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Interventions to prevent obesity in children under 2 years old (Protocol)

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Interventions to prevent obesity in children under 2 years old

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ABSTRACT

Objectives

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

The overall aim of the review is to determine the effectiveness of interventions to prevent obesity in children under two years old. This includes to assess obesity prevention interventions that are conducted during this age bracket (in children under two years old only) and to measure any impacts of these interventions during this age bracket and at any follow-up periods.

The four objectives are:

1. to evaluate the effects of interventions that aim to modify breastfeeding, formula feeding and other dietary intake on changes in zBMI score, BMI and serious adverse events among infants and children under two years old;

2. to evaluate the effects of interventions that aim to modify movement behaviours (physical activity, sedentary behaviour, sleep, play or structured exercise) on changes in zBMI score, BMI and serious adverse events among infants and children under two years old;

3. to evaluate the combined effects of interventions that aim to modify breastfeeding, formula feeding or other dietary intake and movement behaviours on changes in zBMI score, BMI and serious adverse events among infants and children under two years old;

4. to compare the effects of interventions that aim to modify dietary interventions with those that aim to modify movement behaviours on changes in zBMI score, BMI and serious adverse events among infants and children under two years old.

The secondary objectives are designed to explore if, how, and why the effectiveness of interventions on zBMI/BMI varies depending on the following PROGRESS factors.

- Place of residence
- Race/ethnicity/culture/language

- Occupation
- Gender/sex
- Religion
- Education
- Socioeconomic status
- Social capital

The PROGRESS acronym is intended to ensure that there is explicit consideration for health inequity, the unfair difference in disease burden, when conducting research and adapting research evidence to inform the design of new interventions (O'Neill 2014). The PROGRESS acronym describes factors that contribute to health inequity. Recent work on race and religion in the UK suggests that consideration of these factors is critical to the design of new interventions (Rai 2019).

We will also collect, from RCTs, information about the costs of interventions so that policymakers can use the review as a source of information from which they may prepare cost-effectiveness analyses.

BACKGROUND

The growing population levels of overweight and obesity are a major public health challenge internationally (WHO 2016; WHO 2017). The causes are complex: the 2007 foresight report mapped over 100 interconnected factors, all of which contribute to the population prevalence of obesity. These factors include macroeconomic drivers, biological factors, food supply and production, media, healthcare, built environment, transport and recreation, technology, early life experiences and education (Government Office for Science 2007). These factors can operate differently in different people, and partially explain inequalities in childhood obesity. A good example is the relative cost of healthy food, such as fruits and vegetables, which may be prohibitive for families on a low income (Power 2021).

The global evidence suggests that the prevalence of overweight and obesity in children started to rise at the end of the 1980s (Ng 2014). By 2010, 43 million children under five years of age were categorised as having overweight or obesity, with approximately 35 million of these children living in low- and middle-income countries (de Onis 2010). Internationally, childhood obesity rates continue to rise in some countries (e.g. Mexico, India, China, Canada), although there is evidence of a slowing of this increase or a plateauing in some age groups in some countries (WHO 2016; WHO 2017). The World Health Organization (WHO) Commission on Ending Childhood Obesity found that childhood obesity is reaching alarming proportions in many countries and poses an urgent and serious challenge (WHO 2016; WHO 2017). The Sustainable Development Goals, set by the United Nations in 2015, also identify prevention and control of non-communicable diseases, including obesity, as core priorities (United Nations 2018).

Obesity in children can be difficult to reverse through interventions (Al-Khudairy 2017; Mead 2017). Children with obesity have poorer psychological well-being and elevated levels of a number of cardio-metabolic risk factors (Sommer 2018). Obesity comorbidities, including high blood pressure, high blood cholesterol and insulin insensitivity, are being observed at an increasingly early age. Childhood obesity may cause musculoskeletal problems, obstructive sleep apnoea, asthma and a number of psychological issues (NHS England 2014; Papoutsakis 2013; Paulis 2014; Rankin 2016). Childhood obesity is associated with type 2 diabetes and heart disease in adulthood and middle-age mortality (PHE 2022). As obesity tracks through into adulthood (Simmonds 2016), and is associated with increased risks for heart disease, stroke, metabolic syndrome, type 2 diabetes and some cancers (Bhaskaran 2014; Yatsuya 2010), there is a strong case for primary prevention.

Estimates of the economic impacts of obesity (adult and child) as a percentage of gross domestic product (GDP) range from 0.13% in Thailand (Pitayatienanan 2014) to 9.3% in the USA (Waters 2018). However, the methods used to estimate these costs vary between studies, and most studies use a health system perspective rather than a societal perspective. Recently, Okunogbe 2021 estimated current and future national economic impacts of obesity across a sample of heterogeneous contexts globally. They estimated that obesity cost between 0.8% and 2.4% of GDP in 2019 in the eight countries in their study (Australia, Brazil, India, Mexico, Saudi Arabia, South Africa, Spain and Thailand). Their projections revealed an increasing trend in obesity costs as a percentage of GDP over time, estimated to reach 2.4% of GDP in Spain and up to 4.9% in Thailand by 2060. They concluded that economic impacts of obesity are substantial and reach a similar magnitude in low-income and middle-income countries as in high-income contexts. A separate projection for England reports that halving childhood obesity by 2030 could save the National Health Service GBP 37 billion and wider society GBP 202 billion (Hochlaf 2020).

Even in the youngest age groups, epidemiological studies have identified modifiable health behaviours, such as diet and movement behaviours (including sleep), to be associated with obesity (Carson 2017; Chaput 2017; Hewitt 2020; Poitras 2017). The first two years of life following birth is considered a crucial time period for infant development (WHO 2013), and thus for preventing childhood obesity (Larqué 2019). Birth to two years has additionally been identified as the time when exposure to obesogenic environments begins (Ciampa 2010). During this time, weight status, particularly weight gain, and feeding behaviours, are associated with later obesity and metabolic risk (Baidal 2016; Druet 2012; Zheng 2018).

Multiple exposures in this early developmental life course stage are associated with increased (or decreased) risk of subsequent childhood obesity, demonstrating the importance of early preventative intervention. For example, neonatal adiposity (body fat percentage) is significantly associated with an increase in child body mass index (BMI) and childhood overweight and obesity at ages two to six years (Moore 2020). Breastfeeding is shown to reduce the risk of childhood obesity, with a dose-response relationship based on duration of breastfeeding (Qiao 2020). Being born small for gestational age and subsequent catch-up growth have been long-established as predictors of childhood obesity. A recent systematic review and meta-analysis revealed that rapid weight gain (RWG, defined as a change in weight-for-age z-score > 0.67) in this period increased the odds of later obesity by 2.66 times (pooled odds ratio = 3.66, 95% confidence interval: 2.59 to 5.17) (Zheng 2018). RWG in the first three months was found to make a greater contribution to poor cardiometabolic health than in any other three-month period during the first year life (Leunissen 2009). RWG has also been shown to significantly increase infant body fat percentage and BMI z-score by the age of two years (Díaz-Rodríguez 2021), highlighting the importance of early intervention before this age. Further, there is evidence of a cumulative effect of early life exposures to risk factors in the first 1000 days on childhood obesity, including both prenatal exposures (e.g. maternal smoking, gestational weight gain and diet) and exposures from birth to two years (e.g. breastfeeding duration, timing of complementary food introduction and infant sleep duration) (Hu 2021). Therefore, interventions are likely to require targeting multiple early life risk factors before two years of age to have an impact on childhood obesity prevention.

Strong evidence suggests that genetic factors may play a major role in obesity development in childhood, by explaining 47% to 90% of BMI variation (Larqué 2019). However, modifiable factors (e.g. behaviours) can alter the contributions of obesity-related genes, implying that interventions to correct these factors should commence as early as possible. Early-life dietary exposures may contribute to developing obesity, including formula feeding, short period of breastfeeding, early introduction of solid foods, and excess intake of macronutrients (Fogel 2020). Additionally, infant feeding practices (e.g. types and quantities of foods offered, or style carer uses during feeding) have been found to be associated

with the amount of weight gained in the early years and contribute to the development of both child dietary preferences and control mechanisms regarding hunger and satiety (Birch 2014; Thompson 2013). For movement behaviours, emerging evidence in infants suggests that those who spend more time prone have better developmental outcomes and lower BMI-z scores (Hewitt 2020), with increased physical activity in toddlers (and preschoolers) associated with better physical, mental and metabolic health outcomes (Carson 2017). Conversely, suboptimal sleep-wake patterns (such as insufficient sleep duration), insufficient physical activity, a long time spent watching screens, and other sedentary behaviours, are conducive to obesity in the early-life period (Larqué 2019). Interventions to prevent obesity in this age group therefore offer considerable potential to reduce the increasing global prevalence of overweight and obesity, and to improve other long-term health outcomes.

Obesity prevalence is inextricably linked with the degree of relative social inequality, where those in lower social strata are at higher risk of developing obesity in most high-income countries, including infants and young children (Ballon 2018). It is therefore critical that in preventing obesity we are also reducing the associated gap in health inequalities, ensuring that interventions do not inadvertently lead to more favourable outcomes in those with a more socio-economically advantaged position in society. Equally, there is a need to understand how to minimise obesity in more affluent groups in low-income countries. The available knowledge base includes limited evidence on which we can develop a platform of obesity-prevention action and select appropriate public health interventions, whether for the whole population or for those at greatest risk of obesity (Hillier-Brown 2014).

The WHO Commission on Ending Childhood Obesity states that progress in tackling childhood obesity has been slow and inconsistent, and obesity prevention and treatment requires a whole-of-government approach in which policies across all sectors systematically take health into account, avoid harmful health impacts, and thus improve population health and health equity (WHO 2016; WHO 2017). Indeed, it is now acknowledged that tackling obesity requires a systems approach and policy initiatives across government departments that are joined-up (Rutter 2017). The broader system which influences obesity is multi-level and complex in nature (Government Office for Science 2007). Understanding this broader system allows us to identify points that could be targeted for intervention development. Some of these points are upstream (e.g. policy) and some downstream (e.g. individual-level education), and some of the points in the system are more modifiable than others. Downstream interventions rely on individuals (in this case, parents, carers and childcare staff) actively making a choice to provide a healthier diet or a more active lifestyle for the infant or child. These types of interventions, often simply providing education and information on a healthy diet or healthy movement behaviour levels, rely on the individual parent, carer, childcare staff, or all, being willing and able to make these changes. Upstream interventions change policy or the environment in which the child lives (home, childcare, the wider environment), which makes consuming a healthy diet and being physically active the easy choice (sometimes the only choice). Examples include mandatory food standards and guidance on physical education for childcare provision, and policies around marketing of foods with a high level of fat, salt or sugar (HFSS foods), which are targeted at infants and children (including in supermarkets). There is evidence that downstream interventions are more likely to result in intervention-generated inequalities (Adams 2016; McGill 2015). The important point to note is that the most successful approach to tackling childhood obesity is to develop and implement both upstream and downstream interventions.

Experts have noted, in relation to Chapter 2 of the Childhood Obesity Plan for England, that while the main focus of obesity prevention should rely on self-regulation at an individual level (downstream interventions), an equal focus on upstream interventions is also required if a substantial change in childhood obesity is to be realised (Griffin 2021; Knai 2018).

The aim of this Cochrane Review is to synthesise the evidence base for preventing obesity in children under two years old, with particular regard to health equity. We will focus on children under two years old, given that this age period is critical for the development of known modifiable risk factors for childhood obesity, including rapid infant weight gain, curtailed infant sleep, insufficient tummy time, inappropriate bottle use, and introduction of solid food intake before the age of four months (Hewitt 2020; Woo Baidal 2016). Additionally, healthy eating and movement behaviours, which track through childhood into adulthood and are the key determinants of obesity, are starting to be established at this early life stage. Obesity prevention efforts for children under two years old therefore represent a distinct set of interventions with considerable potential to prevent childhood obesity. We will update the Cochrane Review by Brown 2019, which included children from 0 to 18 years old and presented analyses split into three age groups of children: 0 to 5, 6 to 12 and 13 to 18 years. This updated review will focus on children under two years old and is one of four linked update reviews that are based on the Brown 2019 review, but which each focusing on a different age group of child or young person: 2 to 4, 5 to 11 and 12 to 18 years, with a new protocol for each. Findings from the 2019 Cochrane Review suggest that different interventions might work differently in children of different ages (Brown 2019). The objective of this particular review is to assess obesity prevention interventions that are conducted during this age bracket (in children under two years old only) and to measure any impacts of these interventions during this age bracket and at any follow-up periods.

Description of the condition

Overweight and obesity are terms used to describe an excess of adiposity (or fatness) above the ideal for good health. Current expert opinion supports the use of BMI cut-off points to determine weight status (as healthy weight, overweight or obese) for children, and several standardised BMI (zBMI) cut-offs have been developed that account for the child's age and gender (Adab 2018; Bell 2018). Population monitoring of overweight and obesity is best done through use of BMI, but this measure has limitations at an individual level and, in children, zBMI is deemed to be more useful. Despite this, there is no consistent application of this methodology by experts and a variety of percentile-based methods are also used, which can make it difficult to compare randomised controlled trials (RCTs) that have used different measures and weight outcomes.

Overweight and obesity in childhood are known to have significant impacts on both physical and psychosocial health (reviewed in Lobstein 2004). Indeed, many of the cardiovascular consequences that characterise adult-onset obesity are preceded by abnormalities that begin in childhood. Hyperlipidaemia,

hypertension, abnormal glucose tolerance, and type 2 diabetes occur with increased frequency in children with obesity (Freedman 1999). In addition, obesity in childhood is associated with cardiovascular disease risk factors in adults (Umer 2017), underpinning the importance of obesity prevention efforts in children.

Health inequalities

Obesity results from a sustained positive energy imbalance, and a variety of genetic, behavioural, cultural, environmental and economic factors have been implicated in its development (reviewed in Lobstein 2004). The interplay of these factors is complex and has been the focus of considerable research. However, the burden of obesity is not experienced uniformly across a population, with the highest levels of the condition experienced by those who are most disadvantaged. In high-income countries there is a significant trend observed between obesity and lower socio-economic status (e.g. in the UK, NHS Digital 2020). Drawing on data from children aged 4 to 5 years old, body mass trends in the UK are consistently associated with local area deprivation (NHS Digital 2021). In a study of children aged six to nine years old living in 24 countries in the WHO European region, an inverse relationship between the prevalence of childhood overweight/obesity and parental education was found in high-income countries, whereas the opposite relationship was observed in most of the middle-income countries (Buoncristiano 2021). In low-income countries the relationship was variable, and there appears to be a shifting of obesity burden across socioeconomic groups, and different patterns by gender (Jiwani 2019; Monteiro 2004). On this basis, we plan to explore the findings of this review by World Bank category high-, upper-middle-, lower-middle-, and low income countries (World Bank 2021).

Description of the intervention

This review involves assessing interventions aimed at preventing obesity (either the primary aim of the intervention or one of the key aims of the intervention), implemented in any setting, that have been assessed in an RCT. Comparators may be any active intervention or no intervention (usual care).

Note that the 2019 Cochrane Review on preventing obesity in children included many more downstream (individual-level) interventions, compared with upstream (policy and environmental-level) interventions, that met their inclusion criteria (Brown 2019; Nobles 2021). Therefore, the evidence base for preventing obesity should encompass additional, high-quality reviews which focus on the upstream interventions and which include RCT studies and other study designs (e.g. Wolfenden 2016). The insights from this new review of RCTs will help to refine future interventions that can operate within a whole systems approach; one that combines a range of upstream and downstream approaches.

How the intervention might work

Interventions that aim to prevent childhood obesity seek to maintain an energy balance that is ideal for the healthy growth and development of the child. All such interventions work either by limiting the amount of energy (calories) consumed or by increasing the amount of energy expended (which includes basal metabolic rate, physical activity and other movement behaviours, including sleep, and energy required for child growth), or by both limiting the amount of energy consumed and increasing the amount of energy expended. If energy consumed exceeds energy expenditure, excess body fat will accumulate. If sustained energy expenditure (normal metabolic demands plus cost of growth) exceeds energy consumed, the child may become malnourished. A severe energy deficit over a prolonged period in childhood, particularly during rapid periods of growth, may have serious negative consequences for growth and development, and these effects are potentially irreversible. Getting the balance of short-term effectiveness versus a more moderate, safer and more sustained energy deficit in the context of childhood obesity prevention interventions 'right' remains a key public health challenge (Emmett 2015).

The safest and most reliable way to ensure an ideal energy balance in growing children is for the child to eat a healthy diet, be physically active, limit time spent sedentary/restrained, and have sufficient sleep (Larqué 2019; Miller 2018). Most countries have age-specific recommendations for dietary behaviours and 24-hour movement behaviours (including adopting the WHO 2019 guidelines). Dietary and movement behaviour (physical activity/play, sedentary behaviour, sleep) guidelines generally vary by child age. In young children, guidance is normally separated into birth to around one year (infants), aged one year to two years (toddlers), and from around three to five years (preschoolers) (WHO 2001; WHO 2019). Dietary guidelines for infants focus advice on promoting breastfeeding, and for toddlers they focus on appropriate complementary feeding. Movement behaviour guidelines focus advice on promoting tummy time (prone position) for infants and a variety of physical activity for toddlers, advice on reducing time spent restrained (e.g. in prams, strollers) and sedentary screen time, and obtaining a sufficient amount of good quality sleep (WHO 2019). In addition, effective parenting practices generally vary by the child's age, with parenting manuals and programmes separated by age (e.g. First Steps Nutrition Trust). Therefore, the types of interventions which aim to promote healthy dietary and movement behaviours in preschoolers are generally different in nature (because they are targeting different behaviours) compared with those for infants and for toddlers.

Most interventions for infants and children under two years old that include a diet component promote exclusive breastfeeding in the first six months of life following birth, postpone introduction of solid foods, avoid excess macronutrient intake (in particular protein, dietary fat and free sugars), and increase consumption of fruit and vegetables in the first two years (Askie 2020; Butler 2021; Hodder 2020; Mihrshahi 2021). Interventions which include a movement behaviour component for infants and children promote tummy time, active play, healthy sleep, a reduction in sedentary behaviours, or several of these behaviours (Askie 2020; Blake-Lamb 2016; Mihrshahi 2021; Redsell 2016). Examples include improving sleep-wake timing and patterns over a 24-hour period, providing opportunities to be active outdoors, and limiting the time an infant or child is restrained or watching a screen (e.g. TV/tablet) when awake. Though the interventions for preventing obesity for this age group are safe, some serious adverse events have been suggested in previous literature, including choking, food allergy, constipation, iron deficiency (anaemia), and growth-related events (such as growth faltering, insufficient growth) (Paul 2018; Taylor 2017).

Why it is important to do this review

Governments internationally are being urged to take action to prevent childhood obesity and to address the underlying determinants of the condition. To provide decision makers with high quality research evidence to inform their planning and resource allocation, this review aims to provide an update of the evidence from RCTs designed to compare the effect of interventions to prevent childhood obesity in this critical age group with the effect of receiving no intervention, or an active comparator intervention. Previous work has highlighted that the current evidence base focuses mainly on individual-level interventions that are assessed via an RCT. Where possible, the totality of the evidence base should also capture studies that evaluate the effectiveness of upstream interventions (Nobles 2021), mindful of the fact that these types of interventions are not commonly assessed via an RCT because of the design challenges at scale.

There has been considerable growth in the number of studies in this field over the last five to 10 years. We aim to update the age-relevant data (for children under two years old only) collected in the existing Cochrane Review of children aged 0 to 18 years (Brown 2019). From our scope of the literature, it is clear that the number of relevant studies that would be included in this review of children under two years old would approximately triple the number of those included in the 2019 Cochrane Review for this age group. Importantly, many of the relatively recent studies we have identified have reported data on inequalities and provided new evidence that could impact the recommendations.

The burden of obesity in children, and particularly the inequalities in childhood obesity, has been exacerbated in most countries during the Covid-19 pandemic. Early indications in a number of countries show rising levels of childhood obesity (www.worldobesity.org), and an increase in inequalities in childhood obesity. In some countries, particularly low-income countries, the double burden of malnutrition (obesity and undernutrition) has risen sharply during the pandemic (International Food Policy Research Institute 2020; Zemrani 2021). Those responsible for public health in all regions of the world, across countries, and in local communities are planning (and then implementing) their Covid-recovery strategy. As such, our public health policymakers' needs for cost-effective interventions to prevent childhood obesity that are scalable and feasible are more urgent than ever before. These interventions should then feed into a broader strategy that includes upstream interventions.

OBJECTIVES

The overall aim of the review is to determine the effectiveness of interventions to prevent obesity in children under two years old. This includes to assess obesity prevention interventions that are conducted during this age bracket (in children under two years old only) and to measure any impacts of these interventions during this age bracket and at any follow-up periods.

The four objectives are:

1. to evaluate the effects of interventions that aim to modify breastfeeding, formula feeding and other dietary intake on changes in zBMI score, BMI and serious adverse events among infants and children under two years old;

2. to evaluate the effects of interventions that aim to modify movement behaviours (physical activity, sedentary behaviour, sleep, play or structured exercise) on changes in zBMI score, BMI and serious adverse events among infants and children under two years old;

3. to evaluate the combined effects of interventions that aim to modify breastfeeding, formula feeding or other dietary intake and movement behaviours on changes in zBMI score, BMI and serious adverse events among infants and children under two years old;

4. to compare the effects of interventions that aim to modify dietary interventions with those that aim to modify movement behaviours on changes in zBMI score, BMI and serious adverse events among infants and children under two years old.

The secondary objectives are designed to explore if, how, and why the effectiveness of interventions on zBMI/BMI varies depending on the following PROGRESS factors.

- Place of residence
- Race/ethnicity/culture/language
- Occupation
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- Social capital

The PROGRESS acronym is intended to ensure that there is explicit consideration for health inequity, the unfair difference in disease burden, when conducting research and adapting research evidence to inform the design of new interventions (O'Neill 2014). The PROGRESS acronym describes factors that contribute to health inequity. Recent work on race and religion in the UK suggests that consideration of these factors is critical to the design of new interventions (Rai 2019).

We will also collect, from RCTs, information about the costs of interventions so that policymakers can use the review as a source of information from which they may prepare cost-effectiveness analyses.

METHODS

Criteria for considering studies for this review

Types of studies

We will include studies that:

- are individually-randomised, or cluster-randomised with at least three clusters/groups of individuals per intervention arm (including the first period only of trials with a cross-over design, due to important concerns about carry-over);
- measured BMI or zBMI (or weight and length/height from which BMI or zBMI can be calculated) at baseline and after the end of the intervention period (including collection of self-reported measurement);
- included an active intervention period of any duration, provided that the studies reported follow-up outcome data at a minimum of 12 weeks from baseline.

Studies may be written in any language. We will exclude studies published before 1990, since global evidence suggests that the prevalence of overweight and obesity in children started to rise at the end of the 1980s (de Onis 2010; Ng 2014). Given the lag time between the conception, funding, and the completion of RCTs, we considered a 1990 publication date as a pragmatic and reasonable starting point for the literature in the area.

Types of participants

We will include infants from birth to children under two years of age at baseline. We will apply this rule if these results relate only to a subset of children from a trial including a much wider range of ages.

We will consider studies to have eligible infants or children if they meet any one of the following criteria:

- targeted infants or children who are in the general population;
- included infants or children who are part of a family group receiving the intervention, if outcome data can be extracted separately for the children;
- targeted infants or children who are 'at risk' for overweight or obesity, for example because a parent is overweight or obese; or
- targeted infants or children who are from specific place-based areas (e.g. of high deprivation) or specific settings (e.g. religious settings) where that population is known to have relatively low levels of physical activity, high levels of energy intake, high levels of obesity, or a combination of these.

In order to reflect a public health approach that recognises the prevalence of a range of weights within the general population of children, we will include RCTs that include participants with overweight or obesity, with the exception of RCTs that have an aim to treat obesity.

We will exclude:

- RCTs that recruit only children with overweight or obesity at baseline, because we consider these interventions to be focused on treatment rather than prevention; and
- RCTs of interventions designed for children with a critical illness or severe comorbidities.

Types of interventions

Eligible interventions will have a main aim of changing at least one factor from: diet or movement behaviours (physical activity, sedentary behaviour, sleep, play or structured exercise) to help prevent obesity in children.

Examples of interventions that would be included in the review include the following:

- interventions that provide opportunities for infants and children to do more physical activity, including increasing tummy time in infants, to improve co-ordination and balance (e.g. walking, running), and in the longer term, help prevent obesity;
- interventions that alter the food environment within the childcare setting (e.g. offering cut up fruit and water at regular intervals) so as to make it easier to provide healthier food items;
- interventions that provide education to parents with anticipatory guidance on early feeding practices;
- interventions that provide education to parents/carers and childcare staff on how to provide a healthier diet and more physical opportunities to infants and children;
- interventions that regulate how HFSS foods are advertised to infants and children in supermarkets and on the TV.

We will exclude studies of interventions designed primarily to improve sporting performance (focused on strength and sport-specific fitness training). Although we are not expecting such interventions to be targeted at infants and children under two years old, we have included this exclusion criterion for completeness.

Setting

We will include interventions in any setting, including the home, healthcare settings, childcare setting, and the wider community. We will also include digital interventions. There is no single agreed definition of a digital intervention, and we are operationalising it here as one that employs software, hardware and digital services (e.g. example mobile health apps, wearable devices, telehealth and telemedicine, and personalised medicine) to help prevent childhood obesity.

Comparators

We will include studies that compared an eligible intervention with a non-intervention control group who received no intervention or usual care, or with another eligible intervention (i.e. head-to-head comparisons).

Types of outcome measures

The Cochrane Review which will be produced from this protocol will have a range of potential end users, including policymakers and other decision-makers. We considered a range of potential outcome measures which provide some indication of body fatness or are determinants of body fatness. Using the strategies outlined by Wolfenden 2021 for selecting review outcomes for systematic reviews of public health interventions, we have prioritised only a small number of critical outcomes.

Primary outcomes

Our primary outcomes are:

- zBMI score, measured from weight and length/height of the children at least 12 weeks after randomisation and standardised to age-specific local or national tables for BMI; or (where zBMI is not available) BMI, measured from weight and length/height of the children at least 12 weeks after randomisation; and
- serious adverse events, defined as choking, food allergy, constipation, iron deficiency (anaemia), growth faltering (a decrease in the weight z score of more than 1.34) and insufficient growth (weight-for-age below the fifth percentile or downward crossing of two major growth chart percentile lines) (Paul 2018; Taylor 2017).

In the event of presentation of multiple sets of data for BMI and zBMI, we will follow the decision rules set out under Data extraction and management and Measures of treatment effect. We will present these main outcomes in the summary of findings tables.

Note that we will include zBMI and BMI taken from both measured and self-reported (e.g. parental) weight and length/height data, but

we will make it clear where these measures are self-reported and conduct sensitivity analysis.

Time points

We will collect data from all reported postintervention time points at least 12 weeks from baseline. We will group data for analysis into three time periods: i) 12 weeks from baseline to < 9 months; ii) 9 months from baseline to < 15 months; and iii) long term (15 months or more).

Where included studies have collected relevant data on length/height and weight at the start and end of the intervention period but have not presented their findings using zBMI or BMI, we will report this information in tables but not use the data in any summary.

Secondary outcomes

There are no secondary outcomes.

Search methods for identification of studies

This is one of four linked protocols created to update the existing Cochrane Review on this topic (Brown 2019). The Brown 2019 review included children aged 0 to 18 years. This protocol covers infants and children under two years old, with three additional, separate protocols in preparation for ages 2 to 4, 5 to 11 and 12 to 18 years. The search methods for this protocol (children under two years old) will build on, and be an update of, the literature searches and records screening previously undertaken in Brown 2019. We will isolate, at the screening stage, those records relevant to the age group of children under two years old. Details of the searches we are building on are available in Brown 2019. Because our eligibility criteria coincide with those of the Brown 2019 review, we will not repeat these searches.

Electronic searches

For this update review we will search the following databases, from 2018 (the date of the last search in the Brown 2019 review):

- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (Appendix 1);
- MEDLINE (Ovid);
- Embase (Ovid);
- PsycINFO (Ovid);

We will include additional search terms for topics around: infant feeding, marketing; beverages and sweetening agents; food labelling; parental interventions; maternal and child health services; public health; electronic apps and web-based interventions. These search terms will be run only in the Cochrane Library, from 1990 onwards. The reason we chose to limit these terms to CENTRAL and the Cochrane Database of Systematic Review (CDSR) was a pragmatic one, as Cochrane's Centralised Search Service (CSS) uses a highly efficient search strategy to capture reports of RCTs from MEDLINE and EMBASE (for inclusion in CENTRAL) (Noel-Storr 2020). Also, our full search (run across all databases) includes several generic 'prevention' search strings, to capture any type of intervention. See Appendix 1 for an example of this search.

We will also run additional searches on the following education databases (1990 onwards):

- Australian Education Index (AEI) (EBSCOhost);
- British Education Index (BEI) (EBSCOhost);
- ERIC (Education Resources Information Center) (EBSCOhost).

We will examine adverse events only in the studies meeting the main eligibility criteria and will not perform an additional search focusing on adverse events.

Searching other resources

We will search ClinicalTrials.gov with the filter 'Applied Filters: Child (birth–17)' and the WHO International Clinical Trials Registry Platform, search portal (ICTRP), using the filter for studies in children. In addition, we will look at the reference lists and references of included studies.

We will run a pragmatic search for PhD theses (1990 onwards) using the following databases:

- Electronic Theses Online Service (EThOS) - British Library (ethos.bl.uk/Home.do);
- DART - Europe e-theses Portal (dart-europe.eu/basic-search.php);
- Networked Digital Library of Theses and Dissertations (NDLTD) (search.ndltd.org/);
- Open Access Theses and Dissertations (OATD) (oatd.org);
- Proquest Dissertations & Theses Global (search.proquest.com/pqdtglobal/dissertations/).

Data collection and analysis

Selection of studies

Two authors will screen titles and abstracts independently and in duplicate using Covidence systematic review software. They will retrieve full-text articles of records that potentially meet the eligibility criteria, and screen these independently and in duplicate. The two authors will resolve any differences in opinion or uncertainty through a process of discussion and, when necessary will involve a third author.

Data extraction and management

We will modify a data collection form for study characteristics and outcome data that was used in the Brown 2019 Cochrane Review of interventions to prevent obesity in children. Two review authors will extract study characteristics from included studies independently and in duplicate. We will extract the following study characteristics.

- Methods: study design (including number of clusters in cluster-RCTs); total duration of study; details of any 'run in' period; number of study centres and location; study setting; date of study
- Participants: numbers randomised, lost to follow-up/withdrawn and analysed; age (mean and range); sex; inclusion and exclusion criteria
- Baseline zBMI or BMI
- Interventions: description of intervention and comparator intervention or control group conditions, such as type of intervention, duration of intervention, setting, theory behind the intervention, unit of intervention (who is targeted), who delivers the intervention

- Outcomes: zBMI (mean and SD); BMI (mean and SD;); numbers of reported serious adverse events:
  - time points: as described under Types of outcome measures;
  - measurement: we will note if BMI and zBMI are self-reported (by adult) or measured by researchers;
  - effect estimates: we will collect BMI and zBMI data according to these preferences:
    - postintervention mean differences adjusted for baseline zBMI (or BMI) from analysis of covariance; in preference to
    - postintervention mean differences; in preference to
    - differences in change-from-baseline means.
  - effect estimates from cluster-RCTs: we will collect BMI and zBMI data that are adjusted for clustering in preference to analyses that are not adjusted for clustering.
- PROGRESS factors
- Information about the costs of interventions, for the purposes of secondary analysis by healthcare policymakers. We will not analyse costs in this review.
- Notes: funding for trial, and notable conflicts of interest of trial authors

Where desirable statistics cannot be extracted directly (e.g. standard deviations of BMI), we will compute or estimate these using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Li 2019).

Assessment of risk of bias in included studies

We will assess the risk of bias (RoB) for all results using the RoB 2 tool (Sterne 2019), in the following five domains: bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result. Judgements about risk of bias will be determined using the algorithms in the tool, based on answers we give to the relevant signalling questions, although if we feel there is sufficient reason to override the algorithm, we will do this and state a reason for it. An overall risk of bias for each result will be produced, based on the least favourable assessment of bias across the domains. Judgements reached could be low, some concerns or high risk of bias. For cross-over RCTs, as we are using only the first period of the RCT, we will use the main RoB 2 tool for parallel group trials. For cluster RCTs we will use the version of the RoB 2 tool designed for studies using cluster randomisation (Eldridge 2021), which has an additional domain 'bias arising from the identification or recruitment of participants into clusters', and modified signalling questions within the other domains.

We will assess the effect of assignment to the intervention for the outcomes zBMI (or BMI) and serious adverse events at all time points. We will assess risk of bias only for specific results that contribute to the meta-analyses. For studies with multiple intervention arms, we will assess risk of bias for each specific pairwise comparison contributing to meta-analyses.

For studies we identify through new searches, two authors will independently use the RoB 2 tool to carry out the assessments (NH, RH) (Sterne 2019). Bias for results included in the Brown 2019 Cochrane Review have been assessed for risk of bias by two authors independently using the original Cochrane risk of bias tool (RoB 1) (Higgins 2011). We will transform these RoB 1 assessments into RoB 2 assessments as follows. One author (NH, RH) will first undertake an independent RoB 2 assessment (blind to the RoB 1 assessment). They will then compare this with the previous RoB 1 assessment. Differences or uncertainties will be resolved through discussion with a second reviewer (SP, RH) and, where necessary, by involving a third author (CS). To avoid conflict of interest, any authors who are also trialists for an included study in this review will recuse themselves from risk of bias assessment on their trials.

To draw an overall conclusion about the risk of bias in a synthesised result across included studies, we will use the methods set out in Table 14.2.a of the *Cochrane Handbookfor Systematic Reviews of Interventions* (Schünemann 2019).

We will upload a copy of the agreed consensus risk of bias to a data repository such as Figshare or Dryad for submission with the completed review. We will use our overall risk of bias assessment for each result in the review to inform GRADE (see summary of findings section) and for sensitivity analysis (see Sensitivity analysis).

Measures of treatment effect

We will measure intervention effects on zBMI using an unstandardised mean difference (MD) between intervention groups. For BMI, we intend to examine mean difference and will perform sensitivity analyses using a standardised version (standardising by pooled standard deviation) in case of high heterogeneity in MDs across studies in different age groups. For serious adverse events we will measure intervention effects using risk ratios.

Unit of analysis issues

We will examine each cluster-RCT to determine whether the analysis accounted for clustering. For results that were not adjusted for clustering, we will create an approximate analysis by inflating the standard error of the estimated intervention effect according to an estimated 'design effect' (Higgins 2019a). This requires an estimate of the intra-cluster correlation coefficient (ICC), describing the relative variability within and between clusters. Where a study does not report this, we will use external estimates from (in preferential order): (i) other cluster RCTs in the review with similar types of cluster; or (ii) published resources of previously identified cluster-RCTs (Ukoumunne 1999). We will run sensitivity analyses using 1) no adjustment, 2) adjustment for clustering assuming an ICC of 0.02, and 3) adjustment for clustering assuming an ICC of 0.04. We will report all values of unadjusted and adjusted standard errors plus data used to calculate them in Appendices or supplementary data files.

We will address RCTs with more than two intervention groups according to guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019a). For RCTs with more than two experimental (or comparator) arms relevant to the same meta-analysis, we will combine the arms to create a single pairwise comparison. Where this precludes planned investigations of heterogeneity, we will keep the arms separate and halve the number of participants in the control arm. For factorial RCTs we will include each main intervention effect as if they were distinct trials.

Dealing with missing data

We will examine the extent and reasons for missing data as part of the risk of bias assessment of each included RCT. We will write to

authors of trials to seek missing data for RCTs published in the last 15 years. We will not impute missing data.

Assessment of heterogeneity

We will use the I^2 statistic to quantify the degree of inconsistency across results, supplemented by a P value from a test of homogeneity to measure the strength of evidence of statistical heterogeneity (Deeks 2019).

Assessment of reporting biases

We will assess risk of bias arising from (non)reporting bias using the ROB-ME tool (Page 2020), which is based on the framework described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Page 2019). For meta-analyses with more than 10 studies this will include examination of contour-enhanced funnel plots.

Data synthesis

We will undertake meta-analyses of zBMI scores and BMI using the generic inverse variance method with a random-effects model (Deeks 2019). Our main comparisons are:

- dietary interventions versus no intervention/control;
- movement behaviour interventions (including those targeting physical activity, sedentary behaviour, sleep, play and exercise) versus no intervention/control;
- intervention with both dietary and movement behaviour components versus no intervention/control;
- intervention with both dietary and movement behaviour components versus dietary intervention alone;
- intervention with both dietary and movement behaviour components versus movement behaviour intervention alone;
- dietary intervention versus movement behaviour intervention.

Our intention is to analyse postintervention mean differences adjusted for baseline zBMI (or BMI) from analysis of covariance in preference to postintervention mean differences, and postintervention mean differences in preference to differences in change-from-baseline means. We will analyse differences that are adjusted for clustering (including our own approximate adjustments) in preference to analyses that are not adjusted for clustering.

If data are presented in the primary reports that are not immediately useable in our meta-analysis we will transform them, where possible, using methods described in Chapter 6 of the *Cochrane Handbook* (Higgins 2019b). Decision rules regarding which effect measure to extract and analyse when multiple measures are presented are described in the Data extraction and management section.

Synthesis if data cannot be combined with meta-analysis

We expect most studies to contribute to meta-analyses, because measurement of BMI is an eligibility criterion for this review, and we will make extensive efforts to estimate intervention effects from diversely reported results (e.g. from regression coefficients, from P values and from analyses based on dichotomised BMI scores) (Higgins 2019b). We will supplement the meta-analyses with two additional analyses so as to include studies that cannot be included in the meta-analyses. First, we will extract exact one-sided P values from studies that provide them and perform a meta-analysis of P values (Becker 1994; McKenzie 2019a). Second, we will collate the direction of effect (favouring the experimental intervention or the control intervention), and perform a simple test for overall direction of effect (McKenzie 2019b). We will examine the impact of adding additional studies by repeating these analyses including (i) only the studies in the meta-analysis and (ii) all studies for which the statistic can be derived.

Serious adverse events

We will undertake meta-analyses of serious adverse events if there are sufficient numerical data. Since events are expected to be rare, we plan to use the Mantel-Haenszel method for this, and will also perform a random-effects meta-analysis using the generic inverse variance method as a sensitivity analysis. We will use a synthesis without meta-analysis approach if insufficient data are available (Becker 1994).

Subgroup analysis and investigation of heterogeneity

We will explore heterogeneity in the primary analyses by performing the following pre-planned subgroup analyses according to study-level characteristics and (where possible) participant level characteristics:

- main setting of the intervention (childcare, health service, wider community, home);
- duration of active intervention period: (i) 12 weeks from baseline to < 9 months; (ii) 9 months from baseline to < 15 months (iii) long term (15 months or more from baseline);
- income status of country (using World Bank criteria);
- socioeconomic status (low vs high vs mixed, based on categorisations as described by the trial authors); and
- sex (if the predominance of studies present subgroup analyses by sex).

Tests for subgroup differences will be based on standard heterogeneity tests as described in Chapter 10, section 10.11.3.1 of the *Cochrane Handbook* (Deeks 2019).

Sensitivity analysis

We will perform sensitivity analyses to examine the robustness of our findings to inclusion of results: a) assessed as being at high risk of bias or b) where the outcome (BMI/zBMI) has been self-reported, by repeating analyses with such results omitted. We will investigate the impact of imputing ICCs in cluster-RCTs as described in the section Unit of analysis issues. We will repeat analyses of BMI using standardised mean differences as described in the Measures of treatment effect section.

Summary of findings and assessment of the certainty of the evidence

We will prepare summary of findings tables for each of our main comparisons for the time point 12 weeks to < 9 months from baseline. Each summary of findings table will summarise the size and certainty of effects of the interventions for the three outcomes BMI, zBMI and serious adverse events. We will base our assessments of certainty on the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness and publication bias). We will use GRADEpro software (GRADEpro), and

follow methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2019).

Two authors will work independently to make GRADE judgements, resolving any disagreements by discussion or, where necessary, by consulting with a third author. All decisions to rate down certainty in the results will be justified using footnotes, with comments added to aid readers' interpretation of the tables. We will document and incorporate the GRADE judgements into reporting of results for each outcome.

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APPENDICES

Appendix 1. Appendix 1: Search Strategy

Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library

Rolling Search (update)

This search (lines #1 to #83) is an update and will be date limited from January 2018 onwards

[Overweight/Obesity]

#1 MeSH descriptor: [Obesity] explode all trees

#2 MeSH descriptor: [Body Weight Changes] explode all trees

#3 (obes*):ti,ab,kw

#4 ("weight gain" or "weight loss"):ti,ab,kw

#5 (overweight or "over weight" or overeat* or (over next eat*)):ti,ab,kw

#6 (weight next change*):ti,ab,kw

#7 ((bmi or "body mass index") near (gain or loss or change*)):ti,ab,kw

#8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)

[Behavioural Therapy]

#9 MeSH descriptor: [Behavior Therapy] explode all trees

#10 MeSH descriptor: [Social Support] explode all trees

#11 MeSH descriptor: [Psychotherapy, Group] explode all trees

#12 ((psychological or behavior* or behaviour*) near (therapy or modif* or strateg* or intervention*)):ti,ab,kw

#13 ("group therapy" or "family therapy" or "cognitive therapy"):ti,ab,kw

#14 ((lifestyle or "life style") near (chang* or intervention*)):ti,ab,kw

#15 (counseling or counselling):ti,ab,kw

#16 "social support":ti,ab,kw

#17 (peer near/2 support):ti,ab,kw

#18 (children near/3 parent* near/3 therapy):ti,ab,kw

#19 (#9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18)

[Diet]

#20 MeSH descriptor: [Obesity] explode all trees and with qualifier(s): [diet therapy - DH]

#21 MeSH descriptor: [Diet Therapy] explode all trees

#22 MeSH descriptor: [Fasting] this term only

#23 (diets or diet or dieting):ti,ab,kw

#24 (diet* near (modif* or therapy or intervention* or strateg*)):ti,ab,kw

#25 ("low calorie" or (calorie next control*) or "healthy eating"):ti,ab,kw

#26 (fasting or (modified next fast*)):ti,ab,kw

#27 MeSH descriptor: [Dietary Fats] explode all trees

#28 (fruit or fruits or vegetable*):ti,ab,kw

#29 (high next fat*) or (low next fat*) or (fatty next food*):ti,ab,kw

#30 (formula next diet*):ti,ab,kw

#31 (#20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30)

[Exercise]

#32 MeSH descriptor: [Exercise] explode all trees

#33 MeSH descriptor: [Exercise Therapy] explode all trees

#34 exercis*:ti,ab,kw

#35 (aerobics or “physical therapy” or “physical activity” or “physical inactivity”):ti,ab,kw

#36 (fitness near (class* or regime* or program*)):ti,ab,kw

#37 (“physical training” or “physical education”):ti,ab,kw

#38 “dance therapy”:ti,ab,kw

#39 (sedentary next (behavior* or behaviour*)):ti,ab,kw

#40 (#32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)

[Complementary Therapies]

#41 MeSH descriptor: [Complementary Therapies] explode all trees

#42 (“alternative medicine” or (complementary next therap*) or “complementary medicine”):ti,ab,kw

#43 (hypnotism or hypnosis or hypnotherapy):ti,ab,kw

#44 (acupuncture or homeopathy or homoeopathy):ti,ab,kw

#45 (“chinese medicine” or “indian medicine” or “herbal medicine” or ayurvedic):ti,ab,kw

#46 (#41 OR #42 OR #43 OR #44 OR #45)

[Diet Clubs]

#47 (diet* or slim*) near (club* or organization or organisation):ti,ab,kw

#48 (weightwatcher* or (weight next watcher*)):ti,ab,kw

#49 (correspondence near (course* or program*)):ti,ab,kw

#50 ((fat or diet*) next camp*):ti,ab,kw

#51 (#47 OR #48 OR #49 OR #50)

[Health Promotion]

#52 MeSH descriptor: [Health Promotion] explode all trees

#53 MeSH descriptor: [Health Education] explode all trees

#54 (“health promotion” or “health education”):ti,ab,kw

#55 (“media intervention*” or “community intervention*”):ti,ab,kw

#56 (health next promoting next school*):ti,ab,kw

#57 ((school or community) near/2 program*):ti,ab,kw

#58 ((school or community) near/2 intervention*):ti,ab,kw

#59 ((family next intervention*) or (parent* next intervention*)):ti,ab,kw

#60 (parent* near/2 (behavior* or behaviour* or involve* or control* or attitude* or educat*)):ti,ab,kw

#61 (#52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60)

[Health Policy]

#62 MeSH descriptor: [Health Policy] explode all trees

#63 ((health next polic*) or (school next polic*) or (food next polic*) or (nutrition next polic*)):ti,ab,kw

#64 (#62 OR #63)

[Obesity Prevention]

#65 MeSH descriptor: [Obesity] explode all trees and with qualifier(s): [prevention & control - PC]

#66 MeSH descriptor: [Primary Prevention] explode all trees

#67 ("primary prevention" or "secondary prevention"):ti,ab,kw

#68 (preventive next measure*) or (preventative next measure*):ti,ab,kw

#69 ("preventive care" or "preventative care"):ti,ab,kw

#70 (obesity near/2 (prevent* or treat*)):ti,ab,kw

#71 (#65 OR #66 OR #67 OR #68 OR #69 OR #70)

[All Interventions + Overweight/Obesity (rolling search)]

#72 (#19 OR #31 OR #40 OR #46 OR #51 OR #61 OR #64 OR #71)

#73 (#8 AND #72)

[Age Groups (rolling search)]

#74 MeSH descriptor: [Child] explode all trees

#75 MeSH descriptor: [Infant] explode all trees

#76 (child* or adolescen* or infant*):ti,ab,kw

#77 (teenage* or "young people" or "young person" or (young next adult*)):ti,ab,kw

#78 (schoolchildren or "school children"):ti,ab,kw

#79 (pediatr* or paediatr*):ti,ab,kw

#80 (boys or girls or youth or youths):ti,ab,kw

#81 MeSH descriptor: [Adolescent] this term only

#82 (#74 OR #75 OR #76 OR #77 OR #78 OR #79 OR #80 OR #81)

#83 #73 AND #82 [Date limited, records added to CENTRAL trials database, 01/01/2018 onwards]

OR Additional terms for BMI (all years)

#84 (BMIz or BMI-z or zBMI or z-BMI or (BMI* near/2 (z-scor* or zscor*))):ti,ab

#85 ((bmi or "body mass index") near/3 (assess* or calculat* or change? or changing or differ* or increas* or decreas* or reduc* or post-intervention* or "follow* up*" or followup*)):ti,ab

#86 ((bmi or "body mass index") near/3 outcome*):ti,ab

#87 ((adiposity or fat or weight) near/3 (goal* or outcome*)):ti,ab

#88 (#84 OR #85 OR #86 OR #87)

#89 (#88 AND #72 AND #82)

#90 (#89 NOT #83)

OR New Search Topics

This appended section of the search is new and will be back-dated from January 1990 onwards

[Marketing]

#91 MeSH descriptor: [Marketing] explode all trees

#92 MeSH descriptor: [Persuasive Communication] this term only

#93 MeSH descriptor: [Communications Media] explode all trees

#94 (marketing or advert* or campaign* or "mass media" or "social media" or blog* or vlog*):ti,ab,kw

#95 (persuasive or persuasion or persuader*):ti,ab,kw

#96 MeSH descriptor: [Food Packaging] this term only

#97 MeSH descriptor: [Food Labeling] explode all trees

#98 ((food or foods or drink or drinks or product or products or nutrition* or diet* or carb* or sugar* or fat or fats or calori* or warning) NEAR/3 (label* or packag*)):ti,ab,kw

#99 (traffic next light*):ti,ab,kw

#100 (#91 OR #92 OR #93 OR #94 OR #95 OR #96 OR #97 OR #98 OR #99)

[Sweeting Agents/Drinks/Snacks]

#101 MeSH descriptor: [Artificially Sweetened Beverages] this term only

#102 MeSH descriptor: [Beverages] this term only and with qualifier(s): [adverse effects - AE]

#103 MeSH descriptor: [Sweetening Agents] explode all trees

#104 (artificial* near/3 sweeten*):ti,ab,kw

#105 ((sugar* or sweeten* or unsweeten* or diet or "low calorie" or fizzy or carbonated) NEAR/3 (beverag* or drinks or juice or juices or cordial or cordials or pop or smoothie or smoothies or snack or snacks)):ti,ab,kw

#106 (soda or sodas):ti,ab,kw

#107 ("low sugar" or "high sugar" or "high fat" or HFSS):ti,ab,kw

#108 ((sugar or fat or food) near/2 (literacy or education)):ti,ab,kw

#109 (snack or snacks or snacking):ti,ab,kw

#110 (#101 OR #102 OR #103 OR #104 OR #105 OR #106 OR #107 OR #108 OR #109)

[Meals]

#111 MeSH descriptor: [Food Services] explode all trees

#112 MeSH descriptor: [Dietary Services] explode all trees

#113 (school* near/3 (breakfast? or catering or diet* or dinner or dinners or dining or lunch* or meal or meals or food or foods or snack or snacks)):ti,ab,kw

#114 ((childcare or "child care" or daycare or "day care" or kindergarten* or nursery or nurseries or preschool* or pre-school*) near/3 (breakfast* or catering or diet* or dinner or dinners or dining or lunch* or meal or meals or food or foods or snack or snacks)):ti,ab,kw

#115 ((breakfast next club*) or (catering next service*)):ti,ab,kw

#116 (mealtim* or (meal next tim*) or (meal next environment*)):ti,ab,kw

#117 ("packed lunches" or "tuck shops" or "snack shops"):ti,ab,kw

#118 (vending next machine*):ti,ab,kw

#119 (#111 OR #112 OR #113 OR #114 OR #115 OR #116 OR #117 OR #118)

[Out-of-School]

#120 MeSH descriptor: [Child Day Care Centers] explode all trees

#121 ((childcare or "child care" or daycare or "day care" or kindergarten* or nursery or nurseries or preschool* or pre-school*) near/3 (based or centred or centered or focus* or setting or tailored or target*)):ti,ab,kw

#122 ((childcare or "child care" or daycare or "day care" or kindergarten* or nursery or nurseries or preschool* or pre-school*) near/2 (program* or intervention)):ti,ab,kw

#123 MeSH descriptor: [Non-Medical Public and Private Facilities] explode all trees

#124 MeSH descriptor: [Leisure Activities] explode all trees

#125 MeSH descriptor: [Physical Education and Training] this term only

#126 MeSH descriptor: [Sports and Recreational Facilities] explode all trees

#127 ((youth or youths or communit* or holiday* or vacation* or activit* or fitness or sport* or recreation* or leisure) near/3 (center or centers or centre or centres or camp or camps or club or clubs)):ti,ab,kw

#128 ((youth or youths or communit* or holiday* or vacation* or leisure) next based):ti,ab,kw

#129 MeSH descriptor: [Movement] this term only

#130 MeSH descriptor: [Fitness Trackers] this term only

#131 (((movement or activit* or fitness) near/2 (app or apps or based or chang* or monitor* or measur* or track*)) or recreation* or sport* or play):ti,ab,kw

#132 (#120 OR #121 OR #122 OR #123 OR #124 OR #125 OR #126 OR #127 OR #128 OR #129 OR #130 OR #131)

[Sleep]

#133 MeSH descriptor: [Sleep] explode all trees

#134 MeSH descriptor: [Circadian Rhythm] this term only

#135 sleep*:ti or ((sleep* near/3 (duration or efficienc* or hygiene or problem* or quality)) or actigraph* or wake or waking):ti,ab,kw

#136 (bedtime* or (bed next time*)):ti,ab,kw

#137 (nap or naps or napping):ti,ab,kw

#138 (#133 OR #134 OR #135 OR #136 OR #137)

[Parenting]

#139 MeSH descriptor: [Parenting] this term only

#140 MeSH descriptor: [Parents] explode all trees and with qualifier(s): [education - ED, psychology - PX]

#141 ((parent* or family or families or guardian or guardians) near/2 (advice or advisory or (behavi* near chang*) or coach* or educat* or focus* or intervention* or program* or project* or psychoeducat* or strateg* or study or support* or therap* or train* or trial)):ti,ab,kw

#142 ((parent* or family or families or guardian or guardians or nonparent*or non-parent*) next (based or centred or centered or focus* or tailored or target*)):ti,ab,kw

#143 ((mother or mothers or moms or father or fathers) next (based or cent* or focus* or tailored or target*)):ti,ab,kw

#144 (nonparent* or non-parent*):ti,ab,kw

#145 (#139 OR #140 OR #141 OR #142 OR #143 OR #144)

[Religion/Culture]

#146 MeSH descriptor: [Religion] explode all trees

#147 MeSH descriptor: [Culture] explode all trees

#148 (religi* or church or churches or spiritual* or faith or faiths):ti,ab,kw

#149 ((cultur* or multicultur* or race or racial*) near/2 (adapted or appropriate or based or center* or centre* or competent or focus* or tailored or translat* or target*)):ti,ab,kw

#150 (#146 OR #147 OR #148 OR #149)

[Public Health]

#151 MeSH descriptor: [Public Health] this term only

#152 "public health":ti,ab,kw

#153 ((complex or co-ordinated or comprehensive or factorial or interdisciplinary or inter-disciplinary or multiple or (multi* next component*) or multicomponent* or multidisciplin* or (multi* next disciplin*) or multidimension* or (multi* next dimension*) or multifactor* or (multi* next factor*) or multifacet* or (multi* next facet*) or multilevel* or (multi* next level*) or multimodal* or (multi* next modal*) or multiparamet* or (multi* next paramet*) or multiecological or (multi* next ecological)) near (intervention* or program* or project* or strateg* or study or support* or system or systems or therap* or train* or trial)):ti,ab,kw

#154 (#151 OR #152 OR #153)

[Digital Interventions]

#155 MeSH descriptor: [Computer Communication Networks] explode all trees

#156 MeSH descriptor: [Telecommunications] explode all trees

#157 MeSH descriptor: [Mobile Applications] this term only

#158 MeSH descriptor: [Cell Phone] explode all trees

#159 MeSH descriptor: [Therapy, Computer-Assisted] this term only

#160 digital*:ti,kw OR (digital near/3 (assist* or based or deliver* or intervention* or pilot or platform* or program* or project* or strateg* or study or support* or system or systems or technolog* or therap* or train* or trial)):ab

#161 (android or app or apps or avatar* or blog* or CD-ROM or (cell* next phone*) or cellphone* or (chat next room*) or chatroom* or cyber* or DVD or eHealth or e-health or "electronic health" or e-Portal or ePortal or ePsych* or e-Psych* or eTherap* or e-therap* or (electronic next forum*) or gaming or (information next technolog*) or (instant next messag*) or ipad or i-pad or iphone or i-phone or ipod or i-pod or podcast or (smart next phone*) or smartphone* or (social next network* next site*) or "social networking" or mHealth or m-health or multi-media or multimedia or "personal digital assistant" or PDA or SMS or smartwatch* or (smart next watch*) or (social next medi*) or telehealth* or tele-health* or telemed* or tele-med* or telemonitor* or tele-monitor* or telepsych* or tele-psych* or teletherap* or tele-therap* or texting):ti,ab,kw

#162 (internet or technolog* or tele* or web):ti,kw or ((computer or e-mail* or email* or messaging or internet* or mobile or online* or on-line or software or technolog* or telecomm* or tele-comm* or (text next messag*) or virtual* or web or WWW) near/3 (assist* or based or deliver* or intervention* or pilot or platform* or program* or project or projects or strateg* or study or support* or system or systems or technolog* or therap* or train* or trial)):ti,ab,kw

#163 (gaming or gamification or (wearable next device*) or wearables or videogame or "video game" or videoconferenc* or (video next conferenc*)):ti,ab,kw

#164 (synchronous or asynchronous or (electronic near/2 deliver*) or eLearning or e-learning or "blended learning"):ti,ab,kw

#165 (screentime or "screen time"):ti,ab,kw

#166 ("self care" and (computers or internet or software)):kw

#167 (#155 OR #156 OR #157 OR #158 OR #159 OR #160 OR #161 OR #162 OR #163 OR #164 OR #165 OR #166)

[Infant Feeding]

#168 MeSH descriptor: [Child Nutritional Physiological Phenomena] this term only

#169 MeSH descriptor: [Child Nutrition Sciences] this term only

#170 MeSH descriptor: [Feeding Behavior] this term only

#171 MeSH descriptor: [Bottle Feeding] this term only

#172 MeSH descriptor: [Infant Formula] this term only

#173 MeSH descriptor: [Milk Substitutes] this term only

#174 MeSH descriptor: [Breast Feeding] explode all trees

#175 MeSH descriptor: [Milk, Human] this term only

#176 MeSH descriptor: [Milk Banks] this term only

#177 MeSH descriptor: [Weaning] this term only

#178 ((bottle next (feed* or fed)) or (breast next (feed* or fed)) or breastfeed* or breastmilk or milk):ti,ab,kw

#179 (formula or formulas):ti or (baby formula* or infant formula* or formula feed* or formula fed):ab,kw

#180 (compliment* near/3 (feed* or fed or meal*)):ti,ab,kw

#181 (#168 OR #169 OR #170 OR #171 OR #172 OR #173 OR #174 OR #175 OR #176 OR #177 OR #178 OR #179 OR #180)

[Maternal-Child Health Services]

#182 MeSH descriptor: [Intersectoral Collaboration] this term only

#183 MeSH descriptor: [Child Health Services] this term only

#184 (("child health" or childhealth or clinic or clinics or community or "health care" or healthcare or (health next sector*) or healthsector* or (inter sector*) or intersector* or hospital or "primary care" or "general practice") near/2 (based or collaborat*)):ti,ab,kw

#185 MeSH descriptor: [Early Intervention, Educational] this term only

#186 ("early care" or "early intervention"):ti,ab,kw

#187 ("Head Start" or HeadStart):ti,ab,kw

#188 MeSH descriptor: [Maternal-Child Health Services] this term only

#189 MeSH descriptor: [Maternal-Child Health Centers] this term only

#190 ((("maternal child" or "mother child") next health*) or MCH):ti,ab

#191 ((maternal or mother or mothers or moms or father or fathers) near/3 (baby or babies or child* or infant* or neonat* or toddler*) near/3 (based or cent* or "health care" or healthcare or service* or program* or intervention*)):ti,ab,kw

#192 (well near/2 (baby or babies or child* or infant* or toddler*) near/2 (centre* or center* or clinic or clinics)):ti,ab,kw

#193 MeSH descriptor: [House Calls] this term only

#194 ((home next visit*) or homevisit* or (house next call*) or housecall*):ti,ab,kw

#195 (home near/2 (based or help or program* or intervention*)):ti,ab,kw

#196 MeSH descriptor: [Community Health Nursing] explode all trees

#197 MeSH descriptor: [Community Health Workers] this term only

#198 ((district or community) NEAR/3 (nurs* or practitioner* or worker*)):ti,ab,kw

#199 MeSH descriptor: [Child Rearing] this term only

#200 MeSH descriptor: [Maternal Behavior] explode all trees

#201 MeSH descriptor: [Health Behavior] this term only

#202 ("child rearing" or ((maternal or mother* or father*) next behavi*)):ti,ab,kw

#203 (#182 OR #183 OR #184 OR #185 OR #186 OR #187 OR #188 OR #189 OR #190 OR #191 OR #192 OR #193 OR #194 OR #195 OR #196 OR #197 OR #198 OR #199 OR #200 OR #201 OR #202)

[Locomotion]

#204 MeSH descriptor: [Locomotion] explode all trees

#205 MeSH descriptor: [Motor Activity] this term only

#206 MeSH descriptor: [Motor Skills] this term only

#207 MeSH descriptor: [Play and Playthings] explode all trees

#208 MeSH descriptor: [Recreation] explode all trees

#209 MeSH descriptor: [Habits] this term only

#210 MeSH descriptor: [Transportation] explode all trees

#211 ("motor skills" or (motor next activit*) or play or playing or playthings or walker* or walking or walks):ti,ab,kw

#212 ("healthy habits" or (activ* next transport*) or cycling or bicycl* or bike or bikes or scooter*):ti,ab,kw

#213 ("24 hour" near/2 (activit* or movement*)):ti,ab,kw

#214 (#204 OR #205 OR #206 OR #207 OR #208 OR #209 OR #210 OR #211 OR #212 OR #213)

[All New Interventions]

#215 (#100 OR #110 OR #119 OR #132 OR #138 OR #145 OR #150 OR #154 OR #167 OR #181 OR #203 OR #214)

[Age Group: Early Years]

#216 MeSH descriptor: [Infant] this term only

#217 MeSH descriptor: [Infant, Newborn] explode all trees

#218 MeSH descriptor: [Infant Care] explode all trees

#219 MeSH descriptor: [Child] explode all trees

#220 ("early years" or baby or babies or newborn* or neonat* or infant* or infancy or toddler*):ti,ab,kw

#221 (child* or preschool* or pre-school* or boys or girls):ti,ab,kw

#222 (kindergarten* or nursery or nurseries):ti,ab,kw

#223 (pediatric* or paediatric*):ti,ab,kw

#224 (#216 OR #217 OR #218 OR #219 OR #220 OR #221 OR #222 OR #223)

[New Interventions + (Overweight/Obesity or BMI) + Early Years]

#225 ((#8 OR #88) AND #215 AND #224)

[Rolling search including all terms for 'early years']

#226 ((#8 OR #88) AND #72 AND #224)

#227 (#225 OR #226)

#228 (#227 NOT #83) [Difference set, new studies not retrieved by the rolling search]

[Date limited, records added to CENTRAL trials database, 01/01/1990 onwards]

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CONTRIBUTIONS OF AUTHORS

Developed concept of the review: TM, SP, CS

Drafted the protocol: TM, SP, NH, RH, YG, KH, CS

Drafted and developed the search strategy: SD

DECLARATIONS OF INTEREST

- Sophie M Phillips: declares that they have no conflict of interest.
- Theresa HM Moore: reports being employed by Cochrane as a Methodology Editor.
- Nicola Heslehurst: declares that they have no conflict of interest.
- Rebecca K Hodder: reports working as a Program Manager, Hunter New England Population Health, Hunter New England Local Health District, responsible for the delivery of chronic-disease prevention programs in secondary schools.
- Sarah Dawson: declares that they have no conflict of interest.
- Yang Gao: declares that they have no conflict of interest.
- Kathryn Hesketh: declares that they have no conflict of interest.
- Carolyn D Summerbell: reports being affiliated with the WHO, and contributed to their work on 'Ending Childhood Obesity'.

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- No sources of support provided, Other

  No sources of support provided

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- No sources of support provided, Other

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