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To cite this article: Kajsa Landgren, Angela A. Quaye, Elinor Hallström & Irén Tiberg (2020) Family-based prevention of overweight and obesity in children aged 2–6 years: a systematic review and narrative analysis of randomized controlled trials, *Child and Adolescent Obesity*, 3:1, 57-104, DOI: [10.1080/2574254X.2020.1752596](https://doi.org/10.1080/2574254X.2020.1752596)

To link to this article: <https://doi.org/10.1080/2574254X.2020.1752596>



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Published online: 27 Apr 2020.



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Family-based prevention of overweight and obesity in children aged 2–6 years: a systematic review and narrative analysis of randomized controlled trials

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ABSTRACT

Overweight and obesity in childhood are highly preventable and parents are key role models in the establishment of healthy behaviours. The aim of this study was to assess the effectiveness of family-based interventions for prevention of overweight and obesity in children aged 2–6 years. A systematic literature search was performed in the databases such as Medline, PsycInfo, Family Study Abstracts, Embase, and CINAHL, published between 2010 and May 2019. The eligible studies were preventive randomised controlled interventions targeting the child or the child's caregivers. The primary outcome was body mass index (BMI).

Twelve trials were included with a total of 3506 participants. The overall follow-up rate in the intervention groups was 83% as compared to 82% in the control groups. Nine trials had a high or unclear risk of bias. The children were followed for between 6 weeks and 3 years. Four of the interventions showed significant intervention effects on BMI. Significant effects on children's food intake were reported in one (of five) study, whereas no significant changes in physical activity were found (six studies). Two studies (of six) measuring sedentary behaviours and one (of three) measuring sleep showed significant differences between groups favouring the intervention group.

The current evidence for the effects of preventive family interventions is limited. The four trials showing positive effects on BMI were multicomponent interventions, lasting for a minimum of 12 weekly sessions.

ARTICLE HISTORY Received 19 February 2019; Accepted 25 March 2020

KEYWORDS Childhood; overweight; obesity; prevention

Background

The trends in childhood obesity are becoming a growing concern worldwide. According to the World Health Organization (WHO, 2016), it was estimated that over 41 million children under 5 years of age were classified as overweight or obese. Projections suggest that the number of overweight or obese young

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children will increase to 70 million by 2025 if current trends continue ([World Health Organization](#)). Children who are overweight at the beginning of adolescence often have excessive weight as early as 3 years of age (Lagstrom et al. 2008). In addition, inflammatory markers have been associated with obesity in children as young as age three, causing more concern for the high prevalence of obesity among children in the 2–5 age groups (Skinner et al. 2010). In the USA, it has been highlighted that by the time children enrol in school, they have already been exposed to a variety of unhealthy foods and more than 20% of 2- to 5-year-old children are at risk of overweight, or are already overweight (Birch and Ventura 2009). High prevalence rates are evident in North America, Europe, and parts of the Western Pacific (Lobstein et al. 2004; Wang and Lobstein 2006). However, the WHO indicates that the most rapid rises are occurring in low- and middle-income countries ([World Health Organization](#)).

Overweight and obesity are highly preventable and there have been various debates in literature about what may be the most effective approach to tackling childhood obesity. Birch and Ventura (2009) highlight that the majority of obesity prevention interventions have been school-based, focusing on elements of decreasing sedentary behaviours, increasing physical activity, and reducing weight gain. Overall, these interventions have not yielded many significant results, irrespective of the fact that children spend most of their time at school. Meanwhile, it was postulated that childcare settings may prove an excellent catchment area to implement overweight and obesity prevention interventions targeting infants, toddlers, and pre-schoolers (Ward et al. 2010). Parents are most likely to act as role models to their children and influence physical activity, eating behaviours, and other habits of their offspring. Yavuz et al. (2015) concluded that interventions targeting young children that require parental involvement are effective but only at short-term follow-up. Summerbell et al. (2012) and Lopez-Dicastillo et al. (2010) posit that interventions aimed at obesity prevention could include a parental component such as role modelling. Healthy nutrition in the first years of life is critical as food preferences and eating patterns are established early in life (Pearce and Langley-Evans 2013).

The prevailing risk factors for increased childhood overweight and obesity are both modifiable and non-modifiable. The modifiable include factors such as poor nutrition/dietary habits, sedentary behaviour, physical inactivity, increased maternal weight gain, smoking during gestation, suboptimal amounts of sleep, and shorter than the recommended duration of breastfeeding (French et al. 2001; Wojcicki and Heyman 2010; Yan et al. 2014; Felső et al. 2017). The non-modifiable include genetic variants and other obesogenic environments (environments that promote weight gain).

The risk of overweight and obesity can be passed from one generation to the next because of exposure to an unhealthy environment that encourages weight gain (Lake and Townshend 2006). Introduction of energy-dense and nutrient-poor food to infants and young children is identified as a key

contributor to childhood overweight and obesity (World Health Organization; Pearce and Langley-Evans 2013). Parental obesity also has an influence on childhood obesity (Reilly et al. 2005; McPherson et al. 2014). The subsequent trickle-down effects of childhood obesity in adult life pose greater health problems, with an overwhelming burden in medical care involved in treating the outcomes involved in treating the complications of obesity throughout adult life (Katzmarzyk et al. 2014). Obese children are at a higher risk of adverse health conditions such as type 2 diabetes, dyslipidaemia, fatty liver diseases, asthma, hypertension, as well other social and psychological challenges such as stigmatizations and depression (Lobstein et al. 2004; Taras and Potts-Datema 2005; Geier et al. 2007; Foltz et al. 2012). When compared to children with normal weight, obese children have lower health-related quality of life (Katzmarzyk et al. 2014). According to Geier et al. (2007), obesity-related health problems account for absenteeism, and poor school performance among obese children.

There are few systematic literature reviews on prevention of early childhood obesity with focus on family-based interventions, defined as interventions directly targeting parents and/or their children, contrasting to interventions that are for example targeting teachers in schools or nurses in healthcare settings. According to this definition, “targeting children” may not necessarily mean that the child is physically present at the group sessions. Even studies where the child is approached indirectly, like when the parent is taught how to practice behaviour modification strategies to improve nutritional family habits, increase physical activity or reduce the child’s screen time, are defined as targeting parents and children. A review by Waters et al. (2011) highlighted that there were beneficial effects on BMI of child obesity prevention intervention programmes that targeted children in the age ranges 6–12 years. Another review by Loveman et al. (2015) focused on children aged 5–11 years indirectly, by only targeting their parents, and it concluded that parent-only interventions may be effective for overweight or obese children in this age range. A Cochrane review by Colquitt et al. (2016) focused on employing diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years. The conclusions were that multicomponent interventions were more effective in terms of reducing BMI. A review by Ling et al. (2016) examined the effects of prevention and management interventions on overweight/obesity among children aged 2–5 years and concluded that management interventions showed greater effects in weight loss as compared to prevention interventions. Further, a recent systematic review on prevention of obesity (Reilly et al. 2019) reported results for children aged 2–4 years old separately. In this review, including physical activity as intervention, 11 of 16 studies reported no effect on BMI. The trials showing effect had multiple components; physical activity was combined with interventions targeting diet and sedentary behaviour. In line with this, another recent review (Brown et al.

2019) found that multicomponent trials including a combined diet and physical activity intervention reduced BMI in children aged 2–5, while neither diet nor physical activity alone had any effect.

It can be deduced from above that there is a knowledge gap about the effectiveness of interventions targeting parents and/or children with the aim to prevent child obesity. How interventions should be designed and which behavioral changes to target remains unclear. Thus, increased knowledge about effective methods targeting families is important. This review builds on current literature and adds to the evidence-base on effectiveness of preventive interventions targeting children in the age span of 2–6 years with a focus on changing habits in children and their parents. This review involves assessing quantitative literature reporting on educational, behavioural, and health-promotion interventions.

Objectives

To assess the effectiveness of family-based interventions for prevention of overweight and obesity in children aged 2–6 years.

Method

Inclusion criteria

- Randomized controlled trials, randomized either at cluster or individual level
- Preventive lifestyle interventions, targeting parents and/or their children irrespective of the child being underweight, normal weight, overweight, or obese according to BMI percentile or zBMI-score
- Age range of child 2–6 years

Exclusion criteria

- Parents and/or children who were critically ill, or had serious psychiatric impairments
- Interventions that were not targeting parents and/or children, for example school-based projects where the intervention was training teachers

Primary outcome

- Changes in body mass index (BMI) and body weight, defined as changes in BMI (kg/m^2) and body weight (kg) measured at baseline and at follow-up

Secondary outcomes

- Behavioural change defined as validated measures of dietary intake, physical activity, sedentary behaviours and sleep time, measured at baseline and at follow-up
- Adverse events, defined as an adverse outcome that occurred during or after the intervention but was not necessarily caused by it and is measured at baseline and follow-up

Search methods for identification of studies

The databases Medline, PsycInfo, Family Study Abstracts, Embase, and CINAHL were searched for electronic literature during the period 10 February 2016 to 29 February 2016. The search terms “overweight”, “obesity”, and “prevention” were used as key search terms for the searches conducted in the databases. The searches were limited to academic journals published in English between 2010 and 2016, with age limit 2–6 years. The search was later updated on 30 April 2019. Further details on searches made in the databases can be found in Appendix I.

Data selection and analysis

After the search in 2016, three of the four review authors (KL, AQ and IT) independently screened the titles and abstracts of the hits obtained after removal of duplicates. All potentially relevant studies were then assessed as full text. Comparisons of the selected studies were made independently by the authors. After the second search, conducted 2019, IT screened the titles, read abstracts and selected articles. KL assessed the selected articles in full text and discussed inclusion with all authors. Any disagreements arising were discussed collectively and resolved among the review authors. In [figure 1](#), we present an adapted Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Moher et al. [2010](#)) flow diagram showing the selection process. Data from the included trials were extracted by means of a data extraction form agreed upon by all four authors (KL, AQ, EH and IT), and based on the Consolidated Standard of Reporting Trials (CONSORT) checklist (Turner et al. [2012](#)). Extracted information included author name and year, study design, participant characteristics, types of interventions, outcome measures. The Cochrane Handbook for Systematic Reviews of Interventions 5 (Higgins and Green [2011](#)) was used in the risk of bias assessment of the selected studies. The included studies were assessed at six levels: randomizations, concealment of study intervention allocation, blinding, and the completeness of follow-up, selective outcome reporting, and other sources of bias. All six levels of assessment were judged either as

having “Low risk of bias”, “High risk of bias”, or “Unclear risk of bias”, according to the guidelines given in the handbook. Due to variations in interventions, measures of outcome, and participants, it was inappropriate to combine the results statistically across studies. Instead, participant characteristics, intervention components, follow-up, and outcome measures were summarized for each study and results were reported narratively.

Results

Results of the search

Figure 1 shows the study flow diagram with the results of electronic and manual searches from 2016 and 2019. $N = 7103$ hits were retrieved from the databases and $n = 4577$ citations were left after removal of duplicates. Screening of titles and abstracts identified $n = 263$ initial eligible studies. $N = 20$ of the articles were not accessible and had to be ordered through the Lund University Library at the Health Science Centre in Lund. $N = 51$ full-text articles were retrieved. The reference lists of the full-text articles were screened to obtain $n = 1$ more article. Discussions about the eligibility of the articles were held among the review authors, and a final $n = 12$ articles ($n = 10$ from the first search and $n = 2$ from the second search) that fulfilled the inclusion criteria were included in the review.

Included studies

The characteristics of the included studies are presented in Table 1. The 12 included studies had 3506 participants, with 20.5% (731) of the participants from one trial (Smith et al. 2015). Further, 1797 of the participants were allocated to the intervention arm while the remaining 1709 were allocated to the control arm. It was not clearly indicated how many of the 56 participants in the trial by Berry et al. (2011) were randomized to intervention and control groups. In considering the total number of randomized participants, the overall follow-up rate in the intervention groups was 83% as compared to 82% in the control groups for 10 of the trials. Number of completers in two of the trials (Berry et al. 2011; Smith et al. 2015) was not provided.

Excluded studies

Of 51 full-text articles, 39 did not meet the inclusion criteria. The main reasons for exclusion were participant's age at baseline and the study designs employed. See the characteristics of excluded studies in Appendix II for further details.

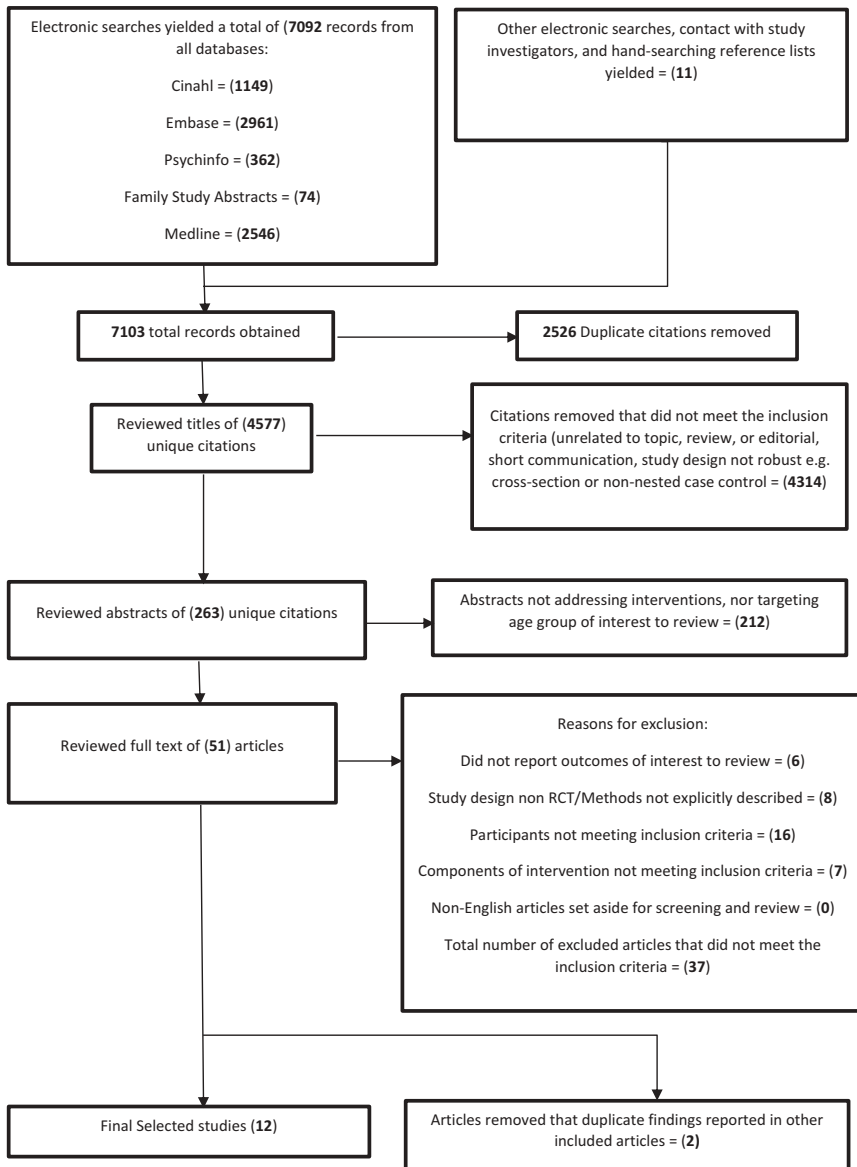


Figure 1. Exam 1 Spreadsheet

Settings

The interventions were conducted in a primary care setting in three of the trials (Slusser et al. 2012; van Grieken et al. 2013; Martínez-Andrade et al. 2014). Six trials were home-based (Østbye et al. 2012; Haines et al. 2013; Smith et al. 2015; Yilmaz et al. 2015; Tomayko et al. 2016; Hart et al. 2016).

Table 1. Characteristics of included studies.

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Barkin et al. 2012 USA	Randomized controlled trial Period: October 2008 and February 2009	• Children aged 2–6 • Underweight (BMI < 5th percentile) • Normal weight (BMI ≥ 5th to < 85th percentile) • Overweight (BMI ≥ 85th to < 95th percentile) • Obese (BMI ≥ 95th percentile)	Focus of intervention: Behavioural intervention on BMI Intervention group component • Weekly 90 minute skills-building sessions for parents and preschool-aged children designed to improve nutritional family habits, increase weekly physical activity, and decrease media use (sedentary activity) • The intervention involved a series of 12 group sessions occurring between March and June 2009 • Participants were also assigned to small social groups where they were assigned small activities and specific group roles Control group component • Brief school readiness programme • Participants met 3 times for 60 minutes over the 12-week study period. The control group programme was designed to improve school readiness in preschool-aged children through increased parental verbal engagement (e.g. daily reading, playing word games, how to talk to children.	• Height and weight • BMI at 3-month follow-up • Acculturation measured by Short Acculturation Scale for Hispanics (follow-up time point unclear)

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Berry et al. 2011 USA	Randomized controlled trial Period: March 2009 and February 2010	• Male and female children aged 2–4 • Children at any BMI percentile	Focus of intervention: weight management Intervention group components • A community health educator taught the nutrition and exercise education and coping skills training classes once a week for 12 weeks • The nutrition education classes focused on learning about healthy, low-cost food choices, portion control, and lowering fats and calories for mothers and also provided tips on how to make these changes with their children • The exercise education classes focused on increasing exercise for both mothers and their children • The coping skills classes used social problem solving, conflict resolution, and cognitive restructuring to help the women make healthy nutrition and exercise choices • Mothers attended exercise programmes while their children's exercise classes included <i>Colour Me Healthy</i> which is a programme that focuses on healthy nutrition choices and increased activity and using examples of new and colourful foods, games, songs, and dancing for children 3–5 years of age Control group components • Waitlist control group	• Weight outcomes, BMI percentiles for children, at baseline and 9 months

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Haines et al. 2013 Healthy Habits, Happy Homes, USA	Randomized controlled trial Period: June 2011 to February 2012	- Male and female children aged 2–5 years - Normal weight children (BMI < 85th percentile) - Overweight children (BMI 85th – <95th percentile) - Obese children (BMI > 95th percentile)	Focus of intervention: Promoting four household behaviours: Eating meals together as a family, obtaining adequate sleep, limiting TV time, and removing the TV from the child's bedroom Intervention group components - Home-based intervention - Motivational coaching by health educator during 4 home visits and 4 health coaching telephone calls, to encourage behaviour change related to excess weight gain - Mailed educational materials and incentives - Weekly text messages (twice for 16 weeks and then weekly for the last 8 weeks of the programme) on adoption of household routines Each home visit included: A check-in to review progress and setbacks to behaviour change, a discussion of behaviour change goals and collaborative goal setting, and a concrete activity or tool the parent could use to support behaviour change Control group components: - Families received 4 monthly mailed packages that included educational materials on reaching developmental milestones during early childhood	Primary outcomes: - eating meals together as a family, - Child's sleep duration - Child's TV viewing time, and - presence of a TV in the room where the child slept Secondary outcomes: - Change in child BMI All primary and secondary outcomes measured at baseline and 6-month follow-up

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Hart et al. 2016 Confident Body, Confident Child (CBCC) Australia	Randomized controlled trial	• Children aged 2-6 years • No exclusion due to weight status	Focus of intervention: to promote body satisfaction, healthy eating, and weight management in early childhood Intervention group components Two intervention groups: (A) received the CBCC resource pack and a 2 h workshop. (B) received the CBCC resource pack only Control group components Two control groups: (C) received a nutrition-only resource (Happy healthy kid). (D) waitlist control	Outcomes • Knowledge Test for Body Image and Eating patterns in Childhood (BEC) • the two subscales (positive and negative behavioral intentions) of the Parenting Intentions for (BEC) • four measures of family meal times • six parental feeding practice scales • BMI for the parent and BMI-z for the child • Outcomes were measured at baseline and after 6 weeks
Martinez-Andrade et al. 2014 The Creciendo Sanos Mexico	Pilot, cluster- randomized trial	• Male and female children between the ages 2 to 5 years • WHO BMI z-score category: • Normal ≤ 1.0 • Risk of overweight ($> 1.0 - \leq 2.0$) • Overweight > 2.0	Focus of intervention: Nutrition and physical activity Intervention group components • Participants received a 6-week curriculum focused on obesity awareness and prevention • A nutritionist led diet, healthy growth and physical activity workshops while a health educator led workshops on instilling healthy habits and routines in childhood • A nurse provided childcare and developed relevant games and activities for children while parents attended workshops • The 6 educational sessions were 2 hours each Control group components Usual standard of care	• Child intake (sweet snacks, fast food, savoury snacks, sugar-sweetened beverages, fruit, vegetables, water, added sugar in beverages) baseline and at 3 and 6 month follow-up • Physical activity at baseline and 3 and 6 month follow-up • Total hours/week of screen baseline and 3 and 6 months • Children's BMI baseline, 3 months and 6 months follow-up

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Slusser et al. 2012 USA	Randomized controlled pilot study	• Children 2–4 years old Children classified as: • Healthy weight • Overweight, and • Obese	Focus of intervention: Promote physical activity and healthy eating Intervention group components • Seven weekly modules followed by two monthly modules of parent training based on social learning. Class sessions were designed to incorporate healthy nutrition and physical activity • Increase caregiver's knowledge about yes and no foods • Teach families how to practice behaviour modification strategies • Teach parents food strategies to increase vegetable and fruit food preferences • Identify barriers to healthy lifestyles and review strategies to review these barriers • Classes lasted 90 minutes • Demonstrations by social worker and roleplaying by the mothers • Mothers received one-page handout with information covered in class Control group components • Mothers received care as usual and received a standard nutritional informational pamphlet • Received intervention after one year follow-up	• BMI percentiles and • BMI z-scores Outcomes measured at baseline, 4 months, and 12 months

(Continued)



Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Smith et al. 2015 USA	Multisite randomized controlled intervention trial	Children 2 years 0 months and 2 • years 11 months Children's BMI was not available at baseline so body size was rated on a 1– 9 scale i.e. • 1=not at all overweight • 5=somewhat overweight 9=overweight	Focus of intervention: Parenting and meal- time behaviours Intervention group components • Intervention participants received the Family Check-UP (FCU) • FCU is a brief, three-session intervention that is tailored to the individual needs of each family. The three meetings include an initial contact session, a home-based multi-informant ecological assessment, and a feedback session • FCU uses an ecological framework to intervene with families to improve children's adjustment by motivating positive behaviour support (PBS) • PBS involves the caregiver being proactive and structuring the home in ways that promote healthy development Control group components • Received the Women, Infants, and Children Nutrition Programme (WIC) as usual.	• BMI and body size BMI • Nutritional quality • Chaotic home environment using the Confusion, Hubbub and Order Scale • Child non-compliance • Inhibitory control assessed with the 13-item Inhibitory Control subscale of the Children's Behaviour Questionnaire • BMI assessed yearly from age 5 to 9.5 years • Follow-up measures of other outcomes not clearly stated
Tomayko et al. 2016 The Healthy Children, Strong Families-study USA	Quasi-RCT (parents who could not attend the meetings were transferred to the control group Period: ?	• Children aged 2.5 years • No exclusion due to weight status	Focus of intervention: Nutritional and behavioural changes Intervention group components • Twelve culturally appropriate lessons were designed by researchers together with tribal mentors, addressing the target ideas 1. To eat more fruit and vegetables, 2. Consume less sugar, 3. Become more active and 4. Watch less TV. • A trained home mentor did 12 monthly home visits. Control group components • Families in the control group got the same lessons delivered by mail monthly.	Primary outcomes • BMI for the parent and BMI-z for the child Secondary outcomes • Three 24 h dietary recall diaries (child intake: fruits and vegetables, sugar-sweetened drinks, candy, junk food) • screen-viewing time • Physical activity was measured using Actical accelerometers • Self-perception of efficacy for health-related behaviours • Outcomes were measured at baseline, after 1 and 2 years

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Walton et al. 2016 Canada	Pilot RCT	• Male and female children in the age ranges 2 to 5 years • Children eligible regardless of weight status	Focus of intervention: Parental roles in promoting healthy nutrition and activity behaviour among their children Intervention group components • Intervention ran for 9 weekly 2-hour group sessions • Approximately 65% of programme content focused on general parenting and 35% on weight-related behaviours • The intervention used video vignettes, facilitated group discussions and homework • Group facilitator received training in group facilitation skills (4 hours) Control group components • Intervention ran for 9 weekly 2-hour group sessions • The programme content focused on child injury prevention • The intervention used video vignettes, facilitated group discussions and homework • Group facilitator received training in group facilitation skills (4 hours)	Primary outcomes • Feasibility and acceptability Secondary outcomes • BMI z scores • Parental warmth • Follow-through on discipline • Parenting stress • Parent use of food as reward • Parental self-efficacy in managing child behaviour and child intake • Child sleep • Child physical activity – active play • Child sugar-sweetened beverage intake • Child TV viewing • Nutrition risk score Primary outcomes assessed by study protocol and post intervention survey. Secondary outcomes assessed at baseline, post-intervention and at 9-month follow-up

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
van Grieken et al. 2013 Be Active Eat Right study The Netherlands	Cluster randomized controlled trial Period: September 2007–October 2008	• 5-year-old children • Normal weight children, • Overweight children, and • The Obese children	Focus of intervention: Behavioural change Intervention group components • Parents received a prevention protocol which offered them information regarding overweight prevention and healthy choices by using a motivational interviewing approach, if needed to motivate the parents to change behaviour • The prevention protocol was initiated during the well-child visit and in addition up to three structured healthy lifestyle counselling sessions to promote overweight-prevention behaviours could be offered approximately 3, 6, and 12 months after the well-child visit • The four lifestyle-related behaviours described in the protocol and could be promoted include: playing outdoors and eating breakfast, and reducing sweet drinks and sedentary behaviour Control group components • Parents were informed about the overweight of their child but usual care was given. Usual care consisted of general information about healthy lifestyle during the well-child visit.	Primary outcomes • BMI • Waist circumference 2-year follow-up

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Yilmaz et al. 2015 Turkey	Randomized controlled trial Period: September 2010 - October 2012	- Male and female children 2–6 year olds - Children's weight status not specified	Focus of intervention: Reducing screen time Intervention group components Intervention had 4 main components: three printed materials and one interactive CD, and one counselling call 1. First set of printed materials given after baseline followed by a counselling phone call two weeks later. The second printed materials were distributed at the 4th and 6th week. Printed materials and CD were aimed to decrease screen time at home and parents read age-appropriate books to their children daily, family meal time with TV turned off, offer alternative activities to watching TV 2. Second component was a counselling call, encouraging families to make their home screen-free, benefits of screen-free home, and difficulties to establish and keep screen-free home 3. Third component included a picture book showing a family while making their home screen-free 4. Fourth component included information about stories of families that were able to decrease their screen time Control group components Control group answered questionnaires and home visits	Primary outcomes Children's TV/video watching and computer/video game playing at 2, 6, and 9 month follow-up BMI measured at baseline and 9 months

(Continued)

Table 1. (Continued).

Author/year/ Intervention name/country	Study Design	Participant characteristics	Intervention components	Outcome measures and follow-up
Østbye et al. 2012 KAN-DO study USA	Randomized controlled trial Period: November 2007–October 2009	- Male and female children in the age ranges 2 to 5 years - Underweight - Normal weight - Overweight ($\geq 85^{\text{th}}$ – $<95^{\text{th}}$ percentile) - Obese $\geq 95^{\text{th}}$ percentile	Focus of intervention: Diet, physical activity and sedentary behaviour Intervention group components - Participants received 8 monthly mailed interactive kits, followed by a 20–30-minute telephone coaching session using motivational interviewing techniques. Kits included child activities and incentives reinforcing the month's topic - Intervention targeted the dyads healthy weight via instruction in parenting styles and skills, techniques for stress management and education about healthy behaviours. - Coaching calls reviewed information in the module and addressed motivation, self-efficacy, and barriers to change. - Intervention also included semi-structured group sessions where study coaches and nutritionist reinforced content from the family kits. Parenting skill and instruction emphasized: An authoritative parenting style, routines for sleep and meal times, a supportive home environment, role modelling of healthy eating and physical activity and improvement of feeding style Control group component: Control arm participants received monthly newsletters emphasizing pre-reading skills. Retention was encouraged by monetary incentives	Outcomes: changes in - Regular family meals, measured by the Family Meals Questionnaire - Child dietary intake of sugary beverages, fast food, fruits and vegetables - Physical activity and sedentary time measured by accelerometer - Television viewing reported by mother - Healthy food availability in the home - BMIz-score - Parenting competence in emotional regulation Outcomes measured at baseline and 12-month follow-up

Three trials used community centres (Berry et al. 2011; Barkin et al. 2012; Walton et al. 2016). Seven of the studies were conducted in the USA (Berry et al. 2011; Barkin et al. 2012; Østbye et al. 2012; Slusser et al. 2012; Haines et al. 2013; Smith et al. 2015; Tomayko et al. 2016). One study was conducted in Mexico (Martínez-Andrade et al. 2014), one in Canada (Walton et al. 2016), one in the Netherlands (van Grieken et al. 2013), one in Turkey (Yilmaz et al. 2015) and one in Australia (Hart et al. 2016).

Participants

The trials enrolled children from 2 years of age, with a range up to age 4 (Berry et al. 2011; Slusser et al. 2012; Smith et al. 2015), age 5 (Østbye et al. 2012; Haines et al. 2013; Martínez-Andrade et al. 2014; Walton et al. 2016; Tomayko et al. 2016) or age 6 (Barkin et al. 2012; van Grieken et al. 2013; Yilmaz et al. 2015; Hart et al. 2016).

The BMI weight status of children in four of the trials (Smith et al. 2015; Yilmaz et al. 2015; Hart et al. 2016) was not specified in the inclusion criteria. Seven trials (Barkin et al. 2012; Østbye et al. 2012; Slusser et al. 2012; Haines et al. 2013; van Grieken et al. 2013; Martínez-Andrade et al. 2014; Tomayko et al. 2016) included children falling in the BMI weight categories of normal weight (<85th percentile), overweight ($\geq 85^{\text{th}}$ – <95th percentile), and obese ($\geq 95^{\text{th}}$ percentile). One trial (Berry et al. 2011) included children at any BMI percentile while two trials (Barkin et al. 2012; Østbye et al. 2012) further included children who were categorized as underweight. Martínez-Andrade et al. (2014) used the WHO zBMI-score categories where normal = ≤ 1.0 , risk of overweight = $>1.0 - \leq 2.0$, and overweight = >2.0 . One trial (Walton et al. 2016) described the weight status of children as normal, overweight, or obese according to WHO cut points. BMI weight statuses of parents were measured in (Barkin et al. 2012; Slusser et al. 2012; Haines et al. 2013; van Grieken et al. 2013; Hart et al. 2016; Tomayko et al. 2016) and parent being either overweight or obese were an inclusion criterium in two of the trials (Berry et al. 2011; Østbye et al. 2012).

Risk of bias in the included studies

The review authors' judgements about each risk of bias per item presented as percentages across all included studies are presented in Figure 2 and the authors' judgements about each risk of bias item for each included study are presented in Figure 3. The authors' detailed judgement and explanation for assessment of risk of bias are presented in Appendix III.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants	Blinding of staff	Blinding of outcome assessment (detection bias)	Blinding of analysts	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Barkin 2012	+	+	-	-	?	?	+	+	+
Berry 2011	+	+	-	-	?	?	?	+	?
Haines 2013	+	+	?	-	?	?	-	+	-
Hart 2016	+	-	-	-	+	?	?	-	?
Martinez-Andrade 2014	+	?	-	-	-	?	+	+	-
Ostbye 2012	+	?	?	?	?	?	+	+	?
Slusser 2012	+	?	?	?	+	?	+	+	?
Smith 2015	?	?	?	?	?	?	?	+	?
Tomayko 2016	?	-	-	-	-	+	?	-	?
van Grieken 2013	+	?	?	-	-	?	+	-	-
Walton 2016	+	?	-	-	?	?	+	?	-
Yilmaz 2015	+	?	-	-	+	?	?	+	-

Figure 2. Exam 1 Spreadsheet

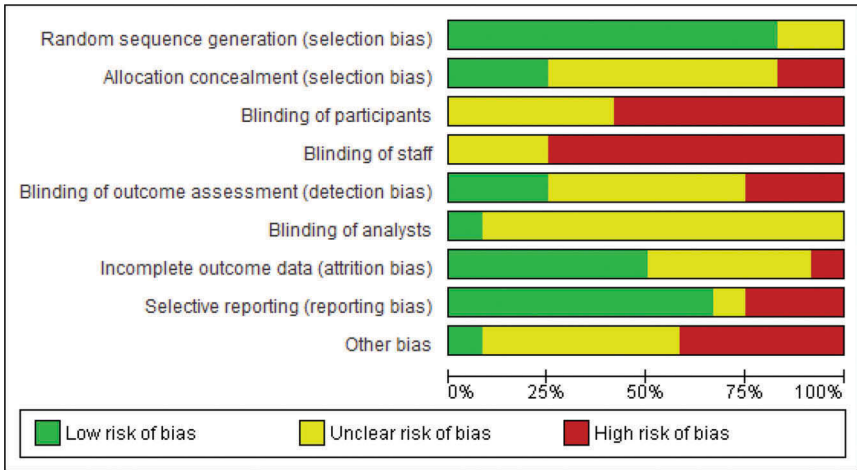


Figure 3. Exam 1 Spreadsheet

Effects of interventions

See the summary of findings for the main comparison in Table 2. The outcomes considered in this review fall into two main categories: physical health status and behavioural change. Physical health status, which is the primary outcome in this review, includes measures of BMI, BMI percentiles or zBMI (all 12 trials). Behavioural change, which is the secondary outcome in this review, includes measures related to food intake (five trials), physical activity (four trials), sedentary behaviour (six trials) and sleep time (three trials).

Primary outcomes

BMI

In the 12 trials, 1797 participants were randomized to the intervention group whereas 1661 participants were randomized to the control group. One trial (Berry et al. 2011) did not specify how many participants were randomized to intervention and control groups. In general, compared with their respective control groups, four of the interventions (Berry et al. 2011; Barkin et al. 2012; Slusser et al. 2012; Smith et al. 2015) showed significant effects of the intervention on BMI, irrespective of the length of follow-up. Barkin et al. (2012), found statistically significant effects of the intervention (12 weekly 90-minutes skill-building sessions) on absolute BMI post intervention, when covariates (child age at baseline, child gender, and baseline absolute BMI) were adjusted for. Focusing on changes in BMI across weight categories, Barkin et al. (2012) found that the most pronounced difference in BMI

Table 2. Summary of main findings on primary outcome; BMI, BMI percentiles and BMI z score.

Author/Year/ Design	No. of randomized participants		Outcome	Follow-up	Results for completors					
	Intervention	Control			Intervention (n=35) Mean ± SD		Control (n=40) Mean ± SD			
Barkin et al. 2012	54	52	Absolute BMI	Post 3 month intervention	Intervention (n=35) Mean ± SD -0.51±0.87		Control (n=40) Mean ± SD 0.06±			
Berry et al., 2012	Unclear (altogether 56 participants)	Unclear	BMI percentiles	9 month post intervention	Baseline		9 months			
					Intervention	control	Intervention	Control		
Haines et al. 2013	62	59	BMI	Post 6 month intervention	Mean (SD)		change			
					Baseline	6 months	change	Difference β (95%CI)		
Hart et al., 2016	Group A: 97 Group B: 111	Group C: 91 Group D: 79	BMI z-score	6 weeks post intervention	Intervention (n=55)	17.34 (1.12)	17.16 (1.99)	-0.40 (-0.98) to 0.00)		
					Control (n=56)	17.36 (2.73)	17.57 (3.22)	0.21 (1.07)		
					BMiz after 6 weeks				Group A (n=64), group B (n=90), group C (n=75), group D (n=68)	
					no significant differences between groups at 6-weeks; F (3,282) = 1.30, p=0.27. There was a slight decrease in the intervention groups and a slight increase in the control groups					

(Continued)

Table 2. (Continued).

Author/Year/ Design	No. of randomized participants			Outcome	Follow-up	Results for completors			
	Intervention	Control	BMI z score	3, and 6 months post intervention	Change BL- 6m Mean (SE)	Unadjusted Est (95% CI)	Adjusted Est (95% CI)		
Martinez-Andrade et al. 2014	168	138	BMI z score	3, and 6 months post intervention					
					Intervention (n=109)				
					Control (n=102)				
Slusser et al., 2012	80	80	BMI and BMI z- score	4 months, and 12 months post intervention					
					Intervention (n=61)				
					Control (n=60)				
					M (SE) P				
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Table 2. (Continued).

Author/Year/ Design	No. of randomized participants		Outcome	Follow-up	Results for completors			
	Intervention	Control			intervention	Post Adjusted difference	9 months	Adjusted difference
Walton et al. 2016	29	25	BMI	Post intervention and 9-month follow-up	BMI Intervention (n=27)	Mean (SD) 16.3 (1.56)	P value -0.22(- 0.57,0.13) P=0.21	Mean (SD) 16.4(1.88) P value -0.07 (0.07,0.58) p=0.82
Control (n=21)	16.4 (1.36)		16.3 (1.61)					
van Grieken et al. 2013	349	288	BMI	2 years follow up	Beta coefficient Model 3 corrected for cluster	Beta coefficient (95% CI) -0.16 (-0.60; 0.27)	BMI (n=505)	p value 0.463
Yilmaz et al. 2015	211	201	BMI z-score	9-month follow- up	Intervention (n=187)	M ± SD -0.19±1.12 -0.13±1.05	Control (n=176)	statistic P=0.375 P=0.80
Østbye et al. 2012	200	200	BMI z-score	Immediately Post intervention (8 months)	Intervention (n=150)	Baseline mean (se*) 0.35 (0.08)	Control (n=151)	Baseline mean (se*) 0.47 (0.08)
					Change mean (se*) 0.03 (0.05)	Change mean (se*) 0.02 (0.05)		

change between treatment and control groups occurred among obese children. Similar trends were reported for those children who were overweight at baseline. Children initially categorized as normal weight at baseline in the intervention group decreased their BMI more than the normal weight children in the control group did. In the trial by Haines et al. (2013), although change in BMI across weight categories was not reported, it was highlighted that child BMI had decreased in both the intervention and the control groups. In this study (Haines et al. 2013), the intervention group received motivational coaching during home visits and by telephone, mailed educational material and text messages while the control group received mailed information on developmental milestones. The Tomayko et al study (2016), where the treatment group received 12 healthy behaviour toolkit lessons delivered by a mentor and the control group received the same kit by mail, found a significant decrease in BMI in both groups but no differences between groups. Smith et al. (2015), having assessed BMI after a 3-year intervention including home visits and meal preparation, still found that there was a significant indirect effect of the intervention on the trajectory of BMI later in childhood. The intervention also prevented progression to overweight and obese status among at-risk children. In two of the trials with long-term follow-up (Berry et al. 2011; Slusser et al. 2012), there were significant differences in BMI between intervention and control groups. Children allocated to the intervention group stabilized their weight and significantly decreased their BMI percentile as compared to children in the control groups whose BMI increased (Berry et al. 2011; Slusser et al. 2012). In these studies, the intervention included nutrition and exercise education, coping skills training and physical activity (Berry et al. 2011) and nine class sessions designed to incorporate healthy nutrition and physical activity (Slusser et al. 2012).

Meanwhile, six of the trials (Østbye et al. 2012; Haines et al. 2013; Martínez-Andrade et al. 2014; Yilmaz et al. 2015; Tomayko et al. 2016; Walton et al. 2016) did not find any significant effects of the intervention on BMI either at short-term follow-up (Østbye et al. 2012; Haines et al. 2013; Martínez-Andrade et al. 2014; Tomayko et al. 2016; Walton et al. 2016) or long-term follow-up (van Grieken et al. 2013; Yilmaz et al. 2015; Walton et al. 2016). In the trial by Yilmaz et al. (2015), there were increases in zBMI scores in both the intervention group (who received four components at two weeks intervals including printed material, interactive CDs and one counselling call aimed to reduce screen time) and in the control group (that constituted a wait-list group) but no differences between groups. The trial by van Grieken et al. (2013), found no significant differences at follow-up with regard to BMI. However, mildly overweight children (BMI 17.25 and 17.50) allocated to the intervention that included information and motivational interviewing and three structured counselling sessions, had

significantly smaller increases in BMI compared to children who were more overweight. There were no effects of the intervention that included group sessions related to parental roles in promoting healthy nutrition and activity on BMI in the trial by Walton et al. (2016), either post intervention or at the 9-month follow-up.

Secondary outcomes

Food intake, location when eating and parental feeding behaviours

Five studies included dietary outcome measures (Østbye et al. 2012; Smith et al. 2015; Walton et al. 2016; Tomayko et al. 2016; Martínez-Andrade et al. 2014). These five studies included in total 831 families in the intervention groups and 810 families in the control groups. In total, 69% of the families completed follow-up in the intervention groups and 75% in the control groups. Data on completers in one of the trials (Smith et al. 2015) were not provided. One of the studies reported a short follow-up (6 months) (Martínez-Andrade et al. 2014) and the other four reported follow-up periods longer than 6 months.

Significant intervention effects between groups on children's food intake were reported in one of the five studies (Martínez-Andrade et al. 2014). Martínez-Andrade et al. (2014) found a significant increase in child intake of vegetables at 3 months follow-up, after 6 weeks intervention delivered at primary care setting with focus on obesity awareness and prevention for parents, no change between intervention and control group was maintained at 6-month follow-up. Positive but insignificant effects were reported for intake of sweet snacks and sugar-added drinks. Tomayko et al. 2016 reported a significant increase in child intake of fruits and vegetables in both intervention and the active control group at 1-year follow-up; however, no significant changes were seen between the groups receiving either a mentored or mailed intervention. No significant differences between groups were found in regard to children's intake of sweet drinks (Østbye et al. 2012; Martínez-Andrade et al. 2014; Tomayko et al. 2016; Walton et al. 2016), fast food (Østbye et al. 2012; Martínez-Andrade et al. 2014), fruit and/or vegetables (Tomayko et al. 2016; Østbye et al. 2012), candy/sweet snacks/junk food (Martínez-Andrade et al. 2014; Tomayko et al. 2016) and nutrition risk score (Walton et al. 2016) in the five studies analysing dietary intake.

Besides changes in children's food intake, the effect on children's eating location and parental feeding behaviours was studied. Two studies reported a significant decrease in meals and snacks eaten in front of the television in the intervention group compared to the control group (Østbye et al. 2012; Hart et al. 2016). Significant intervention effects were reported for healthier parental feeding behaviours, including improved nutritional quality of served meals (Smith et al. 2015), reduced use of food as reward/instrumental

feeding (Østbye et al. 2012; Walton et al. 2016; Hart et al. 2016), reduced emotional feeding (Østbye et al. 2012; Hart et al. 2016), reduced pressure to eat and weight restriction (Hart et al. 2016), increased self-efficacy for health-related behaviour changes (Tomayko et al. 2016) and improved nutrition knowledge (Berry et al. 2011).

Physical activity

No statistically significant changes in physical activity were found in the four trials that assessed physical activity (Østbye et al. 2012; Martínez-Andrade et al. 2014; Walton et al. 2016; Tomayako et al. 2016). These four studies included a total 464 families in the intervention groups, of whom 331 (71%) completed follow-up, and 469 families in the control groups, of whom 343 (73%) completed follow-up. In Østbye et al. (2012) there were neither significant differences nor positive trends in physical activity at the 12-month follow-up. In Tomayako et al. (2016) there were no significant differences between the intervention group who received home-visits and the control group who got the same program delivered by mail and no positive trend after 12 months. Likewise, there were no significant changes in physical activity behaviour in Martínez-Andrade et al. (2014) at the 3-month follow-up. Rather, the usual care group had increased their physical activity more from baseline to the 3-month follow-up (9.5 hours/week compared to 2.9 hours/week in the intervention group). At the 6-month follow-up, the intervention group had caught up and reported 7.4 hours/week of physical activity compared to 6.7 hours in the usual care group. Walton et al. (2016) reported a positive change for the intervention group in active play between baseline and post intervention, remaining at the 9-month follow-up, but the differences did not reach statistical significance.

Sedentary behaviours

Six studies (Østbye et al. 2012; Haines et al. 2013; Martínez-Andrade et al. 2014; Yilmaz et al. 2015; Tomayko et al. 2016; Walton et al. 2016) described outcome measurements of sedentary behaviours in terms of screen time or TV viewing. These six studies included a total of 737 families in the intervention groups where 573 (78%) completed follow-up, and 706 families in the control groups where 575 (81%) completed follow-up. The retention rate was <75% in three of the studies (Østbye et al. 2012; Martínez-Andrade et al. 2014; Tomayko et al. 2016). All six studies reported short follow-up (up to 6 months) while three of them also reported results at 9 months (Yilmaz et al. 2015; Walton et al. 2016) or at 2 years follow-up (Tomayko et al. 2016). Two studies (Haines et al. 2013; Yilmaz et al. 2015), with short follow-up, showed significant differences between groups favouring the intervention group. Three studies (Østbye et al. 2012; Martínez-Andrade et al. 2014; Walton et al. 2016), also with short follow-up, showed no differences between the

intervention group and the control group. Of the three studies (Yilmaz et al. 2015; Tomayko et al. 2016; Walton et al. 2016) that reported on longer follow-up, one of them (Yilmaz et al. 2015) showed significant differences between intervention group and control group, where parents reported greater decrease of children's screen time in the intervention group compared with the control group. One of the studies with longer follow-up periods (Tomayko et al. 2016) reported a significant decrease in screen time but there was no difference between the intervention group who received the toolkit by a mentor and the control group who received the toolkit by mail.

Sleep time

Three studies included outcome measurements of sleep duration (Haines et al. 2013; Martínez-Andrade et al. 2014; Walton et al. 2016), with short follow-up, and one of them also reported on longer follow-up at 9 months (Walton et al. 2016). The three studies included a total of 259 families in intervention groups, where 167 completed the follow-up (65%), and 222 families were included in control groups, where 173 (78%) completed follow-up. Haines et al. (2013) showed a significant intervention effect for sleep duration, where child sleep duration increased in the intervention group who received motivational coaching, mailed educational materials and text messages, and decreased in the control group who received mailed material on child development. Martínez-Andrade et al. (2014) showed no significant differences between the intervention group who participated in a program aimed to promote healthy habits and the control group who received usual care. Walton et al. (2016) did not find any differences at the nine-month follow-up period between the intervention group who participated in group sessions focusing on weight-related topics and the control group who participated in group sessions focusing on child injury prevention.

Adverse events

None of the studies reported any adverse events.

Discussion

This systematic review summarized 12 RCTs examining the effect of family-based obesity preventive interventions. Eleven of the 12 trials were multi-component interventions, targeting more than one behaviour, whereas only one trial was single-component study targeting only screen time (Yilmaz et al. 2015). Of these 11 multicomponent trials, only 4 trials showed significant effects of the interventions on reducing child BMI (Berry et al. 2011; Barkin et al. 2012; Slusser et al. 2012; Smith et al. 2015). The interventions in these four trials included 7–12 skill-building group sessions targeting more than one behaviour (Berry et al. 2011; Barkin et al. 2012; Slusser et al. 2012) or

three sessions tailored to the needs of each family (Smith et al. 2015), supporting findings that interactive interventions are most effective (Yavuz et al. 2015). Neither the remaining seven multicomponent interventions nor the only single-component intervention showed any significant effects of the interventions. Of the four trials whose interventions had a significant effect on child BMI; however, three were assessed to have had an unclear risk of bias overall (Berry et al. 2011; Barkin et al. 2012; Smith et al. 2015), whereas only one trial (Slusser et al. 2012) had a low risk of bias. From the results in this review, it is not possible to conclude which parts of the multicomponent interventions that had effect. However, trials with interventions showing a significant difference between intervention and control groups had interventions with a minimum of 12 weeks, with each session lasting a minimum of 45 minutes, including more than one lifestyle behaviour, in line with Reilly et al. (2019) and Brown et al. (2019). Of the four trials showing effects on child BMI, two targeted both parents and children (Berry et al. 2011; Barkin et al. 2012) while two targeted the parents directly and the children indirectly (Slusser et al. 2012; Smith et al. 2015).

Interventions aimed to change children's habits require parental involvement (Reilly et al. 2019). Such interventions have been shown to have effect only at short time follow-up, specifically if the intervention has many components (Yavuz et al. 2015). The majority of the studies had follow-up periods less than 12 months, a result in line with previous reviews of the targeted age group (Niemeier, Hektner and Enger., 2012; Peirson et al. 2015; Yavuz et al. 2015). It can be questioned if that is an adequate time to demonstrate significant change in BMI and one possible explanation could be that longer follow-up was not published due to failure to demonstrate significant results. Part of the results of this review, which show significant effects of multicomponent trials, must nevertheless be interpreted with caution due to unclear risk of bias. Despite having assessed trials as being of low quality, Colquitt et al. (2016) and Brown et al. (2019) concluded that reductions in zBMI-score were more evident in multicomponent intervention groups as compared to usual care.

Two of the studies included active interventions aimed to prevent obesity in the control groups which makes it difficult to evaluate the full effect of the interventions. In Tomayko et al. (2016), the control group received the same 12 lessons as the intervention group by mail but without the mentor home visits and one of the control groups in Hart et al. (2016) were provided a nutrition only resource, both with possible effects but assumed to have lesser effect than the intervention. Other interventions in the control groups were active but focused on topics other than prevention of obesity, for example a school readiness program including three group sessions (Barkin et al. 2012), monthly mailed packages on developmental milestones (Haines et al. 2013), nine group sessions on child injury prevention (Walton et al. 2016) or monthly newsletters

emphasising pre-reading skills (Østbye et al. 2012). Few studies used standard care (Slusser et al. 2012; van Grieken et al. 2013; Martínez-Andrade et al. 2014; Smith et al. 2015) or waitlist (Berry et al. 2011) as control. Among the four studies showing effect on BMI, two had chosen care as usual (Slusser et al. 2012; Smith et al. 2015) and one had wait list (Berry et al. 2011) as intervention in the control group. One of the studies showing effect had a program focusing on a topic other than obesity prevention (Barkin et al. 2012). This finding might guide the design of future studies.

Four out of five studies that included dietary outcome measures reported results of follow-up periods longer than 6 months (Østbye et al. 2012; Smith et al. 2015; Walton et al. 2016; Tomayko et al. 2016). The risk of bias was assessed to be high in two of these studies (Walton et al. 2016; Tomayko et al. 2016) and unclear in the two others (Østbye et al. 2012; Smith et al. 2015). Significant difference in children's dietary intake between the intervention and control group was reported in one of the five studies including dietary outcome measures (Martínez-Andrade et al. 2014). The design of the intervention in this study included physical meetings in children's centres with follow-up at 3 and 6 months (Martínez-Andrade et al. 2014). The results from this review highlight the difficulty of changing long-term dietary behaviours and more specifically the challenge of reducing children's consumption of unhealthy foods. No significant intervention effects were reported for intake on unhealthy snacks (Martínez-Andrade et al. 2014), sugar (Martínez-Andrade et al. 2014), candy, junk food and fast food (Østbye et al. 2012; Tomayko et al. 2016). On the other hand, two out of five studies found increased consumption of fruits and/or vegetables (Martínez-Andrade et al. 2014; Tomayko et al. 2016) indicating that interventions focusing on increasing healthy foods have been more successful. In line with this, a smartphone-based study (Nyström et al. 2017), a study with 8 weeks' intervention of home-based parental training on habit formation for healthy feeding behaviours (McGowan et al. 2013), and a web-based trial (Knowlden and Conrad 2018) reported changes in children's dietary intake mainly resulting from increased intake levels of healthy foods. A trial targeting the home food environment of preschool children where parents in the intervention group received four weekly 30-minute telephone calls and written resources (Wyse et al. 2014) resulted in a significantly higher fruit and vegetable consumption of parents.

Several of the studies in the present review including dietary measures also reported significant improvements in parental feeding behaviours. This is promising since parental and family modelling of healthy eating behaviours and environments promoting healthy diets are suggested to be factors with great influence on children's eating patterns (Mazarello Paes et al. 2015; DeCosta et al. 2017). However, a recent parent-focused eHealth study targeting parents to overweight

children (Hammersley et al. 2019) provided parents in both groups with internet-based information on preventing obesity in preschoolers and added individual communication with a dietician and a facebook-chat with the dietician and other parents to the intervention group. The results showed improved dietary-related practices but no differences between groups in child BMI, indicating that targeting only the parents is not sufficient. Contrasting to Hammersley et al. (2019), two of the studies in the present review including interventions where the children were not directly involved showed lower BMI in the children (Slusser et al. 2012; Smith et al. 2015). The results of this review, in terms of dietary measures, indicate that the studied interventions can be effective in changing families' eating and feeding behaviours, especially by promoting increased intake of healthy foods. However, more knowledge is needed to draw conclusions on best practices and how to sustain long-term positive effects. Lacking evidence on the factors influencing obesogenic dietary habits in young children has also been stated in previous systematic reviews (Hesketh and Campbell 2010; De Craemer et al. 2012; Te Velde et al. 2012; Mazarello Paes et al. 2015).

No significant changes were found in the four trials that assessed physical activity (Østbye et al. 2012; Martínez-Andrade et al. 2014; Walton et al. 2016; Tomayko et al. 2016), indicating that introducing more physical activity is a challenge. All four studies were assessed to have high and/or unclear risks of bias as they were based on parental self-reports. Although one study (Walton et al. 2016) reported a positive but non-significant change in active play in the intervention group remaining at the 9-month follow-up, Østbye et al. (2012) did not even find a positive trend in physical activity at the 12-month follow-up. Martínez-Andrade et al. (2014) found a negative trend the first 3 months; physical activity actually increased more in the control group. These results are in line with a systematic review (Waters et al. 2011) where the effect of different interventions had no effect on increasing physical activity in any of the four studies including children 0–5 years and with two recent studies (Nyström et al. 2017; Knowlden and Conrad 2018). Waters et al. (2011) concluded that it is important to conduct studies identifying how effective intervention components can be embedded within health. Interventions to increase physical activity in older children showed an effect in some studies, pointing towards a possibility of changing lifestyle towards healthier habits (Waters et al. 2011).

The six studies that included measurement of sedentary behaviours (Østbye et al. 2012; Haines et al. 2013; Martínez-Andrade et al. 2014; Yilmaz et al. 2015; Tomayko et al. 2016; Walton et al. 2016) and the three studies who also reported sleep time (Haines et al. 2013; Martínez-Andrade et al. 2014; Walton et al. 2016) were assessed to have both high and unclear risks of bias. Two studies showed significant differences in

sedentary behaviour between groups, favouring the intervention group (Haines et al. 2013; Yilmaz et al. 2015). One of them (Haines et al. 2013) was a behavioural multicomponent intervention delivered over 9 weeks and the other one (Yilmaz et al. 2015) was a single-component intervention (over 6 weeks) with the focus on reducing screen time. The six studies that did not show any significant differences between groups differed in terms of how intense they were, the length, and focus of the intervention. The results of this review in terms of sedentary behaviour are inconsistent and we found no convincing evidence for the effectiveness of existing interventions. This result is in line with a recently published review of interventions targeting solely sedentary behaviour (Altenburg, Kist-van Holthe, & Chinapaw, 2016). However, a meta-analysis by (Biddle et al. 2014) showed that interventions aiming to reduce children's sedentary behaviour had a small but significant effect, with a trend favouring interventions with children younger than 6 years.

An extensive search of RCTs aimed at childhood overweight and obesity prevention and fulfilling the review's inclusion criteria was conducted. However, there may be a possibility that substantial information could have been missed from non-English publications, as only publications in English were selected, and from articles published before 2010. The evidence of studies in this review is generally applicable to the public health sector of developed countries, and it is not certain whether it is transferable to other countries. Future research may need to focus on developing countries. A number of other limiting factors were present based on the individual risk of bias in the included trials, the quality of the evidence was low due to possible factors observed in the risk assessments. Most of the trials provided clear descriptions of the randomization procedures as well as reporting of pre-specified outcome measures, therefore having a low risk of bias. Overall, most of the studies were assessed to have had an unclear risk of bias across a number of domains. The studies included BMI as an objective measure which could be said to have reduced the impact of the outcome assessors not being blinded. However, the fidelity of most parts of the interventions is unknown, and subjective measures of outcomes such as television viewing time, dietary habits, physical activity and sedentary time need to be interpreted with caution as they were based on parental self-reports, and in addition, staff and participants were not blinded in most of the trials. However, there were inconsistencies in the descriptions of how allocations were concealed, blinding of participants, staff, and outcome assessors. Only one study (Tomayko et al. 2016) reported on the blinding of analysts, which made it impossible to assess the impact on obtainable results. This presents more difficulties in the overall presentation of the data and thus highlights the need for more robust reporting of research methods.

Author's conclusions

Implications for practice

The burden and long-term effects of childhood overweight and obesity are major public health concerns. Effective interventions aimed at preventing childhood obesity need to begin early in life, before children even begin school as such interventions may have meaningful long-term effects in preventing childhood obesity. It is crucial to target parents as role models and empower them to actively be part of childhood overweight and obesity prevention interventions. Also, multicomponent interventions might be an effective treatment in the prevention of childhood overweight and obesity, although more evidence is needed since only four of 12 trials showed a positive effect on BMI. The current evidence is limited as it is not clear what elements should constitute a multicomponent intervention, and most of the trials had an unclear risk of bias. Nevertheless, a common aspect among the four multicomponent trials showing positive effects is that they included an intervention with a minimum of 12 weeks, lasting for a minimum of 45 minutes per session, and focusing on more than one lifestyle behaviour. Since none of the trials reported adverse events, it is crucial for further research to investigate this outcome in the interventions.

- The current evidence is limited as it is not clear what elements should constitute a multicomponent intervention.
- However, a common aspect among the four multicomponent trials showing positive effects is that they included an intervention with a minimum of 12 weeks, lasting for a minimum of 45 minutes per session, and focusing on more than one lifestyle behaviour.

Acknowledgments

The authors would like to acknowledge Alexandra Forsberg and Matthias Bank (Library & ICT Unit, Faculty of Medicine, Lund University) for support in the development of search strategies. The study was supported by FORTE.

Disclosure statement

The authors report no conflict of interest.

Funding

This work was supported by FORTE.

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Appendix I

Database search history

PsycInfo	Search history	Results 2016	Results 2019
1	Overweight OR Obesity	33 079	44,562
2	Prevention	303 286	367 703
3	1 AND 2	7 113	9,817
4	2016: Published Date: 20,100,101– 20,160,210 2019: Published date: 20,160,201–20,190,731 Age: 2–5 years Publication type: academic journals	341	132
5	Selected abstracts	19	21
Medline			
1	Overweight OR Obesity	245,727	321,009
2	Prevention	1,384,835	1,644,312
3	1 AND 2	39,557	53,110
4	2016: Published Date: 20,100,101– 20,160,231 2019: Published date: 20,160,201– 20,190,731 Age: 2–5 years Publication type: academic journals	1,680	866
5	Selected abstracts	78	27
CINAHL			
1	Overweight OR Obesity	80,184	112,070
2	Prevention	457,870	574,639
3	1 AND 2	18,743	25,364
4	2016: Published Date: 20,100,101– 20,160,231 2019: Published date: 20,160,201– 20,190,731 Age: 2–5 years Publication type: academic journals	941	208
5	Selected abstracts	120	25
Family Study Abstracts			
			The database was not available 2019
1	Overweight OR Obesity	602	-
2	Prevention	6,547	-
3	1 AND 2	118	-
4	Published Date: 20,100,101–20,160,231 Age: 2–5 years Publication type: academic journals	74	-
5	Selected abstracts	3	-
Embase			
1	Overweight OR Obesity	388,306	566,543
2	Prevention	1,649,160	2,694,819
3	1 AND 2	54,292	89,145
4	Published Date: 20,100,101–20,160,219 Age: 2–5 years Publication type: academic journals	1924	Published date: 20,160,201–20,190,731 1,037
5	Selected abstracts	76	81

Appendix II

Characteristics of excluded studies

Study, search 2017	Reason for exclusion
Agras, 2012	Study does not report on any of the outcomes of interest to the review
Bocca, 2014	Study does not report on any of the outcomes of interest to the review
Brotman, 2012	Had a number of methodological limitations to be considered for inclusion
Bryars, 2012	Study design was non-experimental, pre-test, post-test design
Cespedes, 2014	Only targeted overweight and obese children
Cloutier, 2015	Used a matched historic control group
Cruz, 2016	Intervention included a teacher training component
Daniels, 2013	Enrolled first-time mothers with 4-month-old infants
Daniels, 2015	Enrolled first-time mothers with 4-month-old infants
Fitzgibbon, 2011	School-based intervention and included training of teachers
Kim, 2016	Included obese and overweight children who were older than 6 years old
Koulouglioti, 2013	Study design was a one-group pre-post design
Machuca, 2016	Enrolled children up to 18 months of age
McKee, 2010	Non-random design
Natale, 2014a	Intervention was school-based and included a teacher-based component as well as environmental changes
Natale, 2014b	Intervention was school-based and included a teacher-based component as well as environmental changes
Navaro, 2013	Paired quasi-experimental design
Nyberg, 2016	Teacher training component was included in the intervention
Paul, 2011	Enrolled newborn babies
Rattanaagree, 2013	Mixed methods design
Skoutiers, 2016	Enrolled children from 20 to 42 months
Taveras,	Only targeted overweight and obese children and included children from 2–6.9 years
Wen, 2015	Enrolled children aged 0–years
Whaley, 2010	Enrolled children aged 1–5 years
Study, search 2019	
Cruz, 2016	Included a teacher training component
Döring, 2016	Enrolled children aged 9–10 months
Döring, 2018	Study does not report on any of the outcomes of interest to the review
Enö Persson, 2018	Enrolled children 9 months to 4 years
Haines, 2018	Enrolled children aged 1.5–5 years
Knowlden, 2018	Does not report BMI
McGowan, 2013	Does not report BMI
Mendoza, 2016	School-based
Nyström, 2017	Does not report BMI at follow-up
Taverno Ross, 2018	Non-randomized
Paul, 2018	Enrolled newborns
Poeta, 2015	Conference abstract

Appendix III

Assessment of risk of bias

Barkin et al. (2012)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from Publication: "A computer-generated permuted block randomization scheme with a block size of 10 was used ..." Comment: Appropriate
Allocation concealment (selection bias)	Low risk	Quote from publication: "A biostatistician generated the randomization list and condition assignments were placed in nontransparent envelopes, which were sealed and numbered consecutively" Comment: Appropriate
Blinding of participants	High risk	Participants were not blinded to other participants' condition allocation
Blinding of staff	High risk	Research staff were not blinded to participants' condition allocation
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Low risk	ITT was employed
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	Study perceived to be free of other risks of bias

Berry et al. (2011)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "A statistician flipped a coin and informed the researchers of the randomization plan" Comment: adequate
Allocation concealment (selection bias)	Low risk	The researchers were informed of the randomization plan after the coin was flipped
Blinding of participants	High risk	Due to the type of intervention, it is deemed that the participants knew the group to which they were assigned
Blinding of staff	High risk	Considering that the control group was a wait-list control group, it can thus be assumed that the researchers were not blinded to which group participants were allocated to
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Unclear risk	Insufficient reporting of attrition to permit judgement of "Low risk" or "High risk"
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

Haines et al. (2013)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Statistical programmer used a computerized routine to randomly assign the intervention and control condition" Comment: Appropriate
Allocation concealment (selection bias)	Low risk	Assignments were implemented through sealed sequentially numbered individual envelopes
Blinding of participants	Unclear risk	Participants judged as not blinded, and the outcome may likely to be influenced by the lack of blinding
Blinding of staff	High risk	It is perceived that study personnel were not blinded, and the outcome likely to be influenced by the lack of blinding
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	High risk	Even though it is stated that ITT was used, outcome measures reports only those who completed the follow-up
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported, therefore free of reporting bias
Other bias	High risk	Participants were not asked to keep any dairies and assessments were based on what they could remember therefore this could be a source of bias in the outcomes reported

Hart et al. (2016)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "two random sequences of group allocation were developed using SPSS ... " to assign families to the two study and two control groups.
Allocation concealment (selection bias)	High risk	Parents who could attend to the initial workshop were randomized to A, B, C or D. Those who could not attend the workshop were randomized to B, C or D.
Blinding of participants	High risk	Participants were not blinded and their reports of the outcome measures may have likely been biased due to their knowledge that reducing the outcome was the aim of the study.
Blinding of staff	High risk	Staff who gave the initial session in the intervention groups were not blinded and this may have likely affected the outcome measure
Blinding of outcome assessment (detection bias)	Low risk	The instruments were distributed via email.
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Unclear risk	Loss to follow-up reported, but reasons for loss to follow-up not given and no ITT employed
Selective reporting (reporting bias)	High risk	All pre-specified outcomes reported from the 6-weeks follow up but not from the 6- and 12-month follow-up
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

Martinez-Andrade

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from Publication "Using a computer-generated randomization list designed by a US-based statistician with no connection to the intervention" Comment: Adequate
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of participants	High risk	It was judged that participants were not blinded as participants got to know of their intervention status
Blinding of staff	High risk	It was judged that study staff were not blinded to the interventions as a substitution of a clinic was made after randomization
Blinding of outcome assessment (detection bias)	High risk	study staff were not blinded to the intervention status at the 3- and 6-month follow-up assessments
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Low risk	Intent-to-treat analyses were used and further still, SAS imputations were used to account for missing data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes have been reported
Other bias	High risk	Study perceived to be of high risk of bias as there were extreme baseline imbalances in levels of physical activity

Østbye et al. (2012)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from Publication: "they were randomized to the study via permuted 8-block randomization, generated by SAS" Comment: Appropriate
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of participants	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of staff	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Low risk	Attrition reported and reasons for loss to follow-up explained. ITT was not employed, but sensitivity analyses were also conducted, in which missing follow-up measurements were imputed to their baseline values.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported as stated
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

Slusser et al. (2012)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "... randomly assigned through a computer programme ..." Comment: adequate
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of participants	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of staff	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of outcome assessment (detection bias)	Low risk	outcome assessor was not aware of group assignment
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Low risk	imputation of missing data was done using a carefully constructed model that included relevant independent variables
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

Smith et al. (2015)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of participants	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of staff	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported as stated
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

Tomayko et al. (2016)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote from publication: "Randomization was conducted at the individual level after stratification for community and child weight status."
Allocation concealment (selection bias)	High risk	Eight families who could not be scheduled for the in-home session switched group to the control group where no in-home sessions were included.
Blinding of participants	High risk	Participants were not blinded and their reports of the outcome measures may have likely been biased due to their knowledge that reducing the outcome was the aim of the study.
Blinding of staff	High risk	Staff were not blinded
Blinding of outcome assessment (detection bias)	High risk	"Community partners" from the tribe reviewed and commented on the collected data.
Blinding of analysts	Low risk	All data were mailed to the University of Wisconsin; data entry and analysis were conducted by researchers who were blinded to group assignment.
Incomplete outcome data (attrition bias)	Unclear risk	The dropout rate was high, especially in the intervention group. (Possible reasons are discussed)
Selective reporting (reporting bias)	High risk	All outcomes for the first year is reported. As both the intervention group and the active control group improved, data for both groups combined are also reported. For year two, we can only find data for BMI.
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

van Grieken (2013)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "teams were randomized for allocation to intervention or control by means of a computer-generated random number list" comment: Appropriate
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of participants	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of staff	High risk	The staff were not blinded and this may have had an effect on the outcome measure
Blinding of outcome assessment (detection bias)	High risk	Study staff who delivered the intervention also took part in the outcome assessments hence they may not have been blinded and this could have an effect on the outcome measure
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Low risk	Loss to follow-up reported and reasons given, and Intention to treat analysis employed
Selective reporting (reporting bias)	High risk	Not all pre-specified outcomes of interest were reported
Other bias	High risk	Study is perceived to may have a high risk of bias due to possible contamination among the groups.

Walton et al. (2016)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: the project manager used a pseudo-random number generator to randomly assign the sessions comment: Appropriate
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Blinding of participants	High risk	Participants were not blinded and their reports of the outcome measures may have likely been biased due to their knowledge that reducing the outcome was the aim of the study.
Blinding of staff	High risk	The staff were not blinded and this may have had an effect on the outcome measure
Blinding of outcome assessment (detection bias)	Unclear risk	There is a possibility that the outcome assessors could engage in conversations with the parents and know which groups they were randomized to
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Low risk	Loss to follow-up reported and reasons given, and Intention to treat analysis employed
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes of interest were reported
Other bias	Unclear risk	Unclear due to Pseudo randomization

Yilmaz et al. (2015)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "a list of random numbers was used to assign families to study or control group" comment: appropriate
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided for a clear judgement
Blinding of participants	High risk	Participants were not blinded and their reports of the outcome measures may have likely been biased due to their knowledge that reducing the outcome was the aim of the study.
Blinding of staff	High risk	Staff were not blinded and this may have likely affected the outcome measure
Blinding of outcome assessment (detection bias)	Unclear risk	Data collecting residents were uninformed about group assignment
Blinding of analysts	Unclear risk	Insufficient information to permit judgement of "Low risk" or "High risk"
Incomplete outcome data (attrition bias)	Unclear risk	Loss to follow-up reported, but reasons for loss to follow-up not given and no ITT employed
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	High risk	Data collected from parents regarding TV time and aggressive behaviours are likely to be biased and thus overestimate the results given, since parents knew that reducing these two outcomes was the aim of the study