up
Selective reporting (reporting bias)	Unclear risk	Comment: clinical trials register entry was retrospectively entered so difficult to assess reporting bias
Other bias	Low risk	Comment: no other bias identified - study generally of low risk of bias in other domains

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design	
Participants	Inclusion criteria: aged 3-11 (but not including their 11th birthday), obese (BMI \geq 95th percentile, CDC growth charts) Exclusion criteria: receiving ongoing weight management in a secondary or tertiary care programme, known endocrine or genetic cause for their obesity, major disability or health conditions precluding participation, family did not speak English sufficiently enough to complete questionnaires and participate in the study Diagnostic criteria: see above	
Interventions	Number of study centres: 22 Run-in period: no Extension period: no Intervention: HopSCOTCH (the shared care obesity trial) intervention Control: usual care	
Outcomes	Outcome measures reported in abstract: attrition, attendance, BMI, BMI z scores, benefit or harm on secondary outcomes	
Study details	Trial terminated early: no Trial ID: ACTRN12608000055303	
Publication details	Language of publication: English Funding: the Australian National Health and Medical Research Council (NHMRC Project Grant 491212) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The aim of the HopSCOTCH trial is to develop, implement and trial an innovative shared-care approach to manage childhood obesity.”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “Randomisation occurred via a concealed, computerised random number sequence stratified by general practitioner and pre-generated by the Clinical Epidemiology and Biostatistics Unit at the Royal Children’s Hospital. Once enrolled (i.e. on receipt of written informed consent and baseline questionnaire) a research assistant, who was not otherwise involved with the trial, randomised children to either the shared-care or usual-

		care arm.” Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Quote from publication: “All families were advised of their child’s allocation by a mailed letter.” Comment: it was likely that allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “Researchers collecting outcome measurements, but not participants, were blinded to group assignment.” Comment: participants were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “Researchers collecting outcome measurements, but not participants, were blinded to group assignment.” Comment: participants were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “Researchers collecting outcome measurements, but not participants, were blinded to group assignment.” Comment: assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “Researchers collecting outcome measurements, but not participants, were blinded to group assignment.” Comment: assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “Figure 2 shows that, of the 118 eligible children enrolled who provided baseline data, 107 (91%) contributed outcome data.” Comment: attrition rates were fairly low at follow-up
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “Figure 2 shows that, of the 118 eligible children enrolled who provided baseline data, 107 (91%) contributed outcome data.”

Wake 2013 (Continued)

		Comment: attrition rates were fairly low at follow-up
Selective reporting (reporting bias)	Low risk	Comment: no differences found between publication, protocol or clinical trials register entry
Other bias	Low risk	Comment: no other bias identified - study generally of low risk of bias in other domains

Waling 2012

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: age- and gender-adjusted BMI \geq 25 kg/m ² (Cole 2000, international survey), born between 1995 and 1998, live in or nearby the city of Umea Exclusion criteria: chronic diseases that could influence metabolic parameters, attention deficit disorders, lack of access to internet Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: family-based intervention Control: usual care control group
Outcomes	Outcome measures reported in abstract: BMI z scores, WC, waist/hip ratio, apo A/ apo B ratio, physical activity level, steps/d, screen time, energy expenditure, time spent at > 3 MET, energy intake, refined sugar, dietary fibre, saturated fatty acids
Study details	Trial terminated early: no Trial ID: NCT01012206
Publication details	Language of publication: English Funding: Vardal Foundation for Healthcare Sciences and Allergy Research; the Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning; the Swedish Research Council; the Medical Faculty and the Faculty of Social Sciences at Umeå University; Västerbotten County Council; Dr PersFood AB; Majblommans Riksförbund, the Magnus Bergvall Foundation; Jamtland Council Research Unit (commercial and non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: “To evaluate the effect of a family-based intervention on anthropometric and metabolic markers in overweight and obese children.”

Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "The children were consecutively randomised (1: 1) and stratified by gender into either an intervention group or a control group by the researchers." Comment: randomisation process described
Allocation concealment (selection bias)	Unclear risk	Comment: author of study was unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: "Neither the researchers nor the participants were blinded." Comment: participants and study personnel were not blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: "Neither the researchers nor the participants were blinded." Comment: participants and study personnel were not blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Quote from publication: "The nurse did not receive information about the allocation group of the child, but blindedness cannot be assured" Comment: unclear if assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Quote from publication: "The nurse did not receive information about the allocation group of the child, but blindedness cannot be assured" Comment: unclear if assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "From baseline to the 1-year measurement, 42% of the children in the intervention group and 33% of the children in the control group dropped out (Figure 1), which left 58 chil-

Waling 2012 (Continued)

		dren who had completed the 1-year measurement” Comment: attrition rates were quite high
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “From baseline to the 1-year measurement, 42% of the children in the intervention group and 33% of the children in the control group dropped out (Figure 1), which left 58 children who had completed the 1-year measurement” Comment: attrition rates were quite high
Selective reporting (reporting bias)	Low risk	Comment: no differences between publications and clinical trials register entry observed
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Warschburger 2016

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: children aged 7-12 years (extended to 13 years due to recruitment problems), obese children: BMI > 97th percentile (Kromeyer-Hauschild 2001 - German references), parent participation at the beginning of their child's inpatient stay, Exclusion criteria: parents who had already done parent training, parents with inadequate language skills or severe mental disorders, children had secondary causes of obesity or suffering from severe mental health problems Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: parental CBT training group plus child inpatient intervention Control: parental information-only group plus child inpatient intervention
Outcomes	Outcome measures reported in abstract: BMI SDS, QoL, healthy food intake, exercise
Study details	Trial terminated early: no Trial ID: ISRCTN24655766
Publication details	Language of publication: English Funding: DFG (German Research Foundation) grant (WA 1143/4-1; 4-2) (non-commercial)

	Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: “The main goal was to develop a brief behaviourally oriented parent training program that enhances ‘obesity-specific’ parenting skills in order to prevent relapse”	
Notes	-	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: “A stratified (gender, age groups (7-10 or 11-13 years), and clinic) and blocked (block size 8) computerized randomization was performed centrally at the Institute of Medical Epidemiology, Biometry and Informatics at the University Halle-Wittenberg, which sent the results of the randomization by fax to the study centers within one day.” Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Comment: the randomisation method described was unlikely to introduce selection bias. Author confirmed allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: unlikely participants were blinded as some crossed over
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Comment: unlikely participants were blinded as some crossed over
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “At the follow-ups, children were asked to visit their physicians, who were blind to trial-group assignment and the study goals.” Comment: assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “At the follow-ups, children were asked to visit their physicians, who were blind to trial-group assignment and the study goals.” Comment: assessment staff were blinded

Warschburger 2016 (Continued)

		to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: "Limitations include the relatively high attrition rate, which might have caused a sample bias for the follow-up analyses." Comment: attrition rates were quite high
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: "Limitations include the relatively high attrition rate, which might have caused a sample bias for the follow-up analyses." Comment: attrition rates were quite high
Selective reporting (reporting bias)	Unclear risk	Comment: clinical trials register entry retrospectively entered
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Weigel 2008

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: aged 7-15 years, obese (> 97th percentile, according to European Childhood Obesity Group and the German Working Group on Pediatric Obesity) Exclusion criteria: none Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: active intervention group Control: usual care control group
Outcomes	Outcome measures reported in abstract: BMI z score, BMI, fat mass, SBP
Study details	Trial terminated early: no Trial ID: -
Publication details	Language of publication: English Funding: Bavarian State Ministry of Environment, Public Health, and Consumer Protection and the health insurance company SBK, Germany. The "Sea Lion Club" was financed by health insurance companies and by membership fees from the parents (commercial and non-commercial) Publication status: peer-reviewed journal

Weigel 2008 (Continued)

Stated aim for study	Quote from publication: "The authors performed a group-based program for obese children and adolescents in Bavaria, Germany to enable them to establish a health-oriented lifestyle and to reduce overweight. The authors compared this program with a control approach based on the patients' own initiative."	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation process not described
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: "Generally, 83% to 100% of participants attended each session, and there was only 1 dropout in the "Sea Lion Club." "Conversely, in the control group, 6 children were lost to follow up despite telephone calls, and none joined the local sports club as offered 12 months after their first visit." Comment: dropout rate very low in intervention group and low in control group
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry available
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Weintraub 2008

Methods	Parallel RCT Randomisation ratio: 1:1 Superiority design
Participants	Inclusion criteria: BMI percentile \geq 85th percentile for age and sex (CDC growth charts), in grades 4 and 5 in a low-income community in northern California Exclusion criteria: had a medical condition or were taking medications which affected growth, had conditions which limited their participation in the study Diagnostic criteria: see above
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Intervention: after-school team sports programme Control: "active placebo" control
Outcomes	Outcome measures reported in abstract: completion rates, BMI z scores, total physical activity, moderate physical activity, vigorous physical activity
Study details	Trial terminated early: no Trial ID: NCT00186173
Publication details	Language of publication: English Funding: co-operative agreement from the CDC through the Association of American Medical Colleges (grants U36/CCU319276 and AAMCID MM-0851-05/05) (non-commercial) Publication status: peer-reviewed journal
Stated aim for study	Quote from publication: "To evaluate the feasibility, acceptability, and efficacy of an after-school team sports program for reducing weight gain in low-income overweight children."
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "After completing baseline assessments, children were randomized using a computer by the Database Manager (K.F.H.) to either an after-school team sports program or a traditional nutrition and health education program." Comment: randomisation process described
Allocation concealment (selection bias)	Low risk	Quote from publication: "Children were notified by the study coordinator (E.C.T.)"

Weintraub 2008 (Continued)

		of their assigned intervention.” Comment: allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear if participants and personnel were blinded
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants and personnel were blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: “Owing to limited staffing for this pilot study, data collectors were not blinded at follow-up assessments” Comment: data collectors were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: “Owing to limited staffing for this pilot study, data collectors were not blinded at follow-up assessments” Comment: data collectors were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: “No participants were lost to follow-up” Comment: no missing data
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: “No participants were lost to follow-up” Comment: no missing data
Selective reporting (reporting bias)	High risk	Comment: clinical trials register has secondary outcomes such as WC and triceps skinfold thickness which were not mentioned in publication - potential reporting bias
Other bias	Unclear risk	Comment: unclear if the study was at risk of any other bias

Methods	Parallel RCT Randomisation ratio: 1:1:1 Superiority design	
Participants	Inclusion criteria: children aged 7-12 years who were 20%-100% overweight (CDC growth charts) and had at least 1 parent with BMI > 25 Exclusion criteria: families were excluded if either the child or parent was currently involved in psychological or weight loss treatment, was using appetite- or weight-affecting medications, or had a psychiatric condition (e.g. eating disorder, psychosis) that would interfere with participation Diagnostic criteria: see above	
Interventions	Number of study centres: 1 Run-in period: no Extension period: no Treatment before study: all participants received a weight-loss treatment focusing on dietary modification, physical activity increases and behaviour change skills (5 months' weight-loss treatment prior to randomisation) Intervention 1: behavioural skills maintenance group Intervention 2: social facilitation maintenance group Control: no-care control group	
Outcomes	Outcome measures reported in abstract: BMI z scores, percentage overweight, weight, attendance, parental weight change, parent BMI, behaviour problems, adherence	
Study details	Trial terminated early: no Trial ID: NCT00301197	
Publication details	Language of publication: English Funding: Grant 5R01HD36904-5 from the National Institute of Child Health and Human Development (NICHD); grant 1K24MH070446-01 from the National Institute of Mental Health (Dr Wilfley); and grant 1K23DK060476-01 from the National Institute of Diabetes and Digestive and Kidney Diseases (Dr Saelens) (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "To determine the short-term and long-term efficacy of 2 distinct weight maintenance approaches vs no continued treatment control following standard family based behavioral weight loss treatment for childhood overweight, and to examine children's social functioning as a moderator of outcome."	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Random assignment was conducted by using computer-generated random numbers."

		Comment: randomisation method described
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear if participants and personnel were blinded
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants and personnel were blinded
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Quote from publication: "It was not possible to keep assessors blind to treatment condition" Comment: assessment staff were not blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	High risk	Quote from publication: "It was not possible to keep assessors blind to treatment condition" Comment: assessment staff were not blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Comment: 42/51 completed behavioural intervention, 43/50 completed social group and 37/49 completed control group (total 81.3% retention)
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Comment: 42/51 completed behavioural intervention, 43/50 completed social group and 37/49 completed control group (total 81.3% retention)
Selective reporting (reporting bias)	Low risk	Comment: no differences found between publication and clinical trial register entry
Other bias	Unclear risk	Comment: unable to assess whether any other biases were present

Woo 2004

Methods	<p>Parallel RCT Randomisation ratio: 1:1 (but 2 initial arms become 3 arms after 6 weeks) Superiority design</p>
Participants	<p>Inclusion criteria: children aged 9-12 years, BMI \geq 21 kg/m² (CDC growth charts), no known medical illness and no alternative cause of obesity, no family history of premature cardiovascular disease, not taking regular medications or vitamin supplementation, resting brachial artery diameter > 2.55 mm Exclusion criteria: history of diabetes, renal disease or cardiovascular disease, sexual maturity status was more advanced than Tanner stage 2 Diagnostic criteria: see above</p>
Interventions	<p>Number of study centres: 1 Run-in period: no Extension period: none Intervention 1: diet plus supervised structured exercise programme with continuing training Intervention 2: diet plus supervised structured exercise programme with detraining Control: diet modification only</p>
Outcomes	<p>Outcome measures reported in abstract: waist-to-hip-ratio, cholesterol, arterial endothelial function, carotid wall thickening, body fat, lipid profiles, vascular function</p>
Study details	<p>Trial terminated early: no Trial ID: -</p>
Publication details	<p>Language of publication: English Funding: Hong Kong Institute of Heart Health Promotion, the Shaw Foundation, and the Research Grant Council of Hong Kong (CUHK4060/2000M) (non-commercial) Publication status: peer-reviewed journal</p>
Stated aim for study	<p>Quote from publication: "To assess the reversibility of such early arterial damage in children, we studied obese children before and after random assignment to an intervention program of diet alone or diet with exercise training to define potentially effective strategies to improve obesity-related vascular abnormalities."</p>
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: study author confirmed via email that randomisation was done via a computer - likely no selection bias
Allocation concealment (selection bias)	Low risk	Comment: study author confirmed via email that allocation was concealed

Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Quote from publication: “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” Comment: dietitian blinded but author confirmed participants and study personnel were not
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	Quote from publication: “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” Comment: dietitian blinded but author confirmed participants and study personnel were not
Blinding of outcome assessment (detection bias) Subjective outcomes	Low risk	Quote from publication: “All ultrasound-derived vascular functions were measured by a blinded investigator, and the high reproducibility between serial observations and in control subjects over time have been documented by us previously.” Comment: study author confirmed all outcome investigators were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Quote from publication: “All ultrasound-derived vascular functions were measured by a blinded investigator, and the high reproducibility between serial observations and in control subjects over time have been documented by us previously.” Comment: study author confirmed all outcome investigators were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Comment: unclear how many dropouts there were and how they were treated
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Comment: unclear how many dropouts there were and how they were treated
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register entry available

Woo 2004 (Continued)

Other bias	High risk	Comment: outcomes reported in this refer to 3 arms that were randomised into 2 arms originally, then 1 arm is split (non-randomly)
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Wright 2012

Methods	Cluster RCT Randomisation ratio: 2:3 Superiority design	
Participants	Inclusion criteria: 8-12 years, English or Spanish speaking, BMI \geq 85th percentile (CDC growth charts), had no physical limitations that prevented regular exercise Exclusion criteria: none Diagnostic criteria: see above	
Interventions	Number of study centres: 5 Run-in period: no Extension period: no Intervention: Kids N Fitness (KNF) intervention Control: general education (GE)	
Outcomes	Outcome measures reported in abstract: BMI, BMI z scores, dietary intake (vegetables, fruit, fruit juice), self-efficacy of healthy food choices, parent and community involvement, TV viewing, daily physical activity, physical education class attendance	
Study details	Trial terminated early: no Trial ID: -	
Publication details	Language of publication: English Funding: partly supported by a grant from the National Institutes of Health/National Institute on Minority Health and Health disparities (NIH/NIMHD) Loan repayment programme and a grant from the Robert Wood Johnson Foundation (grant no. 64195) . (non-commercial) Publication status: peer-reviewed journal	
Stated aim for study	Quote from publication: "The main objective of this study was to measure over a 1 year period whether a CSHP with parental, school and home based components to promote optimal nutrition will reduce BMI percentiles and z scores and improve dietary behaviours in a sample of low-income, school aged children"	
Notes	-	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Wright 2012 (Continued)

Random sequence generation (selection bias)	Unclear risk	Comment: randomisation process not described
Allocation concealment (selection bias)	Unclear risk	Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	Comment: unclear if participants and study personnel were blinded to study group
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: unclear if participants and study personnel were blinded to study group
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	Comment: unclear if assessment staff were blinded to study group
Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: unclear if assessment staff were blinded to study group
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	Quote from publication: “Thirty children (25%) in the KNF© group were lost to follow-up at 12 months, compared to 31 children (23%) in the GE group (P = 0.75) .” Comment: high dropout rates, potential attrition bias
Incomplete outcome data (attrition bias) Objective outcomes	High risk	Quote from publication: “Thirty children (25%) in the KNF© group were lost to follow-up at 12 months, compared to 31 children (23%) in the GE group (P = 0.75) .” Comment: high dropout rates, potential attrition bias
Selective reporting (reporting bias)	Unclear risk	Comment: no protocol or clinical trials register available so unable to assess reporting bias
Other bias	High risk	Comment: was cluster RCT but did not adjust for clustering in their analyses

AMA: American Medical Association; apo A: apolipoprotein A; apo B: apolipoprotein B;
BFC: Big Friends Club; BIA: bioimpedence analysis; BMI: body mass index; BMI SDS: standardised body mass index;

CDC: Centre for Disease Control and Prevention; CSHP: coordinated school health program;
 DVD: digital versatile disc;
 GP: general practitioners;
 HAND: Healthy Activity and Nutrition Directions; HDL: high density lipoprotein; HRQoL: health-related quality of life;
 IOTF: International Obesity Taskforce; ITT: intention-to-treat;
 LDL: low-density lipoprotein; LEAP: Live, Eat and Play; LEAP2: Live, Eat and Play 2; LFD: low fat diet; LGD: low-glycaemic diet;
 LMS: Lambda-Mu-Sigma;
 MEND: Mind, Exercise, Nutrition; MET(s): metabolic equivalents;
 N: number
 PCT: primary care trust;
 QoL: quality of life;
 RCT: randomised controlled trial; RE: Reggio Emilia; ROC: Regulation of Cues; RED: high energy dense;
 NIH: National Institutes of Health; NIHR: National Institute for Health Research;
 SBP: systolic blood pressure;
 SIGN: Scottish Intercollegiate Guidelines Network; SMSMT: short message service maintenance treatment; SWITCH: Screen-Time Weight-loss Intervention Targeting Children at Home;
 TAFF: telephone based adiposity prevention for families;
 WC: waist circumference; WHO: World Health Organization;
 YMCA: Young Men's Christian Association; z-BMI: standardised BMI

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

Study	Reason for exclusion
Adam 2009	Not an RCT
Albala 2008	Duration < 6 months
Alberga 2013	Duration of follow-up < 6 months from baseline
Alexander 2014	Prevention
Amini 2016	Duration: 18 weeks only
Andre 2015	Participants: adolescents
Astrup 2013	Prevention: not all children overweight/obese at baseline
Bachman 2010	Secondary data analysis
Baker 2012	Not an RCT
Ball 2012	Parent-only intervention
Banks 2011	2 alternative interventions, head-to-head trial (no control group)
Banks 2012a	2 alternative interventions, head-to-head trial (no control group)

(Continued)

Banks 2012b	2 alternative interventions, head-to-head trial (no control group)
Banks 2014	2 alternative interventions, head-to-head trial (no control group)
Banos 2009	Not an RCT
Baranowski 2011	Aim - not to treat childhood obesity
Barbeau 2007	Prevention - not all overweight
Bau 2016	Participants: mean age at recruitment = 13 years old (adolescents)
Bauer 2010	Not an RCT
Bayat 2014	Duration of follow-up < 6 months from baseline, non-randomised
Bean 2012	Parent-only intervention
Bean 2014	Parent-only intervention
Benestad 2014	Not an RCT: 2 different treatments, no clear control group
Benson 2008	Aim of study - not to treat childhood obesity
Bernstein 2015	Thesis - not an RCT
Best 2016	Aim of study - not to treat childhood obesity
Bloom 2013	Duration (6-month follow-up only given for intervention group)
Bocca 2014	Participants: preschool children
Bohnert 2013	Aim - not all children overweight/obese at baseline (prevention)
Boutelle 2011	2 alternative interventions, head-to-head trial (no control group)
Boutelle 2013	Duration: follow-up < 6 months for 1 group
Braden 2014	Not an RCT
Braet 1997a	2 alternative interventions, head-to-head trial (no control group)
Braet 1997b	2 alternative interventions, head-to-head trial (no control group)
Braet 2000	2 alternative interventions, head-to-head trial (no control group)
Buhari 2014	Prevention

(Continued)

Burrows 2008	Parent-only intervention
Burrows 2010a	Parent-only intervention
Burrows 2010b	Parent-only intervention
Burrows 2011	Parent-only intervention
Bush 2007	Prevention
Bustos 1997	Not an RCT
Caballero 2003a	Prevention
Caballero 2003b	Prevention
Canas 2012a	Not a lifestyle intervention
Canas 2012b	Not a lifestyle intervention
Canas 2014	Not a lifestyle intervention: main part of trial was carotenoid supplementation
Carrel 2005	Participants: adolescents
Carrel 2007	Participants: adolescents
Cash 2009	Prevention study
Catenacci 2014	Prevention: included healthy weight children
Cespedes 2014	Participants: preschool children
Chen 2013	Not an RCT
Chen 2015	Not an RCT
Chen 2016	Not an RCT
Chirita-Emandi 2014	Not a lifestyle intervention
Chongviriyaphan 2010	Duration of follow-up < 6 months from baseline
Cohen 2012	Duration 12 weeks
Collins 2010	Parent-only intervention
Cooperberg 2014	Participants: preschool children

(Continued)

Coppinger 2016	Protocol for obesity prevention intervention (will include both healthy and overweight children, therefore not treatment)
Cradock 2016	Prevention study - included normal weight children
Crova 2014	Prevention
Cunningham-Sabo 2016	Prevention
da Silva 2015	Participants: adolescents
Dahiya 2012	Secondary data analysis: comparison with normal weight children
Dai 2006	Duration of follow-up < 6 months from baseline
Dalton 2013	Parent-only intervention
Daniels 2009a	Aim of study - not to treat overweight/obese children
Danielsen 2013	Duration: control group only followed up for 12 weeks then given intervention
Danielzik 2007	Prevention
Davis 1999	Prevention
Davis 2011a	Not an RCT
Davis 2011b	Aim - not to treat overweight/obese children
Davis 2014	Duration - only 13 weeks' follow-up
Davis 2016a	2 alternative interventions, head-to-head trial (no control group)
Davis 2016b	Duration of follow up < 6 months from baseline
de Mello 2004	2 alternative interventions, head-to-head trial (no control group)
De Ruyter 2013	Aim of study - not to treat childhood obesity
Dennis 2013	Duration of follow-up < 6 months from baseline
DeVault 2009	Not an RCT
Dias 2016	Duration - 12 weeks
Dodds 2014	Prevention
Donnelly 2009	Aim - not to treat childhood obesity

(Continued)

Doyle-Baker 2011	Duration of follow-up < 6 months from baseline
Dreyer 2014	Participants: adolescents
DuBose 2008	Not an RCT
Duckworth 2009	Duration of follow-up < 6 months from baseline
Duncan 2009	Aim of study - not to treat childhood obesity
Dura 2006	Not an RCT, clinical record reviews
Economos 2007	Not an RCT
El Hage 2012	Aim to investigate hip strength in obese children
Endevelt 2014	Not an RCT
Epstein 1981	2 alternative interventions, head-to-head trial (no control group)
Epstein 1984b	Duration of follow-up < 6 months from baseline
Epstein 1986	2 alternative interventions, head-to-head trial (no control group)
Epstein 1987a	Prevention - not all overweight
Epstein 1987b	2 alternative interventions, head-to-head trial (no control group)
Epstein 1987c	2 alternative interventions, head-to-head trial (no control group)
Epstein 1987d	Not an RCT
Epstein 1990	2 alternative interventions, head-to-head trial (no control group)
Epstein 1993	Secondary data analysis: aim to assess height growth of children
Epstein 1994a	2 alternative interventions, head-to-head trial (no control group)
Epstein 1994b	10-year follow-up (study 2 = Epstein 1984a) - however, does not follow up the control group
Epstein 1995	Not an RCT - unclear which is the control group
Epstein 2000b	2 alternative interventions, head-to-head trial (no control group)
Epstein 2004	2 alternative interventions, head-to-head trial (no control group)
Epstein 2007	Not an RCT

(Continued)

Epstein 2008a	2 alternative interventions, head-to-head trial (no control group)
Epstein 2008b	Duration of follow-up < 6 months from baseline
Epstein 2012	Not an RCT
Erceg 2012	Not an RCT
Escobedo 2014	Not a lifestyle intervention - diet supplements
Escoto 2008	Aim - not to treat obesity
Esfarjani 2013	Parent-only intervention
Estabrooks 2009	Parent-only intervention
Falbe 2015	Duration - 10 weeks
Farpour-Lambert 2009	Follow-up from baseline < 6 months
Ferguson 1999a	Duration: crossover, 4 months only
Ferguson 1999b	Duration: crossover, 4 months only
Ferrara 2013	Duration only 60 d (2 months)
Ferrer 1998	Not an RCT
Figuroa-Colon 1993	2 alternative interventions, head-to-head trial (no control group)
Figuroa-Colon 1996	2 alternative interventions, head-to-head trial (no control group)
Firoozi 2013	Duration of study - 6 weeks
Fischer 2014	Not a lifestyle intervention
Foger 1993	Not an RCT
Follansbee-Junger 2010	Not an RCT
Frohna 2008	Commentary on Wilfley 2007
Fullerton 2007a	Participants: adolescents
Fullerton 2007b	Participants: adolescents
Furze 2008	Not an RCT

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Gajewska 2011	Duration of follow-up < 6 months from baseline
Galhardo 2012	Participants: adolescents
Garipagaoglu 2009	2 alternative interventions, head-to-head trial (no control group)
Gerards 2012	Parent-only intervention
Ghatrehsamani 2010	Duration 3 months
Goldfield 2000	Duration of follow-up < 6 months from baseline
Goldfield 2001	2 alternative interventions, head-to-head trial (no control group)
Goldfield 2006	Duration of follow-up < 6 months from baseline
Goldfield 2007	Duration of follow-up < 6 months from baseline
Goldfield 2008	Not an RCT
Goldfield 2009	Not an RCT
Golley 2007	Parent-only intervention
Golley 2011	Not an RCT
Gong 2014	Prevention study
Graf 2006	Not an RCT
Graf 2008	Not an RCT
Graham 2008	Aim - not to treat overweight/obese children
Graves 1988	2 alternative interventions, head-to-head trial (no control group)
Gregori 2014	Duration of follow-up < 6 months from baseline
Griffin 2013	Not an RCT
Grow 2014	Not an RCT
Guixeres 2009	Not an RCT
Gunnarsdottir 2011b	Not an RCT
Gunnarsdottir 2014	Not an RCT (single group)

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Gunther 2007	Not an RCT
Gussinyer 2008	Not an RCT
Gutin 1996	Not an RCT
Gutin 1999a	Duration of follow-up < 6 months from baseline
Gutin 1999b	Duration of follow-up < 6 months from baseline
Gutin 2008	Prevention
Habib-Mourad 2014a	Prevention
Habib-Mourad 2014b	Prevention
Habib-Mourad 2014c	Prevention
Haemer 2013	Not an RCT
Hager 2016	Not an intervention study
Hajihashemi 2014	Duration of follow-up < 6 months from baseline
Hammarlund 1993	Duration of follow-up < 6 months from baseline
Hansen 2013	Not an RCT
Harder-Lauridsen 2014	Duration of follow-up < 6 months from baseline
Hardman 2009	Duration of follow-up < 6 months from baseline
Harrell 1998	Duration of follow-up < 6 months from baseline (between 8 and 10 weeks)
Harrison 2006	Prevention
Hartlieb 2015	Participants: adolescents
Hashemipour 2009	Not a lifestyle intervention
Haszard 2015	Secondary analysis of RCT data
Heuser 2008	Prevention - not all overweight
Hollinghurst 2014	2 alternative interventions, head-to-head trial (no control group)
Holmes 2008	Not an RCT (discussion paper)

(Continued)

Horsak 2015	Protocol only with primary aim not to treat overweight
Horton 2013	Duration - 14 weeks
Huang 2007	Duration of follow-up < 6 months from baseline
Huang 2015a	Participants: adolescents
Huang 2015b	Participants: adolescents
Hystad 2013	2 alternative interventions, head-to-head trial (no control group)
Iannuzzi 2009	Not an RCT - no control group
Ibarra-Reynoso 2015	Duration - 2 months
Ildiko 2007	Not an RCT
Innes-Hughes 2016	Not an RCT
Israel 1984	Not an RCT
Israel 1985	Duration - control group only 9 weeks long
Israel 1994	2 alternative interventions, head-to-head trial (no control group)
Jacobson 2009	Thesis - duration of follow up < 6 months from baseline
Jago 2013	Prevention
James 2000	Commentary on a prevention intervention
Janicke 2008a	Parent-only intervention
Janicke 2008b	Parent-only intervention
Janicke 2009	Parent-only intervention
Janicke 2011	Duration of follow-up < 6 months from baseline
Janicke 2013	Participants: preschool children
Jansen 2011	Parent-only intervention
Jensen 2012	Duration of follow-up < 6 months from baseline
Jensen 2013	Duration only 10 weeks

(Continued)

Jensen 2015	Not an RCT
Jernigan 2015	Not an RCT
John 2009	Participants: preschool children
Johnston 2013	Prevention
Jones 2015a	Includes children that were not actually overweight or obese (but determined as 'at risk')
Jurg 2006	Prevention
Kain 2009	Prevention
Kalarchian 2013	Not an RCT
Kang 2008	Duration of follow-up < 6 months from baseline
Karacabey 2009	Duration of follow-up < 6 months from baseline
Kelishadi 2008	2 alternative interventions, head-to-head trial (no control group)
Kelishadi 2009	Participants: preschool children
Kelishadi 2010	Participants: preschool children
Kerr 2000	Prevention
Khadilkar 2012	Duration of follow-up < 6 months from baseline
Kim 2016	Duration - 5 weeks
Kipping 2008	Prevention
Kirschenbaum 1984	Alternative interventions, head-to-head trial (no control group)
Klesges 2008	Prevention
Klitzman 2015	Parent-only intervention
Kohno 1994	Not an RCT
Kokkvoll 2014	2 alternative interventions, head-to-head trial (no control group)
Kolko 2010	Participants: preschool children
Krafft 2014a	Aim not to treat obesity, aim to assess brain function

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Krafft 2014b	Aim not to treat obesity, aim to assess brain function
Krafft 2014c	Aim not to treat obesity, aim to assess brain function
Kriemler 2010	Prevention
Kuni 2015	Aim of study - not to treat childhood obesity
Larsen 2010	Prevention
Larsen 2016	Participants: adolescents
Lau 2015	Duration of follow-up < 6 months from baseline
Leach 2008	Aim of study - not to treat childhood obesity
Li 2010	2 alternative interventions, head-to-head trial (no control group)
Looney 2012	Secondary data analysis
Lopes 2009	Prevention
Loughrey 2009	Not an RCT (discussion paper)
Luley 2010	Alternative interventions (no control group)
Madsen 2013	Aim of study - not to treat childhood obesity
Makkes 2011	Participants: adolescents
Maloney 2012	Participants: adolescents
Manchester 1978	Not an RCT
Marcus 2009	Prevention
Marild 2013	2 alternative interventions, head-to-head trial (no control group)
Maron 2014	Not an RCT
Martinez 2008	Prevention
Matheson 2015	Not a lifestyle intervention
Mayurachat 2013	Duration only 18 weeks
Mazzeo 2008	Parent-only intervention

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Mazzeo 2011	Parent-only intervention
Mazzeo 2014	Parent-only intervention
McFarland 2014	Not an RCT
McGuigan 2009	Not an RCT
Medrano 2015	Duration - 22 weeks
Minossi 2014	Duration of follow-up < 6 months from baseline
Minossi 2015	Protocol - inclusion criteria will allow the inclusion of non-overweight children with co-morbidity such as hypertension, dyslipidaemia or diabetes (prevention study)
Mo-suwan 1998	Prevention
Moens 2012	Parent-only intervention
Moreno 2015	Secondary data analysis of 2 RCTs
Morgan 2014	Prevention
Muckelbauer 2009a	Aim - not to treat overweight/obese children
Muckelbauer 2009b	Aim - not to treat overweight/obese children
Munsch 2008	Parent-only intervention
Murphy 2009	Not an RCT
Mustila 2012	Not an RCT
Muth 2008	Prevention
NCT00284557	Not all children were overweight or obese (inclusion criteria stated "at risk of overweight")
Nemet 2006	Duration - 3 months' follow-up, not an RCT
Nemet 2013a	Duration - 3 months' follow-up, not an RCT
Nemet 2013b	Prevention - not all overweight
Nogueira 2014	Trial was not exclusively in overweight children - therefore not a treatment trial
Nogueira 2015	Trial was not exclusively in overweight children - therefore not a treatment trial

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Nowicka 2010	Not an RCT
Nuutinen 1992	Not an RCT
O'Malley 2011	Aim of study - not to treat childhood obesity
Okely 2010	Parent-only intervention
Oliveras 2013	Not a lifestyle intervention
Parente 2006	Duration - only 5 months' follow-up
Parillo 2012	Not an RCT - 2 alternative interventions
Parra-Medina 2011	Duration - only 18 weeks' follow-up
Pedrosa 2011a	2 alternative interventions, head-to-head trial (no control group)
Pedrosa 2011b	2 alternative interventions, head-to-head trial (no control group)
Perman 2008	Not an RCT
Perry 1979	Aim: to assess eating behaviours, not treat obesity
Petty 2009	Aim - not to treat overweight/obese children
Plachta-Danielzik 2007	Prevention
Plummer 2014	Not an RCT
Polacsek 2009	Not an RCT
Pontin 2004	Commentary, prevention
Poulsen 2011	Not an RCT
Prado 2009	Duration of follow-up < 6 months from baseline
Puder 2009	Prevention
Qu 2014	Prevention - not all overweight
Racine 2010	Not a lifestyle intervention
Ramon-Krauel 2013	Aim - to treat fatty liver
Rank 2012	Not an RCT

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Rausch 2013	Prevention
Raynor 2002	2 alternative interventions, head-to-head trial (no control group)
Raynor 2012	Parent-only intervention
Reinehr 2006	Not an RCT
Reinehr 2009	Not an RCT
Reinehr 2011	Commentary on a parent-only intervention
Resaland 2014	Prevention
Resnick 2009	Parent-only intervention
Resnicow 2012	Parent-only intervention
Riddiford-Harland 2012	Parent-only intervention: analysis from the HIKCUPS study
Riddiford-Harland 2016	Secondary analysis of RCT data examining foot-related outcomes
Riggs 2007	Prevention
Robertson 2012	Not an RCT
Robinson 1999	Prevention
Rodearmel 2006	Duration of follow-up < 6 months from baseline
Rohrer 2008	Not an RCT
Rooney 2005	Prevention - not all children overweight at baseline
Rosado 2008	Duration of follow-up < 6 months from baseline
Safavi 2013	Duration of follow up 8 weeks from baseline (<6 months)
Salcedo 2010	Prevention (not all overweight)
Salehi-Abargouei 2014	Duration of follow-up < 6 months from baseline
Sallis 1993	Prevention
Salmon 2008	Prevention
Sanchez-Gomez 2012	Prevention

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Schaeffer 2014	Aim of study - not to treat childhood obesity
Seabra 2014	Duration of follow-up < 6 months from baseline
Senediak 1985	2 alternative interventions, head-to-head trial (no control group)
Sgro 2009	Not an RCT
Shalitin 2009	Not an RCT- no control group identified
Sherman 1992	Not an RCT
Slusser 2013	Prevention - includes healthy weight children
Small 2014	Participants: preschool children
Sothorn 2000a	Not an RCT
Sothorn 2000b	Not an RCT
Soto-Sanchez 2014	Not an RCT
Speroni 2007	Prevention
Spriet 2014	Commentary paper
St-Onge 2009	Duration of follow-up < 6 months from baseline
Steele 2012	2 alternative interventions, head-to-head trial (no control group)
Steele 2014	Secondary data analysis
Stettler 2015	Prevention study
Stevens 2003	Aim - not to treat overweight/obese children
Stewart 2009	Not an RCT
Stone 2003	Aim - not to treat overweight/obese children
Stovitz 2014	Duration of follow-up < 6 months from baseline
Sweeney 2010	Not an RCT
Sze 2015	Duration - 4 weeks
Tak 2007	Duration of follow-up < 6 months from baseline

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Tanas 2011	Not an RCT
Taveras 2014	Not a lifestyle intervention
Taylor 2006	Not an RCT
Taylor 2007	Aim of study - not to treat childhood obesity
Teevale 2015	Qualitative study
Ten 2016	Not an intervention study
Theim 2012	Not an RCT
Thompson 2013	Not all overweight or obese
Tirlea 2016	Participants: adolescents - mean age > 12
Todd 2008	Duration of follow-up < 6 months from baseline
Trinh 2013	Not an RCT
Trost 2014	Duration of follow-up < 6 months from baseline
Tucker 2014	Not an RCT
Uysal 2014	Not an RCT
Van Grieken 2013	Participants: preschool children
Van Grieken 2014	Participants: preschool children
Vandongen 1995	Prevention
Vargo 2012	Not an RCT
Vasickova 2011	Duration of follow-up < 6 months from baseline
Verbeken 2013a	Duration of follow-up < 6 months from baseline
Verbeken 2013b	Duration - 12 weeks follow up (<6 months from baseline)
Verduci 2011	Not an RCT
Verduci 2013	Not a lifestyle intervention
Vetter 2014	Prevention

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Vido 1993	Not a lifestyle intervention
Virgen 2007	Not an RCT
Vos 2011	Participants: adolescents
Vrablik 2014	Participants: adolescents, mean age > 12
Wake 2011	Aim of study - not to treat childhood obesity
Walker 2008	Parent-only intervention
Walsh 2014	Not an RCT
Wang 2013	Not an RCT - uses baseline data from another study
Ward 2011	Aim of study - not to treat childhood obesity
Watowicz 2014	Not an RCT
Wheeler 1976	Duration of follow-up from baseline not clear
Wijesuriya 2011	Participants: adults
Wile 1992	Not an RCT
Williamson 2008	Prevention
Williamson 2010	Prevention
Williamson 2012	Prevention
Wislo 2013	Not an RCT
Wohlfarth 2013	Duration of follow-up < 6 months from baseline
Wong 2013	Duration of follow-up < 6 months from baseline
Wright 2013	Duration of follow-up < 6 months from baseline
Wyatt 2011	Prevention
Xu 2012	Prevention
Yackobovitch-Gavan 2009	Not an RCT
Yam 2012	Prevention

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Yu 2008	Duration of follow-up < 6 months from baseline
Zahner 2006	Prevention
Zask 2012	Aim of study - not to treat childhood obesity
Zhang 2011a	Not a lifestyle intervention
Zhang 2011b	Not an RCT
Zheng 2015	Not an RCT
Zorba 2011	Duration of follow-up < 6 months from baseline

RCT: randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

[ACTRN12611000862943](#)

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrollment: target 107 Inclusion criteria: <ul style="list-style-type: none">• 5-16 year old boys and girls• BMI > 98th WHO centile• significant weight-related co-morbidities and ready to change Exclusion criteria: <ul style="list-style-type: none">• significant co-morbidities that would make programme participation impossible
Interventions	Intervention: 1-h home visits with diet and activity assessment and education, then weekly 1.5-h activity session for 40 weeks and psychology group (2 x 1-h sessions) Control: brief dietary education and diet, activity and well-being assessments
Outcomes	Primary outcome: reduction of 0.5 SDS at 0, 6, 12, 18 and 24 months, quality-of-life improvements and physical activity improvements as the same time points Secondary outcomes: improvements in dietary and sedentary behaviours and improved glycaemic control
Study identifier	ACTRN12611000862943

Official title	Whanau Pakari: a multidisciplinary intervention for child and adolescent obesity
Stated purpose of study	“Our objectives are firstly to undertake a multi-disciplinary intervention which is accessible and appropriate for those most affected by child obesity. Secondary, we aim to assess whether a quantitative RFC questionnaire is useful in predicting response to the intervention.”
Notes	Study author reply: 14/10/16. “I have just submitted the 12-month outcome paper today. I am not sure of your timeframes, but if you like, I can put you on our communications update list, so you hear as soon as it is published.”

ISRCTN45032201

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: investigator-blind Primary purpose: treatment</p>
Participants	<p>Condition: childhood overweight and obesity Enrolment: target 120 families Inclusion criteria:</p> <ul style="list-style-type: none"> ● child overweight (> 91st centile) or obese (> 98th centile) child ● age 7-11 years ● family with at least 1 parent/guardian and child willing to take part <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● insufficiently able to speak English (child or parent) ● metabolic or other medical cause of obesity ● severe learning difficulties or behavioural problems in the child
Interventions	<p>Intervention: 10-week family-based intervention (group-based with children and parents, focusing on parenting, social and emotional development, and changing behaviour) Control: receive usual care given in their area</p>
Outcomes	<p>BMI/BMI z score (primary), waist circumference, percentage body fat, habitual activity via accelerometer, quality of life, fruit and vegetable consumption, parental BMI, parental well-being, family eating and activity, quality of parent-child relationships, Parenting style Health state valuation, economic evaluation, process evaluation Endpoint = 12 months</p>
Study identifier	ISRCTN45032201
Official title	“A randomised controlled trial evaluating the effectiveness and cost-effectiveness of “Families for Health“, a family-based childhood obesity treatment intervention delivered in a community setting for ages 7 to 11”

ISRCTN45032201 (Continued)

Stated purpose of study	<p>“Our objectives are to:</p> <ol style="list-style-type: none"> 1. Assess the effectiveness of the ‘Families for Health’ programme in reducing BMI z-score in children aged 7 to 11 who are overweight and obese 2. Evaluate the cost-effectiveness and cost-utility of the ‘Families for Health’ programme 3. Investigate parents’ and children’s views of the programme and their observations on approaches to maximising impact 4. To investigate facilitators’ views of the programme and their observations on approaches to maximising impact”
Notes	Study author reply: 11 October 2016 Not published yet, should not be too long

ISRCTN97887613

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: unclear Primary purpose: treatment</p>
Participants	<p>Condition: obesity Enrolment: target 200 Inclusion criteria:</p> <ul style="list-style-type: none"> • children aged 8-12 years • obesity type I and II (BMI \geq age- and gender-adjusted 95 percentile) • capacity to walk for 10 min <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • diabetes type I • hyperactivity • morbid obesity • contraindications to do exercise (biological or mental)
Interventions	<p>Intervention: the 6-month programme includes two 1-h sessions of an exercise programme per week. Each session includes 20-min physical exercise to improve fitness, a 30-min activity to improve sport skills, and 10-min of healthy behaviour-changing advice (nutrition, possibilities of doing physical exercise during leisure time) Control: usual care only</p>
Outcomes	Level of physical activity, fitness tests, healthcare costs, health-related quality of life, nutritional intake, blood samples
Study identifier	ISRCTN97887613
Official title	Exercise looks after you: piloting the programme to prevent obesity in children
Stated purpose of study	Not given
Notes	Trial record retrospectively registered. Trial completed. Emailed study author (April 2016) - no reply

JPRN-UMIN000014896

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrolment: target 300 Inclusion criteria: <ul style="list-style-type: none">• elementary school children (6-12 years)• a percent relative body weight of $\geq 20\%$ Exclusion criteria: <ul style="list-style-type: none">• participants who were treated or educated for obesity in medical setting(s)
Interventions	Intervention: educational, counselling, training (pedometer, limit screen time) Control: record pedometer count and screen time without intervention
Outcomes	Percent relative body weight, cardiovascular risk factors
Study identifier	JPRN-UMIN000014896
Official title	Study on the medical check-up system for prevention of behaviour changing diseases including diabetes in underage groups, especially infants, elementary and junior high school children [Study on the Prevention and Treatment of Obesity by Behavioral Approach (Lifestyle modification approach) for Elementary School Children]
Stated purpose of study	“Study on the treatment of childhood obesity by behavioral approach”
Notes	Study completed. Study author reply: 11 October 2016. Results have not been published yet

Jung 1978

Methods	
Participants	
Interventions	
Outcomes	
Study identifier	
Official title	
Stated purpose of study	
Notes	Cannot obtain full publication from the British Library

Methods	<p>Type of study: interventional, efficacy Allocation: randomised Intervention model: parallel Masking: single-blind (assessors) Primary purpose: treatment</p>
Participants	<p>Conditions: obesity Enrolment: 270 Inclusion criteria:</p> <ul style="list-style-type: none"> • Age 4-7 years • Boys or girls, and of any race • BMI > 85th percentile for age • Children and parents must speak and understand English <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Currently participating in a clinical trial, but they may be involved in an observational study • Physical disabilities which inhibit physical activity • Taking drugs known to alter glucose homeostasis • History of diabetes mellitus • History of significant hepatic, renal, gastrointestinal or cardiovascular disease • Diagnosis of hypertension requiring limited physical activity • Psychological disabilities limiting participation • Other medical or behavioural factors which might interfere with the study (judged by principal investigator) • Unable to speak and understand English • No telephone or transportation
Interventions	<p>Intervention: Team PLAY Group (6-month family-centered intervention to increase physical activity and healthy eating patterns, primarily directed at parents) Control: standard care group (primary care physician)</p>
Outcomes	BMI (primary), body composition (DEXA), physical activity via accelerometry, dietary changes, Body Esteem Scale, Flexibility and Cohesion Evaluation Scales, MacArthur Behavior and Health Questionnaire
Study identifier	NCT00528164
Official title	Treating childhood obesity with family lifestyle change
Stated purpose of study	“The purpose of this study is to determine whether an intense family-centered program to help children, 4 to 7 years old, control their weight is more effective than the advice and referrals their health provider gives in the primary care office.”
Notes	<p>There are three publications attached to the trial register. 1 is a protocol, the second provides baseline results and measures of attendance, and the third is a secondary data analysis examining the relationship between BMI and self-esteem. Therefore, emailed study author to ask when the full set of outcome results shall be published</p> <p>Study author reply: 12 October 2016. “I am sorry to report to you that our results have not been published. The study has been completed. We are working on the outcome manuscript - hope to have it published soon.”</p>

[NCT00723853](#)

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: prevention</p>
Participants	<p>Condition: type 2 diabetes and obesity Enrolment: 131 Inclusion criteria:</p> <ul style="list-style-type: none"> • age 9-12 years • overweight (> 85th percentile BMI for age and gender) • African American • family history of type 2 diabetes in a first or second degree relative • parents are secondary participants <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Inability to give informed consent or unwillingness to be randomised • Prior diagnosis of diabetes in the child planning to participate • Pregnancy (women who become pregnant during the study will be omitted from the analysis. Pregnant women will not participate in the exercise sessions) • Uncontrolled hypertension (SBP > 160 or DBP > 100) • Uncontrolled dyslipidaemia by NCEP III criteria • Evidence of significant cardiovascular, pulmonary disease, or other serious illness • Evidence of alcohol or drug abuse (identified by self-report) • Musculoskeletal disease serious enough to prevent participation in exercise sessions • Known or suspected major psychiatric disorder • Inability to participate in aerobic exercise activities • Inability to comply with a calorie- or fat-restricted diet • Age over 65 years
Interventions	<p>Intervention: Reach-Out Program, Nutritional and Exercise Intervention Control: Reach-In Program, Standard of Care</p>
Outcomes	Height, weight, waist and hip circumference, body fat by BIA, biochemical markers (glucose tolerance, lipid panel, insulin, hemoglobin A-1-C)
Study identifier	NCT00723853
Official title	REACH-OUT: Chicago Children's Diabetes Prevention Program
Stated purpose of study	“The purpose of this research study is to evaluate two nutrition and exercise programs in children ages 9-12 who are at risk for developing type 2 diabetes. This study also includes the involvement of parents or guardians who are willing to participate in these programs with the child.”
Notes	Study completed. Emailed study author (April 2016) - no reply

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment</p>
Participants	<p>Condition: childhood overweight and obesity Enrolment: 482 Inclusion criteria:</p> <ul style="list-style-type: none"> • age 7-11 years • \geq 85th percentile for weight • at least 1 parent of the participating child must be overweight (BMI \geq 25) • 1 parent must agree to attend all parent/child treatment meetings as the participating parent • participants must be able to speak and comprehend English <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • participating parent or child having a thought disorder, suicidality, bipolar disorder, or drug or alcohol dependence • participating parent or child having a physical disability or illness that prevents performance of physical activity at level equivalent to a brisk walk or that places severe restriction on diet • participating parent or child being on a medication regimen that affects weight • participating parent or child being involved in active psychiatric treatment for an ongoing problem that causes either social or occupational impairment • parents (participating and nonparticipating) and children having an eating disorder (i.e. anorexia nervosa, bulimia nervosa, binge eating disorder) or having subclinical levels of eating disturbance (i.e. reporting key eating disorder behaviours of purging, fasting, or binge eating more than 2 times per month)
Interventions	<p>Intervention 1: behavioural: SFM + low dose (intervention focuses on helping families create a social environment that supports weight maintenance) Intervention 2: behavioural: SFM + high dose Control: behavioural: weight maintenance education</p>
Outcomes	Child percent overweight
Study identifier	NCT00759746
Official title	Childhood obesity treatment: a maintenance approach
Stated purpose of study	“The purpose of this study is to determine the effect of dose and content of an enhanced weight maintenance treatment on children’s ability to maintain weight loss following a standard weight loss treatment.”
Notes	Study completed. Study author did not reply October 2016. Only 16-week data are currently published

NCT00851201

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: prevention
Participants	Condition: obesity, diabetes Enrolment: 506 Inclusion: <ul style="list-style-type: none"> • age 7-12 years • BMI > 85th percentile for sex Exclusion: <ul style="list-style-type: none"> • health or condition that would interfere with study participation, • unwilling or inability to provide parent/guardian consent or child assent • intention to move from area
Interventions	Intervention: intensive behaviour changing: same as control but add on: 1) 12 core group modules for parents (to address roles and skills) and for children (to enhance motivation and skills and to provide physical activity), 3) Tailored support using a 'toolbox' approach from community health workers as extensions of the Family Weight Management professional education staff, and 4) monthly after-core follow-up groups Control: 1-Standard Intervention: 1) an initial consult, which includes an overview of behaviour-changing goals, 2) quarterly follow-up, 3) and a monthly newsletter
Outcomes	BMI percentile for age and sex, biomarkers (e.g. glucose, insulin, lipids), dietary intake, and physical activity measures
Study identifier	NCT00851201
Official title	Comprehensive approach to family weight management
Stated purpose of study	"The purpose of this study is to address the Healthy People 2010 obesity prevention objective"
Notes	Study completed. Baseline data available but no follow-up data identified

NCT01110096

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrolment: 100 Inclusion: <ul style="list-style-type: none"> • age 7-12 years • BMI > iso-BMI 30 (Coles index) Exclusion: <ul style="list-style-type: none"> • syndromic obesity

NCT01110096 (Continued)

	<ul style="list-style-type: none"> ● obesity related to diseases ● local community not involved ● child has present follow-up because of obesity in secondary health care ● parent has current/planned follow-up because of obesity in secondary health care
Interventions	<p>Intervention: 2-week family camp: Parent Management Training - Oregon (PMTO), motivational interviewing, dynamic group therapy</p> <p>Control: 4-d family behaviour-changing school</p>
Outcomes	BMI SDS, quality of life, physical fitness, behaviour, blood samples
Study identifier	NCT01110096
Official title	Randomised controlled clinical trial comparing two family interventions to treat obesity in children between 7 and 12 years
Stated purpose of study	“The study compares the effect on BMI of two different treatment options for obesity in childhood. Families with at least 1 obese child and parent are invited to join the project. The hypothesis is that family camp gives an additional reduction in BMI compared to a less intensive family lifestyle school.”
Notes	Author reply: 27 November 2016. “Thank you for your interest in our article! It is in the final stage before publishing, we just sent the final proof to the journal. I have not yet received the exact date for publishing (I assume within a week or two), but I will send you the article as soon as it is published.”

NCT01290016

Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: open label</p> <p>Primary purpose: treatment</p>
Participants	<p>Condition: obesity</p> <p>Enrollment: 132</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> ● Aged 6-12 years ● boys and girls, who consume less than 2 servings of milk/milk products ● receptive to recommendations ● BMI > 97 WHO centile <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● serious or chronic illnesses of childhood ● medication use in last 3 months known to affect bone or mineral metabolism ● diabetes ● non dietary hyperlipidaemia
Interventions	<p>Intervention: arm 1: family counselling to maintain 2 servings of dairy/d and physical activity improvement instructions; arm 2 as arm 1 but advised to eat 4 dairy servings (for ages 6-8 years); arm 3: as arm 2 but for 9-12 years</p>

NCT01290016 (Continued)

	Control: diet and exercise information only
Outcomes	Primary outcome: body composition at 0, 3, 6, 9 and 12 months Secondary outcomes: blood biochemistry, satiety and bone mass
Study identifier	NCT01290016
Official title	MY LIFE Study - McGill Youth Lifestyle Intervention With Food and Exercise Study
Stated purpose of study	“The aim of this study is to determine the effects of a 1 y family centered lifestyle intervention, focused on both nutrient dense food including increased intakes of milk and alternatives, plus total and weight bearing PA, on body composition and bone mass in overweight or obese children.”
Notes	Study author reply: 11 October 2016. “Thank you for asking, our work is in press with Can J Public Health, we do not yet have page proofs.”

NCT01506245

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: childhood obesity Enrollment: 75 Inclusion criteria: <ul style="list-style-type: none"> childhood obesity (> 97 percentile WHO references) Exclusion criteria: <ul style="list-style-type: none"> being involved in any weight control, physical activity, behaviour therapy, or gastric surgery programme familial history of dyslipidaemia or essential hypertension medications or hormones, which may influence cardiovascular function, body composition, lipid or glucose metabolism in the preceding 6 months orthopaedic affection limiting physical activity genetic disorder or another chronic disease
Interventions	Intervention: family-based behavioural therapy (6 months) either in group or in individual setting. Parents can choose between the 2 types of therapy Control: no intervention
Outcomes	BMI, total body and abdominal fat, waist circumference, blood pressure, arterial intima-media thickness, arterial flow-mediated dilation, arterial stiffness, cardiorespiratory fitness, physical activity, biological markers, quality of life, child’s behaviour, parental psychological health
Study identifier	NCT01506245
Official title	Exercise training and family-based behavioural treatment in pre-pubertal obese children and their mother

NCT01506245 (Continued)

Stated purpose of study	“The aim of this study is to compare the effects of exercise training and family-based behavioural treatment, either in individual or in group setting, in pre-pubertal children and their mother”
Notes	Estimated completion date June 2012 - trial record not updated since January 2012. Emailed study author (April 2016) - no reply. Conference abstract identified

NCT01610219

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment</p>
Participants	<p>Condition: diabetes mellitus (type 2), obesity Enrollment: 52 Inclusion criteria:</p> <ul style="list-style-type: none"> • age 4-8 year • age- and sex-specific BMI \geq 95th percentile <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • children with serious medical conditions • children who show signs of elevated psychopathology, as assessed by the Child Behavior Checklist (CBCL) • children of parents with significantly elevated psychiatric disorders
Interventions	<p>Intervention: Lifestyle modification for diabetes prevention (traffic light diet, self-monitoring, parental behavioural training, promoting physical activity) Control: Nutrition and physical activity family-based intervention (no behavioural skills training, goal setting, self-monitoring or physical activity tool kit)</p>
Outcomes	BMI/BMI z score (primary), % overweight (primary), waist circumference (primary), blood pressure (primary), pulse (primary), physical activity via accelerometer (primary), glucose (primary), insulin (primary), lipid profile measures (primary), dietary intake (primary), parent BMI
Study identifier	NCT01610219
Official title	Lifestyle modification for type 2 diabetes prevention in overweight youth
Stated purpose of study	“The objective of proposed study was to test a family-based intervention designed to reduce excess body weight, improve metabolic and cardiovascular profile, and improve diet and physical activity levels in 4 - 8 year old youth who are “at risk“ for T2D”
Notes	Author reply: 12 October 2016. “The study is complete. We have not yet published the results.”

NCT01662570

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrollment: 65 Inclusion criteria: <ul style="list-style-type: none"> • ages 4-8 years old • BMI \geq 85th percentile (based on age and sex) • consumes large (\geq 16 oz/d) sugar sweetened beverages Exclusion criteria: <ul style="list-style-type: none"> • child has a serious medical condition • signs of elevated psychopathology are present, as assessed by the Child Behavior Checklist (CBCL) • parent demonstrates elevated psychiatric problems or eating disorders • failure of parent or child to meet BMI criteria
Interventions	Intervention: Beverage choice lifestyle modification Control: Nutrition education (NE)
Outcomes	BMI, BMI z score, BMI percentile, child percent overweight, waist circumference, energy intake, sugar-sweetened beverage intake, treatment acceptance/satisfaction, child preferences and motivation for sugar-sweetened beverages
Study identifier	NCT01662570
Official title	Beverage choice and lifestyle modification in overweight youth
Stated purpose of study	“This research study developed and tested a ”Beverage Choice and Lifestyle Modification“ (BCLM) intervention for 4 to 8 year old children who are at-risk for being overweight or are overweight and who consume large amounts of sugar sweetened beverages and juice.”
Notes	Study completed. Emailed author (April 2016) - no reply

NCT02724943

Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrollment: 549 Inclusion criteria: <ul style="list-style-type: none"> • Age 2-12 years • BMI \geq 85th centile

	<p>Exclusion criteria:</p> <ul style="list-style-type: none"> • obesity-related complications that would interfere with participant • underlying causes of obesity • severe psychological problems • participation in an obesity treatment programme in the year prior to enrolment
Interventions	<p>Intervention: the intervention consists of: (1) BMI screening, (2) Next Steps brief counselling materials for the healthcare provider, (3) a 3-month intensive Mind Exercise Nutrition Do It! and Coordinated Approach To Child Health (MEND/CATCH) phase, which included the Mind Exercise Nutrition Do it! with adapted CATCH activities, and (5) a 9-month transition MEND/CATCH Transition phase of monthly reinforcement sessions for parents and children, and twice-weekly Young Men's Christian Association (YMCA) sports for children. Community Health Workers (CHWs) serve as programme liaisons and assist in delivering all intervention group sessions as well as tracking families</p> <p>Control: (active comparator - additional component to a behaviour-changing intervention and usual care) Next Steps brief clinical intervention which is a 12-month clinic-based programme conducted at 12 partner healthcare clinics and entailed (1) EHR changes to support childhood obesity clinical visits; (2) BMI screening, (3) Next Steps brief counselling materials for the healthcare provider, and (4) Next Steps self-paced booklet for parents and children to work on nutrition and physical activity targets in a self-directed manner. Families were encouraged to seek repeated clinical visits to address child obesity</p>
Outcomes	<p>Primary outcome: change in obesity prevalence at baseline, 3 and 12 months</p> <p>Secondary outcomes: waist-to-height ratio, fat-free mass, blood pressure, fitness, quality of life at the same time points</p>
Study identifier	NCT02724943
Official title	Texas Childhood Obesity Research Demonstration (TX CORD) Project
Stated purpose of study	<p>“Aim 1: To implement and evaluate the efficacy of a systems approach to child obesity on reducing BMI (expressed as %95th percentile) by embedding a 12-month family-based secondary prevention program within a community primary prevention program. The secondary prevention weight management program will target overweight/obese children and their families in the primary prevention catchment areas in Austin and Houston. Overweight/obese children (total N = 576), aged 2-12 years, will be randomly assigned to either the 12-month secondary prevention program (experimental) or the community primary prevention program alone (control), in equal age subgroups (2-5, 6-8, and 9-12 years). Analyses will be conducted by age group, and outcomes will include BMI as expressed as %95th percentile), obesity-related behaviors, quality of life, and program use indicators</p> <p>Aim 2: To quantify the incremental cost-effectiveness of the 12-month family-based secondary prevention program relative to primary prevention alone for child obesity. Activity Based Costing methods will be used to quantify the incremental cost of delivering the secondary prevention program relative to optimized healthcare. These costs will then be combined with the effectiveness data to quantify the incremental cost-effectiveness of the community-based intervention.”</p>
Notes	Study author did not reply, October 2016. Study completed. Protocol and baseline data available but no follow-up data identified

NCT02771951

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: factorial assignment Masking: single-blind (outcome assessor) Primary purpose: treatment</p>
Participants	<p>Condition: obesity Enrollment: 297 Inclusion criteria:</p> <ul style="list-style-type: none"> • aged 6-11 years • Latino boys and girls • clinic visit within past 24 months prior to enrolment in study • BMI % for age/gender between 75th-99.9th centiles • plan on living in target area for following 18 months • have transportation to participating clinic <p>Exclusion criteria: not provided</p>
Interventions	<p>Intervention: participants receive 7 group classes taught by trained clinic health educators; in addition to a series of phone calls; clinical visits with a mid-level provider; and 6 booster group classes over 1 year Control: usual care provision of up to 2 visits with a usual care health educator over 1 year</p>
Outcomes	<p>Primary outcome: BMI over 1 year Secondary outcomes: not stated</p>
Study identifier	NCT02771951
Official title	Clinical/behavioral approach to overweight in Latino youth: luces de cambio
Stated purpose of study	No official aim stated
Notes	Study completed. Study author reply: 11 October 2016. "Still ongoing...give us a few months." Unclear whether healthy weight children are included as it doesn't state which BMI growth reference is being used - however authors state that the overweight participants recruited from paediatric clinics

NCT02779647

Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment</p>
Participants	<p>Condition: obesity Enrollment: 54 Inclusion criteria:</p> <ul style="list-style-type: none"> • age 8-12 years • obese boys and girls <p>Exclusion criteria:</p>

[NCT02779647](#) (Continued)

	<ul style="list-style-type: none"> • hormonal, orthopedic, respiratory or other complications
Interventions	<p>Intervention: physical activity programme (4 x 90 min sessions/wk for 9 months and nutrition advice for children and parents)</p> <p>Control: nutrition advice only</p>
Outcomes	<p>Primary outcome: body composition over 12 months</p> <p>Secondary outcomes: physical activity (1 month), sleep apneas (6 months)</p>
Study identifier	NCT02779647
Official title	Play as a method to reduce overweight and obesity in children. Kids-Play Study
Stated purpose of study	“The aim of this study is to analyse an intervention based on play as a means of improving the body composition of children with overweight or obesity.”
Notes	Study author did not reply, October 2016. Study completed

[NCT02794090](#)

Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: open label</p> <p>Primary purpose: treatment</p>
Participants	<p>Condition: obesity</p> <p>Enrollment: 37</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • age 5-14 years • boys and girls who are outpatients of the paediatric centre • parents had to attend at least 4 or 7 meetings in the parental education group <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • not speaking Swedish • obesity-related syndromes
Interventions	<p>Intervention: telephone consultation every month (except summer holidays) for 18 months. The treating nurse communicating with 1 of the parents</p> <p>Control: usual care according to regular treatment routines at the clinic</p>
Outcomes	<p>Primary outcome: BMI z score - baseline, during intervention and follow-up in total 3.7 years</p> <p>Secondary outcomes: health care personnel time, families' experience of the programme</p>
Study identifier	NCT02794090
Official title	Exclusive telephone coaching in maintaining weight loss - an randomized controlled trial of childhood obesity treatment

NCT02794090 (Continued)

Stated purpose of study	No official aim stated
Notes	Author reply: 12 October 2016. "The paper is submitted and we are waiting for response from our first revision."

Shapiro 1976

Methods	
Participants	
Interventions	
Outcomes	
Study identifier	
Official title	
Stated purpose of study	
Notes	Cannot obtain full publication from the British Library

Terwilliger 2008

Methods	
Participants	
Interventions	
Outcomes	
Study identifier	
Official title	
Stated purpose of study	
Notes	Thesis - unable to obtain

BIA: Bioelectrical impedance analysis; BMI: body mass index; CBCL: Child Behavior Checklist; DBP: diastolic blood pressure; DEXA: dual energy X-ray absorptiometry; EHR: electronic health records; N: number; NCEP: National Cholesterol Education Program; PA: physical activity; SBP: systolic blood pressure; SDS: standard deviation score; SFM: Social Facilitation Maintenance; T2D: Type II diabetes; WHO: World Health Organization

Characteristics of ongoing studies [ordered by study ID]

[ACTRN12613001037796](#)

Trial name or title	Effect of exercise intensity on cardiac and vascular function, and intra-abdominal fat in obese children and adolescents
Methods	<p>Type of study: interventional, efficacy/safety</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: blinded (masking used). The people assessing the outcomes. The people analysing the results/ data</p> <p>Primary purpose: treatment</p>
Participants	<p>Condition: obesity</p> <p>Enrolment: target 60</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • 7-16 years • boys and girls • obese (CDC growth charts) - those above 99th centile will be assessed on an individual basis • all ethnic groups • blood pressure < 95th percentile • fasting total cholesterol < 5.5 mmol/L and low-density lipoprotein cholesterol < 3.0 mmol/L • participants willing to be randomised to high or moderate intensity exercise or control group, and able to follow protocol • successful completing of self-monitoring materials before randomisation <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • participating in another study • smoking • diabetes • taking medications such as steroids • coronary heart disease or congenital cardiac abnormalities • family history of hypertrophic obstructive cardiomyopathy • abnormalities during the resting or exercise stress echo • orthopaedic and/or neurological limitations to exercise • considerable pulmonary disease • self-reported kidney failure • major organ transplant • epilepsy or history of seizures • attention deficit hypersensitivity disorder diagnosis
Interventions	<p>Intervention 1: a high-intensity interval training group (dietary sessions over 3 months, physical activity training sessions plus home training)</p> <p>Intervention 2: a moderate-intensity exercise group (same as above but moderate intensity training instead of high)</p>
Outcomes	<p>Other outcome(s): peak systolic (S') tissue velocity (primary), intra-abdominal fat via MRI (primary), arterial endothelial-dependent dilatation (primary), arterial stiffness, VO2 max, body composition via DEXA, oxidised LDL, adiponectin, total nitrate, HOMA, blood pressure, diet, accelerometry data, height, weight, waist circumference</p>

ACTRN12613001037796 (Continued)

Starting date	Start date: estimated first participant enrolled: 1 October 2013 Completion date: unclear. Estimated last participant enrolled: 1 January 2015
Contact information	Responsible party/principal investigator: Miss Katrin Dias, The University of Queensland, Australia, katrin.dias@uqconnect.edu.au
Study identifier	ACTRN12613001037796 ; NCT01991106
Official title	Effect of exercise intensity on cardiac and vascular function, and intra-abdominal fat in obese children and adolescents
Stated purpose of study	Quote: “The objective of the study is to investigate the effects of high intensity exercise intensity on myocardial and arterial function, intra-abdominal fat and cardiovascular disease risk factors in obese children and adolescents over one year.”
Notes	Study author reply 12 October 2016: “While the study is still ongoing (12-month follow up), we are currently collating results from the three-month supervised phase of the study. We aim to submit two papers with these results to journals by the end of the year. Given the time taken from submission to publication, I would expect them to be published between mid to end 2017.”

[ChiCTR-IOB-15005874](#)

Trial name or title	Effects of weight management program on postural stability and neuromuscular function among obese children
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: single-blind Primary purpose: treatment
Participants	Condition: obesity Enrollment: target 120 Inclusion criteria: <ul style="list-style-type: none"> ● children aged 8-10 years ● obese (IOTF definition) ● tanner stage 1 ● can participate in 3 exercise classes/week for 6 months, ● 1 parent willing to attend treatment meetings and no family member involved in another weight control programme Exclusion criteria: <ul style="list-style-type: none"> ● cannot communicate in Chinese ● diabetic ● suffer from psychiatric disorder ● angina in past 3 months or severe dyspnoea at rest ● syndromic of medicinal cause of obesity ● other illness that prevents participation

ChiCTR-IOB-15005874 (Continued)

Interventions	Intervention: weight management: combined diet and exercise programme: dietary intervention only (6 dietetic visits) and weekly nurse telephone support. Exercise: 50 min session at sports centre 1 x/week to be repeated twice that week at home Control: 60 min weekly education session
Outcomes	Primary outcome: body height and weight Secondary outcomes: waist and hip circumference, % body fat, movement biomechanistics and postural stability tests
Starting date	Start date: unclear Completion date: unclear until completed
Contact information	Responsible party/principal investigator: wanglin@sus.edu.cn
Study identifier	ChiCTR-IOB-15005874
Official title	Not provided
Stated purpose of study	“The present study attempts to investigate the effect of a six-month weight management program on postural stability and neuromuscular control among obese children”
Notes	Study author reply: 11 October 2016. “The study is ongoing now. In fact, we meet a few problems in participant’s recruitment and funding support, therefore, there are not any data currently.”

DRKS00007879

Trial name or title	Development and evaluation of a computer-based self-regulation training for obese children and adolescents
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: blinded patient/subject, investigator/therapist, caregiver, assessor Primary purpose: treatment
Participants	Condition: obesity Enrollment: target 226 Inclusion criteria: <ul style="list-style-type: none"> ● 8-16 years ● boys and girls ● BMI > 97 centile ● informed parental consent Exclusion criteria: <ul style="list-style-type: none"> ● secondary obesity ● hyperkinetic disorder with medication ● mental retardation

DRKS00007879 (Continued)

Interventions	<p>Intervention: self-regulation training with the developed computer program (Approach-Avoidance-Training), in addition to treatment as usual (inpatient rehab treatment), conducted over 6 sessions (10-15 min each), over 2 consecutive weeks</p> <p>Control: placebo training (similar to the intervention computer program but with no learning effect) in addition to treatment as usual (inpatient rehab treatment), conducted over 6 sessions (10-15 min each), over 2 consecutive weeks</p>
Outcomes	<p>Primary outcome: BMI z score pre, post rehab and 6 and 12 months after the end of rehab</p> <p>Secondary outcomes: self-regulation skills pre and post rehab</p>
Starting date	<p>Start date: 6 March 2015</p> <p>Completion date: unclear until study has completed</p>
Contact information	<p>Responsible party/principal investigator: Prof. Petra Warschburger, Karl-Liebknecht-Str. 24/25, 14476 Potsdam, Germany. E-mail: warschb@uni-potsdam.de</p>
Study identifier	DRKS00007879
Official title	Development and evaluation of a computer-based self-regulation training for obese children and adolescents
Stated purpose of study	No formal aims provided
Notes	Author reply: 12 October 2016. "Yes, our study is still ongoing and we expect the results in April/May next year. A paper of our pilot study is in preparation."

ISRCTN81798055

Trial name or title	Child weigHt mANaGement for Ethnically diverse communities study (CHANGE)
Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: -</p> <p>Primary purpose: prevention</p>
Participants	<p>Condition: childhood obesity</p> <p>Enrolment: estimate 160-180</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> ● phase 1 <ul style="list-style-type: none"> ○ aged 4-11 years ○ overweight/obese ○ Bangladeshi and Pakistani parents and carers ○ offered the existing children's weight management service. ● phase 2 <ul style="list-style-type: none"> ○ aged 4-11 years ○ overweight/obese

ISRCTN81798055 (Continued)

	<ul style="list-style-type: none"> ○ children and their families who have been referred to the Birmingham children's weight management service <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● phase 2 <ul style="list-style-type: none"> ○ families who self-refer to the service but do not have an overweight or obese child (defined as \geq 91st centile) aged 4-11 year will be excluded from the study
Interventions	<p>Intervention: an adapted children's weight management programme, 8 weeks</p> <p>Control: existing children's weight management programme, 7 weeks</p>
Outcomes	Completion rates (primary), height, weight, BMI, waist circumference, percentage body fat (BIA), dietary intake, physical activity (accelerometry), parent-reported sedentary behaviours, health-related quality of life, a health utility measure, body image, self-concept
Starting date	<p>Start date: 1 September 2014 (recruitment)</p> <p>Completion date: unclear. 28 February 2017 (recruitment)</p>
Contact information	Responsible party/principal investigator: Dr Miranda Pallan, University of Birmingham, UK
Study identifier	ISRCTN81798055
Official title	Development of a culturally adapted weight management programme for children of Pakistani and Bangladeshi origin
Stated purpose of study	"Therefore the main aim of this study is to develop and assess the feasibility and acceptability of a weight management programme for children aged 4-11 years and their families, tailored to be culturally relevant to Bangladeshi and Pakistani communities, but also suitable for delivery to an ethnically diverse population."
Notes	Study not yet completed

Moore 2013

Trial name or title	Acronym: IMPACT
Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: assessor blinded</p> <p>Primary purpose: treatment</p>
Participants	<p>Condition: childhood obesity</p> <p>Enrolment: unknown</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> ● entering 6th grade ● BMI \geq 85th percentile determined from height and weight measurements (CDC growth charts) ● provision of consent by parents and assent by children <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● medications that alter appetite or weight

Moore 2013 (Continued)

	<ul style="list-style-type: none"> stage 2 hypertension or stage 1 hypertension with end organ damage (e.g. left ventricular hypertrophy, microalbuminuria) sickle cell disease severe behavioural problems that preclude group participation as reported by parent/guardian involvement in another weight management programme family expectation to move from the region within 1 year the presence of a known medical condition that itself causes obesity (e.g. Prader-Willi syndrome)
Interventions	<p>Intervention: HealthyCHANGE intervention (family-based weight management programme based in cognitive-behavioural theory with elements of motivational interviewing (MI))</p> <p>Control: SystemCHANGE intervention (based on system process improvement theory and focuses on redesign of the activities in a family's daily routines related to home, school, and work to support positive behaviour changes)</p>
Outcomes	Weight, height, waist circumference, triceps skinfold, BMI, dietary intake, physical activity (accelerometry), blood pressure, haemoglobin A1c (HbA1c), glucose, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, high-sensitivity C-reactive protein (hs-CRP), insulin and alanine aminotransferase (ALT), child's self-efficacy, social support, motivation, and family problem-solving, systems thinking, self-regulation child's self-efficacy, social support, motivation, and family problem-solving, self-regulation, sleep, stress levels, cardiovascular risk, socioeconomic and demographic factors, environmental (home, school, neighbourhood) factors, peer norms
Starting date	<p>Start date: unclear</p> <p>Completion date: unclear</p>
Contact information	Responsible party/principal investigator: Shirley Moore, Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, USA. smm8@case.edu
Study identifier	-
Official title	A multi-level family and school intervention targeting obesity in urban youth
Stated purpose of study	"The primary aim of this study is to compare the effects of three distinct behavioral obesity management interventions on BMI in overweight/obese middle school, urban youth."
Notes	Author reply: 16 October 2016. "This study is still ongoing. We will not be unblinded until spring 2017 and cannot share results prior to publication of the results (hopefully fall 2017)."

NCT01221220

Trial name or title	Environmental strategies & behavior change to reduce overeating in obese children
Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: single-blind (assessor)</p> <p>Primary purpose: treatment</p>

NCT01221220 (Continued)

Participants	<p>Condition: obesity</p> <p>Enrolment: estimated 160</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> ● 8-15 years ● obese based on 95th percentile (CDC growth references) ● parent and child must both want to join the study ● parent and child must agree to attend sessions and not miss more than 2 consecutive sessions <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● diagnosed with a medical condition affecting growth (e.g. type 1 or 2 diabetes, chronic renal diseases, pregnancy) ● taking medication known to affect growth ● have a condition which would limit their participation in the study or the assessments ● not able to read or understand English or Spanish, or unable to complete consent forms ● within the next 18 months the family plans to move from the San Francisco Bay area
Interventions	<p>Intervention: behavioural: Standard Packard Pediatric Weight Control Program plus home-based advising on environmental changes (6 months program)</p> <p>Control: Standard Packard Pediatric Weight Control Program only</p>
Outcomes	BMI (primary), waist circumference, triceps skinfold, resting heart rate, dietary intake, weight concerns, depressive symptoms, daily energy intake, physical activity, blood pressure, fasting blood lipids
Starting date	<p>Start date: September 2010</p> <p>Completion date: February 2015 (final assessment)</p>
Contact information	Responsible party/principal investigator: Thomas Robinson, Stanford University, USA
Study identifier	NCT01221220
Official title	Environmental strategies & behavior change to reduce overeating in obese children
Stated purpose of study	“There is a need for effective weight control methods for obese children. Environmental strategies such as reducing the size of dishware and serving utensils, storing food out of view and reducing food consumption while watching television may reduce food intake without requiring conscious, cognitive self-control. The investigators propose to test these methods when added to a current state-of-the-art behavioral program.”
Notes	Author reply: 11 October 16. Ongoing. Not yet published

NCT01574352

Trial name or title	Acronym: OOIS
Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: single blind (investigator)</p> <p>Primary purpose: treatment</p>

Participants	<p>Condition: children, overweight, obesity, metabolic syndrome</p> <p>Enrolment: 100</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • live in municipality of Odense, Denmar • overweight or obese (BMI) - IOTF <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • participating in other similar research studies • following a special school programme • the use of weight-altering medicine 3 months before the baseline • motor-skill determined handicap which hinders participation
Interventions	<p>Intervention: behavioural: intervention camp (6-week day-camp: physical activity, health education, healthy foods, social activities)</p> <p>Control: behavioural: small intervention (weekly 1-h session over 6 weeks plus 2 parental diet and exercise information sessions)</p>
Outcomes	<p>BMI (primary), cognitive function, motor skills, body composition by DEXA, brain-derived neurotrophic factor, blood pressure, subclinical atherosclerosis, cardio-respiratory fitness, insulin, glucose, blood lipids, C-reactive protein, waist/hip circumference, clustered CVD risk factor, physical strength measured by hand grip and Sargent vertical jump</p> <p>Endpoint: 12 months</p>
Starting date	<p>Start date: April 2012</p> <p>Completion date: July 2017</p>
Contact information	<p>Responsible party/principal investigator: Lars Bo Andersen, Professor, Center of Research in Childhood Health (RICH), University of Southern Denmark</p>
Study identifier	<p>NCT01574352</p>
Official title	<p>The Odense Overweight Intervention Study (OOIS): a randomized controlled trial on overweight prevention in children</p>
Stated purpose of study	<p>“This study is carried through as a randomized controlled trial which investigates the effect of participating in a 6 week health promoting resident for overweight fifth grade children camp followed by 42 weeks of family support”</p>
Notes	<p>Data collection is complete.</p> <p>Protocol: Larsen et al. Effectiveness of a 1-year multi-component day-camp intervention for overweight children: study protocol of the Odense overweight intervention study (OOIS). BMC Public Health 2014, 14:313</p>

Trial name or title	Acronym: Stanford GOALS
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: single blind (outcome assessment) Primary purpose: treatment
Participants	Condition: obesity Enrolment: 240 Inclusion criteria: <ul style="list-style-type: none"> • 7-11 years • BMI \geq 85th percentile for age and sex on the 2000 CDC BMI reference Exclusion criteria: <ul style="list-style-type: none"> • have been diagnosed with a medical condition affecting growth (a genetic or metabolic disease/syndrome associated with obesity, type 1 diabetes, type 2 diabetes taking medication, chronic gastrointestinal diseases, chronic renal diseases, uncorrected structural heart disease, heart failure, heart transplant, anorexia nervosa or bulimia nervosa or binge eating disorder (present or past), AIDS or HIV infection, pregnancy); <ul style="list-style-type: none"> • take medications affecting growth (systemic corticosteroids > 2 weeks in the past year, insulin, oral hypoglycaemic, thyroid hormone, growth hormone); • have a condition limiting their participation in the interventions (e.g. unable to participate in routine physical education classes at school, requiring oxygen supplementation for exertion, developmental or physical disability preventing participation in interventions, children or parents/guardians who cannot medically participate in mild dietary restrictions and/or increased physical activity for any reason); • have a condition limiting participation in the assessments (child or primary caregiver not able to read surveys in English or Spanish, child 2 or more grade levels delayed in school for reading and writing in native language); <ul style="list-style-type: none"> • are unable to read, understand or complete informed consent in English or Spanish; • plan to move from the San Francisco Bay Area within the next 36 months; • are deemed to have another characteristic that makes them unsuitable for participation in the study in the judgment of the Principal Investigator
Interventions	Intervention: multi-component, multi-level, multi-setting (MMM) - sports programme, home-based family intervention, behavioural counselling Control: enhanced standard care/health and nutrition education intervention
Outcomes	BMI (primary), physical activity (accelerometry), waist circumference, triceps skinfold thickness, resting blood pressure, resting heart rate, cholesterol, triglycerides, insulin, glucose, haemoglobin A1c, HsCRP, ALT, screen time and other sedentary behaviours, energy intake, waist-to-height ratio, weight concerns, depressive symptoms, school performance, sleep habits Endpoint: 3 years
Starting date	Start date: July 2012 Completion date: April 2017
Contact information	Responsible party/principal investigator: Thomas N Robinson, Stanford University, USA

NCT01642836 (Continued)

Study identifier	NCT01642836
Official title	Clinic, family & community collaboration to treat overweight and obese children
Stated purpose of study	“Primary Research Question: Will a 3-year, innovative, interdisciplinary, multi-component, multi-level, multi-setting (MMM) community-based intervention to treat overweight and obese children significantly reduce BMI compared to an enhanced standard care/health and nutrition education active comparison intervention?”
Notes	Ongoing, finished recruiting Protocol: Robinson TN, Matheson D, Desai M, Wilson DM, Weintraub DL, Haskell WL, McClain A, McClure S, Banda JA, Sanders LM, Haydel KF, Killen JD. Family, community and clinic collaboration to treat overweight and obese children: Stanford GOALS-A randomized controlled trial of a three-year, multi-component, multi-level, multi-setting intervention. <i>Contemp Clin Trials</i> . 2013 Nov; 36(2):421-35. doi: 10.1016/j.cct.2013.09.001. Epub 2013 Sep 10

NCT01736748

Trial name or title	Acronym: CIRCUIT
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: double-blind (subject, caregiver, investigator, outcomes assessor) Primary purpose: prevention
Participants	Condition: obesity Enrolment: 100 Inclusion: <ul style="list-style-type: none"> • children aged 6-18 years • BMI > 95th percentile for age and sex Exclusion: <ul style="list-style-type: none"> • children with a physical or psychological condition that would impair their ability to participate in physical activity
Interventions	Intervention: sensor-based PA intervention Control: traditional PA counselling
Outcomes	Change in physical activity levels (primary), blood pressure, glucose homeostasis, lipid status, BMI
Starting date	Start date: January 2015 Completion date: January 2019
Contact information	Responsible party/principal investigator: Melanie Henderson, St. Justine’s Hospital, Canada
Study identifier	NCT01736748

NCT01736748 (Continued)

Official title	Implementing Dynamo: a tailored lifestyle promotion intervention among pediatric patients with cardiometabolic risk factors
Stated purpose of study	“Its primary goal is to promote physical activity and reduce sedentary time to improve children’s cardiometabolic profile”
Notes	This study was not yet open for participant recruitment (as of March 2016)

NCT02082080

Trial name or title	Prevention and control of obesity in primary school children in Tehran
Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: open label</p> <p>Primary purpose: prevention</p>
Participants	<p>Condition: childhood obesity prevention</p> <p>Enrolment: estimated 360</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> ● BMI z score ≥ 1 (WHO) ● students in the fifth or sixth grades (age 9-14) <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● metabolic disorders (hypo or hyperthyroidism) ● any disease which interferes with adherence to the intervention ● intake of any appetite-reducing drug ● doing professional sports ● being on a weight-reduction diet
Interventions	<p>Intervention: education and social support intervention</p> <p>Control: no care</p>
Outcomes	Primary outcome measure(s): Pain on the 11-point Short Pain Scale (SPS-11), BMI
Starting date	<p>Start date: December 2012</p> <p>Completion date: June 2013</p>
Contact information	Responsible party/principal investigator: Tehran University of Medical Sciences, Iran
Study identifier	NCT02082080
Official title	Prevention and control of obesity in primary school children in Tehran
Stated purpose of study	“This study evaluates the effect of an interventional model for preventing and controlling overweight and obesity in male and female fifth-graders”

Notes	Unable to find contact details
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NCT02124460

Trial name or title	Connect 4 Health: an intervention to improve childhood obesity outcomes
Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: single-blind (outcomes assessor) Primary purpose: treatment</p>
Participants	<p>Condition: overweight, obesity Enrolment: 721 Inclusion criteria:</p> <ul style="list-style-type: none"> • aged 2.0-12.9 years at baseline primary care visit, • BMI \geq 85th percentile for age and sex at baseline primary care visit • at least 1 parent has an active email address • at least 1 parent is comfortable reading and speaking in English <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • children who do not have at least 1 parent/legal guardian who is able to follow study procedures for 1 year • families who plan to leave Harvard Vanguard Medical Associates within the study time frame • families for whom the primary care clinician thinks the intervention is inappropriate, e.g. emotional or cognitive difficulties • children who have a sibling already enrolled in the study • children with chronic conditions that substantially interfere with growth or physical activity participation
Interventions	<p>Intervention: Connect 4 Health: using health coaches for behavioural counselling and community connections Control: enhanced primary care</p>
Outcomes	BMI (primary), quality of life (primary), Quality and Family-Centeredness of Pediatric Obesity Care, specified behavioural outcomes, process measures, socioeconomic variables, geographic variables
Starting date	<p>Start date: June 2014 Completion date: November 2016</p>
Contact information	Responsible party/principal investigator: Elsie M Taveras, Massachusetts General Hospital, USA
Study identifier	NCT02124460
Official title	Improving childhood obesity outcomes: testing best practices of positive outliers
Stated purpose of study	“The primary specific aims are to examine the extent to which the intervention, compared to the control condition, results in: A smaller age-associated increase in BMI over a 12-month period Improved parental and child ratings of pediatric health-related quality of life.”

NCT02124460 (Continued)

Notes	This study is ongoing, but not recruiting participants (as of March 2016)
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NCT02258126

Trial name or title	Acronym: EFIGRO
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: <ul style="list-style-type: none"> • non-alcoholic fatty liver disease • obesity • metabolic syndrome Enrolment: 160 Inclusion criteria: <ul style="list-style-type: none"> • 9-11 years • overweight or obesity status Exclusion criteria: <ul style="list-style-type: none"> • medical conditions that hamper their participation in the exercise programme • secondary obesity
Interventions	Intervention: multidisciplinary intervention programme - education programme, behavioural advice, supervised exercise Control: healthy behaviour-changing education including supportive therapy and behavioural advice for both children and parents to improve nutrition and physical activity
Outcomes	Hepatic fat (primary), insulin sensitivity, serum lipid profile, liver enzymes, dietary habits, physical activity, body composition, blood pressure, leptin, adiponectin, C-reactive protein (CRP)
Starting date	Start date: November 2014 Completion date: June 2018
Contact information	Responsible party/principal investigator: Idoia Labayen, Department of Nutrition and Food Sciences, Faculty of Pharmacy, University of the Basque Country, Spain
Study identifier	NCT02258126
Official title	The effect of exercise on hepatic fat in overweight children; the EFIGRO Study
Stated purpose of study	“The objective of the present study is to evaluate the effect of 6 months exercise intervention program on hepatic fat fraction in overweight children”
Notes	Recruiting participants (as of March 2016)

Trial name or title	Acronym: H4K
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: double-blind (caregiver, investigator, outcomes assessor) Primary purpose: treatment
Participants	Condition: paediatric obesity Enrolment: estimated 460 Inclusion criteria: <ul style="list-style-type: none"> • aged 6-11 years • identified as Hispanic (by parent/guardian) • overweight or obese (85th to < 99th percentile for age and gender) • parent/guardian to participate in intervention Exclusion criteria: <ul style="list-style-type: none"> • child who has a mental, emotional, or physical handicap which may interfere with participation • cardiovascular, pulmonary, or digestive disease diagnosis • parent without a cell phone, or parent unable/unwilling to receive text messages • child or parent planning to move from the local area during study
Interventions	Intervention: experimental: paediatric obesity management (standard care plus counselling session face-to face and over the telephone, newsletters, text messages, information on community events) Control: active comparator: standard care - brief behavioural counselling and education materials
Outcomes	Weight (primary), waist circumference (primary), BMI z score (primary), fasting insulin, fasting glucose, cholesterol, MVPA assessed by accelerometry, consumption of sugar-sweetened beverages, consumption of fruit and vegetables
Starting date	Start date: January 2015 Completion date: October 2018 (final assessment)
Contact information	Responsible party/principal investigator: Deborah Parra-Medina, The University of Texas Health Science Center at San Antonio, USA
Study identifier	NCT02343367
Official title	Pediatric obesity management intervention trial for Hispanic families
Stated purpose of study	“Our proposed randomized controlled trial, the Health4Kids (H4K) Trial for Hispanic Families, aims to improve Hispanic children’s body composition by testing a comprehensive, culturally and linguistically relevant, family-oriented intervention for overweight and obese (body mass index (BMI) between the 85th and 99.9th (<99th) percentile for age and gender) Hispanic children ages 6-11 in pediatric clinics in San Antonio, Texas, a largely Hispanic city.”
Notes	Currently recruiting participants (March 2016)

[NCT02560493](#)

Trial name or title	Acronym: GameSquad
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: single-blind (outcome assessor) Primary purpose: treatment
Participants	Condition: obesity Enrollment: target 46 Inclusion criteria: <ul style="list-style-type: none">• aged 10-12 years• overweight or obese (according to CDC charts)• boys and girls• at least 1 family member willing to undertake 3 h/week exergaming Exclusion criteria: <ul style="list-style-type: none">• pregnancy• impairments of normal ambulation• previous cardiovascular disease, muscular-skeletal injury or epilepsy
Interventions	Intervention: 3 h/week of exergame play and encouraged to achieve recommended 60 active min/d Control: no intervention
Outcomes	Primary outcome: BMI z score over 6 months Secondary outcomes: body fat, blood pressure, physical activity, diet and health behaviours over 6 months
Starting date	Start date: October 2015 Completion date: March 2017
Contact information	Responsible party/principal investigator: Amanda Staiano, Principal Investigator, Pennington Biomedical Research Center
Study identifier	NCT02560493
Official title	Gaming technology to encourage healthy weight and activity in youth
Stated purpose of study	“1) establishing the efficacy of exergaming to reduce BMIz among overweight and obese children and 2) demonstrating the potential of exergaming to reduce body fat and improve children’s cardiovascular health.”
Notes	Study has recruited but is ongoing

NCT02573142

Trial name or title	Acronym: BCHF
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrollment: estimated: 100 Inclusion criteria: <ul style="list-style-type: none"> • aged 5-11 years • boys and girls • BMI \geq 95th centile Exclusion criteria: <ul style="list-style-type: none"> • “Inability to read and write in English; Family currently has paid membership to a gym or fitness center; Parent with severe medical or mental health condition limiting ability to attend appointments; Child with severe medical or mental health condition limiting ability to attend appointments or participate in behavioral therapies; Parent and child live greater than 30 miles (48.2km) from the Duke Healthy Lifestyles clinic; Plan to move out of state in next 6 months; Child with medical condition as cause of obesity (e.g., hypothyroidism, Cushing’s Syndrome, Prader-Willi syndrome, drug-induced obesity)”
Interventions	Intervention: Bull City Fit Intervention, where participants will receive standard of care clinical treatment in the Duke Healthy Lifestyles clinic and unlimited access to a community-based wellness programme that includes physical fitness activities and cooking classes Control: This active control is comprised of education only, where participants will receive standard of care clinical treatment in the Duke Healthy Lifestyles clinic and educational materials describing community-based resources for physical activity and how to access them
Outcomes	Primary outcome: BMI 3 and 6 months post enrolment Secondary outcomes: adherence, health habits and cardiovascular fitness at 3 and 6 months post enrolment
Starting date	Start date: October 2015 Completion date: anticipated: October 2017
Contact information	Principal investigator: Sarah C Armstrong, sarah.c.armstrong@duke.edu
Study identifier	NCT02573142
Official title	Integrated child obesity treatment study: Bull City Healthy and Fit (BCHF)
Stated purpose of study	“The primary aim of this study is to reduce body mass index (BMI) among children ages 5-11 who are obese by integrating behavioral treatment strategies in both clinic (Healthy Lifestyles) and community (Bull City Fit) settings.”
Notes	Currently still recruiting

Trial name or title	Implementing Prevention Plus for childhood overweight and obesity in food secure and insecure families
Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: single-blind (outcome assessor) Primary purpose: treatment</p>
Participants	<p>Condition: obesity Enrollment: target 120 Inclusion criteria:</p> <ul style="list-style-type: none"> ● 4-10 years ● boys and girls ● patients at designated clinics ● caregiver willing to participate <p>Exclusion criteria:</p> <ul style="list-style-type: none"> ● caregiver not able to speak English
Interventions	<p>Intervention: “PP+: Following baseline assessment, children will continue to receive standard care at CHS and the monthly newsletter. Additionally, each family will be provided with a scale; wall growth chart to measure height; a BMI wheel to calculate BMI; a BMI-for-age growth chart; a binder for intervention materials; a self-monitoring diary to record child’s monthly height, weight, BMI and BMI percentile; and picture-based diaries to monitor daily energy balance behaviours. Family materials provided at each session will outline a process to measure growth and include information about how children grow, as well as cover behavioral parenting strategies to assist with changing child behavior for energy balance behaviors. Families will meet in person with a BHC at the CHS clinic in which they receive care for 30 minutes during months 1, 3, and 5. In these sessions, child height and weight will be taken, and BMI will be plotted on the BMI-for-age growth chart. Families will receive feedback about growth and the weight status of their child. Additionally, the session materials will be reviewed and behavioral parenting strategies will be encouraged to aid with changing two dietary and two leisure-time activity (energy balance) behaviors of the child. As is traditional in a family-based approach, the caretaker will also change the same energy balance behaviors as the child, as adult caretakers can then model healthy behaviors for the child, assisting the child in learning the new weight-related behaviors.¹³ Thus, both the caretaker and child will be encouraged to change and self-monitor energy balance behaviors with the use of the picture-based diaries. During months 2, 4, and 6, BHCs will complete a 20-minute phone call with the caretaker. Caretakers will be asked to measure the height and weight of their child, calculate BMI and plot it on the BMI-for-age growth chart prior to the call. During the call, the BHC will provide feedback on the changes in child growth since the previous contact. Additionally, the BHC will discuss the family’s progress on achieving child and caretaker energy balance behavior goals and implementation of behavioral parenting strategies. The child’s energy balance behavioral goals will be to consume < 3 sugar-sweetened beverage (e.g., regular carbonated soft drinks, sports drinks, lemonades, ice teas, flavoured milk, juice drinks < 100% juice, and punches) servings /wk, ≥ 1 ½ cups/day of whole vegetables and ≥ 1 cup/day of whole fruit, engage in ≥ 60 minutes/day of moderate- to vigorous-intensity physical activity, and reduce TV viewing to < 2 hours/day. The caretaker’s energy balance behavioral goals will be to consume < 3 sugar-sweetened beverage servings/wk, ≥ 2 ½ cups/day of whole vegetables and ≥ 1 ½ cups/day of whole fruit, engage in ≥ 150 minutes of moderate- to vigorous-intensity physical activity per week, and reduce TV viewing to < 10 hours/wk. To increase self-efficacy, the goals will be incrementally increased, with families implementing the full programme goals at month four. Additionally, children and caretakers will be asked to achieve at least three of the five goals each day (child) or week (adult caretaker).”</p>

NCT02684214 (Continued)

	<p>Control: “PP: This condition will be identical to PP+ except that caretakers will not receive any energy balance behavior goals. Additionally, the caretaker will not self-monitor energy balance behaviors. The focus will be on all other behavioral parenting strategies to assist the child with making changes in the targeted behaviors (i.e., stimulus control, positive reinforcement, and assisting child in self-monitoring energy-balance behaviors).”</p> <p>NB both conditions will be given to high and low household food security</p>
Outcomes	<p>Primary outcomes: baseline to 6 month: demographics, weight history, weight, child and care-giver dietary intake, activity levels, quality control, parent weight history, height, BMI, BMI z score</p> <p>Secondary outcomes: participant rate and characteristics of non participators, programme adherence, implementation costs, programme sustainability</p>
Starting date	<p>Start date: April 2016</p> <p>Completion date: April 2018</p>
Contact information	<p>Responsible party/principal investigator: Hollie Raynor, University of Tennessee, USA</p>
Study identifier	<p>NCT02684214</p>
Official title	<p>Not stated</p>
Stated purpose of study	<p>Not stated</p>
Notes	<p>Trial only just started</p>

NCT02711488

Trial name or title	<p>Acronym: PAAPAS-DC</p>
Methods	<p>Type of study: interventional</p> <p>Allocation: randomised</p> <p>Intervention model: parallel</p> <p>Masking: single-blind (outcome assessors)</p> <p>Primary purpose: treatment</p>
Participants	<p>Condition: obesity</p> <p>Enrollment: estimated: 3000</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • 9-15 years • boys and girls • parental consent to participate <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • pregnancy
Interventions	<p>Intervention: participants will be subject to primary prevention activities at school level combined with secondary prevention at home</p> <p>Control: no intervention</p>

NCT02711488 (Continued)

Outcomes	Primary outcome: BMI over 1 year Secondary outcomes: body composition, physical activity, diet and adherence over 1 year
Starting date	Start date: March 2016 Completion date: anticipated December 2016
Contact information	Responsible party/principal investigator: Rosely Sichieri, MD, PhD. Full Professor of Epidemiology, Rio de Janeiro State University, Brasil
Study identifier	NCT02711488
Official title	Managing adolescent obesity at local level by combining primary and secondary intervention (PAAPAS-DC)
Stated purpose of study	No formal aims provided
Notes	Not yet completed, mean age of participants at baseline will determine whether this trial is included in this review or the adolescent review

NCT02720302

Trial name or title	Acronym: TeleSOFT
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrollment: target 120 Inclusion criteria: <ul style="list-style-type: none"> • aged 9-12 years • boys and girls • overweight but not obese according to the IOTF classification Exclusion criteria: <ul style="list-style-type: none"> • non Swedish speaking • monogenic obesity • present at school less than 80% in the previous year • no foster care for the child or siblings
Interventions	Intervention: SOFT - a programme based on 'systemic and solution-focused theories to change lifestyle', shown to facilitate positive effects on children in terms of obesity, physical fitness, self-esteem and family functioning Control: TeleSOFT - where therapists communicate with the overweight child and family by the SOFT method at distance via video

NCT02720302 (Continued)

Outcomes	Primary outcome: BMI z score at baseline and 12 months Secondary outcomes: change in body fat, activity levels, metabolic health, session rating and dietary habits
Starting date	Start date: March 2016 Completion date: anticipated June 2021
Contact information	Responsible party/principal investigator: Inge Lissau, inlis18@gmail.com
Study identifier	NCT02720302
Official title	Treatment of overweight in children on distance. A comparison between consultations on the hospital with video-consultations on distance
Stated purpose of study	“aim to treat overweight in children 9-11 years of age”
Notes	Currently recruiting

NCT02773823

Trial name or title	A behavior intervention study on cardiovascular health among chinese obese schoolchildren
Methods	Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment
Participants	Condition: obesity Enrollment: target 200 Inclusion criteria: <ul style="list-style-type: none"> • aged 8-12 years • obese • boys and girls Exclusion criteria: <ul style="list-style-type: none"> • history of cardiovascular disease • disability
Interventions	Intervention: diet advice and activity intervention (60 min/d of sport 5 d/week for 8 months) Control: no intervention
Outcomes	Primary outcome: body weight, BMI, blood pressure, blood lipids, glucose and cardiorespiratory fitness at 8 months Secondary outcomes: well-being and depression at 8 months
Starting date	Start date: November 2015 Completion date: June 2017 (anticipated)

NCT02773823 (Continued)

Contact information	Responsible party/principal investigator: Qiqiang He, 4657473@qq.com
Study identifier	NCT02773823
Official title	A comprehensive intervention study on Klotho gene methylation and cardiovascular risk factors
Stated purpose of study	No formal aim stated
Notes	Study not completed

RBR-8ttw64

Trial name or title	Effects of dietary guidance in children attending outpatient preventive cardiology: randomized clinical trial
Methods	<p>Type of study: interventional Allocation: randomised Intervention model: parallel Masking: open label Primary purpose: treatment</p>
Participants	<p>Condition: overweight, obesity, heart disease Enrolment: 74 Inclusion criteria:</p> <ul style="list-style-type: none"> • aged 7-11 years • overweight or obese according to the criteria of the World Health Organization • boys and girls • parents or caregivers signed an informed consent form • reside in the state of Rio Grande do Sul <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • children with neurological disorders that interfere with learning • cognitive deficits e.g. Disorder Attention Deficit Hyperactivity Disorder • contraindications for physical activity group • using drugs that interfere with the body weight or lipid profile, such as statins, ritonavir, furosemide, hydrochlorothiazide, propranolol, nadolol, prednisolone among others
Interventions	<p>Intervention: nutritional education group Control: conventional treatment with a nutritionist</p>
Outcomes	Total cholesterol (primary), BMI
Starting date	<p>First enrolment: October 2013 Last enrolment: April 2014</p>
Contact information	Responsible party/principal investigator: Vanessa Minossi, Instituto de Cardiologia Fundação Universitária de Cardiologia- IC/FUC, Brazil, pellanda.pesquisa@gmail.com
Study identifier	RBR-8ttw64

Official title	Effects of dietary guidance in children attending outpatient preventive cardiology: randomized clinical trial
Stated purpose of study	“The objective of this study is to evaluate the effectiveness of an innovative, simple and cost effective educational program to improve eating habits, physical activity and the knowledge about healthy habits in children, as well as in their families, as compared to routine outpatient care.”
Notes	Recruiting (as of March 2016)

A1c (HbA1c): haemoglobin; ALT: alanine aminotransferase; BIA: bioelectrical impedance analysis; BMI: body mass index; CDC: United States Centers for Disease Control and Prevention; CHS: Community Health Systems; CVD: cardiovascular disease; DEXA: dual energy X-ray absorptiometry; HDL-cholesterol: high density lipoprotein cholesterol; HOMA: homeostasis assessment model; hs-CRP: high-sensitivity C-reactive protein; IOTF: International Obesity Task Force; LDL-cholesterol: low density lipoprotein cholesterol; MVPA: moderate-to-vigorous physical activity; PA: physical activity; PP: Prevention Plus; VO2 max: maximum volume of oxygen; WHO: World Health Organization

DATA AND ANALYSES

Comparison 1. Behaviour-changing interventions versus no treatment/usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in BMI (all trials)	24	2785	Mean Difference (IV, Random, 95% CI)	-0.53 [-0.82, -0.24]
2 Change in BMI z score (all trials)	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
3 Change in weight (all trials)	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
4 Serious adverse events	31	4096	Risk Ratio (M-H, Random, 95% CI)	0.57 [0.17, 1.93]
5 Health-related quality of life (parent-report measures)	5	718	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.06, 0.32]
5.1 PedsQL caregiver-report	4	526	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.13, 0.40]
5.2 CHQ-PF50 - global score, parental report	1	192	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.14, 0.42]
6 Health-related quality of life (child-report measures)	3	164	Std. Mean Difference (IV, Random, 95% CI)	0.15 [-0.34, 0.64]
6.1 PedsQL child-report	2	142	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.60, 0.79]
6.2 KINDL-R child-report	1	22	Std. Mean Difference (IV, Random, 95% CI)	0.33 [-0.51, 1.18]
7 Self-esteem (Harter global score)	2	144	Mean Difference (IV, Random, 95% CI)	0.19 [-0.04, 0.42]
8 Waist circumference	11	1325	Mean Difference (IV, Random, 95% CI)	-2.41 [-3.59, -1.23]
9 Overweight	3	347	Mean Difference (IV, Random, 95% CI)	-3.27 [-7.47, 0.92]
10 Body fat	10		Mean Difference (IV, Random, 95% CI)	Subtotals only
10.1 Bioelectrical impedance	5	1004	Mean Difference (IV, Random, 95% CI)	-1.25 [-2.62, 0.12]
10.2 Dual energy X-ray absorptiometry	5	443	Mean Difference (IV, Random, 95% CI)	-1.04 [-2.88, 0.80]
11 Diet	2	168	Mean Difference (IV, Random, 95% CI)	-161.53 [-583.79, 260.73]
12 Television viewing	2	55	Mean Difference (IV, Random, 95% CI)	-6.60 [-12.88, -0.31]
13 Physical activity (accelerometer MVPA)	6	744	Mean Difference (IV, Random, 95% CI)	-0.76 [-5.30, 3.78]
14 Change in BMI - type of control	24	2785	Mean Difference (IV, Random, 95% CI)	-0.53 [-0.82, -0.24]
14.1 Intervention versus no treatment	11	1452	Mean Difference (IV, Random, 95% CI)	-0.43 [-0.87, -0.00]
14.2 Intervention versus usual care	13	1333	Mean Difference (IV, Random, 95% CI)	-0.67 [-1.12, -0.21]
15 Change in BMI z score - type of control	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
15.1 No treatment	15	1709	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.12, 0.01]
15.2 Usual care	22	2310	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.11, -0.02]
16 Change in weight - type of control	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
16.1 No treatment	7	906	Mean Difference (IV, Random, 95% CI)	-1.73 [-2.47, -0.98]
16.2 Usual care	10	868	Mean Difference (IV, Random, 95% CI)	-1.31 [-1.84, -0.78]
17 Change in BMI - type of intervention	24	2785	Mean Difference (IV, Random, 95% CI)	-0.53 [-0.82, -0.24]
17.1 Diet only	1	73	Mean Difference (IV, Random, 95% CI)	-0.12 [-0.85, 0.61]

Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years (Review)

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17.2 Physical activity only	4	443	Mean Difference (IV, Random, 95% CI)	-0.29 [-0.50, -0.09]
17.3 Diet and physical activity	2	209	Mean Difference (IV, Random, 95% CI)	-1.03 [-3.43, 1.38]
17.4 Diet and behavioural therapy	1	39	Mean Difference (IV, Random, 95% CI)	-0.7 [-3.65, 2.25]
17.5 Physical activity and behavioural therapy	1	230	Mean Difference (IV, Random, 95% CI)	-0.01 [-1.29, 1.27]
17.6 Diet, physical activity and behavioural therapy	15	1791	Mean Difference (IV, Random, 95% CI)	-0.67 [-1.12, -0.23]
18 Change in BMI z score - type of intervention	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
18.1 Diet only	1	73	Mean Difference (IV, Random, 95% CI)	-0.05 [-0.17, 0.07]
18.2 Physical activity only	3	365	Mean Difference (IV, Random, 95% CI)	-0.05 [-0.23, 0.14]
18.3 Diet and physical activity	7	577	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.10, 0.04]
18.4 Diet and behavioural therapy	2	152	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.16, 0.03]
18.5 Physical activity and behavioural therapy	1	230	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.26, 0.20]
18.6 Diet, physical activity and behavioural therapy	24	2622	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.13, -0.02]
19 Change in weight - type of intervention	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
19.1 Diet only	1	73	Mean Difference (IV, Random, 95% CI)	-0.12 [-2.45, 2.21]
19.2 Physical activity only	3	422	Mean Difference (IV, Random, 95% CI)	-1.34 [-1.94, -0.73]
19.3 Diet and physical activity	1	125	Mean Difference (IV, Random, 95% CI)	-0.15 [-3.81, 3.51]
19.4 Physical activity and behavioural therapy	1	230	Mean Difference (IV, Random, 95% CI)	0.21 [-4.29, 4.71]
19.5 Diet, physical activity and behavioural therapy	11	924	Mean Difference (IV, Random, 95% CI)	-1.76 [-2.41, -1.11]
20 Change in BMI - attrition bias	24	2785	Mean Difference (IV, Random, 95% CI)	-0.53 [-0.82, -0.24]
20.1 High	4	238	Mean Difference (IV, Random, 95% CI)	-0.47 [-1.04, 0.10]
20.2 Low	15	1910	Mean Difference (IV, Random, 95% CI)	-0.50 [-0.93, -0.07]
20.3 Unclear	5	637	Mean Difference (IV, Random, 95% CI)	-0.72 [-1.45, 0.01]
21 Change in BMI z score - attrition bias	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
21.1 Low	17	1745	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.16, -0.01]
21.2 Unclear	9	897	Mean Difference (IV, Random, 95% CI)	-0.05 [-0.13, 0.03]
21.3 High	11	1377	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.06, 0.01]
22 Change in weight - attrition bias	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
22.1 Low	9	986	Mean Difference (IV, Random, 95% CI)	-1.20 [-1.73, -0.67]
22.2 Unclear	4	553	Mean Difference (IV, Random, 95% CI)	-1.73 [-3.54, 0.07]
22.3 High	4	235	Mean Difference (IV, Random, 95% CI)	-1.99 [-2.80, -1.17]
23 Change in weight - setting	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
23.1 Schools	1	55	Mean Difference (IV, Random, 95% CI)	-1.20 [-4.20, 1.80]
23.2 Community	1	78	Mean Difference (IV, Random, 95% CI)	-1.37 [-1.99, -0.75]
23.3 Child's home	3	625	Mean Difference (IV, Random, 95% CI)	-0.26 [-1.97, 1.45]
23.4 Primary care	2	191	Mean Difference (IV, Random, 95% CI)	-2.02 [-5.28, 1.24]
23.5 Secondary care (outpatient)	4	248	Mean Difference (IV, Random, 95% CI)	-1.52 [-2.77, -0.27]
23.6 Research clinic	4	374	Mean Difference (IV, Random, 95% CI)	-1.88 [-2.75, -1.02]
23.7 Mixed	2	203	Mean Difference (IV, Random, 95% CI)	-0.54 [-3.17, 2.08]

24	Change in BMI z score - setting	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.03]
	24.1 Schools	2	76	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.17, 0.15]
	24.2 Community	2	76	Mean Difference (IV, Random, 95% CI)	0.04 [-0.04, 0.11]
	24.3 Child's home	6	998	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.12, -0.00]
	24.4 Primary care	8	864	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.12, -0.01]
	24.5 Secondary care (outpatient)	10	583	Mean Difference (IV, Random, 95% CI)	-0.12 [-0.25, 0.01]
	24.6 Hospital inpatient	1	523	Mean Difference (IV, Random, 95% CI)	0.02 [-0.06, 0.10]
	24.7 Research clinic	4	388	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.07, 0.02]
	24.8 Mixed	5	511	Mean Difference (IV, Random, 95% CI)	-0.09 [-0.16, -0.01]
25	Change in BMI - setting	24	2785	Mean Difference (IV, Random, 95% CI)	-0.55 [-0.85, -0.26]
	25.1 Schools	1	21	Mean Difference (IV, Random, 95% CI)	-0.57 [-4.94, 3.80]
	25.2 Community	1	78	Mean Difference (IV, Random, 95% CI)	-0.53 [-1.05, -0.01]
	25.3 Child's home	4	667	Mean Difference (IV, Random, 95% CI)	-0.32 [-0.86, 0.22]
	25.4 Primary care	6	1055	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.35, 0.14]
	25.5 Secondary care (outpatient)	7	384	Mean Difference (IV, Random, 95% CI)	-1.46 [-2.42, -0.50]
	25.6 Research clinic	3	295	Mean Difference (IV, Random, 95% CI)	-0.24 [-0.86, 0.37]
	25.7 Mixed	3	285	Mean Difference (IV, Random, 95% CI)	-0.79 [-1.87, 0.30]
26	Change in BMI - post-intervention follow-up	24	2785	Mean Difference (IV, Random, 95% CI)	-0.53 [-0.82, -0.24]
	26.1 No post-intervention follow-up	15	1573	Mean Difference (IV, Random, 95% CI)	-0.68 [-1.10, -0.27]
	26.2 Post-intervention follow-up < 6 months	3	153	Mean Difference (IV, Random, 95% CI)	-1.49 [-2.93, -0.05]
	26.3 Post-intervention follow-up 6 months to < 12 months	2	282	Mean Difference (IV, Random, 95% CI)	-0.59 [-2.34, 1.15]
	26.4 Post-intervention follow-up 12 months or more	4	777	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.34, 0.20]
27	Change in BMI z score - post-intervention follow-up	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
	27.1 No post-intervention follow-up	21	2278	Mean Difference (IV, Random, 95% CI)	-0.09 [-0.15, -0.04]
	27.2 Post-intervention follow-up < 6 months	6	228	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.15, 0.04]
	27.3 Post-intervention follow-up 6 months to < 12 months	3	168	Mean Difference (IV, Random, 95% CI)	0.04 [-0.09, 0.16]
	27.4 Post-intervention follow-up 12 months or more	7	1345	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.06, 0.03]
28	Change in weight - post-intervention follow-up	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
	28.1 No post-intervention follow-up	12	1365	Mean Difference (IV, Random, 95% CI)	-1.49 [-1.94, -1.04]
	28.2 Post-intervention follow-up < 6 months	1	32	Mean Difference (IV, Random, 95% CI)	-0.50 [-9.28, 8.29]
	28.3 Post-intervention follow-up 6 months to < 12 months	1	40	Mean Difference (IV, Random, 95% CI)	-4.60 [-17.49, 8.29]
	28.4 Post-intervention follow-up 12 months or more	3	337	Mean Difference (IV, Random, 95% CI)	-1.01 [-2.49, 0.47]
29	Change in BMI - type of parental involvement	24	2785	Mean Difference (IV, Random, 95% CI)	-0.53 [-0.82, -0.24]

29.1 Parent involvement	20	2217	Mean Difference (IV, Random, 95% CI)	-0.65 [-1.04, -0.25]
29.2 No parental involvement	3	422	Mean Difference (IV, Random, 95% CI)	-0.29 [-0.50, -0.09]
29.3 Parent targeted	1	146	Mean Difference (IV, Random, 95% CI)	0.0 [-0.81, 0.81]
30 Change in BMI z score - type of parental involvement	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
30.1 Parent involvement	32	2927	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.11, -0.03]
30.2 No parental involvement	2	344	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.24, 0.19]
30.3 Parent targeted	3	748	Mean Difference (IV, Random, 95% CI)	0.01 [-0.06, 0.08]
31 Change in weight - type of parental involvement	17	1774	Mean Difference (IV, Random, 95% CI)	-1.45 [-1.88, -1.02]
31.1 Parent involvement	13	1273	Mean Difference (IV, Random, 95% CI)	-1.32 [-2.09, -0.55]
31.2 No parental involvement	3	422	Mean Difference (IV, Random, 95% CI)	-1.34 [-1.94, -0.73]
31.3 Parent targeted	1	79	Mean Difference (IV, Random, 95% CI)	-2.0 [-3.02, -0.98]
32 Change in BMI z score - baseline BMI z score	37	4019	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.10, -0.02]
32.1 Baseline BMI z score < 2.67 units	29	3549	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.11, -0.03]
32.2 Baseline BMI z score ≥ 2.67 units	8	470	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.11, 0.05]

Comparison 2. Behaviour-changing interventions plus component versus behaviour-changing intervention without component

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in BMI	4	195	Mean Difference (IV, Random, 95% CI)	-0.75 [-1.42, -0.09]
2 Change in BMI z score	5	212	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.10, 0.04]
3 Change in weight	4	106	Mean Difference (IV, Random, 95% CI)	1.59 [-4.58, 7.77]

Comparison 3. Cluster RCTs versus comparator

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in BMI	2	629	Mean Difference (IV, Random, 95% CI)	-0.49 [-1.24, 0.27]

Comparison 4. Maintenance intervention versus no treatment/usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in BMI z score	2	263	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.19, 0.04]

ADDITIONAL TABLES

Table 1. Overview of study populations

Trial (trial design)	Intervention(s) and comparator(s)	Sample size ^a	Screened/eligible (N)	Randomised (N)	ITT (N)	Analysed (N)	Finishing trial (N)	Randomised finishing trial (%)	Follow-up (extended follow-up) ^b
NCT02436: (parallel RCT)	I: exergaming and didactic healthy teaching	-	-	60	-	35	35	58.3	6 months
	C: didactic healthy teaching	-	-	24	-	13	13	54.2	
	total:			84	-	48	48	57.1	
Ho 2016 (parallel RCT)	I: standard nutrition counselling plus portion control equipment	44	185	48	48	37	37	77.1	6 months
	C: standard nutrition counselling	44		51	51	36	36	70.6	
	total:			99	99	73	73	73.7	
Warschburg 2016 (parallel RCT)	I: parental CBT training group plus child inpa-	250	1595	336	249	249	168	50.0	13 months

Table 1. Overview of study populations (Continued)

	tient inter- vention								
	C: parental informa- tion-only group plus child inpa- tient inter- vention	250		350	274	274	268	76.6	
	total:			686	523	523	436	63.6	
Epstein 2015 (parallel RCT)	I: family- based treatment + variety of high en- ergy-dense foods	-	-	13	13	13	-	-	25 weeks
	C: family- based treatment only	-		11	11	11	-	-	
	total:			24	24	24	-	-	
Larsen 2015 (parallel RCT)	I: edu- cation pro- gramme in addition to health con- sultations	20	99	45	40	40	16	36	2 years
	C: health consulta- tions only	20		35	34	34	10	29	
	total:			80	74	74	26	33	
Serra- Paya 2015 (parallel RCT)	I: Nereu group	50	123	54	54	54	44	81.5	8 months
	C: coun- selling group	50		59	59	59	45	76.3	
	total:			113	113	113	89	78.8	

Table 1. Overview of study populations (Continued)

Taveras 2015 (cluster RCT)	I1: computerised point-of-care alerts plus direct-to-parent outreach and support	680	2242	171	171	171	170	99.4	1 year
	I2: computerised point-of-care alerts only			194	194	194	194	100	
	C: usual care			184	184	184	183	99.5	
	total:			549	549	549	547	99.6	
Taylor 2015 (parallel RCT)	I: tailored package	125	1093	104	-	91	89	85.6	2 years
	C: usual care	125		102	-	90	92	90.2	
	total:			206	-	181	181	87.9	
Berry 2014 (cluster RCT)	I: nutrition and exercise education and coping skills intervention	179	2608	189	152	152	-	-	18 months
	C: waiting list control	179		169	145	145	-	-	
	total:			358	297	297	-	-	
Boutelle 2014 (parallel RCT)	I: Regulation of Cues (ROC) programme	-	96	22	-	21	21	95.5	6 months

Table 1. Overview of study populations (Continued)

	C: control group	-		22	-	18	18	81.8	
	total:			44	-	39	39	88.6	
Hamil-ton-Shield 2014 (parallel RCT)	I: standard care plus Mandolean training	36	10230	26	-	-	0	0	5 months (terminated before end-point of 12 months)
	C: standard care only			35	-	-	0	0	
	total:			61	-	-	0	0	
Looney 2014 (parallel RCT)	I1: newsletter and growth monitoring plus behavioural counselling	-	65	7	7	7	6	85.7	6 months
	I2: newsletter and growth monitoring	-		7	7	7	7	100	
	C: newsletter only	-		8	8	8	7	87.5	
	total:			22	22	22	20	90.9	
Maddison 2014 (parallel RCT)	I: SWITCH intervention group	135	-	127	127	117	117	92.1	24 weeks
	C: control group	135		124	124	113	113	91.1	
	total:			251	251	230	230	91.6	

Table 1. Overview of study populations (Continued)

Markert 2014 (parallel RCT)	I: telephone-based adiposity prevention for families (TAFF)	112	4005	154	145	145	54	35.1	1 year
	C: control group	112		149	144	144	113	75.8	
	total:			303	289	289	167	55.1	
Arauz Boudreau 2013 (parallel RCT)	I: behaviour-changing intervention and coaching on behaviour-changing behaviours	21	63	23	-	14	14	60.9	6 months
	C: waiting-list control	21		18	-	12	12	66.7	
	total:			41	-	26	26	63.4	
Davis 2013 (parallel RCT)	I: telemedicine intervention	20	96	31	-	20	20	64.5	8 months
	C: physician-visit intervention	20		27	-	22	22	81.5	
	total:			58	-	42	42	72.4	
Davoli 2013 (parallel RCT)	I: family paediatrician-led motivational interviewing	85	795	187	186	186	167	89.3	2 years

Table 1. Overview of study populations (Continued)

	C: usual care plus a booklet on obesity prevention	85		185	185	185	170	91.9	
	total:			372	371	371	337	90.6	
Lochrie 2013 (parallel RCT)	I: family-based intervention	60	150	65	32	32	32	49.2	12 months
	C: education session	60		65	40	40	40	61.5	
	total:			130	72	72	72	55.4	
Mirza 2013 (parallel RCT)	I: low-glycaemic load dietary group	42	291	57	57	57	33	57.9	2 years
	C: conventional low-fat dietary group	42		56	56	56	31	55.4	
	total:			113	113	113	64	56.6	
O'Connor 2013 (parallel RCT)	I: 'Helping Hand' obesity intervention	40	302	20	-	18	18	90.0	7 months
	C: waiting list control			20	-	16	16	80.0	
	total:			40	-	34	34	85.0	
Saelens 2013 (parallel RCT)	I: self-directed approach	29	195	43	35	25	-	-	29 months

Table 1. Overview of study populations (Continued)

	total:			89	72	59	46	51.7	
Siwik 2013 (cross-over RCT, with first phase analysed only)	I: 'Choices' group of- fice- visit inter- vention	40	75	-		15	15	-	6 months
	C: lagged control group			-		17	17	-	
	total:			35		32	32	91.4	
Vann 2013 (parallel RCT)	I1: pedome- ter + DVD group	-	-	7	-	4	4	57.1	6 months
	I2: pedometer group	-	-	7	-	4	4	57.1	
	I3: DVD group	-	-	7	-	3	3	42.9	
	C: control group	-	-	7	-	3	3	42.9	
	total:			28	-	14	14	50.0	
Wake 2013 (parallel RCT)	I: Hop- SCOTCH (the shared care obesity trial) inter- vention	172	199	62	62	56	56	90.3	15 months
	C: usual care			56	56	51	51	91.1	
	total:			118	118	107	107	90.7	
Croker 2012 (parallel RCT)	I: family- based be- havioural treatment	48	99	37	37	33	22	59.5	6 months

Table 1. Overview of study populations (Continued)

	C: waiting list control			35	35	27	27	77.1	
	total:			72	72	60	49	68.0	
de Niet 2012 (parallel RCT)	I: short message service maintenance treatment and behaviour-changing treatment	64	144	73	73	73	63	86.3	9 months
	C: behaviour-changing treatment only	64		68	68	67	47	70.1	
	total:			141	141	140	110	78.6	
Eddy Ives 2012 (parallel RCT)	I: dietary and physical exercise recommendations during 6 sessions	110	211	87	61	61	61	70.1	12 months
	C: dietary and physical exercise recommendations at 2 sessions only	110		87	64	64	64	73.6	
	total:			174	125	125	125	71.8	
Kirk 2012 (parallel RCT)	I1: low carbohydrate diet plus group exercise/edu-	-	-	35	35	35	25	71.4	12 months

Table 1. Overview of study populations (Continued)

	cation sessions								
	I2: reduced glycaemic load diet plus group exercise/education sessions	-	440	36	36	36	32	88.9	
	C: standard portion-controlled diet plus group exercise/education sessions	-		31	31	31	28	90.3	
	total:			102	102	102	85	83.3	
Lison 2012 (parallel RCT)	I1: hospital clinic group exercise-diet programme	20	120	45	32	32	32	71.1	6 months
	I2: home-based combined exercise-diet programme	20		41	32	32	32	78.0	
	C: control group	20		24	20	20	20	83.3	
	total:			110	84	84	84	76.4	
Waling 2012 (parallel RCT)	I: family-based intervention	82	112	58	48	48	26	44.8	2 years
	C: control group			47	45	45	22	46.8	

Table 1. Overview of study populations (Continued)

	total:			105	93	93	48	45.7	
Wright 2012 (cluster RCT)	I: Kids N Fitness (KNF) intervention	130	335	165	165	91	91	55.2	1 year
	C: general education (GE)			140	140	99	99	70.7	
	total:			305	305	190	190	62.3	
Barkin 2011 (parallel RCT)	I: group - physical activity and goal setting		183	80	-	-	-	-	6 months
	C: standard care counselling and health education session			79	-	-	-	-	
	total:			159	106	72	72	45.3	
Bryant 2011 (parallel RCT)	I: WATCH IT intervention	-	180	35	-	27	27	77.1	12 months
	C: waiting-list control	-		35	-	26	26	74.3	
	total:			70	-	53	53	75.7	
Coppins 2011 (cross-over RCT, with first phase analysed only)	I: multi-component family-focused education package	-	-	35	35	35	28	80.0	12 months
	C: waiting list control			30	30	30	27	90.0	
	total:			65	65	65	55	84.6	

Table 1. Overview of study populations (Continued)

Gunnarsdottir 2011a (parallel RCT)	I: Epstein's family-based behavioural treatment (FBBT)	-	-	8	-	7	7	87.5	-
	C: standard care (waiting-list control)	-	-	8	-	6	6	75.0	
	total:			16	-	13	13	81.3	12 months
Maddison 2011 (parallel RCT)	I: active video game package	165	1932	160	160	160	123	77.0	24 weeks
	C: control group	165		162	162	162	135	83.3	
	total:			322	322	322	258	80.1	
Wafa 2011 (parallel RCT)	I: low intensity intervention	30	365	52	34	34	34	65.4	6 months
	C: waiting-list control	30		55	45	45	45	81.8	
	total:			107	79	79	79	73.8	
Bathrelou 2010 (parallel RCT)	I: behavioural intervention with parental involvement	-	-	24	-	23	16	66.7	18 months
	C: behavioural intervention without parental involvement			23	-	19	16	69.6	

Table 1. Overview of study populations (Continued)

	total:			47	-	42	32	68.1	
Diaz 2010 (parallel RCT)	I: behavioural curriculum plus registered dietitians and physician consultations	26	134	38	33	33 (primary outcomes ITT) 21 (secondary outcomes, completers' analysis)	21	55.3	12 months
	C: physician consultations only	26		38	33	33 (primary outcomes, ITT) 22 (secondary outcomes, completers' analysis)	22	57.9	
	total:			76	66	66 or 43	43	56.6	
Duggins 2010 (parallel RCT)	I: nutrition classes and family YMCA membership	50	98	44	36	36	-	-	12 months
	C: nutrition classes only	50		39	30	30	-	-	
	total:			83	66	66	-	-	
Faude 2010 (parallel RCT)	I: football training programme (FB)	-	-	19	-	11	11	57.9	6 months
	C: established standard sports programme			20	-	11	11	55.0	

Table 1. Overview of study populations (Continued)

	(STD)								
	total:			39	-	22	22	56.4	
Reinehr 2010 (parallel RCT)	I: behaviour-changing intervention	32	80	39	34	34	33	84.6	6 months
	C: waiting-list control	32		32	32	32	27	84.4	
	total:			71	66	66	60	84.5	
Sacher 2010 (parallel RCT)	I: MEND program	40	-	60		37	37	61.7	6 months
	C: control group	40	-	56		45	45	80.4	
	total:			116		82	82	70.7	
Kalarchian 2009 (parallel RCT)	I: family-based, behavioural weight-control group	100	650	97	97	97	81	83.5	18 months
	C: usual care	100		95	95	95	81	85.3	
	total:			192	192	192	162	84.4	
Nowicka 2009 (parallel RCT)	I: summer camp	-	-	20	-	20	20	100	12 months
	C: control group	-	-	28	-	15	15	53.6	
	total:			48	-	35	35	72.9	
Wake 2009 (parallel RCT)	I: LEAP2 behavioural intervention	190	947	139	129	129	115	82.7	12 months

Table 1. Overview of study populations (Continued)

	C: control group	190		119	116	116	115	96.6	
	total:			258	245	245	230	89.1	
Alves 2008 (parallel RCT)	I: exercise programme	32	638	39	39	39	30	76.9	6 months
	C: no care	32		39	39	39	38	97.4	
	total:			78	78	78	68	87.1	
Hughes 2008 (parallel RCT)	I: behavioural programme	34	237	69	45	45	45	65.2	12 months
	C: standard care	34		65	41	41	41	63.1	
	total:			134	86	86	86	64.2	
Weigel 2008 (parallel RCT)	I: active intervention group	-	-	37		36	36	97.3	12 months
	C: control group	-	-	36		30	30	83.3	
	total:			73		66	66	90.4	
Weintraub 2008 (parallel RCT)	I: after-school team sports programme	-	-	9	-	9	9	100	6 months
	C: "Active placebo" control	-	-	12	-	12	12	100	
	total:			21	-	21	21	100	
Berry 2007 (cluster RCT)	I: nutrition and exercise education programme	-	88	40	-	-	-	-	6 months

Table 1. Overview of study populations (Continued)

	plus coping-skills training								
	C: nutrition and exercise education programme only			40	-	-	-	-	
	total:			80	-	-	60	75	
Gillis 2007 (parallel RCT)	I: exercise and diet education with weekly diaries and telephone calls	-	-	14	-	11	11	78.6	6 months
	C: exercise and diet education only	-	-	13	-	7	7	53.8	
	total:			27	-	18	18	66.7	
Kalavainen 2007 (parallel RCT)	I: family-centered group programme	37	83	35	-	34	34	97.1	3 years
	C: routine treatment	37		35	-	34	34	97.1	
	total:			70	-	68	68	97.1	
McCallum 2007 (parallel RCT)	I: LEAP intervention	63	505	81	70	70	70	85.4	15 months
	C: control group	63		82	76	76	76	93.8	
	total:			163	146	146	146	89.6	

Table 1. Overview of study populations (Continued)

Rodearmel 2007 (parallel RCT)	I: 'America on the Move' intervention group	-	-	149	-	95	95	63.8	6 months
	C: self-monitoring group	-	-	149	-	89	89	59.7	
	total:			298	-	184	184	61.7	
Satoh 2007 (parallel RCT)	I: dietary guidance using an easily handled model nutritional balance chart (MNBC)	-	-	29	-	15	15	51.7	6 months
	C: control group	-	-	14	-	8	8	57.1	
	total:			43	-	23	23	53.5	
Wilfley 2007 (parallel RCT)	I1: behavioural skills maintenance group	40	204	51	48	48	42	82.4	2 years
	I2: social facilitation maintenance group	40		50	49	49	43	86.0	
	C: control group	40		49	46	46	37	75.5	
	total:			150	143	143	122	81.3	
Epstein 2005 (parallel RCT)	I: standardised family-	-	77	-	19	19	18	-	24 months

Table 1. Overview of study populations (Continued)

RCT)	based behavioural weight control programme plus reinforcement for increasing alternatives to eating								
	C: standardised family-based behavioural weight control programme only			-	22	22	17	-	
	total:			44	41	41	35	79.5	
Nemet 2005 (parallel RCT)	I: combined dietary and exercise programme	18	-	30	-	20	20	66.7	1 year
	C: control group	18	-	24	-	20	20	83.3	
	total:			54	-	40	40	74.1	
Woo 2004 (parallel RCT)	I1: diet plus supervised structured exercise programme with continuing training	-	-	22	-	22	-	-	1 year

Table 1. Overview of study populations (Continued)

	I2: diet plus supervised structured exercise programme with detraining	-	-	19	-	19	-	-	
	C: diet modification only	-	-	41	-	41	-	-	
	total:			82	-	82	-	-	
Epstein 2001 (parallel RCT)	I: a combination of reducing sedentary behaviour and increasing physical activity	-	-	-	-	-	-	-	12 months
	C: targeting increasing physical activity only	-	-	-	-	-	-	-	
	total:			67	-	56	56	83.6	
Nova 2001 (parallel RCT)	I: enhanced approach	-	-	72	-	50	50	64.9	2 years
	C: routine approach	-	-	114	-	80	80	70.2	
	total:			186	-	130	130	69.9	
Epstein 2000a (parallel RCT)	I1: behavioural weight-control programme	-	162	-	-	17	17	-	24 months

Table 1. Overview of study populations (Continued)

	plus parent and child problem solving								
	I2: behavioural weight-control programme plus child problem solving only			-	-	18	18	-	
	C: standard treatment with no additional problem solving			-	-	17	17	-	
	total:			67	-	52	52	77.6	
Schwingshandl 1999 (parallel RCT)	I: physical activity programme and dietary advice	-	-	14	-	10	10	71.4	1 year
	C: dietary advice only	-	-	16	-	10	10	62.5	
	total:			30	-	20	20	66.7	
Duffy 1993 (parallel RCT)	I: cognitive self-management training plus behaviour therapy	-	-	-	-	9	9	-	6 months
	C: behaviour therapy			-	-	8	8	-	

Table 1. Overview of study populations (Continued)

	apy plus at- tention placebo control methods								
	total:			27	-	17	17	63.0	
Flodmark 1993 (parallel RCT)	I: family therapy	-	-	25	20	20	20	80	2 years
	C: conven- tional treatment	-	-	19	19	19	19	100	
	total:			44	39	39	39	88.6	
Epstein 1985c (parallel RCT)	I: be- haviourally- oriented pro- gramme that em- phasised parent manage- ment	-	-	-	-	-	-	-	12 months
	C: provided equal edu- cation and attention but not be- havioural principles			-	-	-	-	-	
	total:			24	-	-	18	75.0	
Epstein 1985b (parallel RCT)	I: diet and exercise education	-	-	-	-	-	-	-	12 months
	C: diet educa- tion only			-	-	-	-	-	
	total:			23	-	-	19	82.6	

Table 1. Overview of study populations (Continued)

Epstein 1985a (parallel RCT)	I1: diet plus programmed aerobic exercise programme	-	-	-	-	13	13	-	24 months
	I2: diet plus exercise programme	-	-	-	-	12	12	-	
	C: diet plus low-intensity calisthenic exercise programme	-	-	-	-	10	10	-	
	total:			41	-	35	35	85.4	
Epstein 1984a (parallel RCT)	I1: diet-plus-exercise group	-	-	18	-	15	15	83.3	6 months
	I2: diet only	-	-	18	-	18	18	100	
	C: waiting-list control	-	-	17	-	14	14	82.4	
	total:			53	-	47	47	88.7	
Grand total	<i>All interventions</i>			8461^a			5887^d		
	<i>All comparators</i>								<i>All comparators</i>
	<i>All interventions and comparators</i>								<i>All interventions and comparators</i>

- denotes not reported

^aAccording to power calculation in study publication or report.

^bFollow-up under randomised conditions until end of trial or if not available, duration of intervention; extended follow-up refers to follow-up of participants once the original study was terminated as specified in the power calculation.

^c8 studies did not report numbers of randomised participants per intervention/comparator group (Duffy 1993; Epstein 1985a; Epstein 1985b; Epstein 1985c; Epstein 2000a; Epstein 2001; Epstein 2005; Siwik 2013).

^d10 Studies did not report numbers of participants finishing the trial (Barkin 2011; Berry 2007; Berry 2014; Duggins 2010; Epstein 1985b; Epstein 1985c; Epstein 2001; Epstein 2015; Saelens 2013; Woo 2004).

C: comparator; I: intervention; ITT: intention-to-treat; N/A: not applicable; RCT: randomised controlled trial; SWITCH: Screen-Time Weight-loss Intervention Targeting Children at Home

Table 2. Sensitivity analyses

Analysis	Number of studies	Number of participants	Mean difference (95% CI)	Chi ² (P value)	I ² statistic
Change in BMI (all trials) Analysis 1.1	24	Intervention: 1422 Comparator: 1363	-0.53 (-0.82 to -0.24)	66.49 (< 0.00001)	65%
Change in BMI (removing studies with imputed data)	9	Intervention: 653 Comparator: 646	-0.48 (-0.83 to -0.13)	33.87 (< 0.0001)	76%
Change in BMI z score (all trials) Analysis 1.2	37	Intervention: 2054 Comparator: 1965	-0.06 (-0.10 to -0.02)	82.44 (< 0.0001)	56%
Change in BMI z score (removing studies with imputed data)	15	Intervention: 800 Comparator: 791	-0.05 (-0.10 to 0.00)	41.49 (0.0001)	66%
Change in weight (all trials) Analysis 1.3	17	Intervention: 891 Comparator: 883	-1.45 (-1.88 to -1.02)	8.95 (0.92)	0%
Change in weight (removing studies with imputed data)	8	Intervention: 335 Comparator: 339	-1.54 (-1.99 to -1.09)	5.95 (0.55)	0%

BMI: body mass index

BMI z score: “A BMI z score or standard deviation score indicates how many units (of the standard deviation) a child’s BMI is above or below the average BMI value for their age group and sex. For instance, a z score of 1.5 indicates that a child is 1.5 standard deviations above the average value, and a z score of -1.5 indicates a child is 1.5 standard deviations below the average value” (NOO NHS 2011)

WHAT'S NEW

Date	Event	Description
2 March 2017	New search has been performed	This is an update of the former Cochrane Review 'Interventions for treating obesity in children and adolescents.'
2 March 2017	New citation required and conclusions have changed	<p>Given the rapid growth in the treatment of child and adolescent obesity, we have split the original review ('Interventions for treating obesity in children and adolescents') into six separate reviews, with a specific intervention and age focus</p> <ul style="list-style-type: none"> • Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years • Diet, physical activity, and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years • Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years • Drug interventions for the treatment of obesity in children and adolescents • Parent-only interventions for childhood overweight or obesity • Surgery for the treatment of obesity in children and adolescents

HISTORY

Date	Event	Description
11 October 2008	New citation required and conclusions have changed	<p>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</p> <p>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,</p>

(Continued)

		a range of adverse effects was noted
3 July 2008	Amended	Converted to new review format. Authorship changed with new authors and new contact person

CONTRIBUTIONS OF AUTHORS

All review authors read and approved the final review draft.

Emma Mead (EM): acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and future review updates.

Tamara Brown (TB): acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and future review updates.

Karen Rees (KR): acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and future review updates.

Liane Azevedo (LA): acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and future review updates.

Victoria Whittaker (VW): data analysis, data interpretation, review draft.

Dan Jones (DJ): acquiring trial reports, data extraction, data interpretation, review draft.

Joan Olajide (JO): acquiring trial reports, data extraction, data interpretation, review draft.

Giulia M Mainardi (GM): data extraction, data interpretation, review draft.

Eva Corpeleijn (EC): trial selection, data extraction, data interpretation, review draft and future review updates.

Claire O'Malley (CM): acquiring trial reports, trial selection, data extraction, data interpretation, review draft.

Elizabeth Beardsmore (EB): data extraction, data interpretation, review draft.

Lena Al-Khudairy (LA-K): acquiring trial reports, trial selection, data extraction, data interpretation, review draft and future review updates.

Louise Baur (LB): protocol draft, data interpretation, review draft and future review updates.

Maria-Inti Metzendorf (MIM): search strategy development.

Alessandro Demaio (AD): data interpretation, review draft.

Louisa J Ells (LE): protocol draft, acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

DECLARATIONS OF INTEREST

EM: none known.

TB: none known.

KR: none known.

LA: none known.

VW: none known.

DJ: none known.

JO: none known.

GM: none known.

EC: none known.

CM: none known.

EB: none known.

LA-K: none known.

LB: is a co-author on two of the included studies ([McCallum 2007](#); [Wake 2009](#)).

MIM: none known.

Disclaimer: Alessandro Demaio is currently a staff member of the World Health Organization. The author alone is responsible for the views expressed in this publication and they do not necessarily represent the decisions, policy or views of the World Health Organization.

LE: is seconded to Public Health England part-time as a specialist obesity advisor. The author received funding from WHO to complete this review. Louisa Ells also has a part time secondment to Public Health England, but undertook this review within her role at Teesside University.

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Internal sources

- University Medical Center, Groningen, Netherlands.
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- The Wolfson Research Institute, University of Durham, UK.
- Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development, World Health Organization, Switzerland.

Alessandro Demaio is a full time staff of the World Health Organization.

External sources

- Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development, World Health Organization, Switzerland.

Dr Louisa Ells worked as a consultant for WHO during the preparation of this work.

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Donors do not fund specific guidelines and do not participate in any decision related to the guideline development process including the composition of policy questions, membership of the guideline groups, the conduct and interpretation of systematic reviews, or the formulation of recommendations.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Given the rapid growth in the treatment of child and adolescent obesity, we have split the original review ('Interventions for treating obesity in children and adolescents') into six separate reviews, with a specific intervention and age focus:

- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years.
- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in children from the age of 6 to 11 years.
- Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years.
 - Drug interventions for the treatment of obesity in children and adolescents.
 - Parent-only interventions for childhood overweight or obesity.
 - Surgery for the treatment of obesity in children and adolescents.

NOTES

Portions of the background and methods sections, the appendices, additional tables and figures 1 to 3 of this review are based on a standard template established by Cochrane Metabolic and Endocrine Disorders.