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[Intervention Protocol]

# Caregiver involvement in interventions for improving children's dietary intake and physical activity behaviors

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of caregiver involvement in interventions for improving children's dietary intake and physical activity behavior, including those intended to prevent overweight and obesity. We will also describe the intervention content and the behavior change techniques employed, drawing from behavior change technique taxonomy developed and advanced by Abraham, Michie, and colleagues (Abraham 2008; Michie 2011; Michie 2013; Michie 2015). We will identify content and techniques related to the reported outcomes, where such information has been reported in included studies.

## BACKGROUND

### Description of the condition

Non-communicable diseases (NCDs), including cardiovascular diseases, cancer, type 2 diabetes mellitus, chronic respiratory diseases, and chronic kidney disease, are the leading causes of death and disability worldwide (Lozano 2012). In 2010, they accounted for approximately two-thirds of all global deaths (Lozano 2012), and this proportion is projected to continue to rise (Mathers 2006). Poor diet and insufficient physical activity are important independent risk factors for NCD development as well as obesity, and are leading contributors to the global burden of disease (Forouzanfar

2016). In light of this impact, these behaviors have been identified as priority areas for public health action (Beaglehole 2011; WHO 2013; WHO 2016). Because behaviors develop early in life, children and adolescents are a target population for prevention (WHO 2013; WHO 2016).

Low consumption of nutritious foods, such as fruit, vegetables, whole grains, nuts, and seeds, is a major contributor to disease burden (Forouzanfar 2016). Meta-analyses have shown that fruit and vegetables have a significant protective effect on ischemic heart disease and stroke (Gan 2015; Hu 2014), and it is likely that they also protect against some types of cancer (Marmot 2007; Wang 2014). The World Health Organization (WHO) recommends consuming at least 400 g of fruit and vegetables per day (equivalent to five,

80 g servings) to prevent chronic diseases (WHO 2003). However, an estimated 78% of the world population does not meet this recommendation (Hall 2009). Similarly, there is strong evidence linking increased intake of whole grains, nuts, and seeds to reduced risk of cardiovascular disease and type 2 diabetes (Afshin 2014; Ye 2012), but low consumption of these foods is widespread (Micha 2015). Other dietary factors associated with health benefits include omega-3 fatty acids from seafood, fiber, polyunsaturated fatty acids, milk, and calcium (Forouzanfar 2016).

Reducing intake of sodium, processed and red meats, trans fats, and sugar-sweetened beverages is recommended to promote population health and prevent NCDs (Forouzanfar 2016; UN General Assembly 2012; WHO 2013). In 2015, 4.1 million deaths were attributable to high sodium intake, making it the most prominent dietary risk factor globally (Forouzanfar 2016). For decades, sodium intake has been associated with hypertension and NCDs, particularly cardiovascular disease (He 2009). WHO recommends a sodium intake of no more than 2 g per day (equivalent to 5 g of salt) (WHO 2003), but most populations consume much more (Brown 2009). In 2010, global mean sodium intake was nearly twice the recommended limit (Powles 2013). Findings from prospective studies have shown consumption of processed and red meats to be associated with type 2 diabetes (Micha 2012) and colorectal cancer (Chan 2011). There is also a link between processed meat and ischemic heart disease, likely in part, due to processed meat's high sodium content (Micha 2012). Evidence from controlled trials and observational studies indicates that trans fatty acids also adversely affect cardiovascular indicators and increase risk of ischemic heart disease (Mozaffarian 2009; Teegala 2009). Furthermore, meta-analyses of prospective studies have found sugar-sweetened beverage consumption to be associated with weight gain (Malik 2013), type 2 diabetes (Imamura 2015; Malik 2010), hypertension (Xi 2015), ischemic heart disease (Huang 2014; Xi 2015), and chronic kidney disease (Cheungpasitporn 2014).

At the same time, physical activity is associated with numerous health benefits (Lee 2012), including protection against cardiovascular disease (Sofi 2008), type 2 diabetes (Jeon 2007), certain types of cancer (Thune 2001), and cardiovascular-related death (Lee 2012; Nocon 2008). Despite this, available data suggest a global inactivity crisis. Worldwide, 31% of adults and 80% of adolescents do not meet minimum recommendations for physical activity (Hallal 2012). A recent 15-country comparison involving high-, middle-, and low-income countries found no countries had at least 80% of children and adolescents meeting physical activity guidelines (Tremblay 2014). Insufficient physical activity accounts for over 5.3 million deaths per year, or 9% of premature mortality (Lee 2012). Even among physically active people, prolonged sedentary behavior is associated with higher risk of type 2 diabetes, cardiovascular disease, and cardiovascular and all-cause mortality (Biswas 2015; Wilmot 2012).

In all world regions, child and adolescent obesity prevalence has increased in recent decades (Black 2013; De Onis 2010; Lobstein

2015; Ng 2014). A global shift in diets towards highly processed foods, meat and dairy products, combined with increases in sedentary behavior, are believed to have contributed to this phenomenon (Popkin 2013). Social inequalities in child and adolescent obesity are well documented. Although prevalence is highest in high-income countries, most overweight children younger than five years live in low- and middle-income countries (Black 2013). In high-income countries, excess weight is more common among socially disadvantaged groups, but the inverse is true in low- and middle-income countries (Barriuso 2015; Chung 2016; Dinsa 2012; Wu 2015). Epidemiologic evidence suggests that diet quality and activity levels follow a socioeconomic gradient. In high-income countries, greater socioeconomic position is associated with higher quality diets, more physical activity, and less sedentary time (Bauman 2012; Darmon 2008; Mayén 2014; Mielke 2016; Stalsberg 2010). Data from low- and middle-income countries are more limited, but available information suggests that associations between social advantage and obesity-related behaviors differ from those observed in high-income countries. For instance, in low- and middle-income countries, the adolescents from the wealthiest households appear to be the most sedentary (Mielke 2016). A reason for this could be that lower socioeconomic groups have to rely on walking or cycling for transportation and may be more likely to work in physically demanding jobs, such as farm or factory labor. For the most disadvantaged, obesity may co-occur with undernutrition or micronutrient deficiencies due to common underlying factors or physiological links (Tzioumis 2014).

Overweight conditions in childhood and adolescence are associated with immediate and longer-term health risks and decreased quality of life (Buttitta 2014; Daniels 2009). Virtually every organ system is adversely impacted by excess body weight, including the cardiovascular, metabolic, pulmonary, gastrointestinal, and skeletal systems. Related health conditions in overweight and obese youth include cardiovascular disease symptoms, type 2 diabetes, breathing disorders, and fatty liver disease (Daniels 2009; Pulgarón 2014). Excess adiposity during childhood also can influence pubertal development in both boys and girls (Solorzano 2010). In addition, overweight children and adolescents experience psychological comorbidities such as internalizing disorders (e.g. anxiety, depression), externalizing disorders (e.g. impulsivity, attention deficit hyperactivity disorder), sleep problems, and uncontrolled eating (Puder 2010; Pulgarón 2014).

There is a strong correlation between childhood and adult obesity (Simmonds 2016). Current trends suggest that young people today—particularly those from marginalized or otherwise vulnerable population groups—could suffer greater illness and live shorter lives than previous generations (Olshansky 2005). Developing healthy diet and physical activity behaviors during childhood and adolescence is an important step in preventing obesity and NCDs, particularly because these behaviors are likely to track into adulthood (Craigie 2011). For example, long-term prospective cohort studies have found that diet and television viewing habits in childhood are

predictors of similar behavior decades later (Mikkilä 2005; Smith 2015). Consequently, early intervention is emphasized to instill healthy behaviors and prevent the onset of overweight and obesity.

## Description of the intervention

Interventions to improve children's and adolescents' health behavior often encompass multiple components, including education, environmental modifications and caregiver involvement. Narrative reviews have consistently argued that caregiver involvement is important (Bautista-Castaño 2004; Golan 2004; Lindsay 2006; McLean 2003; Sharma 2006). For childhood obesity interventions, some meta-analyses have shown that parent and family involvement contributes to their success (Niemeier 2012; Young 2007), although these results may not be retained in the long run (Yavuz 2015). Caregiver involvement could comprise a range of behavior change techniques such as providing information or instruction; prompting intention formation, identifying barriers, self-monitoring, offering opportunities for social comparison, or restructuring environments (Golley 2011). However, interventions with caregiver involvement show inconsistent effectiveness (Stice 2006), and it is unclear which kinds of caregiver involvement lead to more effective outcomes. Without this information, it is not possible to specify the types of caregiver involvement and intervention strategies that may promote behavior change.

## How the intervention might work

Parents and other adult caregivers have important influences on child development and play an essential role in shaping children's and adolescents' diet and physical activity habits by providing the contextual environment within which they develop these behaviors (De Vet 2011; Draper 2015; Golan 2004; Lindsay 2006; Patrick 2005). There are a number of mechanisms through which caregivers' involvement in interventions could work. Physical aspects of the home environment, which are largely controlled by caregivers, appear to be related to what children eat and their physical activity levels. For example, lower access to fruit and vegetables at home is associated with lower consumption among children and adolescents (Pearson 2009), and the presence of electronic media in children's bedrooms has been related to sedentary behavior (Tandon 2012). Outside of the home, caregivers may serve as gatekeepers to physical activity by establishing the activities in which children can participate.

Caregivers also have an important psychosocial influence in children's habit formation. Children are more likely to eat a healthy diet when their caregivers model healthy eating themselves (De Vet 2011; Golan 2004; Patrick 2005; Pearson 2009; Skouteris 2011). Additionally, caregivers' feeding styles and practices, nutrition knowledge, as well as food beliefs, attitudes, and preferences have been shown to be associated with children's diets

(Blissett 2011; Clark 2007; Draper 2015; Golan 2004; Patrick 2005; Scaglioni 2011; Skouteris 2011). Consequently, it follows that intervention activities targeted also at caregivers may be beneficial for supporting and promoting healthy eating and physical activity in children and adolescents.

Current theories of child development are based on the transactional view, which emphasizes the interdependent and bidirectional effects of interactions between the child and their social settings (Sameroff 2010). Caregivers and children are continuously interacting, both shaping and being shaped by the other's actions. As children move from early childhood into adolescence, caregiver and family influences often decrease as peer influences become more important (National Research Council 2004; Sameroff 2010). However, caregivers continue to influence diet, physical activity, and sedentary behaviors (Draper 2015). Given the continual shifts in child-caregiver relationships as children grow, the most beneficial forms of caregiver involvement and behavior change techniques to promote child behavior change may differ for different child age groups. Some evidence suggests that caregiver interventions may work better when the children are younger (Kader 2015).

## Why it is important to do this review

Improving health-related behavior in children and adolescents has the potential to improve the overall health of the next generation and reduce the burden of NCDs. At least three Cochrane reviews have indicated a need for more attention to the involvement of caregivers in behavior change interventions. Waters 2011 evaluated the effects of childhood obesity prevention interventions but did not distinguish which intervention components contributed to favorable effects. Luttikhuis 2009 focused on treatment of children with obesity and included studies with or without family involvement, but review authors did not perform a subgroup analysis on family involvement. Most recently, Loveman 2015 examined the efficacy of diet, physical activity, and behavioral interventions delivered to parents only for the treatment of overweight and obesity in children and found limited evidence that parental interventions helped reduce child body mass index (BMI).

A number of other reviews have explored the contribution of caregiver involvement (in particular, parents) to children's nutrition and physical activity interventions (Golley 2011; Hingle 2010; Kader 2015; Morris 2015; Niemeier 2012; O'Connor 2009; Van Lippevelde 2012). Some reviews concluded that caregiver involvement promotes intervention success (Golley 2011; Niemeier 2012), while others suggested that evidence to support the claim that caregiver involvement is important in children's nutrition and physical activity interventions is lacking (Hingle 2010; Kader 2015; Morris 2015; O'Connor 2009; Van Lippevelde 2012). In addition, the effects of different behavior change techniques employed with caregivers is not yet established.

Our review aims to fill this evidence gap by updating and expanding a previous review (Van Lippevelde 2012), which sought to assess the contribution of parental (i.e. caregiver) involvement to intervention effectiveness. The previous review focused on “determining the impact of parental involvement in school-based obesity prevention interventions” (targeting both nutrition and physical activity-related behavior) for children aged 6 to 18 years and considered evidence published between 1990 and 2010. Our review will incorporate a broader scope of research evidence by including both school-based and non-school-based interventions as well as studies targeting children and adolescents aged 2 to 18 years. Where the data allow, we will also consider which behavior change techniques employed, if any, have effects on diet and physical activity outcomes. To support the growing demand for information on the effects of interventions on health equity, we also will evaluate how the interventions were implemented and whether the authors reported on sociodemographic factors known to be important from an equity perspective.

## OBJECTIVES

To assess the effects of caregiver involvement in interventions for improving children’s dietary intake and physical activity behavior, including those intended to prevent overweight and obesity. We will also describe the intervention content and the behavior change techniques employed, drawing from behavior change technique taxonomy developed and advanced by Abraham, Michie, and colleagues (Abraham 2008; Michie 2011; Michie 2013; Michie 2015). We will identify content and techniques related to the reported outcomes, where such information has been reported in included studies.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomized controlled trials (RCTs) and quasi-RCTs of parallel group design. The unit of randomization may be individuals or clusters. Due to the nature of our comparator interventions, we do not expect to find cross-over trials. However, if there are eligible RCTs with cross-over designs, we will include only the first period of data from each arm to avoid the risk of contamination.

#### Types of participants

Caregiver-child units, where the child is aged 2 to 18 years and actively part of the intervention. We will exclude caregiver-child units where the child is under two years of age because interventions with this age group are likely to be focused on complementary feeding (which is not the focus of this review) and are unlikely to include children as key intervention participants. We define caregivers as parents, guardians, or other adults responsible for caring for the child in the home setting. We will exclude caregiver-child units residing in orphanages and school hostel environments because the adult-to-child ratio and relationships may differ from traditional home environments. A child may have one or more caregivers involved in the intervention (e.g. mother, mother and father, a parent and a grandparent, foster parent(s)).

Caregiver-child units in which the child is of normal, overweight, or obese weight status will be eligible. However, if a trial includes only children with a pre-existing health condition (e.g. diabetes mellitus, obesity, undernutrition), we will exclude the trial as the focus of this review is not to assess interventions specifically meant as treatment. Thus, trials that include children from the general population-of which some may have pre-existing health conditions-will be eligible. We will include caregivers regardless of their age, weight, nutritional status, or comorbidities.

We will include trials conducted in any country (high-, middle- and low-income) and that targeted caregiver-child units in any setting (e.g. school, community, home, primary health care), except for inpatient hospital settings.

#### Types of interventions

##### Intervention group

Interventions to improve children’s dietary intake or physical activity behavior, or both, with children as active participants and at least one component involving caregivers. For the caregiver component(s), caregiver participation can be active or inactive. We define active caregiver intervention components as those in which caregivers are asked to physically attend events or participate in other intervention activities. We define inactive caregiver intervention components as those where caregiver participation is limited to the provision of information that does not require a response, for example, receipt of a newsletter or pamphlet. Interventions can be delivered to children and caregiver-child units in an individual or group context.

##### Control group

Interventions to improve children’s dietary intake or physical activity behavior, or both, which do not include a component involving caregivers. Multicomponent interventions are appropriate, as long as intervention components across groups are the same, except for caregiver involvement.

## Comparisons

- Dietary behavior change interventions with a caregiver component versus interventions without a caregiver component.
- Physical activity interventions with a caregiver component versus interventions without a caregiver component.
- Combined dietary and physical activity interventions with a caregiver component versus interventions without a caregiver component.

## Types of outcome measures

### Primary outcomes

- Change in children's dietary intake (e.g. fruit and vegetable intake, sugar-sweetened beverage intake, total energy intake, total saturated and trans fat intake, total energy intake as a percentage of estimated energy requirements, salt intake), as measured by validated instruments such as the Automated Self-Administered 24-hour Dietary Recall for Children (Diep 2015), the Block Kids Food Frequency Questionnaire (Cullen 2008), or similar.
- Change in children's physical activity levels (e.g. total physical activity, time spent in moderate to vigorous physical activity), as measured by instruments such as ActiGraph accelerometers (Puyau 2002), the International Physical Activity Questionnaire for Adolescents (Hagströmer 2008), or similar.
- Adverse effects (as defined by the trial authors), such as family conflict or disordered eating or activity behaviors.

### Secondary outcomes

- Change in children's dietary quality, as measured by, for example, the Healthy Eating Index - 2010 (Guenther 2013; Guenther 2014), dietary diversity score (Kennedy 2007), or similar.
- Change in children's sedentary behavior, as measured by, for example, ActiGraph accelerometers (Puyau 2002), the HELENA (Healthy Lifestyle in Europe by Nutrition in Adolescence) Sedentary Questionnaire (Rey-López 2012), or similar.
- Change in prevalence of overweight and obesity among children, as measured using reference cut-points such as those produced by WHO (WHO Multicentre Growth Reference Study Group 2006), the International Obesity Task Force (Cole 2000), or the US Centers for Disease Control and Prevention (Kuczmarowski 2002).
- Change in children's BMI or weight-for-height parameter, as measured by, for example, WHO BMI-for-age or weight-for-height z-scores (WHO Multicentre Growth Reference Study Group 2006).
- Change in caregiver's dietary intake (e.g. fruit and vegetable intake, sugar-sweetened beverage intake, total energy intake, total saturated and trans fat intake, total energy intake as a

percentage of estimated energy requirements, salt intake), as measured by validated instruments such as the Automated Self-Administered 24-hour Dietary Recall (Kirkpatrick 2014; Thompson 2015), the Block Food Frequency Questionnaire (Block 1990; Subar 2001), or similar.

- Change in caregiver's physical activity levels (e.g. total physical activity, time spent in moderate to vigorous physical activity), as measured by, for example, ActiGraph accelerometers (Abel 2008), the International Physical Activity Questionnaire (Hagströmer 2006), or similar.

Studies need to have addressed at least one of the above pre-specified outcomes in order to be eligible. We will include all of the above-mentioned outcomes, if addressed by the included studies, in the 'Summary of findings' tables.

We will report data collected at time points during and after the intervention period (follow-up). Where relevant, and as data allow, we will group time points across studies. For example, we will group interventions of up to 3 months duration, 4 to 6 months duration, 7 to 12 months duration, and more than 12 months duration. We also will apply a grouping approach for results from follow-up periods, for example, from periods of less than 6 months, 6 to 12 months, and more than 12 months after intervention completion.

## Search methods for identification of studies

We will use a comprehensive search strategy to identify eligible studies regardless of year, language, or publication status. When necessary, we will seek translations.

### Electronic searches

We will search the online databases listed below.

- Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library, which includes the Cochrane Developmental, Psychosocial and Learning Problems Specialised Register.
- MEDLINE Ovid (1946 onwards).
- MEDLINE In-Process & Other Non-Indexed Citations Ovid (current issue).
- MEDLINE Epub Ahead of Print (current issue).
- Embase Ovid (1947 onwards).
- ERIC EBSCOhost (Education Resources Information Center; 1966 onwards).
- CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1981 onwards).
- LILACS (Latin American and Caribbean Health Sciences Literature; [lilacs.bvsalud.org/en](http://lilacs.bvsalud.org/en)).
- *Cochrane Database of Systematic Reviews* (CDSR; current issue) in the Cochrane Library.
- Database of Abstracts of Reviews of Effects (DARE; current issue) in the Cochrane Library.

- Epistimonikos ([www.epistemonikos.org](http://www.epistemonikos.org)).
- Conference Proceedings Citation Index - Science Web of Science (CPCI-S; 1990 onwards).
- Conference Proceedings Citation Index - Social Science & Humanities Web of Science (CPCI-SS&H; 1990 onwards).
- ProQuest Dissertations & Theses Global ProQuest (1980 onwards).
- Trials Register of Promoting Health Interventions (TRoPHI; [eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=12](http://eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=12)).
- ClinicalTrials.gov ([clinicaltrials.gov](http://clinicaltrials.gov)).
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; [apps.who.int/trialsearch/default.aspx](http://apps.who.int/trialsearch/default.aspx)).

The strategy we will use to search MEDLINE includes the sensitivity- and precision-maximizing version of the Cochrane Highly Sensitive Search Strategy for identifying randomized trials, presented in [Appendix 1 \(Lefebvre 2008\)](#). We will adapt this search strategy as appropriate for other databases.

### Searching other resources

We will screen the reference lists of included studies and relevant reviews to identify any additional trials that are not found by the electronic searches. We will also email the contact author of each included study to ask for information about any other relevant trials they know of (published, unpublished, or in progress).

## Data collection and analysis

### Selection of studies

Working in pairs, three review authors (EHM, MF, RAS) will independently screen the titles and abstracts of all records identified by the searches and apply the pre-specified eligibility criteria to identify potentially eligible studies ([Criteria for considering studies for this review](#)). Where at least one review author considers a study to be relevant, we will obtain the full-text report, and two review authors will independently assess it for eligibility. In cases where we need additional information to decide whether or not a study is eligible, we will email the trial authors for clarity (e.g. for more detail about the intervention or randomization process). We will resolve any discrepancies through discussion until reaching a consensus. Where necessary we will seek input from another review author (AS). We will list the studies for which we obtained the full-text reports but later excluded, in the 'Characteristics of excluded studies' table, alongside reasons for exclusion. We will record our decisions in a PRISMA diagram ([Moher 2009](#)).

### Data extraction and management

Working in pairs, three review authors (EHM, AS, MF) will independently extract data using a standardized, pre-piloted data extraction form. We will resolve any disagreements through discussion until reaching a consensus. Where we have difficulty reaching consensus, we will ask the input of another review author (RAS). For each included study, we will extract the information described below.

- Background and general information: time period when study took place, type of publication (e.g. full-text journal article, abstract, thesis), study country or countries, funding source(s), and conflicts of interest.
- Study eligibility: study design, age range of the children, characteristics of the children, focus of the intervention, outcome measures.
- Population and setting: description of population and setting, inclusion criteria, exclusion criteria, recruitment methods.
- Methods: aim of the intervention, number of study arms, description of study arms, unit of allocation, sample size per study arm (for individually randomized trials), number of clusters and sample size per cluster (for cluster-randomized trials), start date, end date, duration of participation, other notes on the methods.
- Risk of bias: high, low, or uncertain risk of bias together with a reason for the judgement; judgement criteria are outlined in [Assessment of risk of bias in included studies](#) below.
- Participants: total number randomized, sample representativeness, whether baseline imbalances existed and descriptions of imbalances if they did, number of and reasons for withdrawals and exclusions, child sex, child mean age, child race/ethnicity, PROGRESS-PLUS (place or residence, race/ethnicity/culture/language, occupation, gender/sex, religion, socioeconomic status and social capital; plus any other characteristics that may indicate a disadvantage) categories listed at baseline, other sociodemographic data, description of caregivers, caregiver weight status, caregiver comorbidities.
- Intervention group details: number randomized to group, number measured at baseline, description of intervention, behavior change techniques (BCT) used, theoretical basis for intervention techniques used, duration and follow-up, timing, delivery, providers, co-interventions, economic factors and resources required for replication, strategies to address disadvantage, subgroups.
- Comparison group details: number randomized to group, number measured at baseline, description of comparison intervention, BCTs used, theoretical basis for comparison intervention techniques used, duration and follow-up, timing, delivery, providers, co-interventions, economic factors and resources required for replication, strategies to address disadvantage, subgroups.
- Outcomes: for each outcome: measurement tool, whether

the tool was validated, whether the tool was used as validated or adapted, the person who measured or reported the outcome, whether missing data were imputed, units, PROGRESS-PLUS categories used, total number in intervention and comparison groups, change indicated at each time point.

- Other information: reported limitations, whether a process evaluation was conducted, description of intervention process and implementation factors, references to other relevant studies, documentation of correspondence with the trial authors, other notes.

We will contact the trial authors when reported information is unclear or contradictory, or when important data are missing. We will enter the extracted data into one of the following tables, as relevant: 'Characteristics of included studies', 'Characteristics of studies awaiting assessment', and 'Characteristics of ongoing studies'.

### Assessment of risk of bias in included studies

Working in pairs, three review authors (EHM, AS, MF) will independently evaluate the risk of bias for the included studies. Where different outcomes have different risks of bias, we will indicate that in the 'Risk of bias' table. To perform this evaluation, we will use the following seven criteria for RCTs, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

- Random sequence generation. Did each eligible participant have an equal chance of being allocated to the intervention or control group?
  - Allocation concealment. Was the randomization process kept strictly confidential (i.e. each allocation was unpredictable), especially from researchers and participants?
  - Blinding of participants and personnel. Did the participants or personnel, or both, have any knowledge of the allocated interventions?
  - Blinding of outcome assessment. Did the outcome assessors have any knowledge of the allocated interventions?
  - Incomplete outcome data. Was it clear why certain results or relevant outcome information were omitted? Also, was it clear how many people were randomized to each group and whether (and if so, why) participants from the different groups dropped out?
  - Selective reporting. Were the reported outcomes in line with the trial's protocol or pre-specified methodology? Were statistically significant relationships between intervention groups more likely to be reported compared to non-significant relationships?
  - Other sources of bias. Was the study free from other problems that could put it at high risk of bias, including conflicts of interest and unbalanced baseline characteristics between groups?

Following procedures outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*, we will assign each of these criteria

one of three ratings: 'low risk of bias', 'high risk of bias' or 'unclear risk of bias' alongside reasons for our ratings (Higgins 2011a). We will resolve any disagreements through discussion until reaching consensus, and when needed, we will ask another person who has experience with Cochrane systematic reviews but who is not involved in our review, for arbitration.

For cluster-RCTs, we will also add and assess the domains listed below, as per the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

- Recruitment bias. Were trial participants included in the trial after the clusters were randomized?
- Baseline imbalances. Were there substantial differences of important characteristics between clusters, or between participants within a cluster?
  - Loss of clusters. Were clusters omitted from the analysis, or were there missing outcomes for individuals within clusters?
  - Incorrect analysis. Did the trial authors fail to take clustering into account when performing the analysis?

In addition, and where data allow, we will assess the comparability between individually randomized trials and cluster-randomized trials with sensitivity analyses (see [Sensitivity analysis](#)).

### Measures of treatment effect

We will use Review Manager 5 (RevMan) to manage the data and carry out the review (RevMan 2014). We will report all effect sizes alongside 95% confidence intervals (CIs).

### Dichotomous data

For dichotomous data, we will use the number of events as the numerator and the total sample size per outcome as the denominator in each comparison group and compute the risk ratio (RR).

### Continuous data

For continuous data, we will report results per outcome as the difference in the mean change between the intervention and control groups, and compute the mean difference (MD). Where continuous data have been reported using different units across the studies, we will calculate the standardized mean difference (SMD) for continuous outcomes.

### Unit of analysis issues

#### Multiple treatment groups

In trials where there is more than one intervention or control group, we will first try to create a single pair-wise comparison following procedures provided in Higgins 2011b. If this is not appropriate or feasible, we will choose the intervention and control

pair that are most relevant to our systematic review, and we will exclude the other arms for analysis purposes (Higgins 2011b). In this case, we will still report all study arms of the trial in the 'Characteristics of included studies' table.

### Cluster-randomized trials

Regarding cluster-randomized trials, we will follow guidance for adjusting for clustering outlined in Higgins 2011b. Where the study authors have appropriately adjusted for clustering, we will include the data in a meta-analysis by using the trial's reported effect estimate and its standard error (SE). In this case, we will use the generic inverse variance method in RevMan 2014 for the meta-analyses. Where the study authors did not adjust adequately for clustering, we will apply the 'approximate method', which involves the calculation of an effective sample size for the comparison groups. We will do this by dividing the original sample size by the design effect, which is  $1 + (c - 1) ICC$ , where  $c$  is the average cluster size and ICC is the intracluster correlation coefficient. If available, we will extract the desired information from the study; otherwise, we will email the trial authors. If we do not get the information we need, we will estimate the ICC giving reasons for our choice, and, where feasible, will also perform sensitivity analyses (see Sensitivity analysis). Estimated values are arbitrary, but we prefer to use them to adjust the effect estimates and corresponding SEs due to the implausibility that the ICC is actually zero. For continuous data, only the sample size needs to be reduced; we will not change the means and SDs. For dichotomous outcomes, we will divide the sample size and the number of people that experienced the event by the same design effect. We will then combine the estimates and their corrected SEs from the cluster-randomized trial with those from parallel group designs using the generic inverse variance method in RevMan 2014.

### Dealing with missing data

Where the results reported for one or more outcomes of interest do not include data on all randomized study participants, we first will attempt to contact the trial authors via email to find out whether they have data for the missing cases and, if they do, the reasons why this data was not included in the study results. If we are unable to obtain the missing data from the trial authors, we will apply the 'available case' analysis for dichotomous and continuous data. Following the approach described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b), we will analyse "data for only those participants whose results are known, and address the potential impact of the missing data in the assessment of risk of bias".

Where trial authors have not reported all relevant statistics per outcome (e.g. sample size and number of events per group for dichotomous data and sample size, mean, and standard deviation (SD) of change per group for continuous data), we will first see

if it is possible to calculate or estimate the required data from other statistics reported using formulas specified in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c). If we cannot calculate or estimate these statistics with reasonable confidence, we will attempt to contact the trial authors by email. Where we do not receive a response, or where we receive a response for which we lack confidence, we will not impute the missing values but will report the available results in a table.

For interventions in which there is substantial attrition (15% or more for at least one of the groups) of trial participants (caregivers, children, or caregiver-child units), we will report the attrition rate and perform sensitivity analyses (see Sensitivity analysis).

### Assessment of heterogeneity

We will assess heterogeneity per outcome:

- through visual inspection of forest plots, by looking at the physical overlap of CIs across the included studies;
- statistically, by means of the:
  - $Chi^2$  test for heterogeneity;
  - $I^2$  statistic to quantify heterogeneity; and
  - $Tau^2$  statistic to measure the extent of heterogeneity among the intervention effects across the included studies in the meta-analysis.

In our meta-analyses we will consider heterogeneity as an  $I^2$  greater than 30% and either  $Chi^2$  less than 0.1 or  $Tau^2$  greater than 0. In case of heterogeneity, we will perform subgroup analyses (see Subgroup analysis and investigation of heterogeneity), where feasible. If we identify unexplained heterogeneity, we will not pool results into an overall effect estimate but instead will present the individual effect sizes per study for the specific outcome in a table.

### Assessment of reporting biases

If we have 10 or more studies included for an outcome, we will use funnel plots to assess the possibility of small study effects. In the case of asymmetry we will consider various explanations such as publication bias, poor study design and the effect of study size.

### Data synthesis

Due to the probably diverse nature of the eligible interventions (e.g. components of the intervention, methods of delivery, details on intervention providers and their training, number of sessions and their frequency and duration, BCTs employed), we anticipate heterogeneity across the included studies. Therefore, we will use inverse-variance, random-effects models for all meta-analyses. If we are unable to conduct a meta-analysis for an outcome we will report the available results for each relevant study in a table.

To enable comparison and critique of the specific strategies used to change diet and physical activity behavior in children and adolescents, we will document and categorise BCTs used in interventions

in line with a pre-defined taxonomy. We will apply the BCT taxonomy (version 1; v1), which comprises of a list of 93 hierarchically-clustered BCTs (Michie 2015). We will apply published definitions for each taxonomy item (Michie 2015). The BCT taxonomy (v1) can be used to reliably identify BCTs in lifestyle interventions for children and adolescents, including interventions specifically targeted at caregivers and families (Michie 2015). Because of the considerable power that would be required to use all items in meta-analysis, we will examine taxonomy items in 16 clusters of conceptually coherent BCTs (Michie 2015). We will report the BCTs used in included studies and, where data allow, perform subgroup analyses to examine the effect of the BCT clusters on each outcome (Subgroup analysis and investigation of heterogeneity). We will use the PROGRESS-PLUS checklist to guide our consideration of health equity. We will analyse relevant information descriptively and will consider the potential implications for health equity and whether the review identified research needs relevant to the promotion of health equity in the 'Discussion' section. Where data from primary studies allow, we plan to highlight caregivers' education and paid work hours, household income and setting (rural or urban), as these factors have been associated with children's eating and activity behaviors (Crockett 1995; Gordon-Larsen 2000). Because recruitment strategies and mode of delivery may influence who is able to take part, we will also extract this information. Where data allow, we will also collect data on the intervention process and implementation factors.

### Subgroup analysis and investigation of heterogeneity

Where data allow, we will perform the subgroup analyses listed below, to explore substantial and considerable heterogeneity across studies.

- Age (e.g. 2 to 5 years of age versus 6 to 12 years of age versus 13 to 18 years of age).
- High-income countries or settings versus low- and middle-income countries or settings (according to the World Bank country and lending group classifications ([data.worldbank.org/about/country-and-lending-groups](http://data.worldbank.org/about/country-and-lending-groups)) per the year of publication). If there is a multicenter study with sites in countries classified in different income categories, we will consider the study in a subgroup of its own in the meta-analysis.
- Active caregiver interventions versus inactive caregiver interventions.
- Duration or intensity of intervention (e.g. short versus long term, one-off versus multiple sessions).
- Individual context versus group context (i.e. children receive the intervention individually and with a caregiver versus children receive the intervention in a group and with caregivers).
- Diet only versus physical activity only versus both behaviors.
- BCT cluster versus no BCT cluster (e.g. techniques from

'reward and threat' cluster versus no techniques from 'reward and threat' cluster).

### Sensitivity analysis

Where data allow, we will perform sensitivity analyses to assess the following and will report results in tables.

- Influence of studies' risk of bias (first pool all relevant studies per outcome, and then pool only studies where the random allocation sequence was appropriately concealed).
- Influence of attrition (first pool all relevant studies per outcome, and then pool only studies where there was less than 15% total attrition or less than 10% differential attrition).
- Study design (first pool all relevant studies per outcome, and then pool only individually randomized trials and cluster-RCTs where the primary trial authors appropriately adjusted for clustering in their analyses, i.e. cluster-RCTs where we did not have to calculate effective sample size).

### Summary of findings table

Two review authors (EHM and AS) will use the GRADE approach to assess the quality of the evidence for all eligible outcomes that are addressed by the included studies (Schünemann 2011). This approach assesses quality as high, moderate, low, or very low according to five criteria: limitations in study design and implementation (i.e. risk of bias), directness of evidence, heterogeneity, precision of effect estimates, and likelihood of publication bias. We will use GRADEpro GDT (GRADEprofiler Guideline Development Tool) to import data from RevMan 2014 and construct 'Summary of findings' tables for our three pre-specified comparisons (see [Types of interventions](#)).

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\* Indicates the major publication for the study

## APPENDICES

### Appendix I. Ovid MEDLINE search strategy

- 1 exp child/
- 2 adolescent/
- 3 (child\$ or toddler\$ or preschool\$ or pre-school\$ or schoolchild\$ or schoolage\$ or pre-teen or adolescen\$ or teen\$ or young adult\$ or youth\$ or young person\$ or young people).tw.
- 4 or/1-3
- 5 exp Parents/
- 6 ((parent\$ or mother\$ or father\$) not parenteral\$.tw.
- 7 Caregivers/
- 8 (caregiver\$ or care-giver\$ or carer\$ or guardian\$).tw.
- 9 Grandparents/
- 10 (grandparent\$ or grandfather\$ or grandmother\$).tw.
- 11 family/
- 12 (family or familial or families).tw.
- 13 (home\$ or household\$ or house-hold\$).tw.
- 14 Family Relations/
- 15 parent-child relations/
- 16 father-child relations/
- 17 mother-child relations/
- 18 Parenting/
- 19 or/5-18
- 20 4 and 19
- 21 exp diet/
- 22 exp food habits/
- 23 food preferences/
- 24 exp Nutrition Therapy/
- 25 (health\$ adj2 (diet\$ or eat\$ or food\$ or meal\$)).tw.
- 26 (diet\$ adj5 (modif\$ or therap\$ or intervention\$ or strateg\$)).tw.
- 27 ((eating or food or diet\$) adj2 habit\$).tw.
- 28 exp exercise/
- 29 physical\$ activ\$.tw.
- 30 exp Exercise Movement Techniques/
- 31 exp Exercise Therapy/
- 32 exp "Physical Education and Training"/
- 33 Physical Fitness/
- 34 exp Sports/
- 35 aerobic\$.tw.
- 36 (cycle or cycling).tw.
- 37 (exercise\$ or strength\$ or fitness).tw.
- 38 sport\$.tw.
- 39 (walking or running).tw.
- 40 (aquatic\$ or swim\$).tw.
- 41 Sedentary Lifestyle/
- 42 (inactiv\$ or sedentary or screen-time).tw.
- 43 Health Education/
- 44 exp Health Promotion/
- 45 (health\$ adj2 (educat\$ or lifestyle\$ or live\$ or living or promot\$)).tw.
- 46 or/21-45
- 47 20 and 46

48 randomized controlled trial.pt.  
49 controlled clinical trial.pt.  
50 randomi#ed.ab.  
51 placebo.ab.  
52 clinical trials as topic.sh.  
53 randomly.ab.  
54 trial.ti.  
55 or/48-54  
56 exp animals/ not humans.sh.  
57 55 not 56  
58 47 and 57

## CONTRIBUTIONS OF AUTHORS

EHM and AS conceptualized the review question.

EHM, AS, MF and RAS wrote the protocol, with EHM and RAS focusing on the Background section and AS and MF focusing on the Methods section.

AS and EHM developed the search strategy, with input from MF and RAS.

EHM has overall responsibility for this review.

## DECLARATIONS OF INTEREST

Emily H Morgan (EHM) - is a Postdoctoral Associate at Cornell University and also is part owner of a small business that sells hearing aids. EHM does not believe this poses any conflict but declares it as an interest in the medical/health field.

Anel Schoonees (AS) - is employed by Stellenbosch University and was paid for her work on this review. AS's salary is supported, in part, by the Effective Health Care Research Consortium (EHCRC), specifically related to her research outputs, which is funded by UK Aid from the UK Government Department for International Development. As well as the EHCRC, AS's salary comes from the Faculty of Health and Medicine at Stellenbosch University and Stellenbosch University Rural Medical Education Partnership Initiative, which covers most of her teaching outputs. AS received a bursary award from 3iE to attend the Cochrane Colloquium in 2013.

Marlyn Faure - none known.

Rebecca A Seguin - none known.

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## External sources

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