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Effect of obesity treatment interventions in preschool children aged 2–6 years: a systematic review and meta-analysis

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ABSTRACT

Objectives (1) To summarise the literature on the impact of paediatric weight management interventions on health outcomes in preschool age children with overweight or obesity and (2) to evaluate the completeness of intervention description and real-world applicability using validated tools.

Design Systematic review and meta-analysis.

Data sources MEDLINE, Embase, CINAHL, Cochrane Library and PsychInfo were searched between 10 March 2015 and 21 November 2021.

Eligibility criteria Randomised controlled trials addressing weight management in preschool children (2–6 years) with overweight or obesity.

Data extraction and synthesis Two reviewers independently extracted key information from each study and assessed risk of bias. Random-effects meta-analysis was performed where there was evidence for homogeneous effects. The certainty of evidence was assessed by the Grading of Recommendations Assessment, Development and Evaluation.

Results Of the 16 908 studies retrieved, 9 trials (1687 participants) met the inclusion criteria. These interventions used motivational interviewing (MI) or multicomponent educational interventions related to health behaviour approaches and were 6–12 months in duration. All studies contained some risk of bias. A difference was found in the intervention groups compared with controls for body mass index (BMI) z score (mean difference −0.10, 95% CI −0.12 to −0.09; eight trials, 1491 participants; p<0.001; I^2 68%), though there was substantial heterogeneity. There were no subgroup effects between studies using MI compared with studies using multicomponent interventions. The certainty of the evidence was considered low. The trials were reported in sufficient detail and were considered pragmatic.

Conclusions Paediatric weight management interventions delivered to the parents of young children with obesity result in small declines in BMI z score. The results should be interpreted cautiously as they were inconsistent and the quality of the evidence was low.

PROSPERO registration number CRD42020166843.

Strengths and limitations of this study

► This review updates our understanding of the effectiveness of weight management interventions on health outcomes of preschool-aged children over the past 6 years.

► This review highlights a knowledge gap for the best practice for paediatric weight management in preschool children.

► This review evaluates the description of interventions and their real-world applicability by using the Template for Intervention Description and Replication checklist and Rating of Included Trials on the Efficacy–Effectiveness Spectrum tool, respectively.

► This review investigated children aged 2–6 years old with overweight or obesity and not those with a medical condition known to affect weight status or syndromic causes for obesity.

adolescents with obesity worldwide.[2] Nationally representative data from 144 countries suggests that 43 million children under 5 years of age have obesity.[3] Children with obesity carry an increased risk for cardiometabolic disease and poor psychosocial health.[4–7] Childhood obesity often persists into adulthood and is associated with increased risk of morbidity throughout life.[8–10] These alarming rates and health risks underscore a need for effective interventions to treat obesity in early childhood and to prevent continued obesity-related health issues across the life span.

Family-based behaviour modification remains the foundation of paediatric weight management programmes.[11] In a 2016 Cochrane systematic review, multicomponent interventions tested with randomised controlled trials (RCTs) in preschool children with obesity aged 2–6 years old were effective in reducing body mass index (BMI) z score, a common metric to classify obesity in children.[12] Interventions typically consisted of lifestyle behaviour modification, including dietary and physical activity advice, along

INTRODUCTION

The prevalence of overweight and obesity in children has been increasing globally.[1] There is estimated to be 124 million children and

with parenting skills. Four trials (n=210 participants) were included in that analysis, and a mean change of −0.3 units (95% CI −0.4 to −0.2) in BMI z score was reported. However, the quality of evidence was deemed to be low and a high risk of bias was identified. Since then, there has been increased interest in this field given the increasing prevalence of paediatric obesity.[13] This systematic review will update the effectiveness of weight management interventions on preschool age children since the Cochrane review in 2016.[12]

Although systematic reviews can be invaluable in facilitating clinical decision-making by providing a critical evaluation of the evidence on a specific topic or condition[14]; to do so, the intervention must be adequately described. Further, the pragmatism of the trial will inform the potential for 'real-world' implementation. The Template for Intervention Description and Replication (TIDieR) checklist was created to ensure interventions are described in sufficient detail to allow for replication.[15] The Rating of Included Trials on the Efficacy–Effectiveness Spectrum (RITES) tool is used to assess the real-world applicability and pragmatism of trials.[16]

The objectives of this systematic review were (1) to assess the impact of paediatric weight management interventions on health outcomes in preschool children aged 2–6 with overweight or obesity and (2) to evaluate the description of these interventions using the TIDieR checklist and their real-world applicability using the RITES tool. This knowledge will help inform future clinical practice guidelines and the planning of health programming for the treatment of young children with obesity.

METHODS
This review was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[17] A PRISMA study flow diagram was completed to present a summary of searching, screening and inclusion of studies in this systematic review.[17] The review protocol for this study was registered with PROSPERO (CRD42020166843).

Patient and public involvement statement
No individual participant data were involved in the study; therefore, patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research.

Eligibility
Study designs eligible for inclusion were RCTs with the aim of weight management in preschool children with overweight or obesity. Any type of intervention of at least 6 months' duration and delivered in a clinical setting was included. The interventions could be delivered by a single professional or could be multidisciplinary or multicomponent. Multicomponent interventions typically address health behaviours including diet and physical activity. Participation of family members was

not mandatory. Interventions for prevention of obesity, studies with observational designs and studies with self-reported height and weight were excluded. Participants included children with overweight or obesity who were between the ages of 2 and 6 years at the time of enrolment into a weight management intervention. Studies of children with obesity who had a medical condition known to affect weight status or syndromic causes for obesity were excluded (eg, genetic syndromes such as Prader-Willi syndrome and Bardet-Biedl syndrome). The control group in eligible RCTs was defined as no intervention or usual or standard care.

The primary outcomes were change in BMI or change in BMI z score or BMI percentile. BMI changes with age during normal growth,[6] and so age-specific and sex-specific BMI z scores, based on a normative standard, were included.[18] Additional secondary health outcomes were included in the search terms: body weight, waist circumference, waist-to-height ratio, skin fold thickness, body fat percentage measured with bioelectrical impedance analysis (BIA) or dual-energy X-ray absorptiometry, lipid profile (including low-density lipoprotein, high-density lipoprotein, triglycerides and total cholesterol), blood pressure, glycaemia (fasting plasma glucose, glucose level at 2 hours in a standard oral glucose tolerance test and haemoglobin A1C) and quality of life. Adverse events were defined as any adverse outcome occurring during or after the intervention, including events not necessarily caused by the intervention.

Search of studies
We conducted a comprehensive literature search in the following electronic databases: Ovid MEDLINE, Embase, CINAHL, Cochrane Library, PsychInfo, WHO International Clinical Trials Registry Platform, Web of Science and Clinicaltrials.gov. These databases were first searched from 10 March 2015 (the end date of the 2016 Cochrane review)[12] to 31 January 2020, and this search was updated on 21 November 2021. The search strategy was developed in consultation with a research librarian using the following major themes: 'preschool', 'overweight or obesity' and 'intervention'. Key terms within the search strategy were aligned to Medical Subject Headings in Ovid MEDLINE and were expanded to include more descriptive terms. The search strategy for each database is presented in online supplemental appendix 1. Reference lists of included publications and reviews and of other systematic reviews or meta-analyses were manually searched to identify other studies that might not have been identified through the database searches. The database searches resulted in a combined total of 16 908 studies after removal of duplicates (figure 1).

Study selection
Titles, abstracts and full texts were reviewed independently for eligibility by two groups of two authors (SN and CD, PGM and RG) using a pretested, standardised screening form. Publications selected for inclusion were
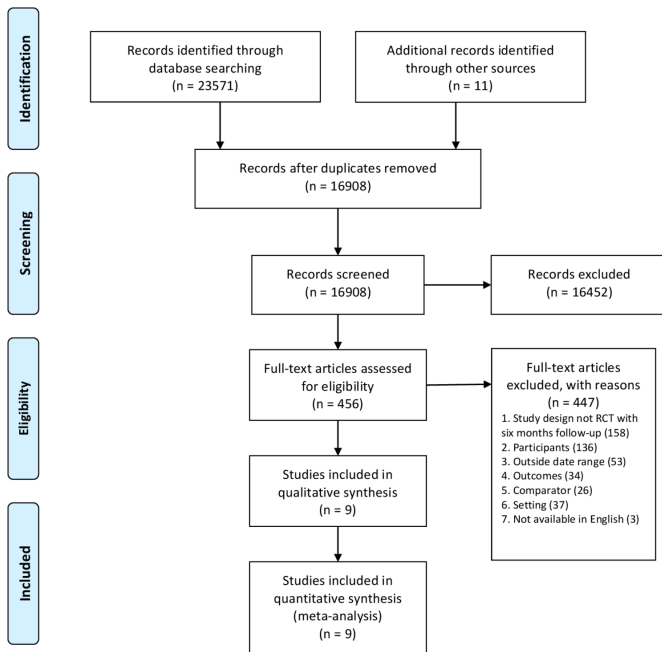
Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

reviewed by an additional author and expert in the field and were compared against the inclusion criteria. Only papers published in English were included.

Every attempt was made to identify duplicate publications or multiple reports/companion pieces based on the same study and, if that occurred, the publication with the longest follow-up period for the primary outcome was included.

Data extraction

Key information from each included study was extracted in duplicate using a screening form and data extraction template. If data were missing, attempts were made to obtain the data from the corresponding author noted in the publication. Any disagreement during screening or extraction was resolved by discussion or in consultation with a third author.

Risk of bias and certainty of evidence

Risk of bias of each of the included studies was assessed using the Cochrane Risk of Bias tool.[14] The overall certainty of the evidence for each outcome was judged using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. The certainty of the evidence was assessed across the domains of risk of bias, precision, consistency and publication bias (internal validity), as well as directness (external validity). The quality of evidence was rated for each outcome (high, moderate, low or very low). Certainty was judged as high (further search is very unlikely to change the confidence in the effect estimate), moderate (further research is likely to have an important impact on the confidence in the effect estimate and may change the estimate), low (further research is very likely to have an important

impact on the confidence of the effect estimate and is likely to change the estimate) or very low (very uncertain about the estimate of the effect). A checklist was created and used to help ensure consistency and reproducibility of the GRADE assessments.[14]

The TIDieR checklist was completed to ascertain if the intervention was reported in sufficient detail to allow for reproduction of the study.[15] The RITES tool was completed to evaluate the pragmatism of the intervention; this tool uses a 5-point Likert scale in four domains: (1) participant characteristics, (2) trial setting, (3) flexibility of the intervention and (4) clinical relevance.[16] Two reviewers independently classified each trial on the Likert scale. Disagreements were resolved with a discussion to achieve consensus. All items were summed for each study to provide an efficacy/effectiveness score. The score is a continuum from maximum efficacy (score of 4) on one end to maximum effectiveness (or most pragmatic) at the other (score of 20). A low total score (ie, 4) suggests a strong emphasis on efficacy, and a high total score (ie, 20) is consistent with a strong emphasis on effectiveness or a more pragmatic trial.

Statistical analysis

Statistical analyses were performed using Review Manager 5 (RevMan 2013) software package (Cochrane Training, Cochrane). For continuous data measured on the same scale, the mean difference (MD) was calculated. Overall effects were reported and classified as small, medium or large based on Cohen's d effect sizes.[19] We used a random-effects model, taking into account the interstudy variation, which provided a more conservative effect than a fixed model. All effect sizes were reported with 95% CIs. The statistic I^2 was calculated to investigate the variation in effect size due to heterogeneity across studies. Zero % to 40% corresponded with low heterogeneity; 30%–60% corresponded with moderate heterogeneity; 50%–90% corresponded with substantial heterogeneity; and >75% corresponded with considerable heterogeneity.[20] For three-arm trials (two interventions with a control group), the control group was split for meta-analyses to compare interventions to control (Cochrane Handbook V.5.1, Ch:16.5.4).[21]

Synthesis of results

Review Manager 5 was used to combine and calculate each outcome (RevMan 2013). If there was good evidence for homogeneous effects (ie, tests of heterogeneity were not significant) across trials, a random effects meta-analysis was performed. If there was substantial heterogeneity, subgroup analyses based on sex, differences in BMI z score at baseline (eg, overweight vs obesity) or intervention setting were to be performed. If substantial heterogeneity remained, a qualitative synthesis was conducted.

Sensitivity analyses excluding trials with high risk of bias or with high rate of participant attrition (>20%) were to be performed (PROSPERO CRD42020166843).

RESULTS

Search results

After title and abstract screening, 456 studies remained and underwent full-text screening. After full text review and removal of studies that did not meet the inclusion criteria and considering articles and ongoing trials from the previous Cochrane review, nine studies remained. A manual search of the articles in the reference lists from the included studies did not generate any additional relevant studies. Therefore, a total of nine RCTs were included in this review.

Current study versus previous Cochrane systematic review

The current study is an updated systematic review and meta-analysis of the previous study by Colquitt *et al.*[12] The previous study included seven RCTs and identified four ongoing trials that might be relevant in future meta-analyses. On review and consideration of these previous studies, four of the seven previously analysed studies were also included in the current meta-analysis.[22–25] Three studies from the previous review were excluded: Bocca *et al* was a 4-month intervention (<6 months)[26]; Lanigan *et al* included an age range of 1–5 years old (<2 years old)[27]; Taveras *et al*[28] included the same participants as Rifas-Shiman *et al.*[29] Consistent with our inclusion criteria, we selected the study with the longest follow-up period[29] and excluded Taveras *et al.*[28] Of the four ongoing trials identified in the previous study,[12] one status was unknown (NCT00916318); another was terminated due to no funding to launch an RCT (NCT01698606); and two were unidentifiable in the literature (NCT02292602, Reifsnider 2012).[30]

Summary of included studies

The nine included studies, published between 2009 and 2021, were conducted either in the USA (n=6),[22 24 25 29 31 32] in Sweden (n=2)[33 34] or in Iran (n=1).[23] Of the 1687 participants, 937 were randomised to an intervention and 750 to a comparator group. Five studies were multicentre trials,[22 29 31 33 34] while four studies were conducted at a single centre.[23–25 32] Five studies were delivered in a primary care setting[29 31–34]; one study was delivered in community-centred programmes and primary care clinics,[31] while four studies were implemented in the outpatient care setting under the guidance of healthcare professionals.[22–25] The interventions included motivational interviewing (MI) for parents[32] or families,[29 34] dietary interventions with an educational component,[23] or education on the principles of good nutrition and activity.[24 25 31–33] (table 1). Interventions ranged from 6[32] to 12 months[29 31 33] in duration; three studies included a 12-month follow-up period[24 25 29]; and one study had a 3-year follow-up.[23] Interventions varied in intensity, from less than 1-hour contact time[34] to 3-hour total contact time (MI)[29] to upwards of 27-hour total contact time (education).[31]

Effects of interventions

The BMI outcome was BMI z score for eight studies, and %BMIp95 was reported for four trials. A difference in BMI z score between intervention and control groups was identified at the end of intervention (MD −0.10, 95% CI −0.12 to −0.09; eight trials, 1491 participants; $p \leq 0.001$; I^2 68%) (figure 2). No between-group difference in %BMIp95 was identified (MD −1.34, 95% CI −3.17 to 0.49; four trials, 349 participants; p=0.15; I^2 79%) (figure 3). Of note, the heterogeneity in both analyses exceeded 50%, indicating substantial heterogeneity. Two RCTs included BMI as a primary outcome. There was a small improvement in BMI between intervention and usual care (MD −0.17, 95% CI −0.33 to −0.01; two trials, 931 participants; p=0.03, I^2 0%) (figure 4).

Subgroup analyses

An exploratory subgroup analysis was completed based on intervention modality (multicomponent educational interventions vs MI) for BMI z score. We saw no subgroup effects when we compared the studies that used MI (MD −0.02, 95% CI −0.11 to 0.06; three trials, 987 participants; p=0.59; I^2 49%) compared with the others (figure 5) or when we compared multicomponent educational interventions (MD −0.11, 95% CI −0.12 to −0.09; six trials, 504 participants; p<0.001; I^2 68%) with the others (figure 6). None of these subgroup analyses explained the heterogeneity. None of the preplanned subgroup analyses were possible due to missing or insufficient reporting of data.

Sensitivity analysis

All the included studies were at high risk of bias and therefore conducting sensitivity analysis based on overall risk of bias was not possible. However, the results from BMI z score in the studies at low risk of bias due to attrition had a similar direction of effect (reducing BMI z score) (ie, attrition <20%; MD −0.10, 95% CI −0.11 to −0.09; four trials, 704 participants; $p \leq 0.001$; I^2 67%), despite substantial heterogeneity (figure 7).

Secondary outcomes

Six of the nine trials included secondary outcomes. Unfortunately, not all data were able to be interpreted in the context of a meta-analysis due to missing results (ie, no mean standard change reported).[31 33] Kelishadi *et al* included many secondary outcomes including waist circumference, body fat, lipid profile and blood pressure; however, this was the only RCT to include these outcomes.[23] Two of the trials[24 25] included paediatric quality of life and noted an improvement in quality of life (MD 6.32, 95% CI 0.91 to 11.73; two trials, 50 participants; p=0.02; I^2 0%) (figure 8). Weight (kilogram) was also reported in two trials,[22 25] with a clinically significant improvement (MD −1.27, 95% CI −1.93 to −0.61; two trials, 129 participants; p<0.001; I^2 0%) (figure 9).

Adverse events

Two trials reported no adverse events,[32 33] while Derwig *et al* reported no adverse events aside from worsening weight status of several participants.[34] Adverse events from the other trials were not reported.

Table 1 Characteristics of included studies

Source	Setting	Intervention/comparator	Sample size	Sex (female), n (%)	Age (years), mean (SD)	BMI measure (baseline)	Intervention (duration)	Effect size (95% CI)	Outcomes
Kelishadi et al[23]	Outpatient	I1: Calcium-rich diet	40	NR	5.4 (0.2)	z score: 2.4 (0.01) BMI: 22.1 (0.9)	6 months with 3-year follow-up >800 mg calcium/day Total contact=6 education sessions	−0.1 (−0.11 to 0.09)	Primary: BMI z score (CDC) Secondary: waist circumference, % body fat, dietary intake, PA, glycaemic control, blood pressure, lipid profile
		I2: Energy-restricted group	40	NR	5.5 (0.7)	z score: 2.3 (0.04) BMI: 22.7 (0.8)	6 months with 3-year follow-up energy content restricted Total contact=6 education sessions	−0.1 (−0.11 to 0.09)	
		C: Control	40	NR	5.7 (0.3)	z score: 2.4 (0.01) BMI: 22.4 (0.5)	No dietary recommendation		
Stark et al[24]	Outpatient	I: LAUNCH	8	2 (25.0)	4.4 (0.9)	BMI %ile: 99.0 (0.9)	6 months with 12-month follow-up Phase I: 12 weekly sessions (90 min) Phase II: 12 biweekly sessions, alternating between group and home Total contact ≥30 hours	−0.6 (−0.92 to 0.26)	Primary: BMI z score, BMI % (CDC) Secondary: dietary intake, home food environment, children's PA, parenting styles Peds QL
		C: Control	10	4 (40.0)	3.9 (1.1)	BMI %ile: 97.7 (2.5)	45 min: diet and PA recommendations		
Quattrin et al[22]	Outpatient	I: Family-based weight control	46	31 (67.4)	4.6 (1.1)	z score: 2.2 (0.8) BMI %: 32.4 (22.4)	12 month, 60 min sessions/month (13 total) Control+behavioural modification Total contact=13 hours (+8 phone calls)	−0.2 (−0.38 to 0.10)	Primary: BMI z score (CDC) Secondary: BMI %
		C: Information control	50	33 (66.0)	4.4 (1.1)	z score: 2.1 (0.7) BMI %: 29.8 (17.1)	60 min sessions/month (13 total) Dietary and PA education Total contact=13 hours		
Stark et al[25]	Outpatient	I1: LAUNCH – home +clinic	10	8 (80)	4.7 (1.3)	z score: 2.1 (0.2)	6 months with 12-month follow-up Phase I: 12 sessions/week (90 min) Phase II: 12 weeks group clinic+home Total contact ≥30 hours	−0.3 (−0.60 to 0.00)	Primary: BMI z score (CDC) Secondary: dietary intake, home food environment, children's PA, parenting styles
		I2: LAUNCH - clinic	11	7 (64)	4.2 (1.1)	z score: 2.5 (0.8)	Phase I: biweekly sessions, months 1–3 Phase 2: monthly clinic visits for months 4–6 for 10 total sessions Total contact=10 hours		
		C: Control	12	8 (67)	4.8 (0.7)	z score: 2.4 (0.4)	45 min: diet and PA recommendations		
Rifas-Shiman et al[29]	Primary care clinics	I: High five for kids (MI)	253	121 (47.8)	4.8 (1.2)	z score: 1.9 (0.7) BMI: 19.2 (2.6)	12 months, 4 (25 min) in-person visits+2 (15 min) phone calls 12-month maintenance: 2 in-person visits Total contact=8 sessions (3 hours)	−0.0 (−0.11 to 0.07)	Primary: BMI z score (CDC) Secondary: television viewing, intake of fast food and sugar sweetened beverages
		C: Usual care	192	94 (49.0)	5.2 (1.1)	z score: 1.8 (0.6) BMI: 19.1 (2.0)	Baseline+annual well child care visits		

Continued

Table 1 Continued

Source	Setting	Intervention/ comparator	Sample size	Sex (female), n (%)	Age (years), mean (SD)	BMI measure (baseline)	Intervention (duration)	Effect size (95% CI)	Outcomes
Butte et al[31]	Primary care clinics+community programmes	I: MEND	100	51 (51.0)	2–5*	BMI %ile: 113.0 (15.2) BMI: 20.5 (0.3)	3-month intense: 9 (90 min) sessions/week 9-month transition: (90 min) sessions/month Total contact=18 sessions (27 hours)	−0.9 (−3.53 to 1.79)	Primary: %BMIp95 (CDC) Secondary: body composition, blood pressure, PedsQL and strengths and difficulties
		C: 12 month clinic-based programme	60	29 (49.0)	2–5*	BMI %ile: 110.2 (13.7) BMI: 20.0 (0.3)	12-month clinic-based programme Total contact=8 hours		
Stark et al[32]	Primary care clinics	I1: LAUNCH	47	25 (53.2)	4.6 (1.0)	z score: 2.4 (0.5) BMI %ile: 98.6 (1.2)	3-month intense: 90/60 min sessions/week 3-month maintenance: biweekly sessions Total contact=18 sessions (23 hours)	−0.2 (−0.35 to 0.03)	Primary: BMI z score (CDC) Secondary: %BMIp95, (CDC) parental BMI
		I2: MI	50	29 (58.0)	4.6 (0.9)	z score: 2.4 (0.6) BMI %ile: 98.5 (1.3)	3-month intense: weekly sessions 3-month maintenance: biweekly sessions Total contact=18 sessions (7.5 hours)	0.1 (−0.06 to 0.22)	
		C: Control	54	32 (59.3)	4.6 (0.9)	z score: 2.5 (0.7) BMI %ile: 98.6 (1.3)	Informed caregivers of child's weight		
Ek et al[33]	Primary care clinics	I1: No booster	43	23 (53.2)	5.2 (0.9)	z score: 3.1 (0.7) BMI: 21.9 (2.3)	12-month 10 (90 min) sessions Total contact=10 sessions (15 hours)	−0.5 (−0.73 to 0.21)	Primary: BMI z score (IOTF) Secondary: child BMI, waist circumference, metabolic health, lifestyle patterns, obesity-related child behaviours, lifestyle-specific self-efficacy
		I2: Booster	44	19 (43.2)	5.2 (0.8)	z score: 3.0 (0.5) BMI: 21.4 (1.5)	12-month 10 (90 min) sessions+booster (7 (30 min) phone calls) Total contact=17 sessions (18.5 hours)	−0.2 (−0.42 to 0.04)	
		C: Standard care	87	56 (64.4)	5.3 (0.7)	z score: 2.9 (0.6) BMI: 21.3 (1.7)	≥4 visits of 30 min over 12 months Total contact=minimum of 4 sessions (2 hours)		
Derwig et al[34]	Primary care clinics	I: CCHD	245	133 (54.3)	4.1 (0.1)	z score: 1.6 (0.3) BMI: 18.1 (0.4)	12-month 10 min dialogue with child, family, clinician 45 min family guidance Total contact=55 min	−0.1 (−0.18 to 0.00)	Primary: BMI z score (IOTF) Secondary: costs for delivery of care, number of extra visits and number of referrals
		C: Standard care	245	132 (53.9)	4.1 (0.1)	z score: 1.6 (0.3) BMI: 18.1 (0.5)	Single visit of a health dialogue of overweight		

*Average age not reported in study.
BMI, body mass index; C, Control; CCHD, Child-Centered Health Dialogue; CDC, Centers for Disease Control and Prevention; I, Intervention; IOTF, International Obesity Task Force; LAUNCH, Learning about Activity and Understanding Nutrition for Child Health; MI, motivational interviewing; NR, Not reported; PA, physical activity.
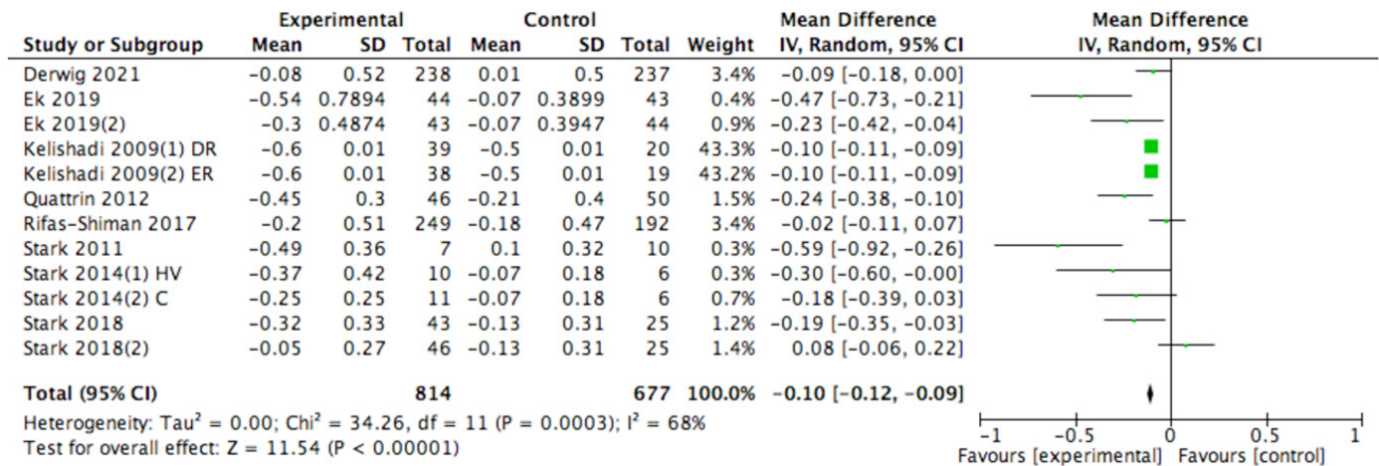
Study or Subgroup	Experimental			Control			Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Derwig 2021	-0.08	0.52	238	0.01	0.5	237	3.4%	-0.09 [-0.18, 0.00]	
Ek 2019	-0.54	0.7894	44	-0.07	0.3899	43	0.4%	-0.47 [-0.73, -0.21]	
Ek 2019(2)	-0.3	0.4874	43	-0.07	0.3947	44	0.9%	-0.23 [-0.42, -0.04]	
Kelishadi 2009(1) DR	-0.6	0.01	39	-0.5	0.01	20	43.3%	-0.10 [-0.11, -0.09]	
Kelishadi 2009(2) ER	-0.6	0.01	38	-0.5	0.01	19	43.2%	-0.10 [-0.11, -0.09]	
Quattrin 2012	-0.45	0.3	46	-0.21	0.4	50	1.5%	-0.24 [-0.38, -0.10]	
Rifas-Shiman 2017	-0.2	0.51	249	-0.18	0.47	192	3.4%	-0.02 [-0.11, 0.07]	
Stark 2011	-0.49	0.36	7	0.1	0.32	10	0.3%	-0.59 [-0.92, -0.26]	
Stark 2014(1) HV	-0.37	0.42	10	-0.07	0.18	6	0.3%	-0.30 [-0.60, -0.00]	
Stark 2014(2) C	-0.25	0.25	11	-0.07	0.18	6	0.7%	-0.18 [-0.39, 0.03]	
Stark 2018	-0.32	0.33	43	-0.13	0.31	25	1.2%	-0.19 [-0.35, -0.03]	
Stark 2018(2)	-0.05	0.27	46	-0.13	0.31	25	1.4%	0.08 [-0.06, 0.22]	
Total (95% CI)			814			677	100.0%	-0.10 [-0.12, -0.09]	

Heterogeneity: Tau² = 0.00; Chi² = 34.26, df = 11 (P = 0.0003); I² = 68%
Test for overall effect: Z = 11.54 (P < 0.00001)

Figure 2 Forest plot showing the mean difference in body mass index z score comparing intervention versus control. IV, inverse variance.

Risk of bias

All trials reported adequate sequence generation and allocation concealment and used a form of computer random generator for randomisation. As noted in the risk of bias assessment presented in figure 10, all but one trial[22] did not blind participants or healthcare providers to the intervention or control groups resulting in a high risk for performance bias for study outcomes. Three of the trials did not mention blinding for data collectors or outcome assessors; these trials were rated as uncertain risk for detection bias.[29 31 34] Four of the RCTs blinded study staff collecting outcome measures to participant assignment and therefore were judged as low risk for detection bias.[22 23 25 32] Ek et al stated that data were collected by child healthcare professionals participating in the study and was therefore rated high risk for detection bias.[33] The drop-out rates were unbalanced across studies: only 38% of intervention participants in the study by Rifas-Shiman et al completed more than one visit.[29] Of the remaining trials, drop-out rates for the intervention groups ranged from 2.5%[23] to 36%.[31] Only four RCTs reported less than a 20% drop-out rate, making these studies low risk for attrition bias.[22–24 34] The remaining five RCTs reported at least a 20% drop-out rate resulting in a high risk for attrition bias. We judged six of nine trials to have low risk of reporting bias.[24 29 31–34] We did not draw funnel plots or perform Egger's test to assess reporting bias due to the limited number of trials per outcome (n=8, BMI z score).

Certainty of the evidence

The overall quality of the evidence was considered low as a result of the high risk for performance bias and attrition bias (table 2). We did not downgrade for blinding of participants when examining overall quality of evidence for the primary outcomes.

Template for Intervention Description and Replication

Most of the studies included adequate information regarding the intervention (online supplemental appendix 2). In three of the studies,[22 31 33] the intervention was well described, although some of the materials required to conduct the intervention were not provided or were not described in sufficient detail to reproduce the intervention. Three of the included trials were variations on the same intervention: Stark et al has published three RCTs using their Learning about Activity and Understanding Nutrition for Child Health intervention.[24 25 32] While the papers did include well-described interventions, there is extensive training required to effectively administer the intervention, and training information was not included. The lack of information regarding the training or education for those implementing the intervention was
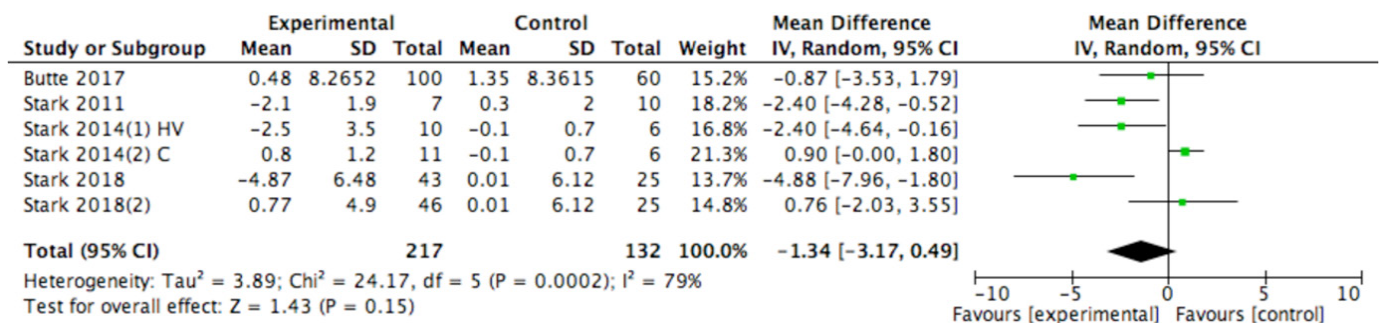
Study or Subgroup	Experimental			Control			Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Butte 2017	0.48	8.2652	100	1.35	8.3615	60	15.2%	-0.87 [-3.53, 1.79]	
Stark 2011	-2.1	1.9	7	0.3	2	10	18.2%	-2.40 [-4.28, -0.52]	
Stark 2014(1) HV	-2.5	3.5	10	-0.1	0.7	6	16.8%	-2.40 [-4.64, -0.16]	
Stark 2014(2) C	0.8	1.2	11	-0.1	0.7	6	21.3%	0.90 [-0.00, 1.80]	
Stark 2018	-4.87	6.48	43	0.01	6.12	25	13.7%	-4.88 [-7.96, -1.80]	
Stark 2018(2)	0.77	4.9	46	0.01	6.12	25	14.8%	0.76 [-2.03, 3.55]	
Total (95% CI)			217			132	100.0%	-1.34 [-3.17, 0.49]	

Heterogeneity: Tau² = 3.89; Chi² = 24.17, df = 5 (P = 0.0002); I² = 79%
Test for overall effect: Z = 1.43 (P = 0.15)

Figure 3 Forest plot showing the mean difference in BMI % of the 95th percentile comparing intervention versus control.
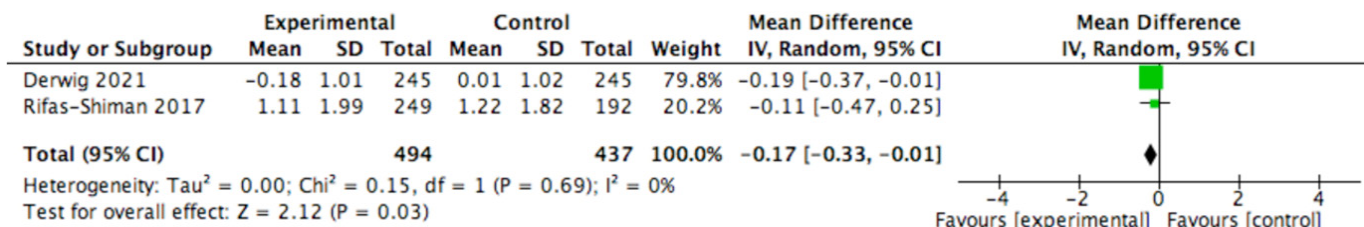
Figure 4 Forest plot showing the mean difference in body mass index comparing intervention versus control.

common throughout many of the included studies.[22–25 31 32] In some cases, the reviewers were required to search for previously described protocols to gain an understanding of the materials and training details.[24 25 31 32] Derwig *et al* did require training to implement their intervention; however they did provide an additional paper describing the training and materials in detail.[34]

While TIDiER is not typically used for describing the standard of care or usual treatment, in the case of preschool age obesity treatment, many of the studies included interventions beyond the current standard of care. As such, this review also included the TIDiER checklist for the control intervention. Both Kelishadi et al and Quattrin *et al*[23] control groups received the same education sessions as the intervention groups, which was significantly more than the standard of care. Butte *et al*[31] and Stark *et al*[24 25] also included additional interventions for their control groups, over and above standard of care. The standard of care was not always adequately described for all the included studies. Ek *et al*[33] described standard of care based on a specific action plan but did not include more detailed information of what this entailed. Butte *et al*[31] described their standard treatment control with

additional material, although the extent to which the material was used was unreported.

Rating of Included Trials on the Efficacy–Effectiveness Spectrum

The RITES tool data for all nine trials are presented in online supplemental appendix 3. All of the included trials scored between 12 and 16, indicating more pragmatic trials. Five of the trials[24 25 31–33] had more explanatory trial settings as they required extensive training for implementation of the intervention and/or ongoing supervision to ensure the precise implementation. All the included studies were found to be highly effective in terms of their clinical relevance. However, all the trials, aside from Derwig *et al*,[34] excluded participants with underlying conditions or comorbidities, resulting in greater emphasis on efficacy for participant characteristics pertaining to overweight or obesity.

DISCUSSION
Summary of evidence

Since the previous review published in 2016, five RCTs examining obesity treatment interventions in young
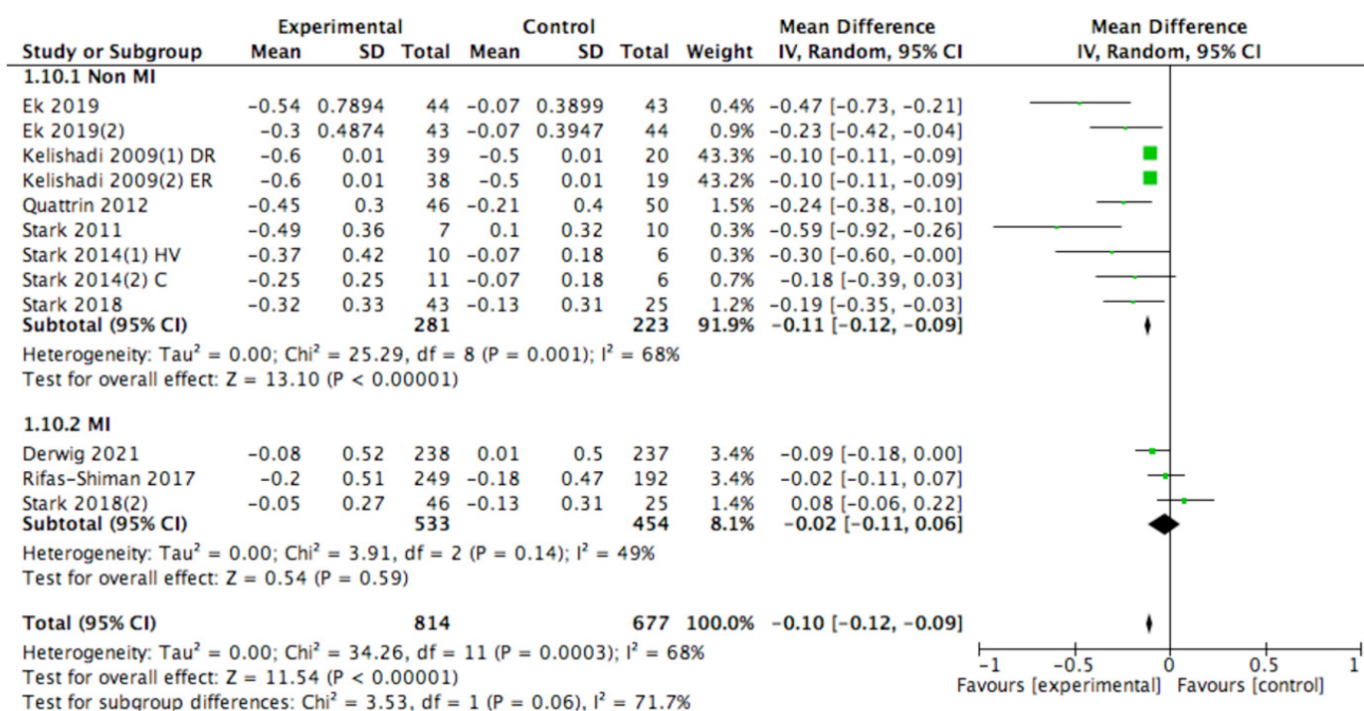

Figure 5 Forest plot showing the mean difference in body mass index z score comparing motivational interviewing versus other trials. MI, motivational interviewing.
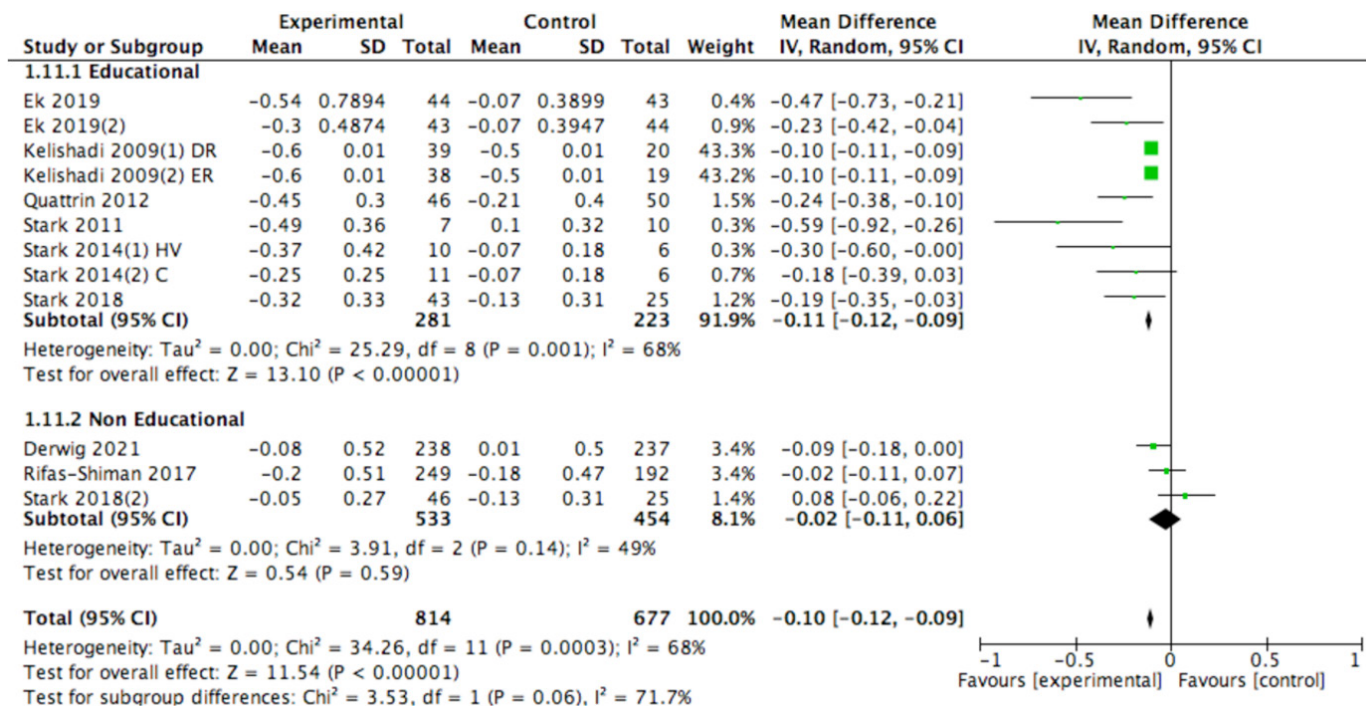
Figure 6 Forest plot showing the mean difference in body mass index z score comparing multicomponent educational intervention versus other trials.

children have been published. This review included RCTs from the original Cochrane study that were consistent with this review's inclusion criteria. This resulted in an additional four studies being included. Seven of the nine RCTs included an educational component as part of the intervention; however, one of those had a primarily

dietary intervention.[23] The other two interventions included family guidance (family-based therapy) and MI.

In the previous Cochrane review, multicomponent interventions were found to be more successful at reducing BMI z score compared with controls.[12] When grouped together, the trials from the Cochrane review,
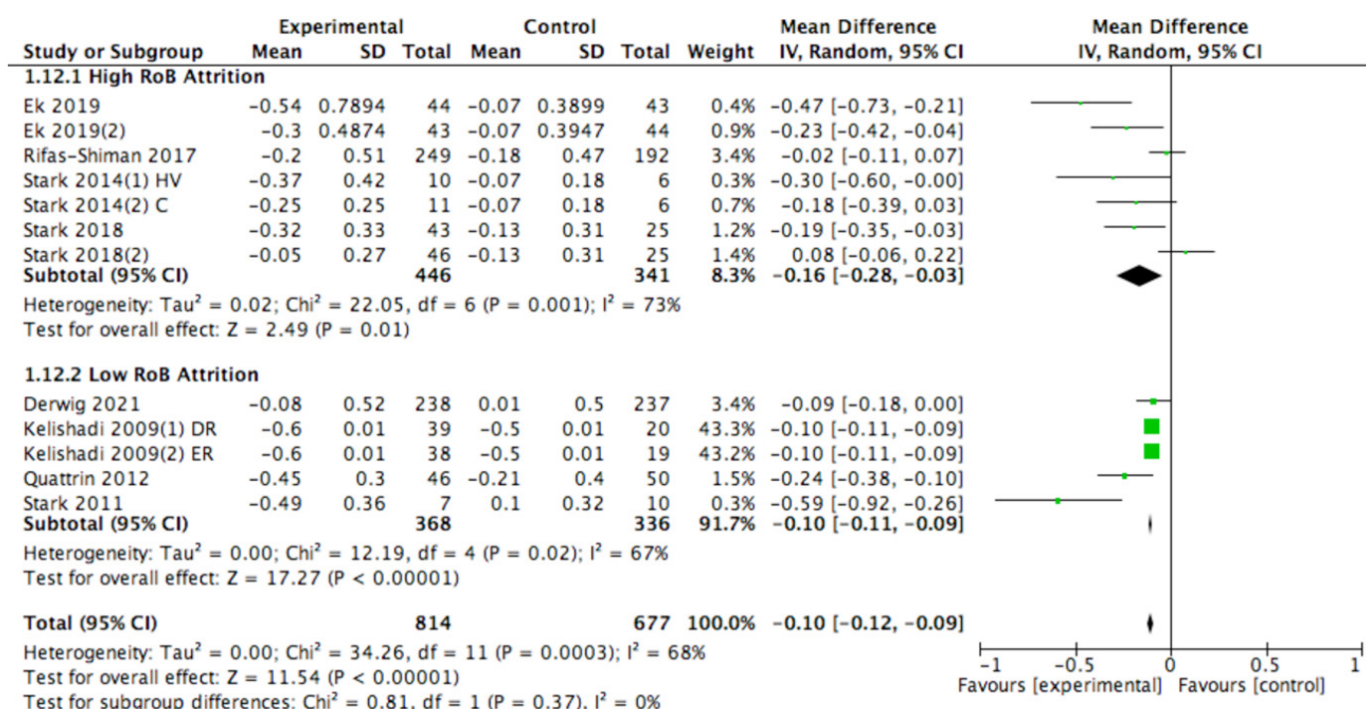
Figure 7 Forest plot showing the mean difference in body mass index z score comparing high versus low attrition bias. RoB, risk of bias.
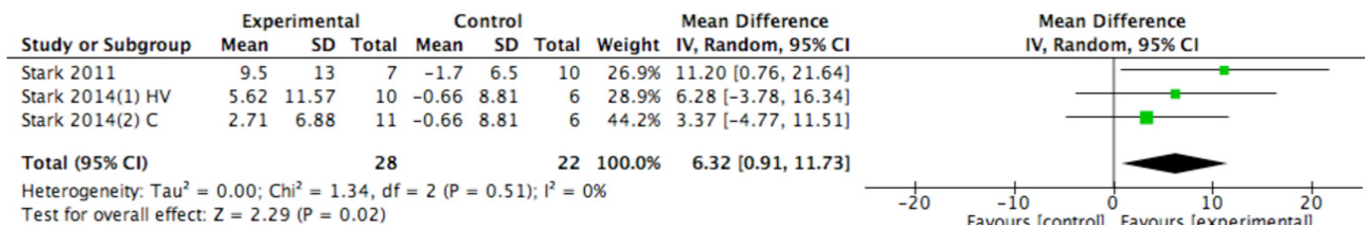
Figure 8 Forest plot showing the mean difference in PedsQL, Paediatric Quality of Life Inventory comparing intervention versus control. HV, home visits.

along with the updated search in this current review, had high heterogeneity with an overall small effect in reducing BMI z score. Most of the trials' interventions were well described using the TIDiER checklist, although some did not include the materials or staff training required for the intervention. The control group did lack some detail in their description. All the trials were noted to be relatively pragmatic, suggesting that they could be applied in real-world settings.

Deviations from protocol

We were unable to perform subgroup analyses based on sex or differences in BMI z score at baseline due to missing data. Similarly, descriptions of outpatient intervention settings were vague and therefore were not compared with other settings (eg, primary care clinics). In the protocol, we planned to report a narrative synthesis in the presence of substantial heterogeneity. However, given the direction of effect and the use of random effects models to incorporate heterogeneity, we have reported a summary measure but do advise caution when interpreting these results.

An exploratory subgroup analysis considering intervention modality (multicomponent educational interventions vs MI) was completed due to substantial heterogeneity in the primary analysis. The six RCTs with a multicomponent educational intervention using BMI z score as their primary outcome showed consistent effectiveness in reducing BMI z score (eight out of nine experimental groups showed that multicomponent educational interventions reduced BMI z score). MI, either focused on the parents, child or the family, did not show consistent effectiveness for the treatment of overweight and obesity in preschool-aged children. Two of the interventions included MI over the telephone if parents missed a session. The implications of providing an intervention virtually are largely unknown and may have affected the overall impact of the intervention.

It is important to note that the multicomponent educational interventions had greater contact time with the families compared with MI or family guidance. A previous systematic review concluded that at least 26 hours of multicomponent intervention over a minimum of 6 months improved BMI z score.[35] Of the included RCTs, only three reported at least 26 hours of intervention time.[24 25 31] Kelishadi et al[23] did not document total intervention contact time. On the contrary, MI interventions were limited to 3.0–7.5 hours of total contact time, while family guidance had very limited contact time at 1 hour.[34] Given these differences, one cannot suggest with confidence that it was the intervention type (ie, education vs MI) and not the 'intensity' of the intervention that led to differences in effectiveness.

Overall, the trials included in this study described their interventions in sufficient detail in the Methods section or via reference to a published protocol paper. However, the standard care provided to the control group was not often described in sufficient detail to allow replication. Trials need to be fully transparent when describing the details of usual or standard care control groups to truly understand the effectiveness of interventions in the real-world setting. This is an important area for further exploration in future studies and reviews.

To the best of our knowledge, this was the first systematic review in children with obesity to use the RITES tool. Generally, the trials were more pragmatic than efficacious on the effectiveness–efficacy scale. Effective or pragmatic trials are similar to routine clinical practices and indicate a more real-world setting. The fact that the majority of trials were conducted in the primary care setting, or a combination of primary care and the community, supports a pragmatic approach; however, the level of training and resources required to implement the interventions in real-world scenarios may pose a challenge.
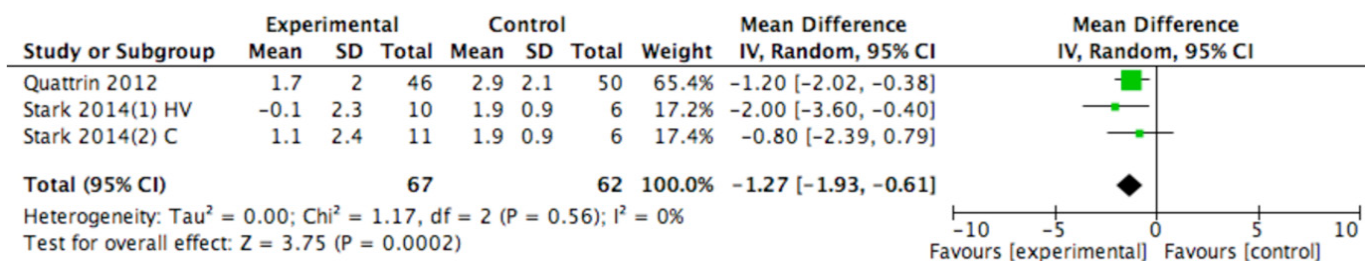

Figure 9 Forest plot showing the mean difference in weight comparing intervention versus control.

Figure 10 Methodological quality summary: authors' judgements for each methodological quality item for each included study.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Kelishadi 2009	+	?	?	+	+	−
Stark 2011	+	+	−	−	+	+
Quattrin 2012	+	?	+	+	+	−
Stark 2014	+	+	−	+	−	−
Rifas-Shiman 2017	+	+	−	?	−	+
Butte 2017	+	+	−	?	−	+
Stark 2018	+	+	−	+	−	+
Ek 2019	+	+	−	−	−	+
Derwig 2021	+	+	−	?	+	+

Legend: Green = Low risk of bias; Yellow = Unclear risk of bias; Red = High risk of bias.

Additionally, most trials recruited participants following stringent criteria, excluding those with comorbidities, and resulting in less pragmatism.[36] This limits the generalisability of the findings beyond preschool-aged children with overweight or obesity only.

Limitations

The search strategy for this systematic review was influenced by the previously published Cochrane review.[12] Bias was introduced as the searches performed and trials included in this review were restricted to English. Splitting the control group in three-arm trials limits the overall variability within trials; however, it is a recommended approach in the Cochrane Handbook to analyse such multicomponent interventions.[37] Further, the methodological heterogeneity between trials weakens our confidence in the conclusion regarding an overall effect of interventions on improving BMI z score. The subgroup analysis based on intervention modality did not result in a change in heterogeneity, which remained >50% and consistent with substantial heterogeneity. As such, we downgraded the certainty of evidence due to inconsistency. Although there was a greater decline in BMI z score for those undergoing educational interventions, it was not statistically significant compared with non-educational interventions, and the certainty of the evidence for this outcome was considered low. The main methodological concern from review authors was the substantial attrition bias in most trials (>20%). Unfortunately, this is common in paediatric weight management.[38] We found that trials with low risk of bias due to attrition had a similar direction of effect (reducing BMI z score), but substantial heterogeneity remained. Most trials declared that the

Table 2 Quality of evidence

Outcome	Studies (n)	Design	Risk of bias	Precision	Consistency	Directness	Other considerations	Patients (n)	Effect (absolute)	Quality	Rating
BMI z score	8	RCT	Serious limitations*	No serious imprecision	Serious consistency†	No uncertainty	None	1491	−0.10 (−0.12 to −0.09)	⊕⊕⊕⊖	Low
%BMIp95	4	RCT	Serious limitations*	Serious‡	Serious consistency†	Uncertainty§	None	349	−1.34 (−3.17 to 0.49)	⊕⊕⊕⊖	Low

*Studies rated down for attrition bias with over 20% loss to follow-up, high risk of performance bias.
†High I² (68% for BMI z score, 79% for %BMIp95).
‡Rated down due to wide CIs.
§Indirectness due to differences in setting between interventions (clinic, home and community centres).
BMI, body mass index; RCT, randomised controlled trial.

participants and healthcare providers were not blinded to their intervention or control group, leading to concerns of performance bias. However, weight management interventions involving services from healthcare providers make it difficult to blind personnel. Due to this, we did not downgrade for blinding when examining overall quality of evidence for the primary outcomes.

Future directions

There continues to be limited evidence surrounding the best practice for paediatric weight management in young children. Furthermore, efficacy has been almost entirely based on anthropometric health outcomes alone. Other health outcomes are inconsistently reported and further evidence of the impact of these intervention programmes on these outcomes, including measures of cardiometabolic health and health related quality of life, will be important, given their relevance to clinical practice. Future interventions should also consistently consider potential adverse health outcomes.

Fundamentally, emphasis on a continued search for novel pathways to intervene on or new approaches to current paradigms must be undertaken, given the modest outcomes to date, while also considering the relevance and potential impact of observational evidence. Furthermore, although modest changes in BMI z score were noted, the persistence of the impact of these interventions over time remains uncertain and is an important area for further research.

CONCLUSIONS

There continues to be limited evidence regarding the treatment of obesity in children of preschool age. In this updated systematic review, there was limited evidence of the benefit of MI as a treatment option, though the interventions were quite brief. There is some evidence education-based programmes involving parents from the start of the intervention appear to assist with BMI z score reduction, but further research is required to improve on the care of young children with obesity.

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