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Obesity Management

Systematic review of the effectiveness of weight management schemes for the under fives

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Summary

Overweight and obesity in pre-school children are an increasing problem, with poor diet and exercise habits laying the foundation for serious health risks in later life. Yet most research into childhood obesity has focused on school-age children. Two previous systematic reviews of pre-school children have included uncontrolled designs and self-report outcomes potentially biasing the results in favour of the interventions. We have conducted a systematic review of the effectiveness and cost-effectiveness of weight management schemes for the under fives restricting the inclusion criteria to controlled trials with objective measures. We found four effectiveness randomized controlled trials of prevention. No treatment or cost-effectiveness studies were found. Only one study in a Latino community showed a statistically significant advantage from the intervention in a slower rate of increase in body mass index. However, trends in decrease in body mass index and weight loss favoured the intervention groups in other studies. From the studies characteristics we hypothesize that important features to include in future interventions may be; cultural sensitivity, sustained moderate to vigorous exercise, active engagement of the parents in the programme and as role models of healthy living and active engagement of the children in nutrition education. Further randomized controlled trials are needed in this population.

Keywords: Children, obesity, systematic review, weight management.

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Introduction

Overweight and obesity are increasing (1,2). The World Health Organisation estimated that 1.6 billion adults were overweight and 400 million were obese in 2005 with a projected increase of 44% and 75%, respectively, over the last decade (3). A systematic review has indicated that the roots of adult obesity lie in the pre-school years (4) where the problems of overweight and obesity are escalating (5–7). The Pro Children Survey of European children (2008) showed a varied picture for 11-year-olds with the lowest prevalence of obesity in Dutch girls (0.3%) and the highest in Portuguese boys (6.2%) (8). While in the USA, between 2003 and 2006, 11.3% of 2–19-year-olds were obese (9). 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 12% to 16% for girls (10). Overall, in the UK, 10% of pre-school children are obese (5) with a quarter of children aged 2–5 years being either overweight or obese (1,6). These figures

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reflect almost a doubling of obese 4–5-year-olds since 1990 and a 30% increase in those overweight in this age group (11).

Most systematic reviews of childhood obesity research have focussed on children of school age. Bluford *et al.* and Campbell and Hesketh have looked specifically at preschool children (12,13). However, they included evidence from controlled and uncontrolled studies, and objective and self-report measures; thus potentially biased results from uncontrolled studies and self-report measures could have influenced their conclusions as participants might over-report their physical activity (2,14), or under-report dietary intake (15,16), exaggerating the benefits of the intervention. Cochrane reviews of childhood obesity have concluded that such reviews have been weakened by the lack of objective measures (17,18).

Therefore, this systematic review addresses the following research question: What is the evidence for the effectiveness and cost-effectiveness for weight management schemes for the under fives?

Methods and procedures

This systematic review was conducted using the principles published by the NHS Centre for Reviews and Dissemination (19).

Search strategies

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], Psychinfo [Ebsco], NHS CRD and NHSEED. Searches were restricted by date from 1990 until February 2009 and by language to English. A cut-off of 1990 was chosen because of resource limitations. Searches for ongoing trials were conducted in March 2009 using the following range of sources: NIHR CRN CC Portfolio Database, Controlled Trials.com and Clinical Trials.gov. The full search strategy is obtainable from the authors.

Inclusion criteria

For the review of clinical effectiveness, systematic reviews with controlled trials, randomized controlled trials (RCTs) and non-randomized controlled designs are included. The interventions considered are weight management schemes that are designed to maintain appropriate weight and/or achieve weight loss and/or manage weight gain. The intervention should be compared with normal practice or an appropriate attention control intervention. The schemes include those aimed at universal prevention, targeted prevention, weight loss, management of weight gain and treatment of those already overweight or obese with a minimum 3-month follow-up period. The schemes can be delivered in any setting including home-based interventions. These include normal practice or non-diet or non-exercise interventions. The population for this assessment are the under fives who do not have any underlying causal morbidity, e.g. Prader–Willi Syndrome. The outcome measures are those of body mass index (BMI), weight, abdominal fat, percentage body fat and waist circumference; each clinical effectiveness study must include at least one measure of adiposity. Other outcomes are health measures, quality of life, objective measures of health behaviour such as physical activity measured objectively, i.e. by accelerometry (not self-reported outcomes), and cost-effectiveness.

The inclusion criteria for economic evaluations include the above and allow other designs (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 are included.

Study selection

Studies were identified in two stages. Titles and abstracts were screened independently by three researchers (MB, KW and JL) for possible inclusion. Disagreements were resolved by discussion. Full texts of identified studies were obtained. The same researchers examined these independently for inclusion, and disagreements were again resolved by discussion. Titles and abstracts returned by the cost-effectiveness searches were examined independently by MB and RT and screened for possible inclusion. Data were extracted by MB and checked by KW and JL.

Critical appraisal

The internal validity of the studies was assessed using standard quality indicators (19). External validity was judged according to the ability of a reader to apply the studies findings to a patient group or service setting.

Results

Quantity of effectiveness research available

The systematic review of electronic databases for clinical effectiveness studies produced 1874 titles and abstracts, of which 1840 were judged not to meet our inclusion criteria and were excluded. Thirty-four full text papers were reviewed to assess if they met the inclusion criteria. Their

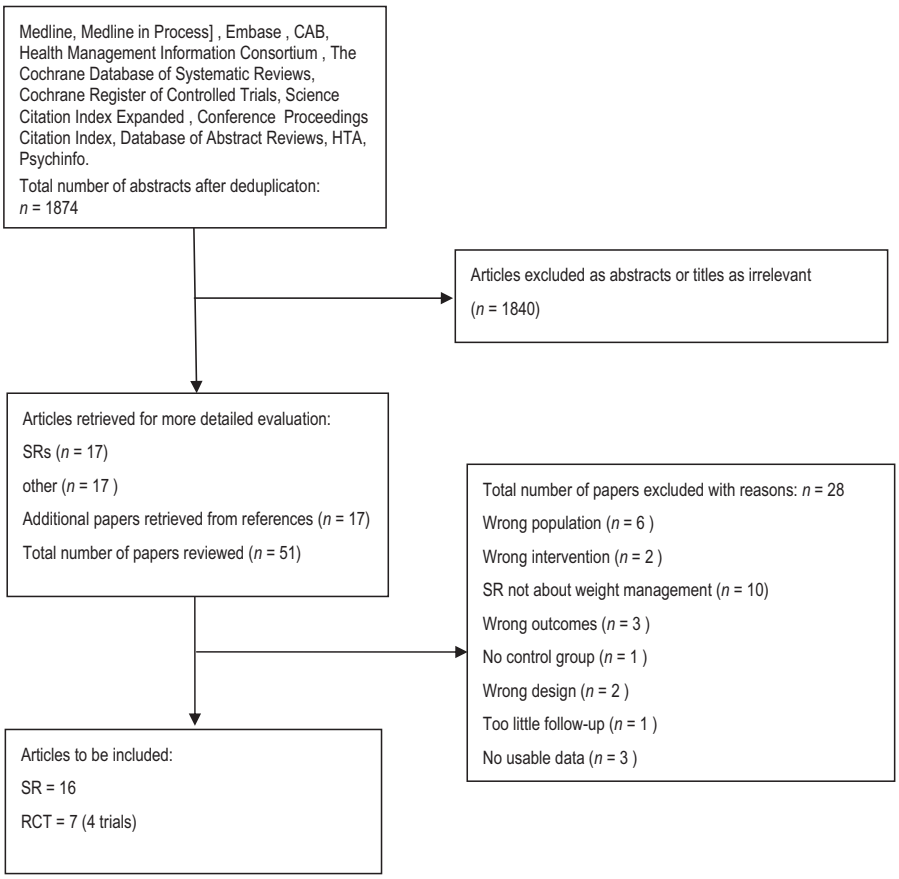

Figure 1 Flow of studies through the assessment process. RCT, randomized controlled trial; SR, systematic review.

references were screened, and an additional 17 papers were retrieved, giving 51 papers in all that underwent paper-level review. From these, an additional 44 papers were excluded. This left seven articles reporting on four RCT trials. No non-randomized trials were found. See Fig. 1 for a flow diagram of the studies.

Quality and characteristics of included studies

Randomized controlled trials

The four RCTs that met our inclusion criteria were all preventative studies; Reilly *et al.* MAGIC trial (Movement and Activity Glasgow Intervention in Children) (20), Hip-Hop to Health Jr. (21–24), Harvey-Berino and Rourke (25) and one was in Thailand, Mo-suwan *et al.* (26). Tables below provide: an overall summary of study characteristics Table 1, details of interventions Table 2 and quality indicators Table 3.

Reilly *et al.*'s (2006) study (20) was a good quality cluster randomized trial, of 545 children (intervention group $n = 268$, control group $n = 277$) 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 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-min sessions a week for 24 weeks. Two members of nursery staff were trained in the intervention and an unblinded researcher monitored the intervention for consistency. This activity was combined with a home intervention consisting of a physical activity resource pack. The children in the control group received their usual programme of activities. Our second study, Hip-Hop to Health Jr. (2002–2006) (21–24), was a moderate quality cluster RCT of a combined nutritional education and exercise intervention, designed to reduce gains in BMI in 778 pre-school minority children in the USA (intervention group $n = 197$, control group $n = 212$). This community-based intervention targeted African–American and Latino pre-school children in the Chicago area. Randomization was between pre-schools and within each ethnic community.

The weight control component consisted of a 14-week (three times weekly) programme of diet and physical activity delivered by trained early childhood educators, in 24 pre-schools, 12 each in African–American and Latino communities, and in the children's homes. Each session consisted of 20 min of a nutrition activity followed by 20 min of moderate to vigorous aerobic activity. The home element

Table 1 Summary characteristics of included randomized controlled trials

Trial	Country	*n*	Definition of obesity	Participants	Intervention	Comparator	Outcomes	Length of follow-up	Setting	Theory	Source of funding
MAGIC, Reilly *et al.* 2006 (20)	UK	545	≥95th UK National BMI percentile	36 nurseries, children in pre-school year mean (SD) age 4.2 (0.2), 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, Stolley *et al.* 2003, Fitzgibbon *et al.* 2005, Fitzgibbon *et al.* 2006 (21–24)	USA	778	≥95th percentile: US growth curves	24 pre-schools, children aged 3–5 years, mean (SD) 4.2 (4.9), plus parents	Diet and physical activity in pre-school plus educational component at home	General health education in pre-school and a related newsletter at home	BMI (US curves) weight, height	5 years	Pre-school and home	Social learning theory, self-determination theory and the trans-theoretical model	National Heart Lung and Blood Institute
Harvey-Berino and Rourke 2003 (25)	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	Home-based parenting skills course to improve behaviour	BMI (US curves) weight, accelerometry	16 weeks	Home	Not explicit	National Institute of Health
Mo-suwan *et al.* 1998 (26)	Thailand	292	Triceps skin-fold thickness >95th percentile US growth curves	Two kindergartens, children mean (SD) age 4.5 (0.4) years	Kindergarten-based physical activity programme: 1-h week physical education plus 15-min walk before classes began and 20-min aerobic dance post pm nap, 3 times per week	1-h week physical education at kindergarten	BMI (US curves) weight/height triceps skin-fold thickness	29.6 weeks	Kindergarten	Not explicit	Not reported

BMI, body mass index.

Table 2 Summary of interventions

Study	Intervention			Control	
	Nursery		Home	Nursery	Home
	Physical activity	Education			
Reilly *et al.* (20)	3 × 30 min 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. (21–24)	3 × 20 min per week × 14 weeks	Nutrition activities 3 × 20 min per week × 14 weeks	Weekly newsletter related to nursery activities, plus homework for parents with financial incentive for completion	Once weekly × 20 min × 14 weeks general health education	Weekly related newsletter
Harvey-Berino and Rourke (25)	×	×	Once weekly × 16 weeks parenting skills programme about healthy eating and exercise	×	Once weekly × 16 weeks parenting skills programme about behavioural goals
Mo-suwan *et al.* (26)	1-h week physical education plus 15-min walk before classes began and 20-min aerobic dance post pm nap 3 times per week	×	×	1-h week physical education	×

included a weekly newsletter that mirrored the children's curriculum with homework designed to reinforce concepts presented in the newsletters. Parents were asked to log specific ways to increase fruit and vegetables in their family's diet. If the homework was completed and returned, parents received a monetary reward ($5.00 grocery voucher). Additionally, parents were offered a twice weekly aerobic class at their child's pre-school.

Children in pre-schools, randomized to the control group, received a once weekly 20-min educational session for 14 weeks that taught general health concepts. The home component consisted of a weekly related newsletter without homework.

The primary outcome measure was BMI; weight and height were also recorded. Children were followed up for 24 months.

It is of some concern as the Latino pre-school groups were not entirely similar at baseline, the children in the control group were more likely to be overweight than those in the intervention group, 51% vs. 40% ($P = 0.019$) or obese 31% vs. 30% ($P = 0.033$) and have a higher mean BMI z-score mean (SD) 1.13 (1.06) vs. 0.87 (1.24) ($P = 0.03$). Similarly, in the African–American pre-school groups the children in the control group were older than those in the intervention group by a mean of 2.2 months ($P < 0.001$). The third RCT, Harvey-Berino and Rourke (2003), was of moderate quality. Participants were 40 Native-American pre-school children in the USA and Canada (25). The aim of this home-based study was to discover if including overweight mothers, 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 randomized individually to intervention or control. Those in the intervention group ($n = 20$) received obesity prevention plus parenting support 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 by their parents modelling healthy behaviours and encouraging a healthy diet and greater physical activity. This intervention was in addition to the parenting support programme taken by those in the control group ($n = 20$). This programme emphasized psychological and behavioural goals, teaching effective parenting styles and age appropriate discipline, routines and rules. The final study that we included was a weak cluster RCT from Thailand by Mo-suwan *et al.* (1998) (26) The study aimed to find out if a specially designed exercise programme for pre-school children would affect their obesity indices. Two kindergartens were recruited and their second year classes of under fives were randomized to intervention and control

Table 3 Key quality indicators of the included randomized controlled trials

Indicator	Reilly *et al.* (20)	Hip-Hop to health Jr. (21–24)	Harvey-Berino and Rourke (25)	Mo-suwan *et al.* (26)
Power calculation	✓	✓	×	×
Explicit eligibility criteria	✓	✓	✓	✓
Adequate randomization	Method not reported	Method not reported	Method not reported	Method not reported
Adequate allocation concealment	✓	Not reported	Not reported	Not reported
Outcome assessors blinded	✓	Unclear	✓	Not reported
Groups similar at baseline	✓	×	✓	×
All participants accounted for	✓	✓	✓	✓
Withdrawals specified	✓	✓	✓	✓
Clear description of intervention	✓	✓	✓	✓
Consistency of intervention measured	✓	Unclear	Unclear	Not reported
Objective outcome measures	✓	✓	✓	✓
Unit of allocation	Group and individual	Group	Individual	Group
Unit of analysis	Individual	Individual	Individual	Individual
Appropriate method of analysis	✓	✓	✓	✓
Analysis by Intention To Treat	✓	✓	✓	✓
Are results generalizable	✓	Partly*	Partly*	Partly*
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	No flow diagram

*There may be socially and culturally determined beliefs about nutrition and exercise that limit the generalizability of these results.

groups. In all 292 children participated (intervention = 147, control = 145) with a mean (SD) age of 4.5 (0.4) years.

The intervention consisted of a 15-min walk before class and a 20-min aerobic dance class in the afternoon (led by specifically trained personnel) three times a week. This was in addition to the children's usual 1-h physical education lesson a week. The control group just received the 1-h week physical education lesson. The study was confounded by one school having a weekly 1-h swimming lesson as well.

Mo-suwan *et al.* measured adiposity levels using BMI, weight height (WHCU) and triceps skin-fold thickness (TSF).

This reasonably sized cluster RCT is difficult to fully appraise as many key quality indicators were not reported. There is no sample size calculation reported, or description of randomization or allocation concealment or whether assessors were blinded. Furthermore the groups were not completely similar at baseline; the TSF, mean (SD), for the girls in the control group was statistically significantly greater than that of the girls in the intervention group (intervention = 9.9 [3.0] mm, control = 11.3 [3.8] mm). However, all participants were accounted for, objective outcome measures are used, appropriate multiple regression analysis was used by Intention to Treat, and the effects of clustering were accounted for in the analysis. Although the rational for clustering was not given and there was no consideration of the effect this might have on sample size.

Study results

Adiposity outcomes

All four studies measured BMI. However, their results are not directly comparable as the BMIs were calculated at different follow-up times or when children were at different ages. One study, Hip-Hop Jr. showed significant differences between intervention and control groups (24) (see Table 4).

The positive result from Hip-Hop Jr. was only found 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 for the Intervention group was 17.1 (2.5) kg m^{-2} 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 $P < 0.05$.

Mo-suwan *et al.*'s results showed that both intervention and control groups' adiposity decreased between baseline and follow-up, although the results failed to reach significance.

Hip-Hop Jr. and Reilly *et al.* (20) had a physical activity component within their interventions. However, despite having longer activity sessions for a greater time than Hip-Hop Jr., Reilly *et al.* found no statistically significant benefit from the intervention. Nevertheless, it should be noted that Reilly *et al.* only had 12-month follow-up and, although

Table 4 Adiposity results

Study	Metric	Baseline			16 weeks			6 months			8 months			12 months			24 months		
		Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*
Reilly *et al.* (20) *n* = 545 (I = 268, C = 277) Mean (SD) age 4.2 (0.2) years	BMI kg m^{-2}	16.3 (1.5)	16.4 (1.5)	n.s.				0.46 (1.05)	0.43 (1.08)	n.s.				0.41 (1.05)	0.43 (1.10)	n.s.			
	BMI *z*-score	0.39 (0.98)	0.41 (1.0)	n.s.															
Hip-Hop Jr. (21–24) *n* = 778 Mean (SD) age 4.2 (4.9) years																			
African–American sites *n* = 409 (I = 197, C = 212)	BMI kg m^{-2}	16.50 (1.50)	16.70 (2.0)	n.s.										16.6 (2.1)	17.4 (3.1)	0.002	17.1 (2.5) .	17.9 (3.3)	0.008
	BMI *z*-score	0.62 (0.9)	0.67 (2.0)	n.s.										0.06 (0.05)	0.13 (0.05)	0.024	0.02 (0.04)	0.16 (0.04)	0.021
	Adjusted change from baseline BMI kg m^{-2}													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)	BMI kg m^{-2}	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
	BMI *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 BMI kg m^{-2}													0.31 (0.16)	0.44 (0.17)	0.6	0.46 (0.19)	0.66 (0.20)	0.49
Harvey-Berino and Rourke 2003 (25) *n* = 40 (I = 20, C = 20) Mean (SD) age 22 (4.9) months	BMI *z*-score	0.79 (1.70)	0.67 (1.60)	n.s.	0.52 (1.10)	0.98 (1.4)	n.s.												
Mo-suwan *et al.* (26) *n* = 292 (1 = 147, C = 145) Mean (SD) age 4.5 (0.4) years	BMI kg m^{-2}	16.25 (2.35)	16.36 (2.22)	n.s.							15.76 (2.46)*	15.94 (2.26)*	n.s.						
	WHCU kg m^{-3}	15.39 (1.97)	15.59 (1.98)	n.s.							14.19 (1.89)*	14.43 (1.98)*	n.s.						
	TSF mm	9.9 (3.7)	10.3 (3.9)	n.s.†							10.03 (3.9)*	10.04 (4.1)*	n.s.						

*Multiple regression analysis.

†A significant difference was found in the girls subgroup, $P < 0.011$.

BMI, body mass index; C, control; I, intervention; n.s., not significant; TSF, triceps skin-fold thickness; WHCU, weight height^{-3}.

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 control group: intervention = 0.41 (1.05), control = 0.43 (1.10). Speculative explanations for these differences in results between studies include that the activity component of Hip-Hop Jr. was more vigorous, or that 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. (who had 24-month 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.

Participants of Harvey-Berino and Rourke were only followed up for 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.

Weight

Two studies, Hip-Hop Jr. and Harvey-Berino and Rourke, measured weight at baseline and follow-up (22,24,25). 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 found a non-significantly greater increase in weight in the control group after 16 weeks. The results can be seen in Table 5 below.

Physical activity

Two studies used an objective measure, accelerometry, to measure physical activity (Reilly *et al.* and Harvey-Berino and Rourke) (20,25). An accelerometer is a small device that is worn by the child on their hip or wrist and measures accelerations the vertical plane thus differentiating between being stationary but with arm movement, walking and running (27). This information allows researchers to characterize the intensity, frequency and duration of children's physical activity. Neither study found any statistically significant differences between groups.

Reilly *et al.* also measured sedentary behaviour (no vertical movement; accelerometer count < 1100 per minute) and the proportion of hours spent in moderate to vigorous

Table 5 Weight results

Study	Metric	Baseline			16 weeks			1 year			2 years			7 years 5 months			13 years 5 months		
		I Mean (SD)	C Mean (SD)	*P*	I Mean (SD)	C Mean (SD)	*P*	I Mean (SD)	C Mean (SD)	*P*	I Mean (SD)	C Mean (SD)	*P*	I Mean (SD)	C Mean (SD)	*P*	I Mean (SD)	C Mean (SD)	*P*
Hip-Hop Jr. (21–24) *n* = 778 Mean (SD) age 4.2 (4.9) years											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)	n.r.	6.84 (0.32)	7.95 (0.31)	n.r.						
Latino sites *n* = 401 (I = 202, C = 199)	kg	18.6 (4.1)	18.8 (3.8)	n.s.				3.84 (0.19)	3.98 (0.20)	n.r.	5.91 (0.31)	6.18 (0.32)	n.r.						
Harvey-Berino and Rourke (25) *n* = 40 (I = 20, C = 20) Mean (SD) age 22 (4.9) months	kg	12.2 (2.4)	12.3 (2.9)	n.s.	13.1 (2.4)	13.8 (3.6)	n.s.												

C, control; I, intervention; n.r., not reported; n.s., not significant.

exercise (accelerometer count > 3200 per minute) and found a slightly higher (but non-significant) level of exercise in the control group (20). These results are shown in Table 6 below.

Quantity of cost-effectiveness research available

The searches returned 595 titles and abstracts. No studies were found that matched the inclusion criteria for this systematic review. The RCT by Reilly *et al.* included in the effectiveness systematic review included the cost of the nursery component capital cost of <£200, €297 or $377. The resource pack for the home element of the intervention cost £16, €24 or $30 (20).

Discussion

Statement of principal findings

Our effectiveness searches produced 1874 titles and abstracts for review. After these had been assessed four RCTs were included in the systematic review (20,21,25,26). No studies were found aimed at the *treatment* of overweight or obesity in the under fives or of costs or cost-effectiveness. This lack of evidence makes explicit conclusions difficult.

There is disparity between our findings and those of the two previous systematic reviews of obesity interventions in under fives. Bluford *et al.* and Campbell and Hesketh (12,13). Overall these two previous reviews found four studies that showed a positive effect on adiposity outcomes, only one of these studies (Hip-Hop Jr.) met our inclusion criteria, two of the other studies were uncontrolled, and the other was an evaluation of a food-supplying service. This difference in findings may reflect the inclusion of uncontrolled evidence that is known to introduce bias and confounding and may produce results more likely to favour the intervention (28,29).

Across the four included RCTs only one study's results reached statistical significance; this was in the African–American subgroup of the Hip-Hop Jr. trial. However, in the other trials and the Latino subgroup of Hip-Hop Jr., we found that intervention groups compared with control groups had trends showing improvements in BMI levels over 6–24 months. Similarly the results for weight showed trends in favour of the intervention. Although, in the studies that measured physical activity, 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

Table 6 Physical activity results

Study	Metric	Baseline			16 weeks			6 months		
		Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*	Intervention mean (SD)	Control mean (SD)	*P*
Reilly *et al.* (20) *n* = 545 (I = 268, C = 277) Mean (SD) age 4.2 (0.2) years	Physical activity count per minute	732 (163)	809 (209)	n.s.				809 (179)	899 (218)	n.s.
	Sedentary behaviour, median (range) % monitored sedentary time	69.3 (50.4–68.6)	66.9 (45.6–88.7)	n.s.				67.0 (47.0–86.0)	62.9 (43.1–81.6)	n.s.
	MVPA, median (range) % monitored MVPA time	2.6 (0.4–11.1)	3.0 (0.3–13.0)	n.s.				3.5 (0.5–12.4)	4.1 (0.6–12.1)	n.s.
Harvey-Berino and Rourke (25) *n* = 40 (I = 20, C = 20) Mean (SD) age 22 (4.9) months	Physical activity Vmag/h	20 457 (8 670)	19 417 (5 735)	n.s.	17 886 (6 746)	17 637 (8 151)	n.s.			

C, control; I, intervention; MPVA, moderate–vigorous intensity physical activity; n.s., not significant; Vmag/h, vector magnitude per hour.

be less well 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 *et al.*'s study had a longer physical activity component (30 vs. 20 min) and Mo-suwan *et al.* had a similar amount of moderate to vigorous exercise plus an additional 15-min walk? 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 pre-school 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 *et al.* 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 *et al.*'s trial; Mo-suwan *et al.*'s trial may have been confounded by one of the study sites additionally having weekly swimming lessons.

It is not possible to 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 ($n = 40$), possibly underpowered, RCT with a very short follow-up time (16 weeks). There was also no direct physical activity intervention, and the children were not directly engaged with the study, whose intervention was aimed at parent education.

Barriers and facilitators

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. The Hip-Hop Jr. authors identified several components from their pilot work that were important in engaging these families, they were: easy and safe access to the programme, being situated in the pre-school 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 considering all levels of literacy (21). This study also engaged parents more fully than Reilly *et al.* by giving them homework that required more active engagement, and Mo-suwan *et al.* who did not involve parents at all. It is likely that greater parental engagement increased the possibility of success as well as the financial incentive to carry out the homework.

Another aspect that requires careful consideration is the delivery of the intervention. Both Reilly *et al.* and the Hip-Hop study commented on the need for properly trained staff to carry out the physical activity component. Reilly *et al.* reported that in their pilot study (which had shown significantly increased accelerometry output of 40% (30)), the intervention was carried out by nursery head teachers but that in the trial (to aid generalizability) the intervention was provided by nursery staff and was possibly less rigorous. The physical activity component of Hip-Hop Jr. was delivered by trained pre-school 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.

Implications for policy makers

Despite the paucity of evidence and mixed findings of our included studies, key messages focussing on the theoretical principle of balancing food intake and energy expenditure 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 (31,32).

It is possible that the four 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; a significant factor may be the training and enthusiasm of these staff for the intervention (33).

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 (24). This supports a recent review of family involvement in paediatric obesity management by Nowicka and Flodmark, which found that the majority of studies endorsed the use of family-based treatment (34), similarly Moore *et al.*'s study has shown that parents act as models for their children in terms of levels of physical activity and diet (35).

Strengths and limitations of the assessment

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

Limiting factors include that (i) The searches were limited to the English language. This may have meant that otherwise includable controlled trials have been omitted. However, Bluford *et al.*'s searches were not restricted in this way and did not find any includable non-English language studies. (ii) The searches only went back to 1990, so we may have missed includable studies. Although Bluford *et al.*'s searches went back to 1966, none of the studies they found prior to 1990 would have been includable in our systematic review.

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. 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 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 are elements that future interventions should consider: effective training for staff involved in the delivery of the intervention, cultural sensitivity, sustained moderate to vigorous physical activity, nutritional education for children, active engagement of parents/carers as participants and role models of a healthy lifestyle, combined with education about healthy diets and exercise.

The lack of evidence indicates that research is urgently needed, in particular: further well-designed RCTs of weight management schemes aimed at the *prevention* and or *treatment* of obesity, that combine with cost-effectiveness studies targeted at pre-school children (under fives) with long-term follow-up (>12 months). These RCTs should specifically consider including the characteristics listed above, with objective outcomes, i.e. body density, skin-fold thickness, waist circumference, BMI, weight, physical activity, health behaviour and cost outcomes. These and smaller observational studies should have a qualitative component to investigate the barriers and facilitators to successful engagement of children, parents and pre-school staff in weight management interventions in addition to quantifying the intensity of parental engagement throughout the intervention.

Conflict of Interest Statement

No conflict of interest was declared.

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