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Systematic review of the effectiveness and cost-effectiveness of weight management schemes for the under fives: a short report

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Abstract

Systematic review of the effectiveness and cost-effectiveness of weight management schemes for the under fives: a short report

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Objective: To search for, review and synthesise studies of the effectiveness and cost-effectiveness of weight management schemes for the under fives.

Data sources: MEDLINE [Ovid], MEDLINE In-Process [Ovid], EMBASE [Ovid], CAB [Ovid], Health Management Information Consortium [Ovid], The Cochrane Database of Systematic Reviews, Cochrane Register of Controlled Trials, Science Citation Index Expanded [Web of Science], Conference Proceedings Citation Index [The Web of Science], Database of Abstract Reviews [CRD; Centre for Reviews and Dissemination], HTA [CRD], PsycINFO [Ebsco], NHS CRD. These databases were searched from 1990 to February 2009. Supplementary internet searches were additionally conducted.

Review methods: Relevant clinical effectiveness studies were identified in two stages. Titles and abstracts returned by the search strategy were examined independently by three researchers and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Three researchers examined these independently for inclusion or exclusion, and disagreements were again resolved by discussion.

Results: One of the randomised controlled trials (RCTs) was from the UK. It measured the effects of a physical activity intervention for children in nurseries combined with home-based health education for their parents; this was compared to usual care. The main outcome measure was body mass index (BMI); secondary measures were weight and physical activity. At the 12-month follow-up, no statistically significant differences were found between the groups on any measure. However, a trend, favouring the intervention, was found for BMI and weight. The other two RCTs were from the USA. The larger trial investigated the effects of a combined preschool and home intervention in African American and Latino communities. Nutrition education and physical activity programmes were aimed at under fives in preschool. The home component consisted of related health education and homework for the parents, who received a small financial reward on completion. The 1- and 2-year results for the African American sites showed a significantly slower rate of increase in BMI than for results at baseline, for the intervention group than for the control group. However, in the Latino communities no such differences were found. The second US trial was a much smaller home-based parental education programme in Native American communities in the USA and Canada. The intervention consisted of a parental skills course for parents to improve their children's diet and physical activity. This was compared with a course providing skills to improve child behaviour. Follow-up was at 16 weeks and showed no significant differences between groups in BMI.

Conclusions: No controlled trials addressing the issue of treating obesity or evidence of cost-effectiveness studies in the under fives' population were found. From the three prevention studies, apart from the larger US trial, the interventions showed no statistically significant differences in BMI and weight between the intervention and control groups (although there was some evidence of positive trends for BMI and weight). It should also be noted that these conclusions are based on only three dissimilar studies, thereby making the drawing of firm conclusions difficult. Further research is urgently needed in well-designed UK-based RCTs of weight management schemes aimed at the prevention of obesity, that combine with cost-effectiveness studies targeted at preschool children with long-term follow-up.

Contents

Glossary and list of abbreviations

Glossary

Adiposity rebound The second rise in body mass index (BMI) kg/m^2 that occurs between the ages of 3 and 7 years.

Obese (children) ≥95th UK National BMI percentile, relevant to the UK 1990 reference data; specific age and sex cut-offs for ages 2–18 years, based on centile curves from data from six countries; or BMI > 98th centile of UK 1990 reference chart for age and sex.

Overweight (children) ≥85th and < 95th UK National BMI percentile, relevant to the UK 1990 reference data; specific age and sex cut-offs for ages 2–18 years, based on centile curves from data from six countries; or BMI > 91st centile of UK 1990 reference chart for age and sex.

Energy balance Energy intake = internal heat produced + external work + energy storage

List of abbreviations

ANOVA	analysis of variance
BMI	body mass index
CRD	Centre for Reviews and Dissemination
ITT	intention to treat
NICE	National Institute for Health and Clinical Excellence
OECD	Organisation for Economic Co-operation and Development
PenTAG	Peninsula Technology Assessment Group
RCT(s)	randomised controlled trial(s)
SD	standard deviation

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

Overweight and obesity in the UK are increasing. A systematic review has indicated that the roots of adult obesity lie in the preschool years where the problems of overweight and obesity are escalating.

The prevalence of childhood obesity in England has risen between 1995 and 2007 for children aged 2–15 years, from 11% to 17% for boys and from 12% to 16% for girls. Overall, in the UK, 10% of preschool children are obese, with a quarter of children aged 2–5 years being either overweight or obese. Recent data from the National Child Measurement Programme show that in 2006–7, 22.9% of children in reception classes were overweight or obese. These figures reflect almost a doubling of obese 4–5 year olds since 1990 and a 30% increase in those overweight in this age group, using the ≥85th and ≥95th percentile respectively.

Objectives

The objective of this systematic review is to search for and review studies from OECD (Organisation for Economic Co-operation and Development) countries of the effectiveness and cost-effectiveness of weight management schemes for the under fives.

Interventions

The interventions considered are weight management schemes and interventions designed to maintain appropriate weight and or achieve weight loss. The schemes include those aimed at universal prevention, targeted prevention, weight loss, management of weight gain and treatment of those already overweight or obese.

Comparators

These include normal practice or non-diet or exercise interventions, e.g. educational programmes about safety in the home.

Population

The population for this assessment are the under fives in OECD countries; this is to ensure that study findings would be transferable to the UK context.

Outcome measures

The main outcome measures are those of body mass index (BMI) and weight. Each clinical effectiveness study must include at least one measure of adiposity. Other outcome measures are: health outcomes, quality of life, objective measures of health behaviour such as accelerometry (not self-reported outcomes) and cost-effectiveness. Self-report outcomes are excluded as they may be under or over reported by participants.

Study design

Study designs included are randomised controlled trials (RCTs) and other non-randomised controlled designs. This was to assure that only high quality studies with minimal bias and confounding were included.

Methods

Data sources

A systematic review of existing cost- and clinical effectiveness studies was undertaken and run on 13 electronic databases: MEDLINE [Ovid], MEDLINE In-Process [Ovid], EMBASE [Ovid], CAB [Ovid], Health Management Information Consortium [Ovid], The Cochrane Database of Systematic Reviews, Cochrane Register of Controlled Trials, Science Citation Index Expanded [Web of Science], Conference Proceedings Citation Index [The Web of Science], Database of Abstract Reviews [CRD; Centre for Reviews and Dissemination], HTA [CRD], PsycINFO [Ebsco], NHS CRD. These databases were searched from 1990 to February 2009 to identify relevant published literature on weight management programmes in the under fives. Supplementary internet searches were additionally conducted.

Study selection

Relevant clinical effectiveness studies were identified in two stages. Titles and abstracts returned by the search strategy were examined independently by three researchers (MB, KWy and JL) and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Three researchers (MB, KWy and JL) examined these independently for inclusion or exclusion, and disagreements were again resolved by discussion.

Data extraction

Data were extracted by MB and checked by KWy and JL.

Data synthesis

Due to the heterogeneity of the studies, no data synthesis was possible.

Results

Number and quality of effectiveness studies

The systematic review of electronic databases for clinical effectiveness studies produced 1874 titles and abstracts, of which 1841 were judged not to meet our inclusion criteria and were excluded.

Thirty-three papers were reviewed to see if they met the inclusion criteria. In addition 17 further papers were retrieved from references, giving 50 papers in all that underwent paper level review. From these, 28 papers were excluded. This left 22 articles included in this systematic review, 16 of these were systematic reviews or meta-analyses and six were RCT papers (reporting on three trials).

Summary of results

One of the RCTs was from the UK (Reilly and colleagues, 2006; $n = 545$). They measured the effects of a physical activity intervention for children in nurseries (30 minutes, three times a week for 24 weeks), combined with home-based health education for their parents; this was compared to usual care. The main outcome measure was BMI; secondary measures were weight and physical activity (measured by accelerometry). At the 12-month follow-up, no statistically significant differences were found between the groups on any measure. However, a trend, favouring the intervention, was found for BMI and weight.

The other two RCTs were from the USA. The larger trial, Hip-Hop Jr (2002–6, $n = 778$), investigated the effects of a combined preschool and home intervention in African American and Latino communities. Nutrition education and physical activity programmes were aimed at under fives in preschool (20 minutes of nutrition education plus 20 minutes of moderate to vigorous exercise, three times a week for 14 weeks). The home component consisted of related health education and homework for the parents, who received a small financial reward on completion (US$5). The 1- and 2-year results for the African American sites showed a significantly slower rate of increase in BMI than for results at baseline, for the intervention group than for the control group [mean (standard deviation), year 1: intervention: 16.6 (2.1) kg/m^2, control: 17.4 (3.1) kg/m^2, $p = 0.002$; year 2: intervention: 17.1 (2.5) kg/m^2, control: 17.9 (9.3) kg/m^2, $p = 0.008$]. However, in the Latino communities no such differences were found. This may have been due to the intervention being delivered more effectively by the staff, or the low level of cultural integration reported in this population, which may have hindered engagement with the research.

The second trial from the USA was much smaller (Harvey-Berino and Rourke, 2003; $n = 40$). This was a home-based parental education programme in Native American communities in the USA and Canada. The intervention consisted of a parental skills course for parents to improve their children's diet and physical activity. This was compared with a course providing skills to improve child behaviour. Follow-up was at 16 weeks and showed no significant differences between groups in BMI.

Speculative reasons for the success of the Hip-Hop Jr trial in affecting BMI increase include:

- Possibly a more effective delivery of the intervention by the Hip-Hop Jr preschool staff.
- The effect of the greater involvement of parents by actively engaging them with homework in the Hip-Hop Jr study than in Reilly and colleagues may have provided sufficient reinforcement of the preschool component to render the intervention effective.
- Targeting of nutrition education directly at the children may have engaged them more fully in this aspect of the intervention.

- The financial rewarding of mothers in Hip-Hop Jr for completing homework may have been an incentive to stay in the study and engage with its messages.
- The Latino sites in Hip-Hop Jr may have failed to show a positive impact from the intervention because the parents had low cultural integration.
- Although Reilly and colleagues' intervention activity time was longer, it may not have been so intense.
- There may not have been as great a difference between the activity levels of the control group and the intervention group in Reilly and colleagues' trial.

Summary of cost-effectiveness results

Titles and abstracts returned by the cost-effectiveness searches were examined independently by MB and RT and screened for possible inclusion.

The searches returned 595 titles and abstracts; none of these met our inclusion criteria.

Conclusions

Implications for health care

Controlled trial evidence of weight management schemes and interventions aimed at the prevention of obesity for the under fives is scarce. No controlled trials addressing the issue of treating obesity or evidence of cost-effectiveness studies in this population were found. What evidence exists from prevention studies, is difficult to draw clear conclusions from as, apart from the Hip-Hop Jr trial (African American sites), the interventions showed no statistically significant differences in BMI and weight between the intervention and control groups (although there was some evidence of positive trends for BMI and weight). It should also be noted that these conclusions are based on only three dissimilar studies, two in low-income ethnic minority groups, in different contexts and settings, thereby making the drawing of firm conclusions difficult. A closer inspection of included studies shows that there may be elements that future interventions should include:

- effective training of the staff delivering the intervention
- cultural sensitivity
- sustained moderate to vigorous physical activity and nutritional advice components for children
- active engagement of parents/carers in reinforcing the messages to the children combined with education about healthy diets and exercise.

Suggested research priorities

The lack of evidence on which to base service commissioning indicates that research is urgently needed, in particular:

- Further well-designed UK-based RCTs of weight management schemes aimed at the prevention of obesity, which combine with cost-effectiveness studies targeted at preschool children (under fives) with long-term follow-up (> 12 months).

- Well-designed UK-based RCTs of weight management schemes that address the issue of treatment of overweight and obesity in the under fives, which combine with cost-effectiveness studies targeted at preschool children (under fives) with long-term follow-up (> 12 months).

These RCTs should specifically consider:

1. Elements of interventions:
   - Effective training of the staff delivering the intervention.
   - Cultural sensitivity.
   - Sustained moderate to vigorous physical activity and nutritional advice components for children.
   - Active engagement of parents/carers in reinforcing the messages to the children combined with education about healthy diets and exercise.

2. Outcomes
   - Body density, skinfold thickness, waist circumference, BMI, weight, physical activity, health behaviour and cost outcomes.

3. Process
   - Studies should also have a qualitative component to investigate the barriers and facilitators to successful engagement of children, parents and preschool staff in weight management interventions. Questions of interest include:
     - Parental views of the intervention; do

they believe there is an overweight problem for under fives? Do they believe the intervention will 'work'? What are the best ways of engaging parents fully?
- What are nursery/preschool staff attitudes to the intervention? Do they view it as an imposition or a help? How does the intervention fit in with the curriculum? Does it put pressure on the staff?
- Do the children enjoy taking part in intervention activities?

Chapter 1
Background

Description of the health problem

Prevalence

Overweight and obesity in the UK are increasing.[1,2] A systematic review has indicated that the roots of adult obesity lie in the preschool years[3] where the problems of overweight and obesity are escalating.[4–6]

The prevalence of childhood obesity in England has risen between 1995 and 2007 for children aged 2–15 years, from 11% to 17% for boys and from 12% to 16% for girls.[7] Overall, in the UK, 10% of preschool children are obese,[4] with a quarter of children aged 2–5 years being either overweight or obese.[1,5] Recent data from the National Child Measurement Programme show that in 2006–7, 23% of children in reception classes were overweight or obese.[8] These figures reflect almost a doubling of obese 4–5 year olds since 1990 and a 30% increase in those overweight in this age group, using the ≥85th and ≥95th percentile cut-offs.[8] *Table 1* lists different definitions of overweight and obesity.

Risk factors associated with childhood obesity

There are a number of identified factors that affect the risk of a child becoming overweight or obese by the age of 5 years:

- coming from a lower socio-economic group[14,15]
- maternal smoking during pregnancy[15]
- parental overweight or obesity[15]
- high birth weight,[16] although questioned by Ong[17]
- being in the highest fifth of weight gain between birth and 5 months[15]
- body mass index (BMI)> 95th percentile at 1 year of age[18]
- age-adjusted BMI > 25 at 2.5 years of age[18]
- having a Black Caribbean, Black African or Asian background.[19]

Conversely, breastfeeding and habitual physical activity in the preschool years may be protection against obesity.[4,20–22]

Aetiology

The aetiology of childhood obesity is complex. Obesity results from an energy imbalance, so that the body uses less energy than it receives.[4] A contributing factor may be the increasingly sedentary behaviour of young children who are spending more time occupied by visual displays of various sorts than in physical activity.[2,23] However, a causal link between less active children and increased obesity has not been established. While there is evidence to show that less active children are more likely to have excess fat in late infancy,[24] the strength of this association has been questioned.[25,26]

TABLE 1 *Definitions of childhood overweight and obesity*

Overweight	Obese	Source
≥85th and <95th UK National BMI percentile, relevant to the UK 1990 reference data	≥95th UK National BMI percentile, relevant to the UK 1990 reference data	Cole *et al.*[9,10] For use in population monitoring
Specific age and sex cut-offs for ages 2–18 years, based on centile curves from data from six countries	Specific age and sex cut-offs for ages 2–18 years, based on centile curves from data from six countries	International Obesity Task Force[11]
BMI >91st centile of UK 1990 reference chart for age and sex	BMI >98th centile of UK 1990 reference chart for age and sex	Institute of Child Health[12] NICE Guideline 43[13]

BMI, body mass index; NICE, National Institute for Health and Clinical Exellence.

The UK Early Bird longitudinal study of early weight gain has concluded that most excess weight before puberty is gained before 5 years of age.[27] This may be influenced by parental feeding practices.[28] Other work has shown that patterns of diet and exercise established in the early years may continue throughout life.[29–31]

Significance for patients including quality of life

The effects of early childhood obesity include an increased risk of obesity in later childhood[27] and later life,[32,33] with an associated increased likelihood of developing heart disease, diabetes or cancer.[34] In childhood, obese and overweight children are at a greater risk of developing insulin resistance, hyperlipidemia, hypertension, hyperinsulinaemia, Type 2 diabetes, cardiovascular disease, depression, eating disorders, obstructive sleep apnoea, asthma, fatty liver and orthopaedic complications.[35,36]

Our systematic searches found no studies reporting the quality of life for overweight and obese under fives. However, seven studies were found that considered these issues in older children,[37–43] with the exception of Hughes and colleagues[41] (who found that in clinical samples of obese children, health-related quality of life was lower than in lean children, especially when rated by their parents) these were uncontrolled studies or reviews whose findings should be treated with caution. Furthermore, how far the findings from these studies can be extrapolated to a younger and less cognitively mature population is open to debate as quality of life deficits might be reduced in younger children (see *Table 2*).

Current guidance

The National Institute for Health and Clinical Excellence (NICE) recommends in Clinical Guideline 43, 2006, '*Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*', that tailored clinical interventions should be considered for children with a BMI at or above the 91st centile, depending on the needs of the individual child and family, and that an assessment of comorbidity should be considered for children with a BMI at or above the 98th centile.[13] Furthermore, its guidance for early years states that:

> The preschool years (ages 2–5) are a key time for shaping lifelong attitudes and behaviours. Childcare providers can create opportunities for children to be active and develop healthy eating habits, and can act as positive role models.
>
> BMI is recommended as a practical estimate of overweight in children but needs to be interpreted with caution, because it is not a direct measure of adiposity. Waist circumference is not recommended as a routine measure.
>
> All action aimed at preventing excess weight gain, improving diet (and reducing energy intake) and increasing activity levels in children should involve parents and carers.
>
> Family programmes should provide ongoing tailored support; incorporate a range of behaviour change techniques; and have a clear aim to improve weight management.

More recently, in Public Health Guidance 17, '*Promoting physical activity, active play and sport for pre-school and school-age children and young people in family, pre-school school and community settings*',[44] NICE recommends with reference to moderate to vigorous intensity physical activity:

> Children and young people should undertake a range of activities at this level for at least 60 minutes over the course of a day. At least twice a week this should include weight-bearing activities that produce high physical stresses to improve bone health, muscle strength and flexibility. This amount of physical activity can be achieved in a number of short, 10-minute (minimum) bouts. Moderate-intensity activity increases breathing and heart rates to a level where the pulse can be felt and the person feels warmer. It might make someone sweat on a hot or humid day (or when indoors). Vigorous activity results in being out of breath or sweating.
>
> Opportunities for moderate to vigorous physical activity include everything from competitive sport and formal exercise to active play and other physically demanding activities (such as dancing, swimming or skateboarding). They also include some of the actions that can be involved in daily life (such as walking, cycling or using other modes of travel involving physical activity).[44]

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TABLE 2 *Summary characteristics of health-related quality of life in older children*

Study	Year	Country	Design	Context	Age	Definition of obesity	Outcome measures: all self-reported	Conclusions
Kurth;[40] *n* = 17,641	2008	Germany	Survey	Community setting	> 11 years	BMI reference values of Kromeyer-Hauschild, 2001	KINDL-R	Genuinely obese adolescents have a better HRQoL than those who only think of themselves as overweight
Zhang;[42] *n* = 297	2008	USA	Survey	Community setting	5–10 years	Overweight, ≥85th <95th percentile; obese, ≥95th percentile	SF-10 for children (parent proxy)	As BMI increased psycho-social summary scores decreased
Hughes;[41] *n* = 197	2007	UK	Controlled trial	Clinical	5–7 years	Obese, ≥95th percentile	PedsQL	Obese children's HRQoL in clinical samples is rated worse than that of lean children, especially by their parents
Warschburger[37]	2005	Germany	Review	Not reported	Not reported	Not defined	Stigmatisation, mental health, school performance, HRQoL	Obesity is associated with poorer psychosocial functioning than chronic diseases
Flodmark[38]	2005	Sweden	Review	Clinical and community	Unclear	Not defined	PedsQL, KINDL, ITIA, Self-Perception Profile for Children	Children studied in community settings reported better quality of life than those in clinical settings
Schwimmer;[39] *n* = 106	2003	USA	Cross-section	Clinical	5–18 years	Obese, ≥95th percentile	PedsQL	Severely obese children have lower HRQoL than healthy children, and similar to those with a diagnosis of cancer

HRQoL, health-related quality of life; ITIA, I think I am; KINDL-R, Questionnaire for measuring health related quality of life in children and adolescents; PedsQL, Pediatric Quality of Life Instrument; SF-10, Short Form-10 item health survey.

Measurement of health

Body mass index and body fat

The most common measure of obesity is the BMI. However, to use this as a universal tool is not without problems; it may be more accurate to consider the proportion of fat in the body as a measure of obesity, which shows a closer correlation to associated morbidities, such as diabetes, than does BMI.[45–47] There are also clear ethnic differences in the relationship between BMI, body fat and related disease. Although more than 30% of US citizens have a BMI of 30 or higher, only 8% of the total population have diabetes, while in India, where only 1% of the population have a BMI greater than 30, 5.8% of the total population (32.7 million) have diabetes.[47] It is possible for two people with the same BMI to have very different percentage body fat levels.[47]

These ethnic differences have also been found in children. Deurenberg and colleagues[48] have shown that the relationship between body fat and BMI is different between Asian and Caucasian children, with Asian children having a significantly higher percentage body fat for the same BMI – mean ± SD (standard deviation) (24.6 ± 0.7 versus 20.03 ± 0.7 kg/m^2). So it is the level of body fat, rather than simply body weight, that is the more important marker of health and potential morbidity. However, highly accurate measures of body fat are more complex (e.g. underwater weighing and bioelectrical impedance) and therefore more expensive to collect than BMI. Therefore, BMI has been the measure of choice for most obesity trials.

There is some variation in how overweight and obesity are defined in children. Typically, measures account for the changing height-to-weight ratio and the different growth patterns of girls and boys to calculate the BMI. Three definitions of childhood overweight and obesity are commonly used in the UK (see *Table 1*).

Current service provision

There is no nationally agreed model for weight management services for children in England and Wales; although the Department of Health has set out detailed guidance for the commissioning of services in its publication '*Healthy weight, healthy lives: commissioning weight management services for children and young people, 2008*'.[49]

In 2005, the Department of Health published '*Obesity training courses for primary care*'. Dieticians working in obesity management were commissioned to produce this directory for primary care trusts, identifying and analysing some existing training packages on obesity prevention and management. The directory listed five training courses with a focus on childhood obesity. Only one of these includes under fives and it has not been externally evaluated (Weight Management Centre, Preventing Childhood Obesity, www.wmc.uk.com).

The HENRY programme (Health Exercise Nutrition for the Really Young) also offers a taught course and an e-learning course. These have been piloted, and assessed in Sure Start Children's Centres.[50] The National Child Measurement Programme weighs and measures children in reception year (4/5 year olds) and Year 6 (10/11 year olds) to assess overweight and obesity levels. All parents of participating children will receive their child's results (unless they request not to); so demand for interventions for the two age groups concerned are likely to rise.

Description of the intervention

The aims of weight management schemes include universal prevention, targeted prevention, weight loss, management of weight gain and the treatment of obesity and overweight. Weight loss may not, however, be an appropriate outcome for schemes aimed at the under fives. Rapid changes in BMI can occur during normal growth and there is great potential to reduce excessive weight gain in childhood. Rapid weight loss and strict dieting are not appropriate for growing children unless under specialist care, as there is a potential danger of compromising growth and intellectual function if weight management is too extreme. A sustainable healthy lifestyle may be the primary goal of management.

The Scottish Intercollegiate Guidelines Network guidelines (2003) agree that a strategy of weight loss should be limited to those children being cared for by secondary care services. For children who are overweight and most children who are obese, weight maintenance is an acceptable goal. In time it is hoped that, to some degree, overweight and obese children might 'grow into their weight'.[51]

The majority of research into the prevention of childhood obesity has been conducted with

children between the ages of 8 and 12 years, an age at which children have begun to determine their own eating habits. It has been suggested that true preventive and early treatment interventions should occur at an age when children's eating patterns may be more easily influenced by parents and environmental changes.[33,52]

The preschool years present a window of opportunity to intervene in the lives of children and babies to prevent later morbidity and premature mortality,[53] to intervene early where treatment is appropriate and to meet the NICE Guidelines' target of halting the annual rise in obesity in children under 11 by 2010.[13] The Government has set itself a new ambition:

> Of being the first major country to reverse the rising tide of obesity and overweight in the population by ensuring that all individuals are able to maintain a healthy weight. Our initial focus is on children: by 2020 we will have reduced the proportion of overweight and obese children to 2000 levels.[54]

Questions addressed by this review

This systematic review addresses the issue of overweight and obesity in the under fives in terms of prevention in those of normal weight and treatment of those overweight or obese. Specifically, the review seeks randomised controlled trials (RCTs) or non-RCTs of schemes and interventions able to maintain appropriate weight for age and/or achieve weight loss. This evidence is sought in comparison with normal practice or active controls not related to weight management, e.g. safety in the home. The success of the schemes is measured objectively by weight and weight maintenance outcomes, health outcomes, quality of life and cost and cost-effectiveness. The context for the schemes is limited to Organisation for Economic Co-operation and Development (OECD) countries in clinical, community or home settings. The question addressed is:

> What is the evidence for the effectiveness and cost-effectiveness for weight management schemes for the under fives?

Chapter 2
Clinical effectiveness

Methods of reviewing clinical effectiveness

The clinical effectiveness of methods for weight management schemes was assessed by a systematic review of research evidence. The review was undertaken following the principles published by the NHS Centre for Reviews and Dissemination (CRD).[55]

Identification of studies

Search strategy

A comprehensive search strategy evaluating the clinical effectiveness of weight management in the under fives was formulated in collaboration with the research team by an experienced information scientist (KWe). Searches were conducted in the following electronic bibliographic databases: MEDLINE [Ovid], MEDLINE In-Process (MEIP) [Ovid], EMBASE [Ovid], CAB [Ovid], Health Management Information Consortium (HMIC) [Ovid], The Cochrane Database of Systematic Reviews (CDSR), Cochrane Register of Controlled Trials (Central), Science Citation Index Expanded (ISI) [Web of Science], Conference Proceedings Citation Index (CPCI) [The Web of Science], Database of Abstract Reviews (DARE) [CRD], HTA [CRD], PsycINFO [Ebsco], NHS CRD.

Searches were restricted by date from 1990 to February 2009 and by language to English. A cut-off of 1990 was chosen because of resource limitations. The references were managed in REFERENCE MANAGER.

Searches for ongoing trials were conducted in March 2009 using the following range of sources: National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database, ControlledTrials.com and ClinicalTrials.gov.

Full details of the search strategies can be found in Appendix 1.

Relevant studies were identified in two stages. Titles and abstracts returned by the search strategy were examined independently by three researchers (MB, KWy and JL) and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Three researchers (MB, KWy and JL) examined these independently for inclusion or exclusion, and disagreements were again resolved by discussion. For a flow chart of studies through the assessment, see Appendix 2.

Inclusion and exclusion criteria

Study design

Inclusion

For the review of clinical effectiveness, systematic reviews of RCTs, RCTs and non-randomised controlled designs are included.

Exclusion

- Uncontrolled studies.
- Animal models.
- Narrative reviews, editorials, opinions.
- Studies of children with morbidities that have a causal association with overweight and obesity, e.g. Prader–Willi syndrome.
- Non-English language papers.
- Reports published as meeting abstracts only, or where insufficient methodological details are reported to allow critical appraisal of study quality.

Interventions

The interventions considered are weight management schemes that are designed to maintain appropriate weight and/or achieve weight loss. The schemes include those aimed at universal prevention (i.e. all under fives regardless of weight), targeted prevention (i.e. only overweight or obese under fives), weight loss, management of weight gain and treatment of those already overweight or obese.

Comparators

These include normal practice or non-diet or non-exercise interventions (e.g. educational programmes about safety in the home).

Population

The population for this assessment is under fives in OECD countries; this is to ensure that study findings will be transferable to the UK context.

Outcomes

The main outcome measures are BMI and weight; each clinical effectiveness study must include at least one measure of adiposity (e.g. BMI, BMI *z*-score or weight). Other outcome measures are health outcomes, quality of life, objective measures of health behaviour such as accelerometry (not self-reported outcomes), and cost-effectiveness.

Self-reported outcomes are excluded because the results they produce may be unreliable as participants may over-report their physical activity,[2,56] or under-report dietary intake[57,58] and so exaggerate the benefits of the intervention. Cochrane reviews of childhood obesity have concluded that such reviews have been weakened by the lack of objective measures.[33,59]

Data extraction

Data were extracted by MB and checked by KWy and JL. Data extraction forms of included studies are available in Appendix 3.

Critical appraisal

Assessments of study quality were performed using the indicators shown below. Results were tabulated and these aspects described in *Table 4* and in the data extraction forms.

Internal validity

Consideration of internal validity addressed:

1. Sample size:
   a. power calculation at design
2. Selection bias:
   a. explicit eligibility criteria
   b. proper randomisation and allocation concealment, for RCTs
   c. similarity of groups at baseline
3. Performance bias:
   a. similarity of treatment other than the intervention across groups
4. Attrition bias:
   a. all participants are accounted for
   b. number of withdrawals specified and reasons described
5. Intervention integrity:
   a. what percent of the population received the intervention?
   b. was the consistency of the intervention measured?
   c. likelihood that participants received a 'contaminated' intervention
6. Detection bias:
   a. blinding
   b. objective outcome measures
7. Analysis:
   a. what is the unit of allocation?
   b. what is the unit of analysis?
   c. appropriate data analysis?
   d. is analysis by intention to treat (ITT)?
   e. is clustering accounted for?

External validity

External validity is judged according to the ability of a reader to consider the applicability of findings to a patient group and service setting. Study findings can be generalisable only if they describe a cohort that is representative of the affected population at large. For the purpose of this review, studies that appeared representative of the UK under fives population with regard to these considerations are judged to be externally valid.

Methods of data synthesis

Public health interventions are frequently diverse and complex; careful consideration is needed of issues of heterogeneity. In this case, in addition to the usual sources of heterogeneity (i.e. population, outcomes, intervention and comparators), differences in definitions of obesity, the context in which the intervention is delivered and any theory underpinning the study need to be taken into account.

Heterogeneity is explored through qualitative assessment of study populations, methods and interventions. In this case the included studies were assessed to be too heterogeneous to pool the data, therefore statistical heterogeneity was not explored.

Results

Quantity of research available

The systematic review of electronic databases for clinical effectiveness studies produced 1874 titles and abstracts, of which 1841 were judged not to meet our inclusion criteria and were excluded.

Number of studies included

Thirty-three full text papers were reviewed to assess if they met the inclusion criteria. In addition, 17 further papers were retrieved from references,

giving 50 papers in all that underwent paper level review. From these, 28 papers were excluded; details of these papers can be found in Appendix 4 with reasons for their exclusion. This left 22 articles included in this systematic review; 16 of these were systematic reviews or meta-analyses and six were RCT papers (reporting on three trials). No non-randomised trials were found. The included systematic reviews and meta-analyses are listed in Appendix 5. We also searched for ongoing trials of interventions to prevent and treat obesity in the under fives, a list of these can be found in Appendix 6.

Assessment of quality and effectiveness

Systematic reviews

Sixteen systematic reviews or meta-analyses had inclusion criteria that overlapped our inclusion criteria.[33,59–72] However, the majority of these ($n = 14$) included children of all ages up to 18 years, with most studies of children of 5 years or older. Only two systematic reviews were of preschool children (Bluford and colleagues [61] and Campbell and Hesketh[62]), although both these reviews included studies of 5 year olds, uncontrolled studies and self-reported outcomes.

Bluford and colleagues[61] reviewed interventions to prevent or treat obesity in preschool children. They searched for studies between 1966 and 2005 with interventions of physical activity or nutritional strategies of at least 3 months' duration, and outcomes of weight, BMI or body fat. Only case reports or case series were excluded as designs and studies were included regardless of whether or not their aim was to change weight. These exclusion criteria differ from ours; we have excluded all uncontrolled designs, studies whose aim is not weight management or not set in OECD countries. Bluford and colleagues found seven studies, only two of these (Hip-Hop Jr[73] and Harvey-Berino and Rourke[74]) met our inclusion criteria. These two studies are considered fully in Randomised controlled trials.

Bluford and colleagues[61] is a moderately good systematic review. They have used a clearly focused research question to identify studies. However, they found only one of three papers reporting on the Hip-Hop Jr trial, this may be due to not searching the Cochrane, CINAHL or EMBASE electronic databases. Bluford and colleagues also failed to comment on the validity of the studies they included and, on discussing the results, made no reference to the differing robustness of results from RCTs, uncontrolled designs and self-report measures. Therefore, the unqualified conclusions they draw, that four of their included studies show effective interventions, are not completely supported by the evidence. Overall, Bluford and colleagues concluded that multi-component programmes were most successful, particularly if parents were involved; this conclusion appears to be largely based on the strength of the Hip-Hop Jr RCT.

In contrast, Campbell and Hesketh's[62] lower quality review considered research produced between 1995 and 2006. Their focus was on interventions to prevent obesity, promote healthy eating and/or physical activity or reduce sedentary behaviour in 0–5 year olds. This review is less robust than Bluford and colleagues':[61] only one person selected the studies searched; these were from limited data sources and inclusion criteria are not formally described. Therefore it is not possible to say whether appropriate studies have been included; although the scope appears to be very broad. However, the objectives are clearly focused. Campbell and Hesketh[62] included nine studies with a range of controlled and uncontrolled designs; the critiquing of these studies was minimal with no attempt to assess validity or discussion of the limitations of the non-RCTs. They found that the self-reported outcomes mostly showed positive change, but only one objective measure (BMI *z*-scores in Hip-Hop Jr, see Study results) did the same. They conclude that 'parents are receptive to and capable of behavioural changes that may promote a healthy weight in young children'; it is not clear how they reached this conclusion as these factors were not directly measured by the studies. Only two of the studies they included matched our inclusion criteria: Hip-Hop Jr[73] and Harvey-Berino and Rourke.[74]

The conclusions from these systematic reviews should be treated with caution as they included uncontrolled studies and self-report measures. A summary of the characteristics and quality of the systematic reviews of preschool children is shown below in *Table 3*.

The three papers that contained meta-analyses were of all age children and did not conduct their analyses by age group,[34,69,70] so it is not possible to comment on the under five population.

TABLE 3 *Included systematic reviews of only preschool children*

Study	Bluford *et al.* 2007[61]	Campbell and Hesketh 2007[62]
Inclusion criteria		
Population	2 to < 6 year olds	0–5 year olds
Type of intervention	Physical activity and nutritional strategies	Prevent obesity, promote healthy eating and/or physical activity or reduce sedentary behaviour
Study designs	All except case reports and case series and with at least 3 months' follow-up. Included uncontrolled studies	Unspecified, included uncontrolled
Type of outcomes	Weight status, BMI or body fat and self-report	Unspecified, included self-report
Settings	Unspecified	Home, group, primary care, preschool/ childcare and mixed settings
Number of included studies	Seven	Nine
Search dates	01/1966 to 03/2005	01/1995 to 06/2006
Results		
Direction of change	Four studies showed positive change in weight status or body fat. Self-report measures showed both significant and non-significant results	Only one objective measure, BMI, showed a positive significant result in one study. All studies showed some effectiveness on some self-report measures
Quality of review		
Structured abstract?	Yes	No
Focused question?	Yes	Yes
Explicit and appropriate inclusion criteria?	Yes	Unclear
Comprehensive search strategy?	Yes	Unclear
Appropriate methods of study selection?	Yes	Abstract screening by only one reviewer; further reviewing by two
Appropriate methods of data extraction?	Not reported	Not reported
Validity of studies assessed adequately?	No	No
Flow diagram of studies, table of study characteristics and synthesis (narrative or quantitative)?	No flow chart	No flow chart
Do conclusions follow from results?	Not convincingly	Not convincingly
Summary of key findings provided?	No	No
Recommendations linked to the strength of evidence?	Yes	No recommendations made

Randomised controlled trials
Quality and characteristics

Three RCTs were found that met our inclusion criteria, these were all preventative studies. One of the trials was in the UK, Reilly and colleagues' MAGIC (Movement and Activity Glasgow Intervention in Children) trial,[75] and two were in the USA, Hip-Hop to Health Jr[73,76–78] and Harvey-Berino and Rourke.[74] Details of these studies can be found in the data extraction tables in Appendix 3 and are summarised below. Additionally, tables provide an overall summary of study characteristics (*Table 4*), details of interventions (*Table 5*) and quality indicators (*Table 6*).

Reilly and colleagues'[75] 2006 study was a good quality cluster randomised trial of 545 children (intervention group $n = 268$, control group $n = 277$)

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TABLE 4 *Summary characteristics of the included randomised controlled trial*

Trial	Country	*n*	Definition of obesity	Participants	Intervention	Comparator	Outcomes	Length of follow-up	Setting	Theory	Source of funding
MAGIC Reilly *et al.* 2006[75]	UK	545	≥95th UK National BMI percentile	36 nurseries children in preschool year mean (SD) age 4.2 (0.2) years, plus parents	Physical activity at nursery plus home-based health education	Usual care	BMI (UK curves) accelerometry	12 months	Nursery and home	Not explicit	British Heart Foundation, Glasgow City Council, Caledonian Research Foundation
Hip-Hop to Health Jr Fitzgibbon *et al.* 2002;[76] Stolley *et al.* 2003;[78] Fitzgibbon *et al.* 2005;[73] Fitzgibbon *et al.* 2006[77]	USA	778	≥95th percentile: US growth curves	24 preschools children aged 3–5 yrs, mean (SD) 30.8 (8.7) months, plus parents	Diet and physical activity in preschool plus educational component at home	General health education in preschool and a related newsletter at home	BMI (US curves) weight height	5 years	Preschool and home	Social learning theory, self-determination theory and the transtheoretical model	National Heart Lung and Blood Institute
Harvey-Berino and Rourke 2003[74]	USA	40	≥95th percentile: US growth curves	Children 9 months – 3 years, mean (SD) 22 (8) months, plus mothers	Home-based parenting skills course to improve diet and increase exercise + comparator intervention	Home-based parenting skills course to improve behaviour	BMI (US curves) weight accelerometry	16 weeks	Home	Not explicit	National Institute of Health

MAGIC, Movement and Activity Glasgow Intervention in Children.

TABLE 5 *Summary of interventions*

	Intervention			Control	
	Nursery				
Study	**Physical activity**	**Education**	**Home**	**Nursery**	**Home**
Reilly *et al.*[75]	3 × 30 minutes per week × 24 weeks	–	Resource pack to encourage physical activity and information about the benefits of physical activity and reducing TV watching	–	–
Hip-Hop Jr[73,76–78]	3 × 20 minutes per week × 14 weeks	Nutrition activities 3 × 20 minutes per week × 14 weeks	Weekly newsletter related to nursery activities, plus homework for parents with financial incentive for completion	Once weekly × 20 minutes × 14 weeks general health education	Weekly related newsletter
Harvey-Berino[74]	–	–	Once weekly × 16 weeks parenting skills programme about healthy eating and exercise	–	Once weekly × 16 weeks parenting skills programme about behavioural goals

TABLE 6 *Key quality indicators of the included studies*

Indicator	**Reilly *et al.*[75]**	**Hip-Hop to Health Jr[73,76–78]**	**Harvey-Berino[74]**
Power calculation	✓	✓	×
Explicit eligibility criteria	✓	✓	✓
Adequate randomisation	Method not reported	Method not reported	Method not reported
Adequate allocation concealment	✓	Not reported	Not reported
Outcome assessors blinded	✓	Unclear	✓
Groups similar at baseline	✓	×	✓
All participants accounted for	✓	✓	✓
Withdrawals specified	✓	✓	✓
Clear description of intervention	✓	✓	✓
Consistency of intervention measured	✓	Unclear	Unclear
Objective outcome measures	✓	✓	✓
Unit of allocation	Group and individual	Group	Individual
Unit of analysis	Individual	Individual	Individual
Appropriate method of analysis	✓	✓	✓
Analysis by ITT	✓	✓	✓
Are results generalisable?	✓	Partly: ethnic minority	Partly: ethnic minority
Rationale for clustering given	✓	✓	Not applicable
Effects of clustering in sample size	✓	✓	Not applicable
Effects of clustering in analysis	✓	Unclear	Not applicable
Flow diagram include clusters and individuals	✓	No flow diagram	No flow diagram

less than 5 years old, set in 36 nurseries and in the home, in Glasgow, UK. The aim of the study was to assess whether a physical activity intervention for children combined with healthy living education for parents would reduce the BMI of young children.

The intervention was aimed at children, parents/carers and nursery staff, and consisted of an enhanced physical activity programme of three 30-minute sessions a week for 24 weeks. Two nursery staff members were trained in the intervention and an unblinded researcher monitored the intervention for consistency. This nursery-based activity was combined with a home intervention consisting of a resource pack with guidance linking physical play at the nursery and home, and two health education leaflets about the benefits of physical activity and encouraging alternatives to television watching, with the aim of increasing physically active play and reducing the amount of television watched. The children in the control group received the usual programme of activities from their nursery and the head teachers agreed not to enhance their physical development and movement curriculum during the trial period.

The primary outcome measure was BMI. Weight and physical activity measured by accelerometry were secondary outcomes (obesity was defined as being ≥95th UK national BMI percentile). Outcomes were reported at baseline, and at 6 and 12 months follow-up.

Although no explicit theory underpins this study, the implicit theory is that increasing physical activity in very young children, combined with a parental education programme about healthy lifestyles, will have a preventative effect on obesity.

Reilly and colleagues' study was a decent quality and adequately powered cluster RCT, with adequate allocation concealment and blinding of assessors. The intervention was monitored for consistency. The data were analysed appropriately by multilevel modelling, to take account of the clustered design and used ITT analysis. However, there was no description of the method of random sequence generation (see *Table 6*).

Our second study, Hip-Hop to Health Jr[73,76–78] (2002–6), was a cluster RCT of a combined nutrition education and exercise intervention, designed to reduce gains in BMI in 778 preschool minority children in the USA (African American sites, intervention group $n = 197$, control group $n = 212$; Latino sites, intervention group $n = 202$, control group $n = 199$). This community-based intervention targeted African American and Latino preschool children in the Chicago area who attended Head Start preschools. Randomisation was between preschools and within each of these ethnic communities. The aim of the programme was to divert the trend towards overweight and obesity in these ethnic minority groups, who have a greater than average prevalence of weight problems in the USA.[79] The weight control component consisted of a 14-week programme (three times weekly) of diet and physical activity delivered by trained early childhood educators in 24 Head Start preschools and in the children's homes. Twelve of the preschools were in predominantly African American communities and 12 were in predominantly Latino communities. Each preschool session consisted of 20 minutes of a nutrition activity followed by 20 minutes of moderate to vigorous aerobic activity. The home-based element included a weekly newsletter that mirrored the children's curriculum with homework designed to reinforce concepts presented in the newsletters. Parents were also asked to write down specific ways to increase fruit and vegetables and reduce fat in their family's diet. If the homework was completed and returned, parents received a small monetary reward (US$5.00 grocery voucher). Parents were also offered twice weekly low-impact aerobic classes at their children's preschools.

Children in preschools, randomised to the control group, received a once weekly 20-minute educational session for 14 weeks that taught general health concepts, e.g. seat-belt safety, immunisation and dental health. The home component consisted of a weekly related newsletter, there were no homework assignments or financial rewards.

The primary outcome measure was BMI, with overweight being defined as BMI ≥85th percentile and obesity as BMI ≥95th percentile of the US National Centre for Health Statistics growth curves. Weight and height were also recorded. Children were followed up for 24 months.

This scheme was theoretically underpinned by social learning theory,[80] self-determination theory[81] and the transtheoretical model that includes stages of change.[82] The implicit theory behind this scheme is that obesity can be prevented by reducing dietary fat, increasing dietary fibre, an increase in physical activity, inclusion of the family

and consideration of the individual developmental needs of the participants.

This was a moderate quality cluster RCT. Although the study's sample size was based on a power calculation that accounted for the effects of clustering, the method of randomisation was not reported. This is of some concern as the Latino preschool groups were not entirely similar at baseline, with the children in the control group being more likely to be overweight than those in the intervention group, 51% versus 40% ($p = 0.019$), or obese, 31% versus 30% ($p = 0.033$), and have a higher mean BMI *z*-score, mean (SD): 1.13 (1.06) versus 0.87 (1.24) ($p = 0.03$). Similarly, in the African American preschool groups, the children in the control group were older than those in the intervention group by a mean of 2.2 months ($p < 0.001$). Furthermore, it is unclear whether the assessors were blinded to treatment allocation or whether the consistency of the intervention was monitored. However, the data were appropriately analysed using multilevel modelling and ITT methods.

The third RCT, Harvey-Berino and Rourke[74] (2003), was of 40 Native American children aged between 9 months and 3 years in the USA and Canada. The aim of this home-based study was to find out if including mothers, with a BMI > 25 kg/m^2, in an obesity prevention programme, in addition to more general parenting support, would reduce the risk of obesity in their children when compared with similar children whose mothers were receiving general parenting support alone. Participants were recruited from three sites: New York state, Ontario and Quebec.

Children were randomised individually to intervention or control. The control group received a home-based parenting support programme which emphasised physiological and behavioural goals, teaching effective parenting styles and age-appropriate discipline and routines and rules. The intervention group ($n = 20$) received the same home-based support plus a parenting support programme about nutrition and exercise, also in their homes. This consisted of a 16-week programme (one lesson per week), to show how improved parenting skills could facilitate the development of appropriate eating and exercise habits in children. The idea being that having parents modelling healthy behaviours would encourage a healthy diet and greater physical activity in their children.

The main outcome measure was BMI, with obesity defined as ≥95th percentile of the US National Centre for Health Statistics growth curve. Participants were followed up for 16 weeks. The implicit theory supporting this trial was that involving mothers in a home-based educational intervention to improve eating and exercise combined with a parent support programme would have a preventative effect, to reduce obesity in young children.

It is difficult to comment comprehensively on the quality of this small RCT, as a number of key quality indicators were not reported. It can only be assumed that is because they were not in place. There appears to have been no power calculation to determine the sample size, and the method of randomisation, sequence generation and concealment were not reported. However, groups were similar at baseline and assessors were blinded to allocation. The consistency of the intervention does not appear to have been monitored, although the analysis was by ITT. The methods for analysing the data were appropriate with *t*-tests for within-group changes and analysis of variance (ANOVA) for between-group changes.

Study results

Body mass index

All three studies measured BMI. However, their results are not directly comparable as the children were at different ages when measures were taken. Only one study, Hip-Hop Jr, showed any significant differences between groups.[73]

The positive result from Hip-Hop Jr was found only in the African American study sites, where the children in the intervention group showed significantly smaller increases in BMI from baseline than those in the control group. At 24 months the mean (SD) BMI was 17.1 (2.5) kg/m^2 for the intervention group and 17.9 (3.3) kg/m^2 for the control group, with the increase in means 0.48 (SD 0.14) kg/m^2 in the intervention group and 1.14 (SD 0.14) kg/m^2 in the control group ($p = 0.008$). When these raw BMI scores were adjusted for age, baseline value and location, the values continued to show significance at $p < 0.05$.

Hip-Hop Jr was one of two studies that had a physical activity component in the intervention. The other study was Reilly and colleagues[75] who actually had longer activity sessions for a greater amount of weeks in their intervention than Hip-Hop Jr, but found no statistically significant benefit from the intervention. Nevertheless, it should

be noted that Reilly and colleagues had only 12 months' follow-up and, although the differences were not statistically significant, at 6 months the BMI *z*-scores, mean (SD), were slightly higher in the intervention group: intervention = 0.46 (1.05), control = 0.43 (1.08). This direction had switched at 12 months with the control group showing a slighter lower BMI *z*-score than the intervention group: intervention = 0.41 (1.05), control = 0.43 (1.10). Speculative explanations for these differences in results between studies include that the Hip-Hop Jr intervention was delivered more effectively by the preschool staff; the activity component of Hip-Hop Jr was more vigorous; or the home element in Hip-Hop Jr was more effective as this included homework for the parents, with a financial incentive, rather than an informative resource pack.

However, the Latino sites of Hip-Hop Jr (which had 24 months' follow-up) also showed no significant differences in BMI. Although, at 12 months the rate of increase in BMI was slightly less for the control group [mean (SD), intervention = 0.50 (0.7) and control = 0.4 (0.4)] and at 24 months the rate of increase was the same in both groups 0.60 (0.8). Although, this result may have been confounded by factors related to ethnic group, as the mothers were reported to have low integration into the prevailing cultural norms. Overall, it remains unclear why these differences should occur.

Harvey-Berino and Rourke's participants were followed up for only 16 weeks; while the change in *z*-score decreased for the intervention group and increased for the control group during this time, the results failed to reach statistical significance.

Table 7 below gives the BMI results for the included studies.

Weight

Two studies, Hip-Hop Jr and Harvey-Berino and Rourke, measured weight at baseline and follow-up.[73,74,77] Hip-Hop Jr's results showed a smaller increase in weight in the intervention than control groups at 12 and 24 months, but did not report whether these results were significant or not. Harvey-Berino and Rourke[74] found a non-significantly greater increase in weight in the control group after 16 weeks. The results can be seen in *Table 8*.

Physical activity

Two studies used an objective measure, accelerometry, to measure physical activity (Reilly and colleagues [75] and Harvey-Berino and Rourke[74]). An accelerometer is a small device that is worn by a child on his or her hip or wrist and measures movement and inactivity. It is able to differentiate between being sedentary but with arm movement, walking and running.[83] Neither study found any statistically significant differences between groups.

Furthermore, Reilly and colleagues[75] also measured sedentary behaviour (no trunk movement; accelerometer count < 1100 per minute) and the proportion of hours spent in moderate to vigorous exercise (accelerometer count > 3200 per minute) and found a slightly higher (but non-significant) level of exercise in the control group. These results are shown in *Table 9*.

Barriers and facilitators

The included studies did not directly address the issue of barriers and facilitators to weight management. However, a number of matters arising from the studies may have affected their success or failure to show a treatment effect. For instance, the Hip-Hop Jr study was careful to be sensitive to the cultural background and limited financial resources of the families it recruited. This study also engaged parents more fully than Reilly and colleagues, by giving them homework which required more active engagement. It is likely that greater parental engagement increased the possibility of success. Although Hip-Hop Jr parents also had a financial incentive to carry out the homework, which should be taken into account if similar research is pursued.

Other evidence suggests that children of physically active parents are more likely to be active than children of non-active parents,[84] as parental activity levels correlate significantly with those of their children.[85] Therefore, involving parents in the physical activity component of an intervention is likely to make it more effective as parents act as role models for children.

Another aspect that requires careful consideration is the delivery of the intervention. Both Reilly and colleagues and the Hip-Hop study commented on the need for properly trained staff to carry out the physical activity component. Reilly and colleagues[75] reported that in their pilot study (which had shown significantly increased accelerometry output of 40%)[72] the intervention was carried out by nursery head teachers, but in the trial (to aid generalisability) the intervention was provided by

TABLE 7 *BMI results*

		Baseline			16 weeks			6 months			12 months			24 months		
		Inter-vention	Control		Inter-vention	Control		Inter-vention	Control		Inter-vention	Control		Inter-vention	Control	
Study	**Metric**	**Mean (SD)**	**Mean (SD)**	***p***	**Mean (SD)**	**Mean (SD)**	***p***	**Mean (SD)**	**Mean (SD)**	***p***	**Mean (SD)**	**Mean (SD)**	***p***	**Mean (SD)**	**Mean (SD)**	***p***
Reilly et al.[75] *n* = 545 (I = 268, C = 277); mean (SD) age, 4.2 (0.2) years	kg/m²	16.3 (1.5)	16.4 (1.5)	NS												
	z-score	0.39 (0.98)	0.41 (1.0)	NS				0.46 (1.05)	0.43 (1.08)	NS	0.41 (1.05)	0.43 (1.10)	NS			
Hip-Hop Jr[73,76–78] *n* = 778; mean (SD) age, 4.2 (4.9) years																
African American sites *n* = 409 (I = 197, C = 212)	kg/m²	16.50 (1.50)	16.70 (2.0)	NS							16.6 (2.1)	17.4 (3.1)	0.002	17.1 (2.5)	17.9 (3.3)	0.008
	z-score	0.62 (0.9)	0.67 (2.0)	NS							0.06 (0.05)	0.13 (0.05)	0.024	0.02 (0.04)	0.16 (0.04)	0.021
	Adjusted change from baseline (kg/m²)										0.06 (0.12)	0.59 (0.12)	0.012	0.54 (0.14)	1.08 (0.14)	0.022
Latino sites *n* = 401 (I = 202, C = 199)	kg/m²	17.00 (2.8)	17.50 (2.2)	0.1							17.5 (3.50	17.9 (2.6)	0.46	17.6 (3.6)	18.1 (3.0)	0.34
	z-score	0.87 (1.24)	1.13 (1.06)	0.023							0.00 (0.09)	0.07 (0.09)	0.56	–0.13 (0.09)	0.00 (0.09)	0.34
	Adjusted change from baseline (kg/m²)										0.31 (0.16)	0.44 (0.17)	0.6	0.46 (0.19)	0.66 (0.20)	0.49
Harvey-Berino[74] *n* = 40 (I = 20, C = 20) Mean (SD) age 22 (4.9) months	z-score	0.79 (1.70)	0.67 (1.60)	NS	0.52 (1.10)	0.98 (1.4)	NS									

C, control; I, intervention; NS, not significant.

nursery staff and was possibly less rigorous. The physical activity component of Hip-Hop Jr was delivered by trained preschool staff. With many curriculum demands being placed on the time of under fives' care providers, clearly, adequate training in age-appropriate physical exercise needs to be carefully considered.

Indeed, the Childcare Act 2006 lays down requirements for learning and development for all early years (0–5 years) care providers.[86] All infants and children must experience a range of activities that promote their personal literacy, numeracy, understanding, and creative and physical development. While the physical development component includes physical activity it does not mention moderate to vigorous exercise or simply running around.[87] It is beyond the scope of this systematic review to investigate what effects (if any) the *Practice Guidance for the Early Years Foundation Stage* may have had on the levels of physical activity in nurseries and playgroups and at childminders. Nevertheless, it would be interesting to know if providers of these services believed that this guidance allowed time for more or less moderate to vigorous play than before it was instigated.

Summary

- The searches produced 1874 titles and abstracts, from these, three RCTs were included.
- The included RCTs were of good to moderate quality and were aimed at preventing obesity.
- No trials were found for the treatment of obesity or overweight in under fives.
- One study (Hip-Hop Jr, African American sites) found significant differences in BMI at 1- and 2-year follow-up in favour of the intervention.
- No other significant differences were found with any other outcome measure in any trial.
- Trends in the BMI and weight favoured the intervention groups.
- Trends in accelerometry results favoured the control groups.
- Speculative reasons for the success of the Hip-Hop Jr in affecting BMI include:
  - Possibly a more effective delivery of the intervention by the preschool staff.
  - The effect of the greater involvement of parents by actively engaging them with homework in the Hip-Hop Jr study (than in Reilly and colleagues) may have provided sufficient reinforcement of the preschool component to render the intervention effective.
  - Targeting nutrition education directly at the children may have engaged them more fully in this aspect of the intervention.
  - The financial rewarding of mothers in Hip-Hop Jr for completing homework may have been an incentive to stay in the study and engage with its messages.
  - The Latino sites in Hip-Hop Jr may have failed to show a positive impact from the intervention because the parents had low cultural integration.
  - Although Reilly and colleagues intervention activity time was longer, it may not have been so intense.
  - There may not have been as great a difference between the activity levels of the control group and the intervention group in Reilly and colleagues' trial.

TABLE 8 *Weight results*

Study	Metric	Baseline			16 weeks			1 year			2 years		
		I	C		I	C	p	I	C		I	C	
		Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	p
Hip-Hop Jr[73,76–78] n = 778; mean (SD) age, 30.8 (8.7) months								Change from baseline			Change from baseline		
African American sites n = 409 (I = 197, C = 212)	kg	17.6 (2.9)	18.3 (3.4)	0.014				3.79 (0.20)	4.65 (0.20)	NR	6.84 (0.32)	7.95 (0.31)	NR
Latino sites n = 401 (I = 202, C = 199)	kg	18.6 (4.1)	18.8 (3.8)	NS				3.84 (0.19)	3.98 (0.20)	NR	5.91 (0.31)	6.18 (0.32)	NR
Harvey-Berino[74] n = 40 (I = 20, C = 20); mean (SD) age, 22 (4.9) months	kg	12.2 (2.4)	12.3 (2.9)	NS	13.1 (2.4)	13.8 (3.6)	NS						

C, control; I, intervention; NR, not reported; NS, not significant.

TABLE 9 *Accelerometry results*

Study	Metric	Baseline			16 weeks			6 months		
		Intervention	Control		Intervention	Control		Intervention	Control	
		Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	p
Reilly et al.[75] *n* = 545 (I = 268, C = 277); mean (SD) age, 4.2 (0.2) years	Physical activity count per minute	732 (163)	809 (209)	NS				809 (179)	899 (218)	NS
	Sendentary behaviour median (range)% monitored sedentary time	69.3 (50.4–68.6)	66.9 (45.6–88.7)	NS				67.0 (47.0–86.0)	62.9 (43.1–81.6)	NS
	MVPA median (range)% monitored MVPA time	2.6 (0.4–11.1)	3.0 (0.3–13.0)	NS				3.5 (0.5–12.4)	4.1 (0.6–12.1)	NS
Harvey-Berino[74] *n* = 40 (I = 20, C = 20); mean (SD) age, 22 (4.9) months	Physical activity (Vmag/h)	20,457 (8670)	19,417 (5735)	NS	17,886 (6746)	17,637 (8151)	NS			

MPVA, moderate to vigorous intensity physical activity; NS, not significant; Vmag/h, vector magnitude per hour.

Chapter 3

Cost-effectiveness

Methods of reviewing cost-effectiveness

Search strategy

A comprehensive search strategy evaluating the cost-effectiveness of weight management in the under fives was formulated in collaboration with the research team by an experienced information scientist (KWe). A cost search filter was included in the strategy. It was applied in the following electronic bibliographic databases: MEDLINE [Ovid], MEIP [Ovid], EMBASE [Ovid], CAB [Ovid], HMIC [Ovid], CDSR, Central, ISI [Web of Science], CPCI [The Web of Science], DARE [CRD], NHS Economic Evaluation Database (EED) [CRD], HTA [CRD] and PsycINFO [Ebsco].

Searches were restricted by date from 1990 to February 2009, and by language to English.

Searches for ongoing trials were conducted in March 2009 using the following range of sources: NIHR CRN CC Portfolio Database, ControlledTrials.com and ClinicalTrials.gov. A general supplementary internet search was run to identify further conference abstracts.

Full details of the search strategies can be found in Appendix 1.

Inclusion and exclusion criteria

The inclusion and exclusion criteria for economic evaluations were identical to those for the systematic review of clinical effectiveness except:

- Non-randomised studies were included (e.g. decision-model based analysis or analysis of person-level cost and effectiveness data alongside observational studies).
- Full cost-effectiveness analyses, cost–utility analyses, cost–benefit analyses and cost–consequence analyses will be included. Stand alone UK cost analysis will also be sought and appraised.
- Titles and abstracts returned by the search strategy were examined independently by two researchers (MB and RT) and screened for possible inclusion.

Study quality assessment

The methodological quality of economic evaluations would have been assessed according to internationally accepted criteria such as the Consensus on Health Economic Criteria list questions developed by Evers and colleagues.[88] Any studies based on decision models would have been assessed against the International Society for Pharmacoeconomics and Outcomes Research guidelines for good practice in decision analytic modelling.[89]

Results

The searches returned 595 titles and abstracts. No studies were found that matched the inclusion criteria for this systematic review. However, one ongoing US cost-effectiveness trial was found but the population was 8–12 year olds and their overweight parents (clinicaltrials.gov/ct2/show/NCT00717132).

The RCT by Reilly and colleagues, included in the effectiveness systematic review, included the cost of the nursery component capital cost: <£200, €297 or US$377. The resource pack for the home element of the intervention cost £16, €24 or US$30.[75]

Chapter 4
Discussion

Statement of principal findings

Our searches produced 1874 titles and abstracts for review. After these had been assessed three RCTs were included in the systematic review.[74–76] No studies were found aimed at the treatment of overweight or obesity in the under fives. No studies of costs or cost-effectiveness were found. This lack of evidence makes explicit conclusions difficult.

Across the three RCTs included in this systematic review, only one study's BMI outcome reached statistical significance; this was in the African American subgroup of the Hip-Hop Jr trial. Nevertheless, the other trials and the Latino subgroup of Hip-Hop Jr consistently showed that intervention groups compared with control groups were associated with trends towards greater improvement in BMI and weight over 6–24 months. However, in the studies that measured physical activity (Reilly and colleagues[75] and Harvey-Berino and Rourke[74]), the accelerometry results supported the control group. It should also be noted that no adverse effects were reported from any of these trials.

The first question that arises is why should there be differences in the results between the African American and Latino communities in the Hip-Hop Jr trial? The answer could be because the Latino mothers were found to be less assimilated into US culture than the African American mothers and may therefore have found it harder to engage with the intervention. However, there could be a range of cultural differences causing this disparity in results.

Secondly, why should the African American Hip-Hop study show a positive effect when Reilly and colleagues' study had a longer physical activity component (30 minutes versus 20 minutes)? There are a number of speculative answers:

- Possibly the intervention was delivered more effectively in Hip Hop Jr.
- The effect of the greater involvement of parents by actively engaging them with homework in the Hip-Hop Jr study may have provided sufficient reinforcement of the preschool component to render the intervention effective.
- Targeting of nutrition education directly at the children may have engaged them more fully in this aspect of the intervention.
- The financial rewarding of mothers in Hip-Hop Jr for completing homework may have been an incentive to stay in the study and engage with its messages.
- Although Reilly and colleagues' activity time was longer, it may not have been so intense and therefore had a lower overall calorific demand.
- There may not have been so great a difference between the activity levels of the control group and the intervention group in Reilly and colleagues' trial.

It is not possible to definitively say which, if any, of these factors may have influenced the outcomes.

It is perhaps easier to see why the Harvey-Barino and Rourke trial did not find an intervention effect. This was a small ($n = 40$), and likely to be underpowered, RCT with a very short follow-up time (16 weeks). Also, there was no physical activity component to the study intervention that was aimed at parent education rather than directly at the children. A Finnish trial looking at atherosclerosis prevention with a nutrition education intervention has followed up participants for 14 years from 7 months old, demonstrating that such long-term follow-up is possible in health/education trials.[90]

The included studies did not formally collect information about the process of the research, although this was touched on in their discussions. As the success of such an intervention is dependent on the degree of acceptance and engagement of the parents and/or preschool staff, it is important to understand their attitudes to and beliefs about overweight and the intervention of interest. A qualitative component addressing these issues would have enhanced all three studies.

Comparison to previous systematic reviews

There is disparity between some of our findings and those of the systematic reviews of Bluford and colleagues[61]and Campbell and Hesketh.[62] Overall they found four studies that showed a positive effect on BMI or weight or body fat, only one of these studies (Hip-Hop Jr) met our inclusion criteria. All three of the other studies were in children older than 5 years, two of the studies were uncontrolled and the other was an evaluation of a food supplying service. This difference reflects the inclusion of uncontrolled evidence which is known to introduce bias and confounding, and may produce results more likely to favour the intervention.[91,92]

Implications for policy

Despite the paucity of evidence and mixed findings of our included studies, key messages focusing on the theoretical principle of balancing food intake and energy expenditure (the energy balance) should continue to drive interventions. Indeed, interventions with older children that have included combined diet and child physical activity have been shown to be successful.[93,94]

It is possible that the three included trials did not provide enough/sufficiently vigorous physical activity and/or dietary change and parental engagement to make a consistent difference in weight-related outcomes. However, the importance of the people delivering the intervention should not be underestimated; an important factor may be the training and enthusiasm of these staff for the intervention.

In the UK, where the timetabling of activities of even infants in the care of child minders is strictly governed by a national curriculum, it may be difficult for those who care for such children to allow sufficient time for physical activities. Nonetheless, Connelly and colleagues'[64] systematic review of obesity interventions, of all age children, found that the key distinguishing factor between interventions that 'worked' and those that did not was the compulsory nature of the physical activity component.

Furthermore, the only study to show a significant benefit from the intervention was the one that most heavily involved parents and included nutrition education for children and parents.[73] This supports a recent review of family involvement in paediatric obesity management by Nowicka and Flodmark[95] that found that the majority of studies endorsed the use of family-based treatment; similarly, Moore and colleagues'[84] study has shown that parents act as models for their children in terms of levels of physical activity and diet.

It is therefore probable that interventions that combine the ingredients of: sufficient training and time for the staff delivering the intervention; compulsory regular moderate to vigorous exercise; nutrition education for children and parents; and active engagement of parents as participants and role models of a healthy lifestyle would help manage weight in younger children and set healthy patterns of physical activity and diet in place.

Contextual issues

The differing results from the Hip-Hop Jr communities indicate the importance of sensitivity to the cultural context. This trial took great care to be culturally sensitive to the minority groups it was working with. The Hip-Hop Jr authors identified several components from their pilot work that were important in engaging these families: easy and safe access to the programme; being situated in the preschool that the children were already attending; having the parental element take place in the home; encouraging identification between those delivering the intervention and participants; addressing cognitive and environmental barriers to exercise and dietary change; emphasis on modelling lifestyle change; and consideration of all levels of literacy.[76]

Strengths and limitations of the assessment

The strengths of this assessment are that it is comprehensive, systematic and up-to-date, used objectively assessed outcome measures and was conducted by an independent research team.

The limitations are that:

- The searches were limited to the English language. This might have meant that otherwise includable controlled trials were omitted. However, Bluford and colleagues'[61] searches were not restricted in this way and did not find any includable non-English language studies.

- The searches went back only to 1990, so we may have missed includable studies. Although Bluford and colleagues' searches went back to 1966, none of the studies they found prior to 1990 would have been includable in our systematic review.
- The inclusion criteria were limited to OECD countries. This was on the grounds of transferability of findings to a UK context.
- Only controlled studies were included. This was to assure that only high quality studies with minimal bias and confounding were included.
- Only three RCTs were found, one of which was small. The trials were too heterogeneous to allow pooling of data.
- No cost or cost-effectiveness studies were found.

Chapter 5
Conclusions

Controlled trial evidence of weight management schemes and interventions aimed at the prevention of obesity for the under fives is scarce. No controlled trials addressing the issue of treating obesity or evidence of cost-effectiveness studies in this population were found. What evidence exists, from prevention studies, is difficult to draw clear conclusions from as, apart from a subgroup in the Hip-Hop Jr trial (African American sites), studies showed no statistically significant differences in weight measures between the intervention and control groups (although there was some evidence of positive trends). It should also be noted that these conclusions are based on only three dissimilar studies, two in low-income ethnic minority groups, in different contexts and settings, thereby making the drawing of firm conclusions difficult. A closer inspection of included studies shows that there may be elements that future interventions should consider:

- effective training of the staff delivering the intervention
- cultural sensitivity
- sustained moderate to vigorous physical activity and nutritional advice components for children
- active engagement of parents/carers in reinforcing the messages to the children, combined with education about healthy diets and exercise.

Suggested research priorities

The lack of evidence on which to base service commissioning indicates that research is urgently needed, in particular:

- Further well-designed UK-based RCTs of weight management schemes aimed at the prevention of obesity that combine with cost-effectiveness studies targeted at preschool children (under fives) with long-term follow-up (> 12 months).
- Well-designed UK-based RCTs of weight management schemes that address the issue of treatment of overweight and obesity in the under fives that combine with cost-effectiveness studies targeted at preschool children (under fives) with long-term follow-up (> 12 months).

These RCTs should specifically consider:

- Elements of interventions:
  - Effective training of the staff delivering the intervention.
  - Cultural sensitivity.
  - Sustained moderate to vigorous physical activity and nutritional advice components for children.
  - Active engagement of parents/carers in reinforcing the messages to the children combined with education about healthy diets and exercise.
- Outcomes:
  - Body density, skinfold thickness, waist circumference, BMI, weight, physical activity, health behaviour and cost outcomes.
- Process:
  - Studies should also have a qualitative component to investigate the barriers and facilitators to successful engagement of children, parents and preschool staff in weight management interventions. Questions of interest include:
    - Parental views of the intervention; do they believe there is an overweight problem for under fives? Do they believe the intervention will 'work'? What are the best ways of engaging parents fully?
    - What are nursery/preschool staff attitudes to the intervention? Do they view it as an imposition or a help? How does the intervention fit in with the curriculum? Does it put pressure on the staff?
    - Do the children enjoy taking part in intervention activities?

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About PenTAG

The Peninsula Technology Assessment Group (PenTAG) is part of the Institute of Health Service Research at the Peninsula Medical School. PenTAG was established in 2000 and carries out independent health technology assessments for the UK Health Technology Assessment (HTA) programme, systematic reviews and economic analyses for the NICE Centre for Public Health Excellence, and systematic reviews as part of the Cochrane Collaboration Heart Group, as well as for other local and national decision-makers. The group is multidisciplinary and draws on individuals' backgrounds in public health, health services research, computing and decision analysis, systematic reviewing, statistics, and health economics. The Peninsula Medical School is a school within the Universities of Plymouth and Exeter. The Institute of Health Research is made up of discrete, but methodologically-related research groups, among which health technology assessment is a strong and recurring theme. Projects to date include:

1. Screening for hepatitis C among injecting drug users and in genitourinary medicine clinics: systematic reviews of effectiveness, modelling study and national survey of current practice. *Health Technol Assess* 2002;**6**(31).

2. The effectiveness and cost-effectiveness of imatinib in chronic myeloid leukaemia: a systematic review. *Health Technol Assess* 2002;**6**(33).

3. Systematic review of endoscopic sinus surgery for nasal polyps. *Health Technol Assess* 2003;**6**(33).

4. The effectiveness and cost-effectiveness of microwave and thermal balloon endometrial ablation for heavy menstrual bleeding: a systematic review and economic modelling. *Health Technol Assess* 2004;**8**(3).

5. Effectiveness and cost-effectiveness of imatinib for first-line treatment of chronic myeloid leukaemia in chronic phase: a systematic review and economic analysis. *Health Technol Assess* 2004;**8**(28).

6. Do the findings of case series studies vary significantly according to methodological characteristics? *Health Technol Assess* 2005;**9**(2).

7. The effectiveness and cost-effectiveness of pimecrolimus and tacrolimus for atopic eczema: a systematic review and economic evaluation. *Health Technol Assess* 2005;**9**(29).

8. The effectiveness and cost-effectiveness of dual-chamber pacemakers compared with single-chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome: systematic review and economic evaluation. *Health Technol Assess* 2005;**9**(43).

9. Surveillance of Barrett's oesophagus: exploring the uncertainty through systematic review, expert workshop and economic modelling. *Health Technol Assess* 2006;**10**(8).

10. The cost-effectiveness of testing for hepatitis C in former injecting drug users. *Health Technol Assess* 2006;**10**(32).

11. The effectiveness and cost-effectiveness of cinacalcet for secondary hyperparathyroidism in end-stage renal disease patients on dialysis: a systematic review and economic evaluation. *Health Technol Assess* 2007;**11**(18).

12. The effectiveness and cost-effectiveness of carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma: a systematic review and economic evaluation. *Health Technol Assess* 2007;**11**(45).

13. The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model. *Health Technol Assess* 2007;**11**(47).

14. Systematic review and economic analysis of the comparative effectiveness of different inhaled corticosteroids and their usage with long-acting beta2 agonists for the treatment of chronic asthma in adults and children aged 12 years and over. *Health Technol Assess* 2008;**12**(19).

15. Systematic review and economic analysis of the comparative effectiveness of different inhaled corticosteroids and their usage with long-acting beta2 agonists for the treatment of chronic asthma in children under the age of 12 years. *Health Technol Assess* 2008;**12**(20).

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Professor John J. Reilly, Professor of Paediatric Energy Metabolism, University of Glasgow. Dr Richard Tomlinson, Consultant Paediatrician, Royal Devon and Exeter Foundation Trust Hospital.

Contribution of authors

Mary Bond provided overall project management, wrote the protocol, assessed abstracts and titles and papers for inclusion and exclusion in both systematic reviews, led the clinical effectiveness and cost-effectiveness systematic reviews, wrote the report and contributed to its editing. Katrina Wyatt assessed abstracts, titles and papers for inclusion and exclusion in the effectiveness systematic review, she also contributed to the clinical effectiveness systematic review and to the editing of the report. Jenny Lloyd assessed abstracts, titles and papers for inclusion and exclusion, she also contributed to the clinical effectiveness systematic review and to the editing of the report. Karen Welch compiled and ran the search strategies for clinical effectiveness and cost-effectiveness. Rod Taylor assessed abstracts, titles and papers for inclusion and exclusion in the cost-effectiveness systematic review; he contributed to the editing of the report and was overall director of the project and guarantor of the report.

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Appendix 1

Literature search strategies

Clinical searches

MEDLINE (OVID) 1990–2009

1 exp Obesity/
2 exp weight gain/
3 exp weight loss/
4 Overweight/
5 (overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.
6 (weight gain or weight loss).ti,ab.
7 ((bmi or body mass index) adj5 (gain or loss or change)).ti,ab.
8 obes*.ti,ab.
9 or/1–8
10 Child, Preschool/
11 Infant/
12 (baby or babies or toddler* or infant* or newborn* or neonat* or preschool* or pre school* or playschool* or playgroup* or kindergarten* or kindergarden*).ti,ab.
13 infant newborn/
14 or/10–13
15 family therapy/
16 Health Knowledge, Attitudes, Practice/
17 Diet Therapy/
18 Obesity/dh [Diet Therapy]
19 Diet, Fat-Restricted/
20 Diet, Reducing/
21 diet therapy/
22 (diet or diets or dieting).ti,ab.
23 Professional-Family Relations/
24 health behavior/
25 parenting/px
26 caregivers/px
27 Schools, Nursery/st [Standards]
28 Nutrition Policy/
29 Preventive Health Services/
30 obesity/pc
31 child care/st
32 Nurseries/st [Standards]
33 Community Health Planning/or Community Health Services/
34 Counseling/
35 (low calorie or calorie control* or healthy eating).ti,ab.
36 (diet* adj (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.
37 exercise/
38 exercise therapy/
39 "Play and Playthings"/
40 (aerobic* or physical therap* or physical activit* or physical inactivity).ti,ab.
41 (fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.
42 sedentary behavio?r reduction.ti,ab.
43 reduc* sedentary behavio?r.ti,ab.
44 dance.mp. and (therapy or activity or class* or program* or group* or session* or scheme*).ti,ab.
45 ((playschool or communit* or toddler* or kindergarten) adj2 (program* or scheme*)).ti,ab.)
46 (family* scheme* or families scheme* parent* scheme* or carer* scheme* or guardian* scheme*).ti,ab.
47 (family* intervention* or families intervention* parent* intervention* or carer* intervention* or guardian* intervention*).ti,ab.
48 (parent adj2 (behavio?r or involvement or control* or attitude* or education*)).ti,ab.
49 (group adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab.
50 (community adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab.
51 (health polic* or preschool polic* or playschool polic* or food polic* or nutrition polic*).ti,ab.
52 primary prevention/
53 (preventive measure* or preventative measure*).ti,ab.
54 (individual* adj (therapy or intervention* or program* or strateg* or management)).ti,ab.
55 (exercise and (therapy or activity or class* or program* or group* or session* or scheme*)).ti,ab.
56 (population adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab.
57 Health Education/
58 health promotion/
59 secondary prevention/
60 health scheme*.ti,ab.
61 (weight adj2 manag*).ti,ab.
62 (weight adj2 scheme*).ti,ab.
63 (weight adj2 interven*).ti,ab.
64 or/15–63

65 Randomized Controlled Trials as Topic/or Clinical Trials as Topic/or Random Allocation/
66 Controlled Clinical Trial/
67 controlled clinical trial.pt.
68 randomized controlled trial.pt.
69 Random Allocation/
70 double blind method/or single blind method/
71 ((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).ti,ab.
72 research design/
73 ((random* or control*) adj5 (trial* or stud*)).ti,ab.
74 (randomised or randomized).ti,ab.
75 Comparative Study/
76 Evaluation Studies as Topic/
77 (matched communities or matched populations).mp.
78 (control* adj (trial* or stud* or evaluation*)).mp.
79 (comparison group* or control* group*).mp.
80 Matched-Pair Analysis/
81 matched pair*.ti,ab.
82 (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
83 Meta-Analysis/
84 meta analy*.ti,ab.
85 "Outcome Assessment (Health Care)"/
86 outcome stud*.ti,ab.
87 Intervention Studies/
88 Prospective Studies/
89 follow up studies/
90 exp clinical trial/
91 or/65–90
92 9 and 14 and 64 and 91
93 limit 92 to (english language and humans)
94 imit 93 to yr="1990 – 2009"

MEDLINE In-Process (OVID) 1990–2009

Strategy as per MEDLINE (using only free text terms)

EMBASE (OVID) 1990–2009

1 exp Obesity/
2 exp Weight Gain/
3 exp Weight Reduction/
4 (overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.
5 (weight gain or weight loss).ti,ab.
6 ((bmi or body mass index) adj5 (gain* or loss* or change*)).ti,ab.
7 obes*.ti,ab.
8 or/1–7
9 Preschool Child/
10 Infant/
11 Toddler/
12 (baby or babies or toddler* or infant* or newborn* or neonat* or preschool* or pre school* or playschool* or playgroup* or kindergarten* or kindergarden*).ti,ab. (299389)
13 Infant/
14 Newborn/
15 ("under 5" adj3 age).ti,ab.
16 16 ("under 5" adj3 year*).ti,ab.
17 "under 5's".ti,ab.
18 "aged under 5".ti,ab.
19 "under 5 yr".ti,ab.
20 or/9–19
21 family therapy/
22 Health Behavior/or Attitude to Health/
23 exp Diet Therapy/
24 Low Fat Diet/
25 Low Calory Diet/
26 (diet or diets or dieting).ti,ab.
27 Health Care Policy/
28 community care/
29 Parent Counseling/or Counseling/or Nutritional Counseling/
30 (low calorie or calorie control* or healthy eating).ti,ab.
31 (obes* adj2 prevent*).ti,ab.
32 (obes* adj2 guidance).ti,ab.
33 (obes* adj2 manag*).ti,ab.
34 (obes* adj5 interven*).ti,ab.
35 (weight adj2 manag*).ti,ab.
36 (weight adj2 scheme*).ti,ab.
37 (weight adj2 interven*).ti,ab.
38 nutrition polic*.ti,ab.
39 nutrition strateg*.ti,ab.
40 Preventive Health Service/
41 public health/
42 exp Exercise/or Aerobic Exercise/
43 (aerobic* or physical therap* or physical activit* or physical inactivity).ti,ab.
44 (fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.
45 (sedentary behavio?r adj2 reduc*).ti,ab.
46 dance.mp. and (therap* or activit* or class* or program* or group* or session* or scheme*).ti,ab.
47 (exercis* adj3 (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.
48 ((playschool or communit* or toddler* or kindergarten) adj2 (program* or scheme*)).ti,ab.
49 (family* scheme* or families scheme* parent* scheme* or carer* scheme* or guardian* scheme*).ti,ab.

50 (family* intervention* or families intervention* parent* intervention* or carer* intervention* or guardian* intervention*).ti,ab.
51 (parent adj2 (behavio?r or involvement or control* or attitude* or education*)).ti,ab.
52 (group adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab.
53 (community adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab.
54 (health polic* or healthcare polic* or preschool polic* or playschool polic* or food polic* or nutrition polic*).ti,ab.
55 Primary Prevention/
56 (preventive measure* or preventative measure*).ti,ab.
57 (individual* adj (therapy or intervention* or program* or strateg* or management)).ti,ab.
58 (population adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab.
59 health education/
60 health promotion/
61 secondary prevention/
62 health scheme*.ti,ab.
63 or/21–62
64 exp Randomized Controlled Trial/
65 Controlled Clinical Trial/
66 Randomization/
67 Double Blind Procedure/
68 Single Blind Procedure/
69 placebo/
70 ((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).ti,ab.
71 placebo*.ti,ab.
72 ((random* or control*) adj5 (trial* or stud*)).ti,ab.
73 (randomized or randomised).ti,ab.
74 Comparative Study/
75 Evaluation/
76 (matched communities or matched populations).mp.
77 (control* adj (trial* or study or studies or evaluation*)).mp.
78 (comparison group* or comparative group* or control* group*).mp.
79 statistical analysis/
80 matched pair*.ti,ab.
81 (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab.
82 Meta Analysis/
83 meta analy*.ti,ab.
84 Outcome Assessment/
85 outcome stud*.ti,ab.
86 Intervention Study/
87 Prospective Study/
88 Follow Up/
89 (medline or medlars or embase or scisearch or cinahl).ti,ab,sh.
90 "Systematic Review"/
91 (systematic* adj5 review*).mp.
92 (systematic adj5 overview*).mp.
93 (methodolog* adj5 review).mp.
94 (methodolog* adj5 overview*).mp.
95 (methodolog* adj5 research).mp.
96 ((hand adj5 search*) or (manual* adj5 search)).mp.
97 (electronic* database* or bibliographic* database* or computer* database* or online database*).mp.
98 (Health Technology Assessment* or Medical Technology Assessment*).ti,ab,in.
99 exp Methodology/
100 or/64–99
101 8 and 20 and 63 and 100
102 obesity/dt
103 102 and 20 and 100
104 101 or 103
105 limit 104 to (human and english language and yr="1990 – 2009")

CAB ABSTRACTS (OVID) 1990–2009

1 exp pre school children/or (toddler* or baby or babies or preschool or pre school or newborn* or infant* or neonat* or playschool* or playgroup* or kindergarten* or kindergarden*).mp.
2 exp OBESITY/25258
3 exp preventive measures/or (policy or policies or prevention or evaluation* or intervention* or program* or strateg* or management or scheme*).mp.
4 1 and 2 and 3
5 exp CLINICAL TRIALS/or exp randomized controlled trials/
6 (trial* or study* or studies).ti,ab.
7 4 and (5 or 6)
8 limit 7 to yr="1990 – 2009"
9 child nutrition.sh.
10 and 2 and 9
11 10 and (5 or 6)
12 or 11
13 limit 12 to (english language and yr="1990 – 2009")

Health Management Information Consortium (OVID) 1990–2009

1 exp pre school children/or (toddler* or baby or babies or preschool or pre school or newborn* or infant* or neonat* or

playschool* or playgroup* or kindergarten* or kindergarden*).mp.
2 exp OBESITY/
3 exp preventive measures/or (policy or policies or prevention or evaluation* or intervention* or program* or strateg* or management or scheme*).mp.
4 1 and 2 and 3 25
5 exp CLINICAL TRIALS/or exp randomized controlled trials/
6 (trial* or study* or studies).ti,ab.
7 4 and (5 or 6)
8 limit 7 to yr="1990 – 2009"

Science Citation Index Expanded & Conference Proceedings Citation Index (web of science) 1990–2009

1 TS=(obes* OR overweight OR "weight gain")
2 TS=((diet or nutrition or food) SAME (scheme* or therapy OR interven* or strateg* OR program* or management or modif* OR reduc* OR policy OR policies))
3 TS=((lifestyle or behaviour OR behavior) SAME (scheme* or therapy OR interven* or strateg* OR program* or management or modif* OR reduc* OR policy OR policies))
4 TS=((exercis* OR fitness OR aerobic* OR dance OR "physical therapy" OR "physical therapies") SAME (class* OR regime* OR group* or session* OR scheme* or therapy OR interven* or strateg* OR program* or management or modif* OR reduc* OR policy OR policies))
5 TS=((parent OR family or families or guardian* or carer*) SAME (educat* or scheme* OR intervent* or program*))
6 TS=(weight management OR weight maintain* OR weight modific* OR weight control* OR weight reduc*)
7 TS=(toddler* OR preschool or pre-school or "pre school" OR infant*) >100,000
8 (#1 and #7)
9 (#2 OR #3 OR #4 OR #5 OR #6)
10 #8 and #9
11 TS=((random* or placebo* or control* or blind*) SAME (trial or study or studies))
12 TS=(systematic review*)
13 TS=(meta analy*)
14 TS=(controlled trial)
15 TS=(randomized controlled trial)
16 #11 OR #12 OR #13 OR #14 OR #15
17 #10 AND #16
18 TI=(obes* and trial*) AND TI=(toddler* or infant* or preschool or pre-school or "pre school")
19 TI=(weight or overweight OR "over weight" OR "over-weight") AND TI=(trial* OR study or studies) AND TI=(toddler* or infant* or preschool or pre-school or "pre school")
20 TI=("low birthweight") or ("low birth weight")
21 #19 NOT #20
22 #17 OR #18 OR #21

PsycINFO (EBSCO) 1990–2009

Search Limiters – English; language: English; age groups: neonatal (birth–1 month), infancy (2–23 months), preschool age (2–5 years); population group: human

S1 exp obesity/
S2 TX obesity
S3 KW obesity
S4 KW overweight
S5 TX overweight or over weight
S6 TX overeat* or over eat* or overfeed* or over feed
S7 MJ obesity
S8 (S1 or S2 or S3 or S4 or S5 or S6 or S7)
S9 DE "Random Sampling" or MM "Clinical Trials"
S10 TX random* or placebo*
S11 DE "Experiment Controls"
S12 s8 and (s9 or s10 or s11
S13 TX weight management
S14 TX s12 or s13
S15 TX exercise or play or fitness or physical
S16 s8 and s15
S17 TX trial and (random* or blind* or mask*)
S18 TX study and (random* or blind* or mask*)
S19 TX studies and (random* or blind* or mask*)
S20 s16 and (s9 or s10 or s11 or s17 or 18 or 19
S21 TX diet* and (modif* or therap* or intervention* or strateg* or program* or scheme* or management*)
S22 TX behav* and (modif* or therap* or intervention* or strateg* or program* or scheme* or management*)
S23 TX s8 and (s21 or s22)
S24 s23 and (s9 or S10 or S11 or S17 or S18 or S19)
S25 s12 or s20 or s24

Cochrane CENTRAL & Cochrane Database of Systematic Reviews

1 MeSH descriptor Obesity explode all trees with qualifiers: TH,DH
2 MeSH descriptor Overweight explode all trees with qualifiers: DH,TH
3 (preschool or infant* or toddler* or baby or babies)
4 "under 5"

5 (#3 OR #4)
6 (#1 OR #2)
7 (#5 AND #6)
8 (obes* or overweight or over next weight or weight next gain or over next eat* or overeat*)
9 (bmi or body next mass next index) near (gain or loss or change)
10 (#8 OR #9)
11 child-preschool:kw
12 infant:kw
13 (#10 AND (#5 OR #11 OR #12))
14 (management or scheme* or program* or reduc* or class or classes or service* or therap* or intervention* or strateg* or counsel* or modif* or support)
15 (lifestyle or life style) adj (chang* or intervention* or modific*)
16 family therapy:kw
17 (#13 AND (#14 OR #15 OR #16))
18 (health next promotion or health next prevention)
19 (#13 AND #18)
20 (#17 OR #19)
21 (random* or placebo*):ti,ab
22 MeSH descriptor Controlled Clinical Trials as Topic, this term only
23 MeSH descriptor Randomized Controlled Trials as Topic explode all trees
24 meta analy*:ti,ab,kw
25 systematic:ti,ab,kw
26 (singl* blind* or doubl* blind* or tripl* blind* or trebl* blind*)
27 (singl* mask* or doubl* mask* or tripl* mask* or trebl* mask*)
28 "controlled clinical trial":kw
29 controlled study:kw
30 random allocation:kw
31 (#21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30)
32 (#20 AND #31)

CRD HTA, CRD DARE

1 MeSH Obesity EXPLODE
2 MeSH Overweight EXPLODE
3 MeSH Weight Gain EXPLODE
4 weight AND maintenance
5 MeSH Weight Loss EXPLODE
6 obes*
7 "weightgain" OR "weight gain*" OR "weight loss*"
8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
9 MeSH Child, Preschool EXPLODE
10 (toddler* OR preschool OR pre?school OR pre-school OR infant* OR baby OR babies)
11 ("under 5" OR "under 5's")
12 #9 or #10 OR #11
13 #8 and #12

Economic searches

MEDLINE (OVID) 1990–2009

1 exp economics/
2 exp economics hospital/
3 exp economics pharmaceutical/
4 exp economics nursing/
5 exp economics medical/
6 exp "Costs and Cost Analysis"/
7 Cost Benefit Analysis/
8 value of life/
9 exp models economic/
10 exp fees/and charges/
11 exp budgets/
12 (value adj2 (money or monetary)).tw.
13 (economic adj2 burden).tw.
14 (expenditure* not energy).tw.
15 budget*.tw.
16 (economic* or price* or pricing or financ* or fee* or pharmacoeconomic* or pharma economic* or pharmaco-economic*).tw.
17 (decision adj1 (tree* or analys* or model*)).tw.
18 Resource Allocation/
19 (unit cost or unit-cost or unit-costs or unit costs or drug cost or drug costs or hospital costs or health-care costs or health care cost or medical cost or medical costs).tw.
20 ((value or values or valuation) adj2 (money or monetary or life or lives or costs or cost)).tw.
21 Markov Chains/
22 Monte Carlo Method/
23 exp Decision Support Techniques/
24 (resource adj2 (use* or utili* or allocat*)).tw.
25 (cost adj2 (util* or effective* or efficac* or benefit* or consequence* or analys* or minimi* or saving* or breakdown* or lowering or estimate* or variable* or allocation* or control* or illness* or affordable* or instrument* or technolog* or fee* or charge* or charges)).tw.
26 or/1–25
27 limit 26 to (comment or editorial or letter)
28 26 not 27
29 exp Obesity/
30 exp weight gain/
31 overweight/
32 (overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.
33 (weight adj1 gain*).ti,ab.
34 ((bmi or body mass index) adj5 (gain* or loss* or chang*)).ti,ab.
35 ((bmi or body mass index) adj5 (gain* or chang*)).ti,ab.

36 obes*.ti,ab.
37 or/29–36
38 child preschool/
39 infant/
40 (baby or babies or toddler* or infant* or newborn* or neonat* or preschool* or pre school* playschool* or playgroup* or kindergarten* or kindergarden*).ti,ab.
41 infant newborn/
42 (age adj5 "under 5").ti,ab.
43 (age adj5 "under 5's").ti,ab.
44 (year* adj5 "under 5").ti,ab.
45 (year* adj5 "under 5's").ti,ab.
46 or/38–45
47 family therapy/
48 Health Knowledge, Attitudes, Practice/
49 diet therapy/
50 Obesity/dh, th [Diet Therapy, Therapy]
51 diet fat restricted/
52 diet reducing/
53 diet therapy/
54 (diet or diets or dieting).ti,ab.
55 professional family relations/
56 health behavior/
57 parenting/px
58 caregivers/px
59 Schools, Nursery/st [Standards]
60 nutrition policy/
61 Preventive Health Services/
62 obesity/pc
63 child care/st
64 nurseries/st
65 Community Health Planning/or Community Health Services/
66 counseling/
67 (low calorie or calorie control* or healthy eating).ti,ab.
68 (eat* adj1 health*).ti,ab.
69 (diet* adj2 (modific* or therap* or intervention* or strateg* or program* or management or scheme*)).ti,ab.
70 exercise/or exercise therapy/
71 "Play and Playthings"/
72 (aerobic* or physical therap* or physical activit* or physical inactivity).ti,ab.
73 (fitness adj (class or regime* or program* or group* or session* or scheme* or therap*)).ti,ab.
74 (sedentary behavio?r adj2 reduc*).ti,ab.
75 (reduc* adj2 sedentary).ti,ab.
76 dance.mp. and (therap* or activit* or class* or program* or group* or session* or scheme*).ti,ab.
77 Dance Therapy/
78 dancing/and (therap* or activit* or class* or program* or group* or session* or scheme*).ti,ab.
79 ((playschool or communit* or toddler* or kindergarten) adj2 (program* or scheme*)).ti,ab.
80 (family* scheme* or families scheme* parent* scheme* or carer* scheme* or guardian* scheme*).ti,ab.
81 (family* intervention* or families intervention* parent* intervention* or carer* intervention* or guardian* intervention*).ti,ab.
82 (parent adj2 (behavio?r or involvement or control* or attitude* or education*)).ti,ab.
83 (group adj (therap* or intervention* or program* or strateg* or management or scheme*)).ti,ab.
84 (community adj (therap* or intervention* or program* or strateg* or management or scheme*)).ti,ab.
85 (health polic* or preschool polic* or playschool polic* or food polic* or nutrition polic*).ti,ab.
86 primary prevention/
87 (preventive measure* or preventative measure*).ti,ab.
88 (individual* adj (therap* or intervention* or program* or strateg* or management)).ti,ab.
89 (exercise and (therap* or activity or class* or program* or group* or session* or scheme*)).ti,ab.
90 (population adj (therap* or intervention* or program* or strateg* or management or scheme*)).ti,ab.
91 health education/or health promotion/
92 secondary prevention/
93 (health scheme* or health program*).ti,ab.
94 (weight adj2 manag*).ti,ab.
95 (obes* adj2 manag*).ti,ab.
96 (weight adj5 scheme*).ti,ab.
97 (weight adj5 interven*).ti,ab.
98 or/47–97
99 28 and 37 and 46 and 98
100 limit 99 to (english language and humans and yr="1990 – 2009")

MEDLINE In-Process (OVID) 1990–2009

Strategy as per MEDLINE (using only free text terms)

EMBASE (OVID) 1990–2009

1 exp Obesity/
2 exp Weight Gain/
3 exp Weight Reduction/
4 (overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.
5 (weight gain or weight loss).ti,ab.

6 ((bmi or body mass index) adj5 (gain* or loss* or change*)).ti,ab.
7 obes*.ti,ab.
8 or/1–7
9 Preschool Child/
10 Infant/
11 Toddler/
12 (baby or babies or toddler* or infant* or newborn* or neonat* or preschool* or pre school* playschool* or playgroup* or kindergarten* or kindergarden*).ti,ab.
13 Infant/
14 Newborn/
15 ("under 5" adj3 age*).ti,ab.
16 ("under 5" adj3 year*).ti,ab.
17 "under 5's".ti,ab.
18 "aged under 5".ti,ab.
19 ("under 5 yr" or "under 5 yrs").ti,ab.
20 or/9–19
21 family therapy/
22 Health Behavior/or Attitude to Health/
23 exp Diet Therapy/
24 Low Fat Diet/
25 Low Calory Diet/
26 (diet or diets or dieting).ti,ab.
27 Health Care Policy/
28 community care/
29 Parent Counseling/or Counseling/or Nutritional Counseling/
30 (low calorie or calorie control* or healthy eating).ti,ab.
31 (obes* adj2 prevent*).ti,ab.
32 (obes* adj2 guidance).ti,ab.
33 (obes* adj2 manag*).ti,ab.
34 (obes* adj5 interven*).ti,ab.
35 (obes* adj5 program*).ti,ab.
36 (weight adj2 manag*).ti,ab.
37 (weight adj5 scheme*).ti,ab.
38 (weight adj5 interven*).ti,ab.
39 nutrition polic*.ti,ab.
40 nutrition strateg*.ti,ab.
41 Preventive Health Service/
42 public health/and (therap* or intervention* or program* or strateg*).ti,ab.
43 exp Exercise/or Aerobic Exercise/
44 (aerobic* or physical therap* or physical activit* or physical inactivity or physical education*).ti,ab.
45 (fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.
46 (sedentary behavio?r adj2 reduc*).ti,ab.
47 dance.mp. and (therap* or activit* or class* or program* or group* or session* or scheme*).ti,ab.
48 (exercis* adj3 (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.
49 ((playschool or communit* or toddler* or kindergarten) adj2 (program* or scheme*)).ti,ab.
50 (family* scheme* or families scheme* parent* scheme* or carer* scheme* or guardian* scheme*).ti,ab.
51 (family* intervention* or families intervention* parent* intervention* or carer* intervention* or guardian* intervention*).ti,ab.
52 (parent adj2 (behavio?r or involvement or control* or attitude* or education*)).ti,ab.
53 (group adj2 (therap* or intervention* or program* or strateg* or management or scheme*)).ti,ab.
54 (community adj (therap* or intervention* or program* or strateg* or management or scheme*)).ti,ab.
55 (health polic* or healthcare polic* or preschool polic* or playschool polic* or food polic* or nutrition polic*).ti,ab.
56 Primary Prevention/
57 (preventive measure* or preventative measure*).ti,ab.
58 (individual* adj (therap* or intervention* or program* or strateg* or management)).ti,ab.
59 (population adj (therap* or intervention* or program* or strateg* or management or scheme*)).ti,ab.
60 health education/
61 health promotion/
62 secondary prevention/
63 health scheme*.ti,ab.
64 (health* adj2 program*).ti,ab.
65 (health* adj2 intervention*).ti,ab.
66 or/21–65
67 exp Health Economics/
68 *economics/
69 monte carlo method/
70 cost*.ti.
71 cost minimization analysis/
72 cost of illness/
73 cost utility analysis/
74 health care cost/
75 economic evaluation/
76 pharmacoeconomics/
77 budget/
78 (econom* or pharmacoeconomic* or pharmaco economic* or cost or costs or costly or costing or costed or expenditure* or budget*).ti,ab.
79 markov.mp.
80 (resource adj2 (use* or utili* or allocat*)).ti,ab.
81 (cost adj2 (util* or effective* or efficac* or benefit* or consequence* or analys* or

minimi* or saving* or breakdown* or lowering or estimate* or variable* or allocation* or control* or illness* or affordable* or instrument* or technolog* or fee* or charge* or charges)).ti,ab.
82 ((value or values or valuation) adj2 (money or monetary or life or lives or costs or cost)).tw.
83 or/67–82
84 8 and 20 and 66 and 83
85 limit 84 to (human and english language and yr="1990 – 2009")
86 limit 85 to (editorial or letter)
87 85 not 86

CAB abstracts (OVID) 1990–2009

1 exp pre school children/or (toddler* or baby or babies or preschool or pre school or newborn* or infant* or neonat* or playschool* or playgroup* or kindergarten* or kindergarden*).mp
2 exp OBESITY/
3 exp preventive measures/or (policy or policies or prevention or evaluation* or intervention* or program* or strateg* or management or scheme*).mp.
4 1 and 2 and 3
5 child nutrition.sh.
6 1 and 3 and 5
7 (overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab
8 (weight gain* or weight loss* or weight management).ti,ab.
9 ((bmi or body mass index) adj5 (gain* or loss* or change*)).ti,ab.
10 weight reduction/
11 or/7–10
12 1 and 3 and 11
13 4 or 6 or 12
14 (costs or economic analysis or "cost benefit analysis").sh.
15 13 and 14

Health Management Information Consortium (OVID) 1990–2009

1 exp pre school children/or (toddler* or baby or babies or preschool or pre school or newborn* or infant* or neonat* or playschool* or playgroup* or kindergarten* or kindergarden*).mp.
2 exp OBESITY/
3 exp preventive measures/or (policy or policies or prevention or evaluation* or intervention* or program* or strateg* or management or scheme*).mp.
4 1 and 2 and 3
5 (overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.
6 (weight gain* or weight loss* or weight management).ti,ab.
7 ((bmi or body mass index) adj5 (gain* or loss* or change*)).ti,ab.
8 exp WEIGHT WATCHING/
9 exp BODY WEIGHT/or exp CLINICAL WEIGHT MEASUREMENT/or exp WEIGHT
10 or/5–9
11 1 and 2 and 10
12 4 or 11
13 exp HEALTH ECONOMICS/
14 exp TREATMENT COSTS/
15 exp "COST BENEFIT ANALYSIS"/
16 (cost adj2 (util* or effective* or efficac* or benefit* or consequence* or analys* or minimi* or saving* or breakdown* or lowering or estimate* or variable* or allocation* or control* or illness* or affordable* or instrument* or technolog* or fee* or charge* or charges)).ti,ab.
17 (resource adj2 (use* or utili* or allocat*)).ti,ab.
18 exp MODELS/
19 exp ECONOMIC EVALUATION/
20 markov.ti,ab.
21 (economic* or budget*).ti,ab.
22 or/13–21
23 12 and 22

Science Citation Index Expanded & Conference Proceedings Citation Index (web of science) 1990–2009

Search Restricted to Document Type=(Article OR Meeting Abstract OR Meeting Summary OR Meeting-Abstract OR Proceedings Paper) AND Language=(English)

1 TS=(toddler* OR preschool or pre-school or "pre school" OR infant*)
2 TS=(obes* OR overweight OR "weight gain" or "weight loss")
3 TS=(cost or economic* or markov or "monte carlo")
4 TS=(scheme* or program* or therapy or therapies or intervention* or strategy or strategies)
5 #1 and #2 and #3 and #4
6 TS=("cost benefit analysis" or "cost benefit analyses")
7 TS=("health economics")
8 #6 or #7
9 #1 and #2 and #4 and #8
10 #5 or #9
11 TI=(obes*) and TI=(cost*)
12 TI=(overweight)and TI=(cost*)

13 #11 or #12
14 1 #1 and #13
15 #10 or #14

Cochrane CENTRAL & Cochrane Database Of Systematic Reviews

1 MeSH descriptor Obesity explode all trees
2 MeSH descriptor Overweight explode all trees
3 (#1 OR #2)
4 (preschool or infant* or toddler* or baby or babies)
5 (#3 AND #4)
6 Obes*:ti,ab,kw
7 (#4 AND #6)
8 (#5 OR #7)
9 (management or scheme* or program* or reduc* or class or classes or service* or therap* or intervention* or strateg* or counsel* or modif* or support)
10 (#8 AND #9)
11 MeSH descriptor Economics explode tree
12 MeSH descriptor Costs and Cost Analysis explode all trees
13 MeSH descriptor Models, Economic explode trees 1, 2 and 4
14 cost-effective*
15 MeSH descriptor Resource Allocation explode all trees
16 "economic evaluation"
17 (#11 OR #12 OR #13 OR #14 OR #15 OR #16)
18 (#10 AND #17)
19 cost*:ti or economic*:ti 22117
20 (#8 AND #19)
21 (#20 AND NOT #18)
22 (#18 OR #21) 11

NHS EED, HTA, DARE, (CRD)

1 MeSH Obesity EXPLODE
2 MeSH Overweight EXPLODE
3 MeSH Weight Gain EXPLODE
4 weight AND maintenance
5 MeSH Weight Loss EXPLODE
6 obes*
7 "weightgain" OR "weight gain*" OR "weight loss*"
8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
9 MeSH Child, Preschool EXPLODE
10 (toddler* OR preschool OR pre?school OR pre-school OR infant* OR baby OR babies)
11 ("under 5" OR "under 5's")
12 #9 or #10 OR #11
13 #8 and #12
14 MeSH Economics, Medical EXPLODE 1 241
15 MeSH Cost of Illness EXPLODE 1 2 2632
16 cost AND benefit AND analysis 6515
17 MeSH Cost-Benefit Analysis EXPLODE 1 11354
18 MeSH Health Care Costs EXPLODE 1 2 9189
19 MeSH Models, Economic EXPLODE 1 2 3 4 1763
20 "cost effectiveness" 10411
21 #14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20
22 22#13 AND 21
23 RESTRICT YR 1990 2009

PsycINFO (EBSCO) 1990–2009

1 (((DE "Obesity") or (DE "Overweight"))) or (DE "Weight Gain")
2 DE "Costs and Cost Analysis"
3 TX scheme* or TX program* or TX group* or TX therapy or TX therapies or TX activity or TX activities or TX intervention* or TX management
4 s1 and s2 and s3
5 TX weight n5 manag* or TX "weight loss" n5 manag* or TX "weight gain" n5 manag*
6 TX obes* n5 manag* or TX obes* n5 manag* or TX obes* n5 manag*
7 s5 OR s6
8 s2 AND s7
9 s4 OR s8
10 TX exercise or TX aerobic* or TX dance or TX dancing or TX gym* or TX play*
11 s1 and s2 and s10
12 TX obes*
13 TX preschool or TX "pre school" or TX infant* or TX baby or TX babies or TX tot* or TX "under 5" or TX newborn* or TX neonat* or playschool* or playgroup* or kindergar?en
14 s12 and s13
15 TX cost* or TX economic* or TX markov
16 s14 and s15
17 s14 and s15 Narrow by Age0: – Preschool Age (2–5 yrs)
18 s9 or s11 or s17

Quality of life searches

MEDLINE (OVID) 1990–2009

1 exp obesity/
2 exp weight gain/
3 overweight/
4 Child, Preschool/)
5 ("under 5" adj5 age*).ti,ab.
6 "under 5's".ti,ab.
7 "under 5 years of age".ti,ab.
8 (baby or babies or toddler* or infant*).ti,ab.
9 or/1–3
10 or/4–8
11 9 and 10

12 value of life/
13 quality adjusted life year/
14 quality adjusted life.ti,ab.
15 (qaly* or qald* or qale* or qtime*).ti,ab.
16 disability adjusted life.ti,ab.
17 daly*.ti,ab.
18 health status indicators/
19 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirty six or short form thirtysix).ti,ab.
20 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).ti,ab.
21 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab.
22 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab.
23 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab.
24 (euroqol or euro qol or eq5d or eq 5d).ti,ab.
25 (hql or hqol or h qol or hrqol or hr qol).ti,ab.
26 (hye or hyes).ti,ab.
27 health* year* equivalent*.ti,ab.
28 health utilit*.ti,ab.
29 (hui or hui1 or hui2 or hui3).ti,ab.
30 disutil*.ti,ab.
31 rosser.ti,ab.
32 quality of well being.ti,ab.
33 quality of wellbeing.ti,ab.
34 qwb.ti,ab.
35 willingness to pay.ti,ab.
36 standard gamble*.ti,ab.
37 time trade off.ti,ab.
38 time tradeoff.ti,ab.
39 tto.ti,ab.
40 (quality adj2 well being).mp.
41 (index adj2 well being).mp.
42 (health adj3 util* ind*).mp.
43 ((multiattribute* or multi attribute*) adj3 (health ind* or theor* or health state* or utilit* or analys*)).mp.
44 quality adjusted life year*.mp.
45 (15D or 15 dimension*).mp.
46 (12D or 12 dimension*).mp.
47 rating scale*.mp
48 linear scale*.mp.
49 linear analog*.mp.
50 visual analog*.mp.
51 (categor* adj2 scale*).mp.
52 (obes* and child*).mp. and scale*.ti.
53 from 52 keep 1–14
54 (scale* adj2 measur*).ti,ab.
55 Pediatrics/px, is [Psychology, Instrumentation]
56 psychometrics/
57 Sickness Impact Profile/
58 "children's physical self-concept scale".ti,ab.
59 "pedsQL".ti,ab.
60 (pediatric* adj2 quality of life).ti,ab.
61 (paediatric* adj2 quality of life).ti,ab.
62 (child* adj2 quality of life).ti,ab.
63 (child* adj2 qol).ti,ab.
64 (pediatric adj2 qol).ti,ab.
65 (paediatric* adj2 qol).ti,ab.
66 or/12–65
67 11 and 66
68 (letter or editorial or comment).ti,ab.
69 67 not 68
70 limit 69 to (english language and humans and yr="1990 – 2009")

MEDLINE In-Process (OVID) 1990–2009

Strategy as per MEDLINE (using only free text terms)

EMBASE (OVID) 1990–2009

1 exp obesity/
2 exp weight gain/
3 (overweight or obes* or "over weight").ti,ab.
4 child preschool/or (Preschool or pre-school).ti,ab.
5 ("under 5" adj5 age*).ti,ab.
6 "under 5's".ti,ab.
7 "under 5 years of age".ti,ab.
8 (baby or babies or toddler* or infant*).ti,ab.
9 or/1–3
10 or/4–8
11 9 and 10
12 "value of life".mp.
13 quality adjusted life year/
14 quality adjusted life.ti,ab.
15 (qaly* or qald* or qale* or qtime*).ti,ab.
16 disability adjusted life.ti,ab.
17 daly*.ti,ab.
18 health status indicator*.ti,ab.
19 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirty six or short form thirtysix).ti,ab.
20 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).ti,ab.
21 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab.
22 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab.

23 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab.
24 (euroqol or euro qol or eq5d or eq 5d).ti,ab.
25 (hql or hqol or h qol or hrqol or hr qol).ti,ab.
26 (hye or hyes).ti,ab.
27 health* year* equivalent*.ti,ab.
28 health utilit*.ti,ab.
29 (hui or hui1 or hui2 or hui3).ti,ab.
30 disutil*.ti,ab.
31 rosser.ti,ab.
32 quality of well being.ti,ab.
33 quality of wellbeing.ti,ab.
34 qwb.ti,ab.
35 willingness to pay.ti,ab.
36 standard gamble*.ti,ab.
37 time trade off.ti,ab.
38 time tradeoff.ti,ab.
39 tto.ti,ab.
40 (quality adj2 well being).mp.
41 (index adj2 well being).mp.
42 (health adj3 util* ind*).mp.
43 ((multiattribute* or multi attribute*) adj3 (health ind* or theor* or health state* or utilit* or analys*)).mp.
44 quality adjusted life year*.mp.
45 (15D or 15 dimension*).mp.
46 (12D or 12 dimension*).mprating scale*.mp.
47 linear scale*.mp.
48 linear analog*.mp.
49 visual analog*.mp.
50 (categor* adj2 scale*).mp.
51 (obes* and child*).mp. and scale*.ti.
52 quality of life.ti,ab.
53 (scale* adj2 measur*).ti,ab.
54 [Pediatrics/px, is [Psychology, Instrumentation]]
55 psychometric*.ti,ab.
56 (Sickness adj2 impact*).ti,ab.
57 "children's physical self-concept scale".ti,ab.
58 "pedsQL".ti,ab.
59 (pediatric* adj2 quality of life).ti,ab.
60 (paediatric* adj2 quality of life).ti,ab.
61 (child* adj2 quality of life).ti,ab.
62 (child* adj2 qol).ti,ab.
63 (pediatric adj2 qol).ti,ab.
64 (paediatric* adj2 qol).ti,ab.
65 or/12–65
66 11 and 66
67 (letter or editorial or comment).ti,ab.
68 67 not 68

Science Citation Index Expanded & Conference Proceedings Citation Index (web of science) 1990–2009

1 TS=(obes* OR overweight OR "weight gain")
2 TS=(toddler* OR preschool or pre-school or "pre school" OR infant*)
3 TS=("quality adjusted life")
4 TS=("quality indicator*")
5 TS=(qaly* or qald* or qale* or qtime* or daly or euroqol or "euro qol" or eq5d or "eq 5d" or hql or hqol or "h qol" or hrqol or "hr qol")
6 TS=(health utilit*)
7 TS=("health utilit*")
8 TI=("quality of life" or "life quality" or qol)
9 TS=("rating scale" same quality)
10 TS=(child* same "quality of life")
11 TS=(child* same qol)
12 TS=(paediatric* SAME "quality of life") OR TS=(pediatric* SAME "quality of life") OR TS=(paediatric* SAME QOL) or TS=(pediatric* SAME qol)
13 TS=(obes* SAME child*) AND TS=(rating same measur*)
14 TS=(obes* SAME child*) AND TS=(scale* same measur*)
15 TS=(obes* SAME stigma*)
16 TS=(15D or "15 dimension" or 12D or "12 dimension" or hui or "hui1" or "hui2" or "hui3" or rosser)
17 #1 AND #2
18 (#3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16)
19 #17 and #18

PsycINFO (EBSCO) 1990–2009

Adapted from MEDLINE search

1 DE obesity or DE overweight or DE weight gain
2 TX obes*
3 s1 OR s2
4 TX preschool or TX "pre school" or TX "under 5" or TX baby or TX babies or TX infan* or TX "tot" or TX "tots"
5 s3 AND s4
6 MM "Quality of Life"
7 TX "quality adjusted life" or TX "quality indicator*" or TX "health utilit*" or TX Rosser
8 DE "Rating Scales" OR DE "Likert Scales"
9 TX euroqol or TX euro qol or TX eq5d or TX eq 5d or TX hql or TX hqol or TX h qol or TX hrqol or TX hr qol or TX hye or TX hyes
10 TX quality of wellbeing or TX quality of well being
11 TX SF 36 or TX SF36 or TX SF 12 or TX SF12 or TX SF 6 or TX SF6 or TX SF 16 or TX SF16 or TX SF 20 or TX SF20
12 TI quality of life
13 DE "Ability Level"
14 TX stigma* N5 obes*
15 TX impact* N5 obes*

16 TX emotion* N5 obes*
17 DE "Body Image" OR DE "Body Image Disturbances"
18 DE "Learning Ability"
19 DE "Self Esteem" or DE "Self Confidence" or DE "Conduct Disorder" or DE "Self Concept" or DE "Self Perception"
20 (s6 or s7 or s8 or s9 or s10 or s11 or s12 or s13 or s14 or s15 or s16 or s17 or s18 or s19)
21 s5 and s20
22 TX preschool or TX "pre school" or TX baby or TX babies or TX infant or TX infants or TX "tot" or TX "tots"
23 s3 and s20 and s22
24 TX "under 5" N3 age or TX "under 5" N3 years
25 s3 and s20 and s24
26 s23 or s25 Results (Limited to 1990–2009 & English language)

Cochrane CENTRAL & Cochrane Database Of Systematic Reviews

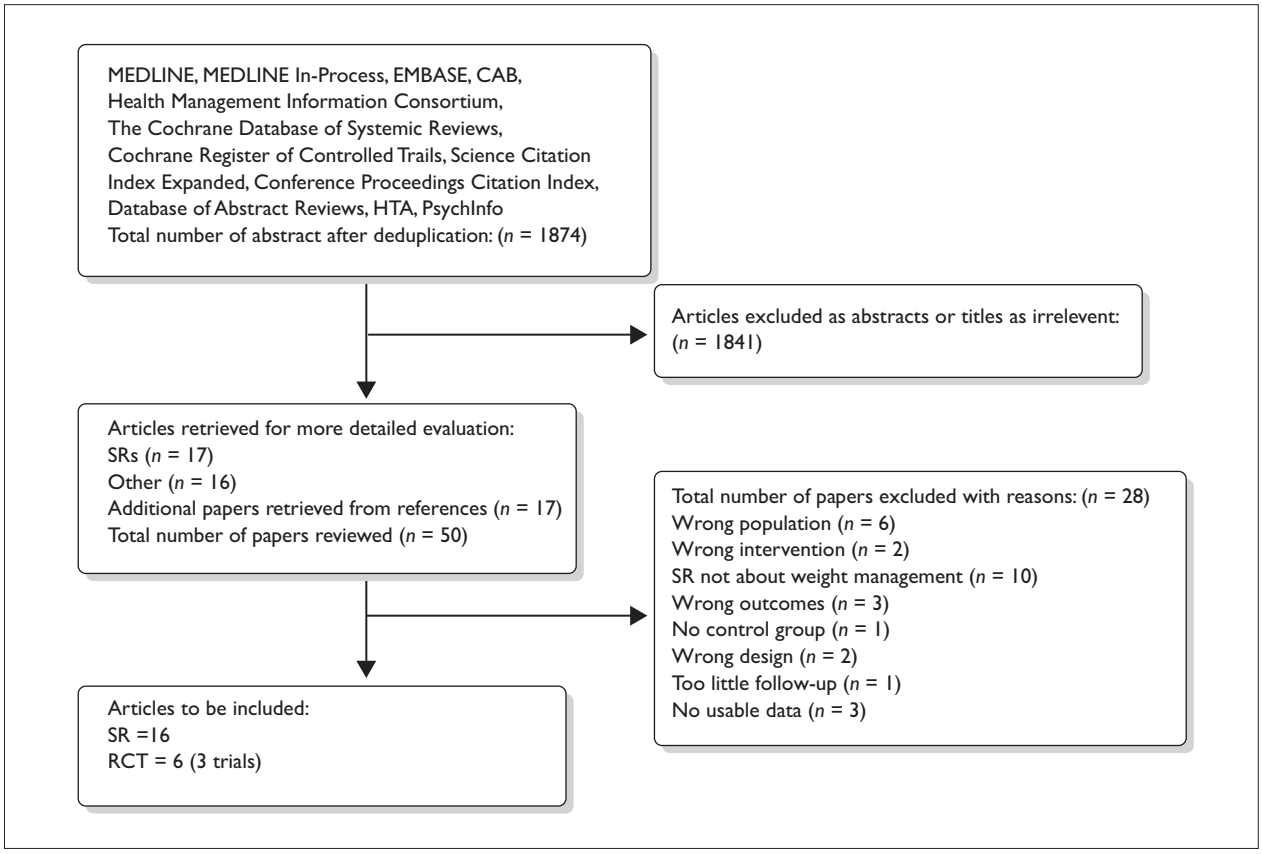
1 MeSH descriptor Obesity explode
2 MeSH descriptor Overweight explode
3 (#1 OR #2)
4 ("preschool" or "pre-school" or "pre school" or toddler* or infant* or baby or babies or "tot" or "tots")
5 "young child" or "young children"
6 (#4 OR #5) 39277
7 MeSH descriptor Quality of Life explode all trees
8 (euroqol or "euro qol" or "eq5d" or "eq 5d" or hql or "hqol" or "h qol" or "hrqol" or "hr qol" or hye or hyes)
9 ("SF 36" or "SF36" or "SF 12" or "SF12" or "SF 6" or "SF6" or "SF 16" or "SF16" or "SF 20" or "SF20")
10 (hui" OR "hui1" OR "hui2" OR "hui3" or rosser)
11 (QALY* OR QUALY*)
12 MeSH descriptor Sickness Impact Profile explode
13 (stigma*)
14 (impact* and quality)
15 "quality of life"
16 "quality indicator"
17 "quality indicators"
18 (#7 OR #8 OR #9 OR #10 OR 11 OR #12 OR 13 OR #14 OR #15 OR #16 OR 17)
19 (#3 AND #6 AND #18)

CRD HTA, CRD DARE

1 MeSH Obesity EXPLODE
2 MeSH Overweight EXPLODE
3 MeSH Weight Gain EXPLODE
4 MeSH Weight Loss EXPLODE
5 weight AND maintenance
6 obes*
7 weightgain OR "weight gain" OR "weight loss"
8 #1 or #2 or #3 or #4 or #5 or #6 or #7
9 MeSH Child, Preschool EXPLODE
10 preschool OR "pre-school" OR "pre school"
11 baby OR babies OR toddler OR toddlers OR tot OR tots OR infant*
12 "under 5"
13 "under 5's"
14 young AND child
15 young AND children
16 #9 or #10 or #11 or #12 or #13 or #14 or #15
17 #8 and #16
18 quality AND life
19 MeSH Quality of Life EXPLODE
20 "quality adjusted life"
21 "quality indicator" AND "quality indicators"
22 "quality of wellbeing" OR "quality of well being"
23 "quality-of-life"
24 stigma* OR impact*
25 "SF 36" OR "SF36" OR "SF 12" OR "SF12" OR "SF6" OR "SF 16" OR "SF16" OR "SF 20" OR "SF20"
26 "euroqol" OR "euro qol" OR "eq5d" OR "eq 5d" OR "hql" OR "hqol" OR "hqol" OR "h qol" OR "hrqol" OR "hr qol" OR "hye" OR "hyes"
27 "hui" OR "hui1" OR "hui2" OR "hui3" OR "rosser"
28 MeSH Sickness Impact Profile EXPLODE
29 "health state" AND "health states"
30 QALY OR QUALY
31 #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or 32
32 #17 and #31

Appendix 2

Flow of studies



Appendix 3

Data extraction tables

Reilly and colleagues[75]

Study	Population	Outcomes	Context	Theory	Notes	Arms	OUTCOMES
ID: Reilly *et al.*[75] MAGIC trial: Movement and activity Glasgow intervention in children Date of publication: 2006 Design: cluster RCT Country: UK Definition of overweight: not reported Definition of obesity: ≥ 95th UK National BMI percentile Ethnic group: not reported Source of funding: British Heart Foundation, Glasgow City Council, and the Caledonian Research Foundation	*n* = 545 Age of children: mean age 4.2 (SD 0.2) years Intervention target population: children, parents and staff	BMI: × Weight: × Health outcomes: not measured Height: × Quality of life: not measured Length of follow-up: 12 months	Community: the context of this intervention was in the nursery and in the home Home: ×	Implicit: the implicit theory behind this trial is that increasing physical activity in very young children will have a preventative effect on obesity	Additional comment: this is a high quality cluster randomised controlled trial	**Arm No:** 1 Name: intervention child level *n* = 268 Description: an enhanced physical activity programme, in the nursery, of three 30-minute sessions of physical activity each week for 24 weeks. Two members of staff were trained in the intervention and an unblinded researcher monitored the intervention. This was combined with a home intervention consisting of a resource pack with guidance linking physical play at the nursery and home and two health education leaflets about the benefits of physical activity and encouraging alternatives to television watching, with the aim of increasing physically active play and reducing the amount of television watched **Arm No:** 2 Name: control child level *n* = 277 Description: usual care; the head teachers agreed not to enhance their physical development and movement curriculum	BMI SD score at 6 months SD score at 12 months Accelerometry count per minute % monitored time sedentary % monitored time in MVPA

MVPA, moderate to vigorous physical activity.

Baseline characteristics

	Intervention child level			Control child level				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Age (years)	268		4.2 (SD 0.3)	277		4.1 (SD 0.3)		
Number (%) overweight	268	62		277	61			
Number (%) obese	268	62		277	28			
Accelerometry per minute	268		732 (SD 163)	277		809 (SD 209)	MD = –77.000 (SE 16.026)	< 0.001[a]
% monitored time sedentary (median)	268		69.3 (rng 50.4–86.6)	277		66.9 (rng 45.6–88.7)		
% monitored time MVPA (median)	268		2.6 (rng 0.4–11.1)	277		3 (rng 0.3–13)		
BMI								
kg/m^2	268		16.3 (SD 1.5)	277		16.4 (SD 1.5)	MD= –0.100 (SE 0.129)	0.437[a]
SD score	268		0.39 (SD 0.98)	277		0.41 (SD 1)	MD = –0.020 (SE 0.085)	0.814[a]

k, a subset of *n*; MD, mean difference; MVPA, moderate to vigorous physical activity; rng, range; SE, standard error.
a student's *t*-test (calculated by reviewer).

Results

	Intervention child level			Control child level				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Accelerometry count per minute	231		809 (SD 179)	250		899 (SD 218)	MD = –90.000 (SE 18.133)	<0.001[a]
% monitored time sedentary (median)	231		67 (rng 47–86)	250		62.9 (rng 43.1–81.6)		
% monitored time in MVPA (median)	231		3.5 (rng 0.5–12.4)	250		4.1 (rng 0.6–12.1)		
BMI								
SD score at 6 months	231		0.46 (SD 1.03)	250		0.43 (SD 1.08)	MD = 0.030 (SE 0.096)	0.756[a]
SD score at 12 months	231		0.41 (SD 1.05)	250		0.43 (SD 1.1)	MD = –0.020 (SE 0.098)	0.839[a]

k, a subset of *n*; MD, mean difference; MVPA, moderate to vigorous physical activity; rng, range; SE, standard error.
a student's *t*-test (calculated by reviewer).

DOI: 10.3310/hta13610

Quality appraisal

1.1.	Was the sample size based on a power calculation? YES
1.2.	Are the eligibility criteria explicit? YES
1.3.	Was the randomisation to groups adequate? NOT REPORTED. Randomisation was stratified but the method used was not specified
1.4.	Was the intervention allocation concealed adequately? YES
1.5.	Were the groups similar at baseline? YES
1.6.	Did the groups receive similar treatment other than the intervention? NOT REPORTED
1.7.	Were outcome assessors blinded to treatment allocation? YES
1.8.	Were all participants accounted for? YES
1.9.	Were the number of withdrawals specified? YES
1.10.	Was the percentage of the population who received the intervention reported? YES
1.11.	Was the consistency of the intervention measured? YES. An unblinded researcher visited nurseries to monitor the intervention
1.12.	Was the likelihood of participants receiving a 'contaminated' intervention reported? NO
1.13.	Were the outcome measures objective? YES
1.14.	What was the unit of allocation? GROUP AND INDIVIDUAL
1.15.	What was the unit of analysis? INDIVIDUAL AND GROUP
1.16.	Was the method of data analysis appropriate? YES. Multilevel modelling, using iterative generalised least squares for model fitting
1.17.	Was the analysis by ITT? YES
1.18.	Are the results generalisable? YES
1.19.	Were appropriate methods used to account for missing data? UNCLEAR
1.20.	CLUSTER TRIALS ONLY – was a rationale for the design given? YES
1.21.	CLUSTER TRIALS ONLY – are the effects of clustering included in the sample size calculation? YES
1.22.	CLUSTER TRIALS ONLY – were the effects of clustering incorporated into the analysis? YES
1.23.	CLUSTER TRIALS ONLY – does the flow diagram include both clusters and individuals? YES

Hip-Hop Jr

Study	Population	Outcomes	Context	Theory	Notes
ID: Protocol for the Hip-Hop to Health research programme[76] Date of publication: 2002 Design: cluster RCT Country: USA Definition of overweight: BMI ≥85th percentile Definition of obesity: BMI ≥95th percentile Ethnic group: African American and Latino	Age of children: 3–5 years Intervention target population: children and parents	BMI: × Weight: × Health outcomes: - Height: × Quality of life: - Length of follow-up: 5 years	Community: the context for this intervention was 12 Head Start preschools aimed at supporting low income families Home: ×	Implicit: the implicit theory behind this scheme is that obesity can be prevented by reducing dietary fat and increasing dietary fibre, and by an increase in physical activity and inclusion of the family Explicit: this scheme was theoretically underpinned by social learning theory, self-determination theory and the transtheoretical model	Additional comment: This paper is the study protocol

Study	Population	Outcomes	Context	Theory	Notes	Arms
ID: Stolley *et al.*[78] Hip-Hop to Health Jr Baseline characteristics Date of publication: 2003 Design: Cluster RCT Country: USA Definition of overweight: BMI ≥85th percentile Definition of obesity: BMI ≥95th percentile Ethnic group: African American and Latino Source of funding: National Heart Lung and Blood Institute	*n* = 778 Age of children: mean age (SD) at entry 4.2 (4.9) years Intervention target population: children and parents	BMI: × Weight: × Health outcomes: - Height: × Quality of life: Not reported Length of follow-up: baseline data only	Community: the context for this intervention was 24 Head Start preschools aimed at supporting low income families (12 in mainly African American sites and 12 in mainly Latino sites) Home: ×	Implicit: the implicit theory behind this scheme is that obesity can be prevented by reducing dietary fat and increasing dietary fibre, and by an increase in physical activity and inclusion of the family Explicit: this scheme was theoretically underpinned by social learning theory, self-determination theory and the transtheoretical model	Additional comment: as this paper only reports on baseline characteristics the quality assessment for the study has not been completed as this is reported in the associated papers by Fitzgibbon *et al.* 2005[73] and 2006[77]	Description: this paper only reports baseline characteristics

DOI: 10.3310/hta13610

Study	Population	Outcomes	Context	Theory	Notes	Arms	OUTCOMES
ID: Fitzgibbon *et al.*[73] Hip-Hop to health Jr. African American Date of publication: 2005 Design: cluster RCT Country: USA Definition of overweight: BMI ≥85th percentile Definition of obesity: BMI ≥95th percentile Ethnic group: African American Source of funding: National Heart Lung and Blood Institute	*n* = 409 Age of children: mean age 4.2 (SD 4.9) years Intervention target population: children and parents	BMI: × Weight: × Health outcomes: - Height: × Quality of life: not measured Length of follow-up: 24 months	Community: the context for this intervention was 12 Head Start preschools aimed at supporting low income families. Home: ×	Implicit: the implicit theory behind this scheme is that obesity can be prevented by reducing dietary fat and increasing dietary fibre, and by an increase in physical activity and inclusion of the family Explicit: this scheme was theoretically underpinned by social learning theory, self-determination theory and the transtheoretical model	Additional comment: this study was aimed at preventing obesity and did not target overweight children but sought to take young children off a path towards obesity as they grew older	**Arm No:** 1 Name: intervention *n* = 197 Description: child intervention: Hip-Hop to health is a combined diet and exercise intervention designed to reduce gains in BMI in preschool minority children in the USA. The weight control component consists of a 14-week (3 times weekly) programme of diet and physical activity delivered by trained early childhood educators. Each session consists of 20 minutes of a nutrition activity followed by 20 minutes of moderate to vigorous aerobic activity Parent intervention: this consists of a weekly newsletter that mirrors the children's curriculum with homework designed to reinforce concepts presented in the newsletters. Parents are also asked to write down specific ways to increase fruit and vegetables in their family's diet. If the homework is completed they receive a small monetary reward **Arm No:** 2 Name: control *n* = 212 Description: the control group received a 14-week (once a week) for 20 minutes session that taught general health concepts, e.g. seat belt safety, immunisation and dental health. The parent component consists of a weekly related newsletter, there were no homework assignments	Post-intervention: BMI (kg/m^2) Adjusted BMI (kg/m^2) BMI z-score Adjusted BMI z-score Weight (kg) Height (cm) 12 months' follow-up: BMI (kg/m^2) Adjusted BMI (kg/m^2) BMI z-score Adjusted BMI z-score Weight (kg) Height (cm) 24 months' follow-up: BMI (kg/m^2) Adjusted BMI (kg/m^2) BMI z-score Adjusted BMI z-score Weight (kg) Height (cm) High-density lipoprotein cholesterol (mmol/l)

Baseline characteristics

	Intervention child level			Control child level				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Age (years)	197		4.1 (SD 0.6)	212		4.2 (SD 0.5)		
Height (cm)	197		102.8 (SD 6.4)	212		104.6 (SD 5.9)		
Gender (% female)	197	50	(24.1%)	212	51	(25.4%)		
Black (%)	197	99	(38.2%)	212	81	(50.3%)		
Hispanic (%)	197	0	(6.1%)	212	13	(0.0%)		
Other (%)	197	1	(3.3%)	212	7	(0.5%)		
kg/m^2	197		16.5 (SD 1.5)	212		16.7 (SD 2)		
z-score for age and sex	197		0.62 (SD 0.9)	212		0.67 (SD 1.11)		
≥85th percentile (%)	197	32	(17.0%)	212	36	(16.2%)		
<85th percentile	197		15.7 (SD 0.7)	212		15.6 (SD 0.9)		
≥85th percentile	197		18.2 (SD 1.3)	212		18.5 (SD 2)		
Age 7 months: weight (kg)	197		17.6 (SD 2.9)	212		18.3 (SD 3.4)		

k, a subset of *n*.

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Results

	Intervention child level			Control child level				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Post-intervention								
BMI (kg/m^2)	197		0.05 (SD 0.05)	212		0.14 (SD 0.05)	MD = –0.090 (SE 0.005)	< 0.001[a]
Adjusted BMI (kg/m^2)	197		0.06 (SD 0.05)	212		0.13 (SD 0.05)	MD = –0.070 (SE 0.005)	< 0.001[a]
BMI z-score	197		0.06 (SD 0.03)	212		0.08 (SD 0.03)	MD = –0.020 (SE 0.003)	< 0.001[a]
Adjusted BMI z-score	197		0.05 (SD 0.04)	212		0.08 (SD 0.04)	MD = –0.030 (SE 0.004)	< 0.001[a]
Weight (kg)	197		1.14 (SD 0.06)	212		1.2 (SD 0.06)	MD = –0.060 (SE 0.006)	< 0.001[a]
Height (cm)	197		3.04 (SD 0.14)	212		2.92 (SD 0.14)	MD = 0.120 (SE 0.014)	< 0.001[a]
12 months' follow-up								
BMI (kg/m^2)	197		0.02 (SD 0.11)	212		0.64 (SD 0.11)	MD = –0.620 (SE 0.011)	< 0.001[a]
Adjusted BMI (kg/m^2)	197		0.06 (SD 0.12)	212		0.59 (SD 0.12)	MD = –0.530 (SE 0.012)	< 0.001[a]
BMI z-score	197		–0.06 (SD 0.05)	212		0.13 (SD 0.05)	MD = –0.190 (SE 0.005)	< 0.001[a]
Adjusted BMI z-score	197		–0.08 (SD 0.05)	212		0.16 (SD 0.05)	MD = –0.240 (SE 0.005)	< 0.001[a]
Weight (kg)	197		3.79 (SD 0.2)	212		4.65 (SD 0.2)	MD = –0.860 (SE 0.020)	< 0.001[a]
Height (cm)	197		10.37 (SD 0.3)	212		10.1 (SD 0.3)	MD = 0.270 (SE 0.030)	< 0.001[a]
24 months' follow-up								
BMI (kg/m^2)	197		0.48 (SD 0.14)	212		1.14 (SD 0.14)	MD = –0.660 (SE 0.014)	< 0.001[a]
Adjusted BMI (kg/m^2)	197		0.54 (SD 0.14)	212		1.08 (SD 0.14)	MD = –0.540 (SE 0.014)	< 0.001[a]
BMI z-score	197		0.02 (SD 0.04)	212		0.16 (SD 0.04)	MD = –0.140 (SE 0.004)	< 0.001[a]
Adjusted BMI z-score	197		0 (SD 0.04)	212		0.17 (SD 0.04)	MD = –0.170 (SE 0.004)	< 0.001[a]
Weight (kg)	197		6.84 (SD 0.32)	212		7.95 (SD 0.31)	MD = –1.110 (SE 0.031)	< 0.001[a]
Height (cm)	197		16.36 (SD 0.37)	212		16.08 (SD 0.36)	MD = 0.280 (SE 0.036)	< 0.001[a]

k, a subset of *n*; MS, mean difference; SE, standard error.
a student's *t*-test (calculated by reviewer).

Quality appraisal

1.1. Was the sample size based on a power calculation? YES
1.2. Are the eligibility criteria explicit? YES
1.3. Was the randomisation to groups adequate? NOT REPORTED
1.4. Was the intervention allocation concealed adequately? NOT REPORTED
1.5. Were the groups similar at baseline? NO. The children in the control arm were older by 2.2 months ($p = 0.001$), they were also taller ($p < 0.01$) and weighed more ($p = 0.014$)
1.6. Did the groups receive similar treatment other than the intervention? UNCLEAR
1.7. Were outcome assessors blinded to treatment allocation? UNCLEAR
1.8. Were all participants accounted for? NO
1.9. Were the number of withdrawals specified? YES
1.10. Was the percentage of the population who received the intervention reported? YES
1.11. Was the consistency of the intervention measured? NO
1.12. Was the likelihood of participants receiving a 'contaminated' intervention reported? NO
1.13. Were the outcome measures objective? YES
1.14. What was the unit of allocation? GROUP
1.15. What was the unit of analysis? INDIVIDUAL
1.16. Was the method of data analysis appropriate? UNCLEAR. *t*-test to assess baseline data, other methods of assessment not given
1.17. Was the analysis by ITT? NO
1.18. Are the results generalisable? PARTLY. The population were from minority Latino and African American groups
1.19. Were appropriate methods used to account for missing data? UNCLEAR
1.20. CLUSTER TRIALS ONLY – was a rationale for the design given? YES
1.21. CLUSTER TRIALS ONLY – are the effects of clustering included in the sample size calculation? YES
1.22. CLUSTER TRIALS ONLY – were the effects of clustering incorporated into the analysis? NO
1.23. CLUSTER TRIALS ONLY – does the flow diagram include both clusters and individuals? NO. No flow diagram is presented

DOI: 10.3310/hta13610

Study	Population	Outcomes	Context	Theory	Notes	Arms	OUTCOMES
ID: Fitzgibbon *et al.*[77] Hip-Hop to Health Jr Latino Date of publication: 2006 Design: cluster RCT Country: USA Definition of overweight: BMI ≥ 85th percentile Definition of obesity: BMI ≥ 95th percentile Ethnic group: Latino Source of funding: National Heart Lung and Blood Institute	*n* = 401 Age of children: mean age 4.2 (SD 4.9) years Intervention target population: children and parents	BMI: × Weight: × Health outcomes: - Height: × Quality of life: not reported Length of follow-up: 24 months	Community: the context for this intervention was 12 Head Start preschools aimed at supporting low income families Home: ×	Implicit: The implicit theory behind this scheme is that obesity can be prevented by reducing dietary fat and increasing dietary fibre, and by an increase in physical activity and inclusion of the family Explicit: this scheme was theoretically underpinned by social learning theory, self-determination theory and the transtheoretical model	Additional comment: this study was aimed at preventing obesity and did not target overweight children but sought to take young children off a path towards obesity as they grew older	**Arm No:** 1 Name: Intervention *n* = 202 Description: child intervention: Hip-Hop to health is a combined diet and exercise intervention designed to reduce gains in BMI in preschool minority children in the USA. The weight control component consists of a 14-week (3 times weekly) programme of diet and physical activity delivered by trained early childhood educators. Each session consists of 20 minutes of a nutrition activity followed by 20 minutes of moderate to vigorous aerobic activity Parent intervention: this consists of a weekly newsletter that mirrors the children's curriculum with homework designed to encourage active interaction between children and parents. Parents receive 12 homework assignments during the 14-week intervention, if these are completed they receive a small monetary reward **Arm No:** 2 Name: control *n* = 199 Description: The control group received a 14-week (once a week) for 20 minutes session that taught general health concepts, e.g. seat belt safety, immunisation and dental health. The parent component consists of a weekly related newsletter, there were no homework assignments	Post-intervention: BMI (kg/m^2) [the unadjusted mean (SD) for BMI at baseline was 17.1 (2.8) kg/m^2 for the intervention group and 17.4 (2.2) kg/m^2 for the control group] Adjusted BMI (kg/m^2) (adjusted for baseline age quartile, baseline value, months from baseline and Head Start site) BMI z-score (deviation from the mean BMI for age and sex for the reference population divided by the age- and sex-specific SD for the reference population) Adjusted BMI z-score Weight (kg) Height (cm) (outcomes were adjusted for group randomisation by Head Start site and months from baseline) 12 months' follow-up: BMI (kg/m^2) Adjusted BMI (kg/m^2) BMI z-score Adjusted BMI z-score Weight (kg) Height (cm) 24 months' follow-up: BMI (kg/m^2) Adjusted BMI (kg/m^2) BMI z-score Adjusted BMI z-score Weight (kg) Height (cm)

Baseline characteristics

	Intervention			Control				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Age (years)	202	148	4.2 (SD 0.6)	199		4.3 (SD 0.6)		
Height (cm)	202		104 (SD 5.9)	199		103.3 (SD 6.1)		
Black (%)	202	16	(3.5%)	199	7	(7.9%)		
Hispanic (%)	202	73	(44.7%)	199	89	(36.1%)		
White (%)	202			199				
Other (%)	202	11	(2.0%)	199	4	(5.4%)		
kg/m^2	202		17 (SD 2.8)	199		17.5 (SD 2.2)		
z-score for age and sex	202		0.87 (SD 1.24)	199		1.13 (SD 1.06)		
≥85th percentile (%)	202	40	(25.6%)	199	51	(19.8%)		
≥95th percentile (%)	202	22	(15.6%)	199	31	(10.9%)		
Age 7 months: weight (kg)	202		18.6 (SD 4.1)	199		18.8 (SD 3.8)		

k, a subset of *n*.

Results

	Intervention			Control				
	n	*k*	Mean	*n*	*k*	Mean	Δ	*p*
Post-intervention								
BMI (kg/m^2)	202		0.11 (SD 1.56)	199		0.13 (SD 0.11)		
Adjusted BMI (kg/m^2)	202		0.12 (SD 1.56)	199		0.12 (SD 0.11)		
BMI z-score	202		0.07 (SD 0.99)	199		0.05 (SD 0.07)		
Adjusted BMI z-score	202		0.07 (SD 0.85)	199		0.07 (SD 0.06)		
Weight (kg)	202		1.13 (SD 1.70)	199		1.2 (SD 0.12)		
Height (cm)	202		2.69 (SD 1.85)	199		2.79 (SD 0.13)		
12 months' follow-up								
BMI (kg/m^2)	202		17.5 (SD 3.5)	199		17.9 (SD 2.6)		
Adjusted BMI (kg/m^2)	202		0.31 (SD 2.27)	199		0.44 (SD 2.40)		
BMI z-score	202		0 (SD 0.09)	199		0.07 (SD 0.09)		
Adjusted BMI z-score	202		–0.01 (SD 0.99)	199		0.11 (SD 0.07)		
Weight (kg)	202		3.84 (SD 0.19)	199		3.98 (SD 0.2)		
Height (cm)	202		8.97 (SD 0.16)	199		8.77 (SD 0.16)		
24 months' follow-up								
BMI (kg/m^2)	202		17.6 (SD 3.6)	199		18.1 (SD 3)		
Adjusted BMI (kg/m^2)	202		0.46 (SD 0.19)	199		0.66 (SD 0.2)		
BMI z-score	202		–0.13 (SD 0.09)	199		0 (SD 0.09)		
Adjusted BMI z-score	202		–0.13 (SD 0.07)	199		0.02 (SD 0.07)		
Weight (kg)	202		5.91 (SD 0.31)	199		6.18 (SD 0.32)		
Height (cm)	202		13.49 (SD 0.2)	199		13.34 (SD 0.2)		

k, a subset of *n*.

Quality appraisal

1.1. Was the sample size based on a power calculation? YES
1.2. Are the eligibility criteria explicit? YES
1.3. Was the randomisation to groups adequate? NOT REPORTED. Unclear, merely states that 12 schools were randomly assigned
1.4. Was the intervention allocation concealed adequately? NOT REPORTED
1.5. Were the groups similar at baseline? NO. Children in the control group were more likely to be overweight ($p = 0.019$) or obese ($p = 0.033$) and have a higher mean BMI z-score ($p = 0.023$)
1.6. Did the groups receive similar treatment other than the intervention? NOT REPORTED
1.7. Were outcome assessors blinded to treatment allocation? UNCLEAR. Not reported
1.8. Were all participants accounted for? YES
1.9. Were the number of withdrawals specified? YES
1.10. Was the percentage of the population who received the intervention reported? YES
1.11. Was the consistency of the intervention measured? UNCLEAR
1.12. Was the likelihood of participants receiving a 'contaminated' intervention reported? NO
1.13. Were the outcome measures objective? YES
1.14. What was the unit of allocation? GROUP
1.15. What was the unit of analysis? INDIVIDUAL
1.16. Was the method of data analysis appropriate? UNCLEAR. *t*-test to assess baseline data, other methods of assessment not given
1.17. Was the analysis by ITT? NO
1.18. Are the results generalisable? PARTLY. The population was from minority Latino and African American groups
1.19. Were appropriate methods used to account for missing data? UNCLEAR. Missing data were not reported
1.20. CLUSTER TRIALS ONLY – was a rationale for the design given? YES
1.21. CLUSTER TRIALS ONLY – are the effects of clustering included in the sample size calculation? YES
1.22. CLUSTER TRIALS ONLY – were the effects of clustering incorporated into the analysis? UNCLEAR
1.23. CLUSTER TRIALS ONLY – does the flow diagram include both clusters and individuals? NO. Not reported

Harvey-Berino and Rourke[74]

Study	Population	Outcomes	Context	Theory	Notes	Arms	OUTCOMES
ID: Harvey-Berino *et al.*[74] Date of publication: 2003 Design: RCT Country: USA Definition of overweight: not reported Definition of obesity: BMI ≥ 95th percentile Ethnic group: Native American Source of funding: NIH Grant R03 DK56290	*n* = 40 Age of children: 9 months – 3 years Intervention target population: children and parents	BMI: × Weight: × Health outcomes: Physical activity as accelerometry Height: × Length of follow-up: 16 weeks	Community: - Home: ×	Implicit: that involving mothers in a home-based educational intervention to improve eating and exercise would have a preventative effect, to reduce obesity, in young children	Additional comment: the 16-week follow-up is too short to reliably show any long-term benefits from this intervention	**Arm No:** 1 Name: intervention *n* = 20 Description: obesity prevention plus parenting support. A 16-week programme in the home of the participant, to show how improved parenting skills could facilitate the development of appropriate eating and exercise habits in their children **Arm No**: 2 Name: control *n* = 20 Description: parenting skills lessons. A 16-week programme in the home of the participant, to show how improved parenting skills could help develop behavioural goals	BMI z-score Weight (kg) ≥ 85th ≥ 95th Physical activity (Vmag/h)

NIH, National Institutes of Health.

Baseline characteristics

	Intervention			Control				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Weight (kg)	20		12.2 (SD 2.4)	20		12.3 (SD 2.9)		
BMI z-score	20		0.79 (SD 1.2)	20		0.67 (SD 1.6)		
≥85th percentile	20	5	(15.0%)	20	3	(25.0%)		
≥95th percentile	20	3	(25.0%)	20	5	(15.0%)		
Physical activity (Vmag/h)	20		20,457 (SD 8670)	20		19,417 (SD 5735)		

k, a subset of *n*.

Results

	Intervention			Control				
	n	***k***	**Mean**	***n***	***k***	**Mean**	Δ	***p***
Post-intervention								
BMI z-score	20		0.52 (SD 1.1)	20		0.98 (SD 1.4)		
Weight (kg)	20		13.1 (SD 2.4)	20		13.8 (SD 3.6)		
≥85th percentile	20	3	(15.0%)	20	3	(15.0%)		
≥95th percentile	20	1	(30.0%)	20	6	(5.0%)		
Physical activity (Vmag/h)	20		17,886 (SD 6746)	20		17,637 (SD 8151)		

k, a subset of *n*.

DOI: 10.3310/hta13610

Quality appraisal

1.1. Was the sample size based on a power calculation? NO
1.2. Are the eligibility criteria explicit? YES
1.3. Was the randomisation to groups adequate? NOT REPORTED
1.4. Was the intervention allocation concealed adequately? NOT REPORTED
1.5. Were the groups similar at baseline? YES
1.6. Did the groups receive similar treatment other than the intervention? YES
1.7. Were outcome assessors blinded to treatment allocation? YES
1.8. Were all participants accounted for? YES
1.9. Were the number of withdrawals specified? YES
1.10. Was the percentage of the population who received the intervention reported? YES
1.11. Was the consistency of the intervention measured? UNCLEAR
1.12. Was the likelihood of participants receiving a 'contaminated' intervention reported? NO
1.13. Were the outcome measures objective? YES
1.14. What was the unit of allocation? INDIVIDUAL
1.15. What was the unit of analysis? INDIVIDUAL
1.16. Was the method of data analysis appropriate? YES. *t*-tests for changes within groups and ANOVA for changes between groups
1.17. Was the analysis by ITT? YES
1.18. Are the results generalisable? PARTLY. The population was Native American and the intervention was culturally adapted
1.19. Were appropriate methods used to account for missing data? UNCLEAR
1.20. CLUSTER TRIALS ONLY – was a rationale for the design given?
1.21. CLUSTER TRIALS ONLY – are the effects of clustering included in the sample size calculation?
1.22. CLUSTER TRIALS ONLY – were the effects of clustering incorporated into the analysis?
1.23. CLUSTER TRIALS ONLY – does the flow diagram include both clusters and individuals?

Appendix 4

Table of excluded studies

Study	Reason for exclusion
Adams J, Dixon J, Pettit J, Zask A. *Tooty fruity vegie in preschools Program Report.* 2008. New South Wales, Australia: North Coast Area Health Service.	No usable data
Baird J, Fisher D, Lucas P, Kleijnen J, Roberts H, Law C. Being big or growing fast: systematic review of size and growth in infancy and later obesity. *BMJ* 2005;**331**:929.	Not about weight management
Chau J. *A review of physical activity interventions for children from 2 to 5 year of age.* CPAH06–003. 2007. New South Wales Centre for Physical Activity and Health.	Not a systematic review
Cottrell L, Spangler-Murphy E, Minor V, Downes A, Nicholson P, Neal WA. A kindergarten cardiovascular risk surveillance study: CARDIAC-Kinder. *Am J Health Behav* 2005;**29**:595–606.	Follow-up not long enough
Dennison BA, Russo TJ, Burdick PA, Jenkins PL. An intervention to reduce television viewing by preschool children. *Arch Pediatr Adolesc Med* 2004;**158**:170–6.	Wrong intervention
Epstein LH, Roemmich JN, Robinson JL, Paluch RA, Winiewicz DD, Fuerch JH, *et al.* A randomized trial of the effects of reducing television viewing and computer use on body mass index in young children. *Arch Pediatr Adolesc Med* 2008;**162**:239–45.	Wrong population, includes over fives
Hakanen M, Lagstrom H, Kaitosaari T, Niinikoski H, Nanto-Salonen K, Jokinen E, *et al.* Development of overweight in an atherosclerosis prevention trial starting in early childhood. The STRIP study. *Int J Obes* 2006;**30**:618–26.	No usable data
Kaitosaari T, Ronnemaa T, Raitakari O, Talvia S, Kallio K, Volanen I, *et al.* Effect of 7-year infancy-onset dietary intervention on serum lipoproteins and lipoprotein subclasses in healthy children in the prospective, randomized Special Turku Coronary Risk Factor Intervention Project for Children (STRIP) Study. *Circulation* 2003;**108**:672–7.	Not about weight management
Kamath CC, Vickers KS, Ehrlich A, McGovern L, Johnson J, Singhal V, *et al.* Clinical review: behavioral interventions to prevent childhood obesity: a systematic review and metaanalyses of randomized trials. *J Clin Endocrinol Metab* 2008;**93**:4606–15.	Wrong outcomes
Lagstrom H, Jokinen E, Seppanen R, Ronnemaa T, Viikari J, Valimaki I, *et al.* Nutrient intakes by young children in a prospective randomized trial of a low-saturated fat, low-cholesterol diet. The STRIP Baby Project. Special Turku Coronary Risk Factor Intervention Project for Babies. *Arch Pediatr Adolesc Med* 1997;**151**:181–8.	Wrong outcomes
Lapinleimu H, Viikari J, Jokinen E, Salo P, Routi T, Leino A, *et al.* Prospective randomised trial in 1062 infants of diet low in saturated fat and cholesterol. *Lancet* 1995;**345**:471–6.	Not about weight management
Niinikoski H, Viikari J, Ronnemaa T, Lapinleimu H, Jokinen E, Salo P, *et al.* Prospective randomized trial of low-saturated-fat, low-cholesterol diet during the first 3 years of life. The STRIP baby project. *Circulation* 1996;**94**:1386–93.	Not about weight management
Niinikoski H, Viikari J, Ronnemaa T, Helenius H, Jokinen E, Lapinleimu H, *et al.* Regulation of growth of 7- to 36-month-old children by energy and fat intake in the prospective, randomized STRIP baby trial. *Pediatrics* 1997;**100**:810–16.	Not about weight management
Niinikoski H, Lagstrom H, Jokinen E, Siltala M, Ronnemaa T, Viikari J, *et al.* Impact of Repeated Dietary Counseling Between Infancy and 14 Years of Age on Dietary Intakes and Serum Lipids and Lipoproteins: The STRIP Study. *Circulation* 2007;**116**:1032–40.	Not about weight management
Nova A, Russo A, Sala E. Long-term management of obesity in paediatric office practice: experimental evaluation of two different types of intervention. *Ambulatory Child Health* 2001;**7**:239–47.	Wrong population, includes over fives
Parsons TJ, Power C, Logan S, Summerbell CD. Childhood predictors of adult obesity: a systematic review. *Int J Obes Relat Metab Disord* 1999;**23**(Suppl. 8):S1–107.	Not about weight management
Rask-Nissila L, Jokinen E, Ronnemaa T, Viikari J, Tammi A, Niinikoski H, *et al.* Prospective, randomized, infancy-onset trial of the effects of a low-saturated-fat, low-cholesterol diet on serum lipids and lipoproteins before school age: The Special Turku Coronary Risk Factor Intervention Project (STRIP). *Circulation* 2000;**102**:1477–83.	Not about weight management
Rogers L, Gerner B, Wake M. LEAP trial. *Aust Fam Physician* 2007;**36**:887–8.	Wrong population, includes over fives

Study	Reason for exclusion
Sanigorski AM, Bell AC, Kremer PJ, Cuttler R, Swinburn BA. Reducing unhealthy weight gain in children through community capacity-building: results of a quasi-experimental intervention program, Be Active Eat Well. *Int J Obes* 2008;**32**:1060–7.	Wrong population, includes over fives
Saarilehto S, Lapinleimu H, Keskinen S, Helenius H, Simell O. Body satisfaction in 8-year-old children after long-term dietary counseling in a prospective randomized atherosclerosis prevention trial. *Arch Pediatr Adolesc Med* 2003;**157**:753–8.	Not about weight management
Shelton D, Le GK, Norton L, Stanton-Cook S, Morgan J, Masterman P. Randomised controlled trial: A parent-based group education programme for overweight children. *J Paediatr Child Health* 2007;**43**:799–805.	Wrong population, includes over fives
Shutter L, Garell DC. Obesity in children and adolescents: a double-blind study with cross-over. *J Sch Health 1966*;**36**:273–5.	No usable data
Tanas R, Marcolongo R, Pedretti S, Gilli G. A family-based education program for obesity: a three-year study. *BMC Pediatr* 2007;**7**:33.	Wrong population, includes over fives
Tedstone A, Dunce N, Aviles M, Shetty P, Daniels L. *Effectiveness of interventions to promote healthy feeding of infants under one year of age.* Meyrick J, editor. 1998. Health Education Authority.	Not about weight management
Tedstone A, Aviles M, Shetty P, Daniels L. *Effectiveness of interventions to promote healthy eating in preschool children aged 1 to 5 years.* Meyrick J, editor. 1998. Health Education Authority.	Not about weight management
Williams CL, Strobino BA. Childhood diet, overweight, and CVD risk factors: the Healthy Start project. *Prev Cardiol* 2008;**11**:11–20.	No control group
Williams CL, Strobino BA, Bollella M, Brotanek J. Cardiovascular Risk Reduction in Preschool Children: The "Healthy Start" Project. *J Am Coll Nutr* 2004;**23**:117–23.	Wrong intervention
Wofford LG. Systematic review of childhood obesity prevention. *J Pediatr Nurs* 2008;**23**:5–19.	Literature review

Appendix 5

Included systematic reviews

1. Bautista-Castana I, Doreste J, Serra-Majem L. Effectiveness of interventions in the prevention of childhood obesity. *Eur J Epidemiol* 2004;**19**:617–22.

2. Bluford DA, Sherry B, Scanlon KS. Interventions to prevent or treat obesity in preschool children: a review of evaluated programs. *Obesity* 2007;**15**:1356–72.

3. Campbell KJ, Hesketh KD. Strategies which aim to positively impact on weight, physical activity, diet and sedentary behaviours in children from nought to five years. A systematic review of the literature. *Obes Rev* 2007;**8**:327–38.

4. Collins CE, Warren J, Neve M, McCoy P, Stokes BJ. Measuring effectiveness of dietetic interventions in child obesity: a systematic review of randomized trials. *Arch Pediatr Adolesc Med* 2006;**160**:906–22.

5. Connelly JB, Duaso MJ, Butler G. A systematic review of controlled trials of interventions to prevent childhood obesity and overweight: a realistic synthesis of the evidence. *Public Health* 2007;**121**:510–17.

6. DeMattia L, Lemont L, Meurer L. Do interventions to limit sedentary behaviours change behaviour and reduce childhood obesity: a critical review of the literature. *Obes Rev* 2007;**8**:69–81.

7. Flodmark CE, Marcus C, Britton M. Interventions to prevent obesity in children and adolescents: a systematic literature review. *Int J Obes* 2006;**30**:579–89.

8. Flynn MA, McNeil DA, Maloff B, Mutasingwa D, Wu M, Ford C, *et al*. Reducing obesity and related chronic disease risk in children and youth: a synthesis of evidence with 'best practice' recommendations. *Obes Rev* 2006;**7**(Suppl. 1):7–66.

9. Gibson LJ, Peto J, Warren JM, Silva IdS. Lack of evidence on diets for obesity for children: a systematic review. *Int J Epidemiol* 2006;**35**:1544–52.

10. Kamath CC, Vickers KS, Ehrlich A, McGovern L, Johnson J, Singhal V, *et al*. Clinical review: behavioural interventions to prevent childhood obesity: a systematic review and meta-analyses of randomized trials. *J Clin Endocrinol Metab* 2008;**93**:4606–15.

11. McGovern L, Johnson JN, Paulo R, Hettinger A, Singhal V, Kamath C, *et al*. Clinical review: treatment of pediatric obesity: a systematic review and meta-analysis of randomized trials. *J Clin Endocrinol Metab* 2008;**93**:4600–5.

12. Oude LH, Baur L, Jansen H, Shrewsbury VA, O'Malley C, Stolk RP, *et al*. Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2009;(1):CD001872.

13. Reilly JJ, Wilson ML, Summerbell CD, Wilson DC. Obesity: diagnosis, prevention, and treatment; evidence based answers to common questions. *Arch Dis Child* 2002;**86**:392–4.

14. Reilly JJ, McDowell Z. Physical activity interventions in the prevention and treatment of paediatric obesity: systematic review and critical appraisal. *Proc Nutr Soc* 2003;**62**:611–19.

15. Summerbell CD, Waters E, Edmunds LD, Kelly S, Brown T, Campbell KJ. Interventions for preventing obesity in children. *Cochrane Database Syst Rev* 2005;(3):CD001871.

16. Wilfley DE, Tibbs TL, Van Buren DJ, Reach KP, Walker MS, Epstein LH. Lifestyle interventions in the treatment of childhood overweight: a meta-analytic review of randomized controlled trials. *Health Psychol* 2007;**26**:521–32.

Appendix 6

Ongoing trials

NIHR CRN CC Portfolio database (UKCRN)

http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=4880

EMPOWER

Empowering parents to prevent obesity at weaning – exploratory research: RCPCH pilot and feasibility study

Research summary
Study type: interventional
Design type:
Disease(s): public health research
Phase: pilot/feasibility
Current status: open
Closure date: 30 September 2008
Sample size: 64
Accrual to date: 62%
Geographical scope: UK multicentre
Lead country: England
Open to new sites: unknown
Main inclusion criteria: unknown
Main exclusion criteria: unknown
Chief investigator(s): Professor Jane Barlow

Further details, please contact:
Ms Sandra Whitlock
Warwick Medical School
Gibbet Hill Road
Coventry
West Midlands
CV4 7AL
UK
Tel: 02476 574270
s.whitlock@warwick.ac.uk

Funder(s): Department of Health – NSF for Children, Young People and Maternity Services

http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=5067

EPPOC

Early prediction and prevention of obesity in childhood

Study type: observational
Design type:
Disease(s): all diseases
Phase: experimental medicine
Current status: open
Closure date: 31 December 2008
Sample size: 186
Geographical scope: UK multicentre
Lead country: England
Open to new sites: no
Main inclusion criteria: health professionals consulting with parents of children < 1 year; parents of children < 1 year
Main exclusion criteria: health professionals who do not consult with children; parents of children > 1 year
Chief investigator(s): Dr Sarah Redsell

Further details, please contact:
Dr Sarah Redsell
University of Nottingham
School of Nursing A Floor
South Block Link
Queens Medical Centre
Nottingham
Nottinghamshire
NG7 2HA
UK
Tel: 0115 8230809
Sarah.Redsell@nottingham.ac.uk

Funder(s): Burdett Trust for Nursing
Sponsor(s): University of Nottingham

http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=5125

The metabolic and environmental determinants of obesity: observational and intervention studies in children and young people

Disease(s): metabolic & endocrine (not diabetes)
Phase: II/III
Current status: open
Closure date: 1 January 2010
Sample size: 30
Accrual to date: 3%
Geographical scope: single centre
Lead country: England
Open to new sites: unknown
Main inclusion criteria: unknown
Main exclusion criteria: unknown
Chief investigator(s): Tim Barrett

Further details, please contact
Tim Barrett
t.g.barrett@bham.ac.uk

Funder(s): Wellcome Trust

http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=6192

The Cambridge Baby Growth Study
Study of antenatal, nutritional and common genetic factors on infant weight gain, body composition and fat distribution: The Cambridge Baby Growth Study
Research summary
Study type: observational
Design type:
Disease(s): reproductive health and childbirth
Phase: N/A
Current status: open
Closure date: 31 May 2016
Sample size: 4000
Geographical scope: single centre
Lead country: England
Chief investigator(s): Dr Kenneth Ong

Further details, please contact:
Dr Jill Landsbaugh
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Funder(s): Medical Research Council

ControlledTrials.com

The effectiveness of multidisciplinary treatment in young overweight children
http://www.controlled-trials.com/ISRCTN47185691
GECKO outpatients clinic, a randomised controlled trial

Source of record: ISRCTN Register
ISRCTN: ISRCTN47185691
Date ISRCTN assigned: 8 February 2007
Local reference number(s): N/A

Public title: the effectiveness of multidisciplinary treatment in young overweight children: GECKO outpatients clinic, a randomised controlled trial
Scientific title:
Acronym: N/A
Disease/condition/study domain: obesity, overweight
Hypothesis: does a multidisciplinary treatment program consisting of dietary advice, life style activity and psychological counselling, aimed at preschool overweight children, as well as their parents, influence the progression of body mass index (BMI)?
Design/methodology: randomised, active-controlled, parallel group, single blinded trial
Anticipated start date: 10 October 2006
Anticipated end date: 1 August 2009
Status of trial: ongoing
Target number of participants: 180
Sources of funding:
1. Menzis Zorgverzekeraar (the Netherlands)
2. A.S. Watson (Europe) Holding BV (the Netherlands)

Sponsor name: University Medical Centre Groningen (UMCG) (the Netherlands)

Sponsor details:
Beatrix Children's Hospital
P.O. Box 30001
Groningen
Netherlands
9700 RB

Sponsor website: www.rug.nl/umcg/index?lang=en
Contact name: Dr H Oude Luttikhuis

Contact details:
Universitair Medisch Centrum Groningen (UMCG)
Beatrix Kinderkliniek
P.O. Box 30001
Groningen
Netherlands
9700 RB

Contact telephone: +31 (0)50 361 0585
Contact email: h.oudeluttikhuis@bkk.umcg.nl
More information: For more up-to-date information please go to the ISRCTN link below.
Link to record in ISRCTN Register:
ISRCTN47185691
Date last extracted from ISRCTN register: 5 March 2009

Clinicaltrials.gov – search ongoing studies

http://clinicaltrials.gov/ct2/show/NCT00675662

Trim Tots preschool obesity prevention programme
Study type: interventional
Study design: prevention, randomised, single-blind (investigator), factorial assignment
Ages eligible for study: 12–72 months
Genders eligible for study: both
Estimated enrolment: 96
Study start date: April 2008
Estimated primary completion date: September 2009 (Final data collection date for primary outcome measure)

http://clinicaltrials.gov/ct2/show/NCT00377767

Improving primary care to prevent childhood obesity
This study is currently recruiting participants.
Study type: interventional
Study design: prevention, randomized, double-blind, active control, single group assignment, efficacy study
Estimated enrolment: 500
Ages eligible for study: 2–6 years
Genders eligible for study: both
Accepts healthy volunteers: no
Study start date: September 2006
Estimated study completion date: September 2009

http://clinicaltrials.gov/ct2/show/NCT00563264

KAN-DO: a family-based intervention to prevent childhood obesity
This study is currently recruiting participants.

Study Type: interventional
Study Design: prevention, randomised, open label, active control, parallel assignment, efficacy study
Estimated enrolment: 800
Study start date: October 2007
Estimated study completion date: March 2012

Estimated primary completion date: September 2011 (Final data collection date for primary outcome measure)

Inclusion criteria:
- Recent delivery of a baby (~2 months ago)
- A preschooler in the home (2–5 years old), and a current BMI ≥25 (with confirmatory BMI ≥25 measured at baseline).
- Knowledge of English.
- Regular access to a telephone and mailing address.
- Mother's age of 18 or older.
- Willingness to participate in a healthy lifestyle correspondence and telephone intervention.

http://clinicaltrials.gov/ct2/show/NCT00756626

Feeding Young Children Study: bottle weaning intervention (FYCS)
Study type: interventional
Study design: prevention, randomised, single-blind (outcomes assessor), active control, parallel assignment
Estimated enrolment: 464
Study start date: October 2008
Estimated study completion date: December 2010
Estimated primary completion date: March 2010 (final data collection date for primary outcome measure)
Ages eligible for study: 12–13 months
Genders eligible for study: Both

http://clinicaltrials.gov/ct2/show/NCT00615641

Diet, exercise and body fat in 3–5 year olds
Study type: observational
Study design: cohort, prospective
Official title: relationship of dietary factors and physical activity to body fat in 3- to 5-year-old children
Estimated enrolment: 65
Study start date: June 2007
Estimated study completion date: September 2009
Estimated primary completion date: September 2009 (final data collection date for primary outcome measure)

1. 3-year-old children
2. 4-year-old children
3. 5-year-old children

http://clinicaltrials.gov/ct2/show/NCT00428805

Child Health Initiative for Lifelong Eating and Exercise (CHILE)
Study type: interventional
Study design: prevention, randomised, open label, factorial assignment, efficacy study
Official title: site specific approaches to prevention or management of paediatric obesity: child health initiative for lifelong eating and exercise – CHILE
Ages eligible for study: 3–5 years
Genders eligible for study: both
Accepts healthy volunteers: yes

Estimated enrolment: 640
Study start date: March 2006
Estimated study completion date: June 2010
Estimated primary completion date: June 2010 (final data collection date for primary outcome measure)

http://clinicaltrials.gov/ct2/show/NCT00528164

Team PLAY (positive lifestyles for active youngsters)
Study type: interventional
Study design: treatment, randomised, single-blind (outcomes assessor), active control, parallel assignment, efficacy study
Official title: treating childhood obesity with family lifestyle change
Estimated enrolment: 240
Study start date: September 2006
Estimated study completion date: March 2012
Ages eligible for study: 4–7 years

http://clinicaltrials.gov/ct2/show/NCT00454948

Nutrition intervention and play group exercise for low income Latinas (CHICOS)
Study type: interventional
Study design: prevention, randomised, single-blind, active control, parallel assignment, efficacy study
Official title: home-based nutrition intervention and play group exercise for low-income Latinas
Estimated enrolment: 250
Study start date: March 2007
Estimated study completion date: August 2009
Inclusion criteria:
- Mother is of Mexican descent.
- Mother has a child between the ages of 3 and 4.9 years.

http://clinicaltrials.gov/ct2/show/NCT00788203

Prevention of childhood obesity
Study type: observational
Study design: prospective
Official title: the development of an early intervention for the prevention of childhood obesity
Estimated enrolment: 320
Study start date: August 2008
Inclusion criteria: For study 1, 60 families (120 parents) with a child between the age of 2–4 years will be entered to the study. Children of these families will be at risk for overweight because the family will contain at least one obese parent. For study 2, 100 families (200 parents) will be entered to the study. Children of these families will be at risk for overweight and have a reactive temperament. The reason for using this population is that a combination of parental obesity and a child with a reactive temperament appears to put the child at high risk for the development of overweight

http://clinicaltrials.gov/ct2/show/NCT00717132

Cost-effectiveness of family based paediatric obesity treatment
Study type: interventional
Study design: treatment, randomised, single-blind (subject), dose comparison, parallel assignment
Estimated enrolment: 50
Study start date: October 2007
Estimated study completion date: November 2009
Estimated primary completion date: November 2009 (final data collection date for primary outcome measure)

http://clinicaltrials.gov/ct2/show/NCT00635518

Randomised controlled trial of dietary advice in primary care to promote healthy feeding of infants
Study type: interventional
Study design: health services research, randomised, single-blind (investigator), parallel assignment, efficacy study
Official title: randomised controlled trial of dietary advice in primary care to promote healthy feeding of infants
Estimated enrolment: 2000
Study start date: April 2008
Estimated study completion date: November 2009
Estimated primary completion date: October 2008 (Final data collection date for primary outcome measure)
Inclusion criteria: all pregnant women with gestational age of 30 weeks and more, who are registered in the participating PSF centres

Clinicaltrials.gov – or ongoing and no longer recruiting patients
http://clinicaltrials.gov/ct2/show/NCT00674544

Influence of a multidisciplinary lifestyle intervention in kindergarten children on body mass index (BMI), body fatness, fitness, physical activity and psychological parameters (Ballabeina)

This study is ongoing, but not recruiting participants

Study type: interventional
Study design: prevention, randomised, double-blind (subject, investigator, outcomes assessor), placebo control, parallel assignment, efficacy study
Estimated enrolment: 650
Study start date: May 2008
Estimated study completion date: July 2012
Estimated primary completion date: July 2011 (final data collection date for primary outcome measure)
Ages eligible for study: 3–7 years
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00259324

Childhood obesity treatment targeting specific behaviours
This study is ongoing, but not recruiting participants

Study type: interventional
Study design: treatment, randomised, single-blind (outcomes assessor), active control, parallel assignment
Estimated enrolment: 135
Study start date: September 2005
Estimated study completion date: February 2009
Age between 4 and 9 years. We propose to use this age group as parents are in control of the eating and exercise choices of such children, and thus a program that focuses on parenting behaviours (i.e. positive reinforcement, stimulus control, parental modelling) should be developmentally appropriate. This age group also meets the Expert Committee's goal of intervening early; moreover, children aged 4–8 years have similar nutritional needs

http://clinicaltrials.gov/ct2/show/NCT00336128

Population-based intervention to prevent obesity in kindergartens (TigerKids)
Estimated enrolment: 30,000
Study start date: October 2003
Estimated study completion date: July 2009
Primary completion date: May 2006 (final data collection date for primary outcome measure)
Ages eligible for study: 3–7 years
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00241878

Preschool-based obesity prevention effectiveness trial
This study is ongoing, but not recruiting participants

Study type: interventional
Study design: prevention, randomised, open label, placebo control, parallel assignment
Estimated enrolment: 648
Study start date: September 2006
Estimated study completion date: May 2009
Estimated primary completion date: May 2009 (final data collection date for primary outcome measure
Ages eligible for study: 3–5 years
Genders eligible for study: both
Accepts healthy volunteers: no

http://clinicaltrials.gov/ct2/show/NCT00200265

Changing eating behaviours in young children: should healthy foods be increased or unhealthy foods decreased?
This study is ongoing, but not recruiting participants

Study type: interventional
Study design: treatment, randomised, open label, active control, parallel assignment
Official title: changing eating behaviours in young children: should healthy foods be increased or unhealthy foods decreased?
Estimated enrolment: 210
Study start date: July 2005
Estimated study completion date: July 2009
Ages eligible for study: 4–9 years
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00065052

Modifying the home television watching environment
This study has been completed

Study type: interventional
Study design: prevention, randomised, open label, active control, parallel assignment, efficacy study
Enrolment: 70
Study start date: September 2002
Study completion date: May 2007
Ages eligible for study: 4–7 years

http://clinicaltrials.gov/ct2/show/NCT00359242

The SLeeping and Intake Methods Taught to Infants and Mothers Early in Life (SLIMTIME) Project

This study is ongoing, but not recruiting participants

Study type: interventional
Study design: randomised, open label, active control, crossover assignment, efficacy study
Official title: primary prevention of obesity through infancy interventions
Ages eligible for study: up to 12 months
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00623844

Prevention through Activity in Kindergarten Trial (PAKT)

This study is ongoing, but not recruiting participants

Study type: interventional
Study design: prevention, randomised, open label, parallel assignment, efficacy study
Official title: prevention through activity in kindergarten trial
Ages eligible for study: 43–67 months
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00503074

Starting Healthy Staying Healthy Pilot Trial

This study is ongoing, but not recruiting participants

Study type: interventional
Study design: prevention, randomised, open label, active control, parallel assignment, efficacy study
Estimated enrolment: 70
Study start date: July 2007
Estimated study completion date: July 2008
Primary completion date: February 2008 (final data collection date for primary outcome measure)
Ages eligible for study: 2–5 years
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00338689

European Childhood Obesity Project

This study is ongoing, but not recruiting participants

Study type: interventional
Study design: prevention, randomised, double blind (subject, caregiver, investigator, outcomes assessor), dose comparison, parallel assignment, efficacy study
Official title: childhood obesity – programming by infant nutrition
Estimated enrolment: 1759
Study start date: October 2002
Estimated study completion date: March 2013
Primary completion date: August 2006 (Final data collection date for primary outcome measure)
Ages eligible for study: up to 8 weeks
Genders eligible for study: both
Accepts healthy volunteers: yes

http://clinicaltrials.gov/ct2/show/NCT00241878

Preschool-based obesity prevention effectiveness trial

The purpose of this study is to compare changes in body mass index (BMI) among 3- to 5-year-old minority children randomised to a weight control intervention (WCI) or a general health control intervention
Estimated enrolment: 648
Study start date: September 2006
Estimated study completion date: May 2009
Estimated primary completion date: May 2009 (final data collection date for primary outcome measure)

This study builds upon the findings of the 'Hip-Hop to Health' programme. The primary aim of Hip-Hop was to compare changes in body mass index [BMI (kg/m^2)] in two groups of 3- to 5-year-old minority children randomised to a weight control intervention (WCI) or a general health control intervention (GHI). Results for the children at the Year 1 and 2 follow-ups showed that children in the WCI had significantly smaller relative changes in BMI than children in the GHI control group. The success was among the schools that served predominantly Black children. Hip-Hop to Health was an efficacy trial delivered by trained specialists in early childhood education, and the first efficacy trial to document change in BMI in preschool children

This study will test a 14-week teacher-delivered weight control intervention (TD-WCI) to a 14-week teacher delivered general health control intervention (TD-GHI) in a randomised community trial occurring in 16 preschools in the Chicago school district. The study has the following aims: (1) to compare children in these two

conditions on changes in BMI post intervention and at year 1 follow-up; (2) to compare children in these two conditions on changes in television viewing, physical activity, and fat, fibre, fruit and vegetable intake at post-intervention and year 1 follow-up; and (3) to compare classroom teachers in these two conditions on nutrition and exercise knowledge, nutrition attitudes, and support for healthy eating at post-intervention and year 1 follow-up

No publications provided

Responsible party:
Office of Research Services, University of Illinois at Chicago (Eric Gislason)
Study ID numbers: 334, R01 HL81645
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ClinicalTrials.gov identifier: NCT00241878 history of changes (http://clinicaltrials.gov/ct2/show/NCT00241878)
Health authority: United States; Federal Government

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The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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