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Article

A review of registered randomized controlled trials for the prevention of obesity in infancy

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Abstract: Childhood overweight and obesity is a worldwide public health issue. Our objective was to describe planned, ongoing and completed randomized controlled trials (RCTs) designed for the prevention of obesity in early childhood. Two databases (World Health Organization International Clinical Trials Registry Platform, ClinicalTrials.gov) were searched to identify RCTs with the primary aim of preventing childhood obesity and at least one outcome related to child weight. Interventions needed to start in the first two years of childhood or earlier, continue for at least 6 months postnatally, include a component related to lifestyle or behaviors, and have a follow up time of at least 2 years. We identified 29 unique RCTs, implemented since 2008, with most being undertaken in high income countries. Interventions ranged from advice on diet, activity, sleep, emotion regulation and parenting education through individual home visits, clinic-based consultations or group education sessions. Eleven trials have published data on child weight related outcomes to date, though most were not sufficiently powered to detect significant effects. Many trials detected improvements in practices such as breastfeeding, screen time and physical activity in the intervention groups compared to the control groups. Further follow-up of ongoing trials is needed to assess longer-term effects.

Keywords: Behaviours; Childhood; Infant feeding; Interventions; Obesity; Prevention; Physical activity.

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1. Introduction

Childhood obesity is a worldwide public health issue with an estimated 38.3 million children under five years affected by overweight or obesity in 2019 (1). Between 1980 and 2015, the global prevalence of obesity in children in the 2-4 year age group rose almost twofold, from 3.9 to 7.2% in boys and from 3.7 to 6.4% in girls (2). Children who are overweight in early childhood are more likely to remain overweight or obese in later childhood, adolescence and adulthood (3). Obesity in childhood can affect a child's immediate health as well as their educational attainment and quality of life (4). Obesity has been associated with an increased risk of non-communicable diseases such as type 2 diabetes, cardiovascular disease and many cancers (5). This in turn has implications for health systems as well as economies.

With recognition of the rise in prevalence of obesity in early life and its resulting consequences, there has been an increasing focus on the first 1000 days, from conception to 2 years, as a critical life stage to prevent obesity (4, 6). Obesity-related behaviours such as poor diet quality, decreased physical activity, increased sedentary behaviours and decreased sleep duration are established in, and track from, early life (7). Evidence has accumulated about the best ways to support parents to establish protective behaviours and influence their child's trajectory toward healthy growth, and several early intervention trials have been conducted. In Australasia, for example, four RCTs of early obesity prevention interventions including over 2000 mother-child dyads have been undertaken since 2008 (8-11) and the results have been combined in an individual participant data prospective meta-analysis (12) undertaken by the Early Prevention of Obesity in Childhood (EPOCH) Collaboration (13). The interventions that were tested included a combination of promoting and extending the duration of breastfeeding, introducing appropriate healthy solid foods after 6 months, limiting discretionary foods, promoting parental responsiveness to feeding cues, ensuring adequate sleep and activity patterns and limiting screen time. The prospective meta-analysis showed that children in the intervention group had lower body mass index (BMI) z-scores at 18 to 24 months than children in the control group (−0.12 adjusted mean; 95% confidence interval, −0.22 to −0.02, P =0.017), which is equivalent to a 2% absolute reduction in the prevalence of overweight and obesity. Improvements were also detected in behaviours which may protect against obesity, such as reduced television viewing time, improved feeding practices, and increased breastfeeding duration. Although the effect size of the interventions on BMI z-score was modest, it is important on a population-level scale, and the observed improvements in behaviours in early life may have consequences in later childhood.

Several trials evaluating interventions for obesity prevention in early life started in the last decade. However, intervention content and delivery features within these trials are often not clearly defined, and therefore interventions are difficult to replicate. In addition, because of the complexity of most interventions it is not clear which components of the intervention have contributed to the positive effects, if any, of the interventions. It also remains unknown at which age to commence interventions, the optimal duration and intensity of the interventions, and the best delivery methods and agents for effective implementation. Important contextual factors that underlie interventions such as level of background health care and features of the target population may influence the level of effectiveness (14). Qualitative analyses including process analysis of behavioural interventions showing how they work and in which population groups are lacking (15).

Clinical trial registries offer a valuable resource to understand the landscape of planned and ongoing clinical trials in a particular area (16). Since the International Committee of Medical Journal Editors (ICMJE) declared clinical trial registration an 'ethical obligation' in 2005, registration rates of trials have increased substantially, providing a more complete database of clinical trials that are planned, ongoing or recently completed (17, 18). The Australian NHMRC Centre of Research Excellence in the Early Prevention of Obesity in Childhood (EPOCH CRE) has established a repository of registered trials to identify and describe the features of early obesity prevention intervention trials and identify evidence gaps in this critical area (19). Trial registries are regularly searched to identify RCTs evaluating preventive behavioural interventions designed to reduce childhood obesity according to predefined criteria. The ultimate aims of this repository are to improve data quality by sharing information about tools and measurements and to promote collaboration among trialists.

In this review we aim to conduct descriptive analyses to understand features of registered RCTs which aim to reduce the risk of overweight and obesity in children in the first two years. We review the

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intervention components, the features of delivery and implementation including mechanisms and agents, the theoretical models that they are based on, the target populations, and examine funding sources. Our purpose is to summarise the accumulating evidence for the primary prevention of obesity in children and identify promising intervention features, in order to inform future health promotion programmes and policies.

2. Methods

2.1 Search strategy

As part of our ongoing research work in the EPOCH CRE, the World Health Organisation (WHO) International Clinical Trials Registry Platform and ClinicalTrials.gov have been searched every three to five months since April 2016 by K.H. in order to identify eligible trials to add to the EPOCH CRE Trial Repository (19). Search terms included variations of 'infant', 'child' 'overweight', 'obesity' and 'prevention'.

Registration records were screened and studies were included if (1) they were RCTs, (2) the main aim was to prevent childhood obesity, (3) the intervention commenced within the first two years or antenatally, (4) continued for at least 6 months postnatally, (5) included a component related to lifestyle, and (6) the trial had a follow-up period of at least two years from baseline. Published papers for each of the eligible trials were identified using the registration number and/or study title via the PubMed database. For trials with multiple publications, all relevant publications were used to extract pertinent information. For studies which had published results, information was extracted from the final published papers, while studies with only a protocol or clinical trial registration record were coded as per the latest protocol or record. The latter studies were included as our purpose was to describe not only completed interventions and their results, but also the type of interventions that are currently being planned or undertaken.

2.2 Data extraction

For each eligible trial the following information was extracted: registration number, study title, principal investigator, protocol/results publication year, recruitment country/ies, study design, number of participants, timing of intervention commencement, timing of baseline data collection, primary outcome(s), secondary outcome(s), delivery agent, main intervention components and the type of control group.

Detailed data on intervention characteristics were extracted using an adapted version of the Template for Intervention Description and Replication (TIDieR) reporting guidelines (20). Intervention commencement was coded as antenatal or post-natal and intervention setting was coded as clinic/community-based, home-based or both. Delivery agent was coded according to who provided the intervention to participants (e.g. nurses, dietitians, psychologists, etc.) and intervention mode was coded as individual, group, individual and group, telephone or mobile application, or a combination of these. Intervention delivery referred to the implementation materials (such as educational handouts, educational videos) as well as procedures (such as home visits or through mobile applications). Target populations were coded by ethnicity, socio-economic position, literacy level and parental weight status. Funding sources were categorised as government, non-government organisation, university, industry, or mixed. Where available, theoretical model, cost data and biomarkers were also extracted. Where data for some variables were missing, trialists were contacted to provide further information.

Data were extracted by two investigators (D.M.J. and L.R.) then cross-checked for accuracy by a third investigator (S.M). Inconsistencies were settled through discussion.

2.3 Quality assessment

All trials with published weight related data were included in the quality assessment using the Cochrane Risk of Bias tool version 2 (RoB2) for randomised trials (21). Risk of bias assessment was undertaken on all publications including follow up publications. Each trial was assessed independently by

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two reviewers (S.M. and D.J.) as "low risk" or "high risk" of bias or having "some concerns". Disagreements were resolved through discussion. No trials were excluded from the review based on the results of the risk of bias assessment.

2.4 Data synthesis

Findings are presented in data tables and summarised in the text. Only descriptive comparisons were performed as described in section 2.2 above.

3. Results

Electronic searches identified 2292 records. After removing duplicates and applying the inclusion and exclusion criteria, 29 unique trials met our eligibility criteria and are summarised in Table 1. To date 38% (n=11) have published outcomes (22-32). Of the trials that haven't yet published outcomes, 12 are ongoing, one has not progressed because of funding issues, and the remaining 5 trials have a status which is unclear in terms of their level of progression/completion. Most trials have been conducted/planned in high income countries, with the majority being undertaken in the USA (n=12, 41%), with the remainder being in Australia (n=5, 17%), the Netherlands (n=3, 10%), Sweden (n=2, 7%), New Zealand (n=2, 7%), Italy (n=1, 3%) and Spain (n=1, 3%). Three trials (10%) have been planned in low- and middle- income countries (Mexico, Guatemala, and China) although one has not progressed due to lack of funding (33).

The majority of trials are parallel group RCTs (n=20, 69%). There are three trials with factorial RCT designs, which have more than one intervention arm, and there are six cluster RCTs for which participants were randomised at the group level.

It is worth noting that three trials - INFANT Extend (34), CHAT (35) and Greenlight Plus (36) - build on the earlier foundation trials of INFANT (9), Healthy Beginnings (8) and Greenlight (37), respectively. There are similarities to the foundation trials in the intervention components but the duration of interventions are lengthened (34) or new methods of delivery are being trialled (35, 36).

INSERT Table 1: Summary of early intervention studies for the prevention of obesity in infancy (N=29)

3.1 Intervention Characteristics

In approximately a third of the 29 trials (n=9, 31%) the interventions have commenced or plan to commence antenatally, and in a further eight trials (28%) intervention commencement occurs when the child is one month old or younger. In the remaining 12 trials (41%) the interventions commence when the child is between 1 and 12 months of age. The duration of interventions ranges from nine months to six years, with an average duration of 23.3 months (SD 14.8). In three trials, the duration of the intervention is unclear (and there was no response from trial authors who were contacted). A total of 83% (n=24) of trials targeted 'parents' or 'mothers and caregivers' while 17% (n=5) specifically targeted mothers.

Most interventions (55% n=16) were delivered or plan to be delivered in community settings such as clinics, a further six (21%) were based within the home and seven interventions (24%) use a combination of home and community settings.

In terms of intervention mode, the majority of interventions (n=10, 34%) were delivered face-to-face individually, four (14%) are delivered in a group setting, such as a parent support group, and a further four (14%) use a combination of individual and group delivery. In two trials (7%) the interventions were completely delivered via telephone or mobile application, and the remaining trials used a combination of delivery modes for the interventions (n=9, 31%).

Most trials involve multiple forms of delivery methods (Table 2). In terms of materials, the majority use some form of educational handouts (n=24, 83%) and are either delivered at the home visit, clinic or group session or mailed out. Two trials (7%) involve educational videos and five trials (17%) include an

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educational website or application. Three trials use an "educational tool kit" which was tailored to low literacy populations. In terms of the procedures, six trials (21%) involved consultations with health professionals over the phone and in four trials (14%) the intervention was delivered through text messages.

INSERT Table 2: Intervention delivery materials and procedures

Interventions were delivered by a range of health professionals and researchers (Table 3), with nurses being the most common (n=9, 31%). Five interventions were nurse-led in clinics and four were delivered through nurse home visits. Dietitians delivered the intervention in five trials (17%), community health workers also in five trials (17%), trained research assistants in four (14%), and paediatric residents/paediatricians also in four (14%). Other delivery agents included lactation consultants, general practitioners, midwives, physiotherapists and trained sleep specialists. In six trials (21%) a combination of delivery agents was used.

Insert Table 3: Intervention delivery agents

3.2 Intervention components/content

Most trials include between three and eight intervention components and target multiple behaviours as part of the interventions (Table 4). The most common component was providing general advice about healthy dietary behaviours in children (n=24, 83%), followed by encouraging play and activity (n=20, 69%), breast/bottle feeding advice (n=16, 55%), and targeted parenting practices, especially education around hunger and satiety cues (n=13, 45%). Several trials targeted sleep promotion (n=13, 34%), parental modelling of behaviour (n=13, 45%) or limiting small-screen and TV time (n=9, 31%). Other intervention components included how and when to introduce solids (n=10, 34%), limiting junk foods (n=6, 21%), and how to deal with fussy eating (n=5, 17%). Only one trial included information about growth monitoring and growth charts as part of the intervention.

Insert Table 4: Intervention components/key messages

In terms of the specific techniques of delivery, 'anticipatory guidance' was referred to in six (20%) (23, 24, 29, 34, 37, 38) of the 29 trials and 'motivational interviewing' was explicitly used in eight (28%) (27, 37, 39-44) of the 29 trials.

3.3 Target Populations

Fifty-two percent of trials (n=15) target a locally representative population while the remainder target either those of low socio-economic position (n=7, 24%), ethnic minorities (n=5, 17%), a low literacy population (n=1), or a population of parents affected by overweight/obesity (n=1, 3%). It should be noted that the five studies that targeted ethnic minorities could also be grouped as low socio-economic status populations, but they were coded to the ethnic minority group as this was the main focus of the study (40, 45-48).

3.4 Theoretic basis of trials

Of all trials, the use of a theoretic model or theory was stated in 12 (41%) and many of these (n=7, 24%) used multiple theories (Appendix Table 1). The most commonly used theories were Social Cognitive Theory (n=9, 31%) and Social Learning Theory (n=5, 17%). Three trials (10%) used the Health Belief Model.

3.5 Funding Sources

A total of six trials (21%) report solely government funding. Of the remaining trials, the majority (n=14, 48%) reported some form of governmental funding in addition to other funding sources. Most of

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these were jointly funded by non-governmental organisations, universities and industry. The majority of US studies (n=9, 75%) were funded by the National Institutes of Health and The National Institute of Diabetes and Digestive and Kidney Disease, while the Australian and NZ studies were funded by the Australian National Health and Medical Research Council and the Health Research Council NZ, respectively (Appendix Table 2). Universities co-funded (n=10) 34%of studies.

While no studies were solely funded by industry, 6 (21%) had some industry funding, with Meat and Livestock Australia, Heinz, Danone Nutricia and Karitane Products Society contributing to three studies (10%). Two Latin American studies, the SPOON studies in Mexico (33) and Guatemala (49), were to be partially funded by the PepsiCo Foundation but in recent communications one trial has been cancelled (48). In addition to providing funding, Danone Nutricia provided jars of baby food and printed information materials for participants in the Baby's First Bites trial (41).

3.6 Cost effectiveness data

Only five (17%) of the trials stated in the protocols or other publications that they planned to collect (or have already collected) data on costs of the intervention or conduct cost effectiveness analyses. The Healthy Beginnings trial completed a retrospective economic evaluation, where intervention resources were determined from local health district records (50). Healthcare utilisation was determined using patient level data linkage and it was estimated that the program could be delivered for just over AUD$700 per child with a cost-effectiveness ratio of AUD$376 per 0.1 reduction in BMI z-score, which is regarded as a moderately priced intervention.

Three trials (10%) indicated that they will conduct detailed cost effectiveness analyses (35, 44, 51). In addition, the PRIMROSE trial plans to conduct a cost utility analysis (44). The INFANT Extend trial (34) plans to conduct an economic analysis and monitor use of health services in both control and intervention groups to assess whether the program reduces parent's health seeking behaviour elsewhere.

3.7 Biomarkers

Of the 29 trials, only two have planned to collect biomarkers and of these; neither has published results. The INSIGHT trial (52) has conducted genetic testing for appetite, growth, and temperament on the child, mother and father. The SCHeLTI (53) trial will collect blood from the infant as well as other samples (saliva, stool), and blood and other samples will also be collected from the mother and father. It is unclear which tests will be conducted but the samples will form part of a Biobank and be kept for at least 20 years.

3.8 Weight related outcomes

To date 11 trials have reported weight related outcomes (22-32) while nine [(9, 34, 35, 37, 39-41, 47, 48, 54)] have published protocol papers only, and eight [(33, 36, 42, 43, 46, 49, 53, 55)] are in the planning stages and information is only available from the clinical trial registration record.

A comparison of the reported weight related outcomes showed heterogeneity in reported measures, with BMI, BMI z-scores, weight-for-length percentiles, waist circumference and prevalence of overweight and obesity being reported. In addition, the outcomes were reported at different time points.

Of the 11 trials with published outcomes, five [19,39,41,43,44] have follow-up weight outcomes at later time points, up to age 5 years from baseline [20,40,42,57,45], providing further insight into the duration of intervention effects. Retention rates at the first follow up where outcomes were reported ranged from 73% to 92%.

Of the 11 trials, three - POI.nz, Healthy Beginnings and INSIGHT [19, 39,67] - have demonstrated statistically significant differences in weight outcomes between the intervention and control groups at the first follow up. Healthy Beginnings demonstrated a significantly lower BMI at 2 years in its intervention group when compared with the control [Mean difference -0.29 (95% CI 0.02 to 0.55), p=0.04], however there

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was no statistically significant reduction in BMI observed in follow up at 3.5 or 5 years of age. INSIGHT reported different outcomes at 1 and 3 years and demonstrated a reduced weight for length percentile at 1 year of age and a reduced BMI z-score at 3 years of age [Mean difference -0.28 (95% CI -0.53 to 0.01), p=0.04] in the intervention group compared to the control group; however there was no difference in mean BMI percentiles at 3 years of age. An overall group effect for the prevalence of obesity at 2 years was observed in the POI.nz study (p=0.027). Participants receiving the "sleep intervention" (including the sleep and combination group) demonstrated a lower prevalence of obesity when compared to the "food, physical activity and breastfeeding" (FAB) and control groups (OR= 0.54, 95% CI 0.35–0.82). Children who received the sleep intervention (sleep and combination groups) had significantly lower BMI *z*-scores at age 3.5 years (−0.24; 95% CI: −0.38, −0.10) and at age 5 years (−0.23; 95% CI: −0.38, −0.07) than children who did not (control and FAB groups).

It is important to note that many of the studies were not adequately powered to achieve statistical significance for weight-related outcomes. The effect sizes were generally small and BMI ranged from mean differences of 0.06 to 0.3 kg/m2, and for BMI z-scores differences ranged from 0.01 to 0.3.

INSERT table 5: Effectiveness of trial interventions on weight outcomes

3.9 Secondary outcomes

Secondary outcomes are shown in Table 5. They were related to behaviour change and included duration of breastfeeding, child diet and eating habits, physical activity, screen time, sleep and health-related parenting practices. Of the 11 trials with published outcomes we identified a total of 105 unique secondary outcomes collected across the trials, with 75% (n=81) related to diet and infant feeding.

INSERT table 6: Secondary outcomes

3.10 Risk of bias assessment

Risk of bias assessment was undertaken on the fifteen publications (of 11 trials) [13,15,19,15, 26,27,28,31, 35,39,41,43,44, 54,(56-58)] with weight related outcomes. Ten of the fifteen were judged as low risk in all risk of bias domains (67%), a further 4 were judged as high risk, and one study was judged as having "some concerns". Almost all (14/15) had a low risk of bias arising from the randomisation process, and one study was deemed as high risk. Two of fifteen studies had some concerns or a high risk of bias arising from "the effect of assignments to interventions" and "measurements of outcomes", while the remaining thirteen in both domains were low risk. Most studies were judged as low risk in regard to missing outcome data (13/15; 87%), however the remaining two studies were deemed as high risk of bias in this domain. For selection of reported results, all 15 studies had low risk of bias in this domain. Assessments by trial are shown in Appendix table 3 and Figure 1 shows the summary of risk of bias assessments.

4. Discussion

This review examined RCTs with a behavioural/lifestyle intervention focused on obesity prevention in infancy and shows the range of trials and intervention components being implemented in different contexts at varying stages of completion. We summarised the key characteristics and features of interventions including the behavioural targets, delivery mechanisms and agents, duration of interventions and target populations. We also examined the theoretical basis for interventions and whether economic evaluations were carried out and assessed the funding sources of these interventions. Interventions were designed to influence a range of important behavioural targets including early feeding and diet, physical activity, sleep, sedentary time and parenting.

Of the 11 trials that were completed and reported weight related outcomes, two (22) (56) have shown a small but significant beneficial effect of interventions on child BMI z-score at 2 years of age and one found significant improvements in the prevalence of obesity, but not BMI (59). It is possible that some trials

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may not have been powered to detect intervention effects for weight-related outcomes, so it remains uncertain whether these interventions are effective in reducing BMI z-score. The EPOCH Collaboration demonstrated how combining trial data in a meta-analysis can substantially increase the statistical power to detect an intervention effect for weight-related outcomes. The four included trials had minimal power on their own (all less than 0.35) to detect the observed intervention effect of 0.12 on BMI z-score at $p<0.05$. However, their combined power was 0.83 (60).

Encouragingly, many trials showed impacts on weight-related behaviours such as improving the duration of breastfeeding, improving healthy food intake and reducing discretionary foods. These behaviours may be important for long term obesity risk and other health outcomes. This also demonstrates the need to understand the intervention components that are responsible for the changes in behaviours, how they work and for whom, so that they can be implemented in the most efficient manner in the most appropriate populations (61).

It is also important to note that to date only one trial (56) has shown a sustained effect on BMI lasting until 3 years. This phenomenon, described as the 'fade out effect'(62), is common in interventions that begin in early childhood and are delivered for short time frames, resulting in the effects not being sustained. This may imply that early interventions need to be of a longer duration and may need complementary interventions as children grow, in order for impacts to remain and make substantial changes to a child's growth trajectory. Trials which have begun recently with duration of implementation of the interventions over 3 and up to 6 years will be able to contribute more definitive answers on whether early interventions can contribute to preventing obesity in the longer term (39, 53).

Our review has shown a high degree of heterogeneity in the way primary and secondary outcomes are collected and reported. For example, there was a wide range of weight related outcomes such as BMI, BMI Z-score, weight for length percentile, waist circumference and prevalence of overweight and obesity that were assessed at differing ages and time points. Likewise, for dietary outcomes there was a wide range of different measures for similar outcomes. For example, intake of fruit and vegetables was reported as grams/day, times/day and serving size/day which varies with age and between countries. These variations precluded our ability to pool data and conduct a meta-analysis. This highlights the need for standardisation of outcomes related to infant weight and behaviours to facilitate outcome harmonisation and synthesis (63), and the need for a core outcome set for early childhood obesity interventions (64).

Our review included interventions focused on individual behaviours rather than targeting the wider environmental determinants such as the food and built environments, despite many of the interventions being delivered in a community setting. These interventions are important, given the age group – most infants spend a large proportion of their time at home with their parents. Although we are not able to draw specific conclusions given the small sample sizes and lack of power to show effects in most trials, the home setting was used in some studies and may be more advantageous in terms of dose, tailoring, delivery and participant convenience. Individual or face-to-face interventions may have some advantages over group or indirect methods, such as online interventions (65). In general, with face-to-face interactions the intervention delivery agents are more tuned to the individual's needs and capabilities and can tailor the intervention to suit (66). During the first year, parents are likely to seek extra advice and therefore they may be more receptive to skill development and parental advice promoting healthy family eating and physical activity (9). As children learn from, and model parental physical and health-related activity levels, targeting parental engagement in infancy also features heavily in recent studies.

The rise in interventions that use online modes of delivery and delivery through telephone or text messages is encouraging as it means that interventions can be delivered cheaply, quickly and conveniently at scale. The question remains whether these interventions are effective and as acceptable as those delivered face-to-face individually or in group settings. Process and impact evaluation of these modes of delivery are currently lacking (15) however, with situations such as the coronavirus disease (COVID-19) crisis these modes may be a pragmatic way for interventions to be delivered (67), and future studies should focus on the effectiveness of alternative modes of delivery.

The studies were coded to seventeen domains of intervention content which targeted multiple areas, demonstrating the complexity in the evaluation of trials. In most studies there is a lack of detail about the

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specific content used within interventions, and this limits the transferability of the study approach. This highlights the importance of deconstructing interventions to their smallest common elements (61) to determine which components are actually driving the effects. In addition, it was difficult to ascertain dose of intervention delivered with few studies providing statistics and information on the average number of clinics/groups/home visits attended and adherence to the protocol, which again may influence the effectiveness of study results. Although some interventions were based on theory, and some on multiple theoretical models, most did not state the theoretic basis for the intervention.

It is logical to conclude that by improving health-related behaviours the flow-on effect will be to improve weight related outcomes, but as highlighted, many trials did not achieve statistical significance and this may have been because of a lack of power to show effects. An alternative explanation may be that most of the interventions were delivered for a relatively short duration over one or two years. Longer durations may be important to create sustained change and prevent intervention 'fade out'. Interventions in this age group were focused at the individual level of diet and activity and as children get older it would be important to look at the wider social and environmental factors which may play an additional role in the development of obesity.

There is a critical knowledge gap with respect to the ideal duration of interventions and when to intervene. Accumulating evidence has highlighted the influence of the preconception and perinatal periods for preventing childhood obesity and non-communicable disease later in life (68-71). It is possible that many trials have not targeted women early enough, with only three trials with published outcomes starting antenatally. Only one trial (which is currently in progress) has randomised women preconception (53). Interventions starting in preconception could prove more effective and at least one study has found a dose response association between preconception BMI and offspring's childhood BMI, so future research in this area is warranted (69).

5. Limitations

This review was limited by the fact that we only searched trial registries to identify eligible trials. This may mean that some unregistered trials were not identified, however, registration has been a requirement for all trials since 2005 (18), and a recent study found high rates of registration since this requirement came into effect (17). Another limitation was that for some of the trials the intervention characteristics were coded from clinical trial registry information and in some cases these were very brief and not up-to-date. This may have led to some missing information. We attempted to contact trialists for missing information and where possible published protocol papers were used to code and categorise the intervention components.

Effectiveness in all of the trials was defined as a statically significant difference in weight related outcomes in favour of the intervention compared to controls as described by the trial authors. Because some trials had small sample sizes this would have resulted in inadequate power to detect a significant effect. This problem has been overcome in the four Australasian trials, which have collaborated to conduct an IPD prospective meta-analysis, resulting in improved power to detect effects (72).

In many of the trials there were high loss to follow up rates. This suggests that the intensity of interventions and participant burden should be considered when designing interventions and health promotion programs. It also shows that some form of early process analysis signifying participant satisfaction with trials should be considered (15).

There were a relatively small number of trials with published data that met the review criteria and many of the studies included multi-component interventions which made comparisons between trials difficult. However, the number of studies that will progress to reporting outcomes in the future holds promise for more definitive evidence for effective intervention strategies.

6. Conclusion

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This review shows the breadth of work that is occurring across trials for the prevention of obesity in children, globally. We have described the key characteristics and features of trials including the behavioural targets, delivery mechanisms and agents, duration of interventions and key target populations. In the coming years, more trials are likely to publish their results and it will be possible to ascertain which intervention strategies are most effective for prevention of childhood obesity. The complexity of multicomponent interventions means that evaluating these interventions is difficult and complex methods will need to be employed to show which intervention components at which doses and via which delivery methods are most effective. This may be achieved by bringing together researchers from all relevant trials to share data and learnings to transform the thinking and practices around early childhood obesity prevention- the TOPCHILD collaboration aims to achieve this (73).

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Table 1: Characteristics of early intervention studies for the prevention of obesity in infancy (N=29)

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	Registration No	Trial Name/Acronym	Ref no Author, Year (if published)	Country	Study design	Number randomized	Intervention commencement	Duration of follow up	Primary outcome(s)	Secondary outcome (s)	Delivery mode	Intervention components	Controls
1.	ACTRN12607000168459	Healthy Beginnings	Wen 2012 (74) Wen 2015 (57)	Australia	RCT	N=667 mother-child dyads	Antenatally	Birth until 5 years	Child BMI z score at child age 2 and 5 years	Infant feeding practises, TV viewing time, active play time, mothers dietary behaviours	Nurse home visits	The nurse visited eight times at home, once at 30-36 weeks' gestation and seven times after the birth (at 1, 3, 5, 9, 12, 18 and 24 months). Four key areas included infant feeding practices, child nutrition and active play, family physical activity and nutrition, and social support.	Usual care: 1x Community health nurse home visit plus home safety promotion materials at 6 and 12months.
2.	ISRCTN81847050	InFANT	Campbell 2013 (23)	Australia	Cluster RCT	N= 542 parent-child dyads	Mean 3.8 months	Child age 4months until 20 months	Child diet (3x 24 hour diet recalls), child physical activity (accelerometry) and child TV viewing (parent report)	BMI z scores	Sessions with dietician in pre-existing mothers groups, supportive materials (DVD, written materials and newsletter)	Six 2 hour sessions of education delivered by dietician targeting nutrition, physical activity and sedentary behaviour occurred within pre-existing mothers groups, commencing at 3 months at 3monthly intervals (3, 6, 9, 12, 15 and 18 months). Didactic sessions, group discussion and peer support. Reinforced by purpose designed DVD and written materials plus newsletter between sessions	Usual care with Maternal and Child health nurse plus 6 newsletters regarding unrelated aspects of child health or development
3.	ACTRN12608000056392	NOURISH	Daniels 2013 (24) Daniels 2015 (58)	Australia	RCT	N=698 mother-child dyads	Child age 4 months	Child age 4 months until 5 years	BMI z score at 24months and 5 years	Maternal feeding practices	Educational group sessions in supported by detailed written information	Two educational group session modules (6 fortnightly sessions each) commencing at infant age 4-7months and again at 13-16months supported by detailed written information regarding repeat food exposure to variety of foods, responsive feeding and cues, health child food intake, reduce TV viewing, promotion of authoritative parenting style, managing food fussiness	Usual care: standard community child health services

4.	NCT 00756626	Feeding Young Children Study: Bottle Weaning Intervention (FYCS)	Bonuck 2013 (75)	USA	RCT	N=300 parent-child dyads	12months of age	Child age 12 months until 24 months	Bottle use frequency	Anthropometric measurements, age and sex specific weight-for-length. Dietary intake and nutrient density	Educational counselling, education materials and a incentive sippy cup	Conducted at WIC; Educational counselling about bottle feeding via a flip-chart was given to parents (with messages about healthy weight, dental caries and iron def anaemia), an education pamphlet to share with family members and a sippy cup was provided. Baseline anthropometric measurements (height and weight), sociodemographic survey and dietary intake assessment were all completed at baseline (12months), 15months, 18months, 21months and 24months	Usual care: Routine visits to Women, Infants and Children's (WIC) sites
5.	NCT 00892983	POI.nz	Fangupo 2015 (38) Taylor 2016 (ref) Taylor 2018 (26)	New Zeal and	2x2 factorial RCT	N=802 parent-child dyads	Antenatally	Antenatally to 2 years of age (follow up study has data at 3.5 and 5 years of age)	Weight velocity (0-6, 6-12, 12-24months) and BMI z scores at 24months	Sleep and physical activity (parent report, accelerometry), duration of breastfeeding, timing of solid introduction, diet quality, measures of family function and well being	Home visits and group sessions	3 intervention groups. FAB (Feeding, Activity and Breastfeeding): 8 additional visits for education and support around breastfeeding, food and activity (breastfeeding focus at antenatal and 1 weeks of age, food related at 4,7,13 and 18months and physical activity at 3,9 and 18months age) provided by lactation consultants and trained research nurses. Reinforced with written and visual information. SLEEP: 2 additional reviews providing guidance and resources home sleep (group antenatal session and home visit at 3 weeks). Combination: both (i.e. 9 intervention visits/sessions	Usual care: Routine Well Child checks (6 core visits in the first 18months)

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6.	NTR 1831	The BeeBOFT Study	van Grieken 2017 (27)	Netherlands	Cluster RCT	N=2102 parent-child dyads	1month of age	Child age 1 month to 36 months	Health-related behaviour (breakfast daily, activity and outside play, sweetened beverage consumption, television viewing and computer time), BMI and prevalence of overweight and obesity at 36 months of age	None listed	Web-based eHealth module and discussion of personalised advice during regular well child visit	E-health4Uth Healthy Toddler- parents completed an online module which provided personalised education regarding their childs nutritional habits and physical activity at 18months and 24 months. This was followed by face-to-face counselling by the YHC professional to parents during routine well child visits. Parents completed questionaries regarding family characteristics and health-related behaviours when child 1month, 6months, 14months and 36months of age	Usual care: Routine well baby visits at 18 and 24 months with general information on child health-related behaviour was provided to parents
7.	**NCT01040897**	GREENLIGHT	Sanders (37)	USA	RCT	N= 865 parent-infant dyads	Child age 2months	Child age 5months to 2 years	BMI at 2 years	Child dietary intake, physical activity and injury prevention behaviours	Tool kit' with written information, routine reviews with trained paediatric resident in primary care clinics	Low-literacy toolkit for parents, a health-communication curriculum for child-health providers, including modules on goal-setting techniques, educational toolkit, a clinician-centred curriculum for providing low-literacy guidance on obesity prevention. - Behaviour-change components administered by paediatric residents at each well-child visit from 2 months to 24 months.	Usual care: plus, injury prevention program (attention placebo)
8.	NCT03370445	Addressing Health Literacy and Numeracy to Prevent Childhood Obesity	Cruzatt (42)	USA	RCT	N= 450 parent-child dyads (estimate)	Child age 2 months	Child age 2months to 5 years	Proportion of children at 24months who are not overnight (BMI)	Weight status of children at 5 years of age (BMI z score)	'Tool kit' with written information, routine reviews with trained paediatric resident in primary care clinics	Interaction with Paediatric resident physicians who are trained in improved health communication skills. Also provided with low literacy handouts and study-related 'gifts' to assess nutrition and physical activity behaviours and reinforce evidence based	Usual care: plus injury prevention program (attention placebo)

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												recommendations about early childhood nutrition and physical activity	
9.	NCT 0116 7270	INSIGHT	Savage 2016 (28) Adams 2018 (76) Savage 2018 (77) Paul 2018 (56)	USA	RCT	N= 279 mother-child dyads	Child age 1-2 weeks	Child age 1-2 weeks to 3 years	BMI at 3 years	Patterns of infant weight gain, infant sleep duration, maternal responsiveness, , maternal feeding style, infant dietary content and physical activity.	Mailed educational visits, trained nurse home visits, research centre visits and phone calls to deliver messages	At 2 weeks post -partum, intervention materials were mailed to the participant's home. Research nurses conducted home visits at 3,16, 28, and 40 weeks, and a research centre visit occurred at 1 year. parents are taught how to identify and respond to infant hunger and satiety cues and are also educated on growth charts	Usual care: Routine care plus trained research nurse home visits, research centre visits, phone calls that delivered home safety intervention (strategies to prevent Shaken Baby Syndrome and child abuse, treatment of fever and other first aid remedies, fire, bath, and car seat safety are discussed.)
10.	NCT 0119 8847	Early STOPP	Sobko (39)	Swe den	RCT	N= 200 families	Child age 1 year	Child age 1 year to 6 years	BMI at 6 years	Physical Activity, sedentary behaviour, motor function/development, sleeping habits, food intake, eating patterns and quality of life.	Trained coach (dietitian, physiotherapist or a nurse), phone calls, mailed information, home visits, clinic visits, booklets	One educational and one individually targeted coaching. The educational material (booklets) is developed for correspondent age (1, 2, 3, 4, 5 and 6 years) and is given to the parents. The coaching is delivered by a trained coach four times the first year and twice a year after which takes place in the family's home, or at the clinic.	Usual care: Routine Child Health Care Clinic plus general health newsletter at baseline
11.	ACT RN1 2611 0003 8693 2	INFANT Extend	Campbe ll (34)	Aust ralia	Cluster RCT	N= 540 mother-child dyads	Child age 3months	Child age 3 months to 36 months	BMI z score and waist circumference at 36 months	Dietary quality, physical activity, screen time	Online educational content, emailed newsletters, nutrition expert	Melbourne InFANT Program content will be delivered via six emailed newsletters (3 monthly from child age 18 months to 3 years Educational content will be made available online. First-time parent group will be mediated by a nutrition expert, for up to one hour per week.	Usual care: Routine care in Maternal and child Health Centres plus general health newsletters ever three months for three years

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12.	NCT 01541761	Starting Early Obesity Prevention Program	Gross (78)	USA	RCT	N= 533 women-child dyads	Antenatally	Antenatally to 3 years (published data exists at 3 months)	Reduction in prevalence and degree of obesity at 3years (BMI percentiles), diet composition, infant lifestyle behaviours (better sleep habits, reduced screen time, increase physical activity), improvement in parent feeing knowledge attitudes, styles and practices.	(2x 3month published data: Infant feeding practices and maternal infant feeding knowledge (study 1) and infant activity time (Study 2)	Individual nutrition/breast feeding counselling, educational curriculum in group sessions at well baby visits supported by handouts and DVDs	Individual nutrition/breastfeeding counselling, 15 nutrition and parenting support groups (NPSG) coordinated with well child visits, supported with plain language handouts and nutrition education DVDs. (Visits: prenatal consultation on breastfeeding, lactation support on postnatal ward, then 15 group sessions at 1,2,4,6,9,12, 15,18,21,24,27,30 and 33 months)	Usual care: Standard prenatal visits then standard Paediatric primary care (at 5days, 1month, 2months and 4months) then
13.	NCT 01649115	HLPP	Reddy (54)	USA	RCT	N=150 parent-child dyads	Antenatally	Birth to 5 years	Change in child's gender-specific WFL z-score at 4 to 6 months of age	BMI at child age 2 and 5 years, Mothers Knowledge,	Two face to face meetings with registered dietician and once on phone, nutritional education handout	The first meeting, they will be receiving the Healthy Lifestyles Passport, including the interactive nutrition education. The second meeting is a post-test assessment and Newest Vital Sign Assessment Tool.	Usual care plus meeting with registered dietician twice and once on home with standard care information and handouts
14.	ACTRN12612001133820	Baby-led introduction to solids (BLISS)	Taylor 2017 (29)	New Zeal and	RCT	N= 206 women	Antenatally	Antenatally until child age 24months	Body Mass Index at 12months (and follow-up at 24 months)	Energy self regulation Eating behaviours Energy intake	Home visits, face to face meetings and phone calls with lactation consultant and trained researcher.	8 additional contacts from pregnancy to 9 months of age. 5 meetings with lactation consultant antenatally, at 1 week, 3-4 weeks, 3-4months and 5 months (3x face to face and 2x via telephone,10-60mins duration) to support prolonged milk feeding and delay of complementary feeding until 6months. Followed by face to face meetings (30-60min) with trained researcher at 5.5, 7and 9	Usual care: routine midwifery and well child care

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												months with individualised advice to support to assist mothers with above plus further education on appropriate foods and feeding cues. Questionnaires on baby led approach adherence at 6, 7, 8, 9, 12, and 24 months. BMI calculated at 12 and 24 months. Secondary outcomes assessed via questionnaires at 12 and 24 months.	
15.	NCT 01905072	Preventing Childhood Obesity through Early Guidance	Reifsnider 2013 (48)	USA	RCT	N=140 pregnant women	Antenatally	Child age 1 week to 3 years	BMI at 3 years	Age of solid food introduction and dietary intake, Breast/Bottle feeding practises, Sleep, Screen time	Child health care worker home visits, phone calls, Women Infant and Children's (WIC) clinic	Monthly phone calls regarding breastfeeding status. Home visits at 36 weeks of pregnancy; at 3 days after birth; at 2 weeks of age; and at 2, 4, 6, 9, 12, 18, and 24 months. Printed materials with key concepts; growth monitoring, feeding, parenting, activity, and sleep.	Usual care: Routine WIC clinic care plus home visits to monitor measurements and monthly breastfeeding survey calls
16.	ISRCTN 16991919	PRIMROSE	Doring, 2016 (44)	Sweden	Cluster RCT	N=1369 infants (1355 families)	Child age 9-10months	Child age 9-10 months to 4 years	Four-year-old children's BMI and Waist Circumference	Mother and child eating habits (FFQ), Mother and child physical activity (accelerometer/ validated questionnaire), Mothers' BMI & waist circumference.	Intervention operates within Child Healthcare Centres, 5 sessions with CHC trained nurses on child health behaviours	Nurses assist parents to change their own health behaviours and to promote healthy dietary and physical activity behaviours in their children. Parents are offered individual session when child is 9-10 months old, then group and phone sessions at 1.5,2,3, and 4 years old.	Usual care: Regular age-related health check ups
17.	PMC4424409	Early Obesity Prevention	Schroeder, 2015 (31)	USA	Cluster RCT	N= 232 infants	Paediatric visit at 1 month of age	All paediatric visits at 1, 2, 4, 6, 9, 12, 15, 18, and 24 months of age, and at annual	BMI, BMI Z score, triceps skinfolds, weight	Parental dietary practices, breastfeeding duration, SNAP participation	Face to face, during all paedatric visits up till 24 months. Supportive phone call once a month and reminder post cards with short	Families receive "growing leaps and bounds " program which includes : nutrition, physical activity, feeding practices, eating patterns, enhancing parents self-efficiency to care for infants, helping parents make healthy food choices for their infants and themselves	Usual care: standard paediatric visits

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								visits up to age 5 years			educational messages	The 12 sets of educational brochures are discussed at 1, 2, 4, 6, 9, 12, 15, 18, and 24 months paediatric visits	
18.	ACTRN12616001470482	CHAT	Wen 2017 (35)	Australia	RCT (3 arm)	N=1056 mother-child dyads	Antenatally	Third trimester to child age 1 year	BMI z-score at 12 and 24 months, breastfeeding rate at 12 months, and timing of introduction of the solids at 6 months	Child TV viewing time at 12 and 24 months; dietary quality at 24 months	Mailed educational material, telephone or SMS support	Intervention arm 1 (SMS): Text messages providing information about healthy infant and child feeding and lifestyle twice a week for 4 weeks. Intervention arm 2 (telephone support) 6 staged intervention packages by mail followed by a phone call from the research nurse within 1–2 weeks nurse and discuss the issues or concerns raised by the mother.	Usual care: Routine childhood nursing services from Community Health Services plus home safety promotion material and newsletter on Kids Safety 4 times over the study period
19.	NCT03077425	CHALO	Karasz, 2018 (47)	USA	RCT	N=360 mothers of children 4-6 months old	Home visits at 6 months of age	Children aged 6 months till 18 months	Quantity of sippy cups/ bottles, number of sippy cups/bottles a day (My smile buddy)	Weight for length, BMI for age Z score, weight velocity Z score, added sweeteners/solids, fruit and vegetables/day, sweetened beverages, use of bottles/sippy cup at bed time, sweet and salty snacks, physical activity, screen time, tooth brushing, dental visits, caries	Home visits by community health workers, follow up telephone support, patient navigation to keep timely dental visits, pamphlets	n=6 home visits by health works: four of the home visits include only mother-child dyads which focus on building rapport, intimacy, identifying risks or family concerns, education, discussing goals, enhance mother skills to identify infant hunger/satiety cues, and oral hygiene practices. Two of the home visits at 8 and 14 months included either the father or mother in law	Enhanced usual care, pamphlet containing ECC and obesity prevention messages. and dental referrals,
20.	NCT03131284	Prevention of Obesity in Toddlers (PROBIT) Trial	Morandi 2019 (32)	Italy	RCT	N=529 parent-newborn dyads (confirm)	First 2 weeks of life	Newborn to 2years of age	BMI at 24 months of age	BMI at 12months, lifestyle and feeding practices in the first 2 years of life	Educational programme by Paediatricians during routine visits	Paediatricians were trained to provide parents with standardized lifestyle counselling supported by educational written material about the first two years of life during routine visits at 1, 3, 6, 12 and 24 months.	Usual care: Routine visits with regular Paediatrician at 1, 3, 6, 12 and 24 months

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21.	NL6727 (NTR6938)	"Samen Happie!" An mHealth intervention to prevent obesity through parenting	Karssen L 2017 (55)	The Netherlands	RCT	N= 300 parent-child dyads (estimate)	7-11months	7-11months until 4 years	Child BMI at 6months, 12months to 4 years.	Parental parenting weight-related behaviours (eating, drinking, sleeping, physical activity/screen time) Weight-related behaviours of the child (healthy eating, drinking, sleeping, and exercise) General parenting style Parental wellbeing (e.g., including depression, self-reported health, happiness) Parental cognitions (e.g., including parenting related self-efficacy and motivation)	Mobile application	Mobile application that teaches parents about health parenting practises and styles, but also allows parents to practice through various challenges. The information is grouped into four important determinants: eating, drinking, sleeping and exercise	Waitlist control condition (receive the app after the 12month intervention period)
22.	NCT03334266	Preventing Early Childhood Obesity, Part 2: Family Spirit Nurture, Prenatal - 18 Months	Ingalls 2019 (40)	USA	RCT	N=338 expectant mothers (estimate)	Antenatally	Antenatal (36 weeks) until child age 24months	BMI z scores Breast and complementary feeding rates Implementation of infant and toddler responsive feeding behaviours Consumption of fruits and vegetables Calorie intake from sugar sweetened beverages (SSB), snacks, and desserts,	Maternal stress Maternal depression Maternal alcohol and drug use Infant and maternal metabolic health	Home visits by trained Family Health Liaison	36 comprehensive lessons delivered biweekly from 28 weeks until birth, weekly from birth until 3months, bi weekly from 3 to 6months, monthly from 6months to 18months.	Standard Optimised Standard of Care (OSC) transportation assistance to prenatal appointments and well-baby clinic appointments PLUS 8 home visits with educational lessons on injury prevention topics (attention placebo)

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									Physical activity levels. Screen time and other sedentary activities				
23.	NCT 03348176	Baby's First Bites: Promoting Vegetable Intake in Infants and Toddlers	Van der Veek 2019 (41)	Netherlands	RCT factorial	N= 240 mother-child dyads	Child age 4 months	Child age 4 months until 36 months	Vegetable consumption, vegetable liking and self-regulation of energy intake	Child eating behaviours, child anthropometrics (BMI) and maternal feeding behaviour	Phone calls, home visits, video feedback	3x intervention arms. Repeated vegetables exposure (RVE)- exposure to either green beans or cauliflower as target vegetable during first 19days of weaning. 5x phone calls to motivate parents to exposure children at 4-6, 8, 13 and 16months. Video feedback Intervention to promote Positive Parenting Feeding of infants (VIPP-FI)- exposure to fruits and sweet vegetables during first 19days of weaning, 5x home visits using video feedback to promote sensitive feeding at 4-6, 8, 13 and 16months. COMBI-RVE+VIPPFI	Usual care: plus attention control condition- 5x phone calls with mother about development of child, no advice on complementary feeding
24.	NCT 03399617	SPOON: Guatemala	Gonzalez 2018 (49)	Guatemala	RCT	N= 1500 care giver-child dyads (estimate)	0-6months	0-6months until 24months	Infant and young child feeding practices Child Height Weight gain rate Haemoglobin Prevalence of obesity in children (BMI) Prevalence of stunting Prevalence of anaemia	Adherence to Nutritional Supplement Regime, Exclusive Breastfeeding	Home visits, group sessions and community mobilisation activities, dietary supplement	2x intervention groups: SPOON behavioural change strategy+SQ-LNS: Participants will receive Small Quantity Lipid-based Supplements (SQ-LNS) from 6-24 months and a behavioural change to promote adequate infant and young child feeding practices and the use of SQ-LNS will be delivered to mothers or caregivers. SPOON behavioural change strategy+MNPs: Participants will receive micronutrient powders (MNPs) from 6-24 months and a behavioural change to promote adequate	Usual care: Participants receive standard health care services provided by the Ministry of Health, including micronutrient powders (MNPs)

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												infant and young child feeding practices and the use of MNPs will be delivered to mothers or caregivers. Behaviour change strategy uses ethnographic and marketing methods to promote adequate infant and young child feeding practices and the use of SQ-LNS	
25.	NCT 0343 8721	Strong Futures	Beck 2018 (46)	USA	RCT	N=240 parent-child dyads (estimate)	Child age 2weeks	Child age 2 weeks until 24months	Child dietary intake Child screen time Parent health-related quality of life	Child anthropometrics (BMI z score at 6, 12, 15 and 24months) Parent financial stress Child sleep Parental feeding styles	Education program during well child visits	Parents will receive education on infant feeding, sleep, and screen time practices just after well-child visits in the first year of life (2 weeks, 2, 4, 6, 9 and 12months). The education will be provided by a lay health educator. Parents will also receive text messages to reinforce the intervention content	Usual care: plus financial coaching; education on financial topics i.e. budgeting, savings, managing debt (provided by lay health educators trained in financial coaching), reinforced by text messages
26.	NCT 0344 4415	PROGESPI	Perez-Lopz 2018 (43)	Spain	Cluster RCT	N=414 parent-child dyads (estimate)	Antenatally	Antenatally until 24months age	BMI at 24months	Weight growth rate, Food intake habits in parents, physical activity in parents, Smoking habit in parents, Anthropometry of parents (BMI), duration of breastfeeding, Child dietary habits, Physical activity patterns in children, Sleep habits, sociodemographic variables	Motivational Interviewing in groups	6x 90minute group workshops (2x during pregnancy, 4x within two years after birth) by trained researchers (GP, nurses, Paediatricians and midwives) to encourage healthy lifestyles to parents, encourage breastfeeding and increase knowledge and self-efficacy to promote health habits re diet, physical activity and sleep habits	Usual care: General information about height, weight and BMI percentile by health professionals during well child visits

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27.	Chi CTR 1800 0177 73	SCHeLTI (Sino-Canadian Healthy Life Trajectory Initiative)	Wu 2018 (53)	Chin a	Cluster RCT	N=4000 mother-child dyads (estimate)	6 weeks	6 weeks until 5 years	BMI at 5 years	Fat mass index (child) at 5 years, skinfold thickness at 5 years, birthweight for gestational age prior to hospital discharge after delivery, weight-for-length z-score at <2 years of age	Face to face education sessions, group educational activities, text messaging, motivational web-based tools and apps, community based activities	Multifaceted intervention aiming to positively change behaviour with patient centred face to face sessions, group educational activities and social supports, text messaging to encourage personal goals and barriers to behaviour changes, motivational web-based tools and apps for self monitoring and community based activities	Usual care: plus access to web-based tools and Apps that provide information on child health and safety.
28.	NCT 0375 2762	SPOON-Mexico	Martine z 2018 (33)	Mex ico	RCT	N=1200 care giver-child dyads (estimate)	0-6months	0-6months until 24months	Infant and young child feeding practices Height Weight gain rate Haemoglobin Prevalence of obesity Prevalence of stunting Prevalence of anaemia	Adherence to Nutritional Supplement Regime, Exclusive Breastfeeding	Home visits, group sessions, dietary supplement	SQ-LNS supplement from 6-24 months and an innovative behavioural change strategy designed using ethnographic and marketing methods to promote adequate infant and young child feeding practices and the use of SQ-LNS via home visits and group sessions. Data recorded at child age 6, 9, 12, 15,18, 21 & 24 months	Usual care: Standard health care services provided by the Health Secretary
29.	NCT 0404 2467	Greenlight plus study(55)	Rothma n 2019 (36)	USA	RCT	N=900 parent-infant dyads	First newborn clinic visit	All child Dr visits from 0-24 months	Child weight for length trajectory	Weight for length Z score, BMI Z score trajectory, child overweight or obese	During all child clinic visits from 0-24 months	Families will receive the Greenlight intervention plus a health information technology (HIT) intervention aimed at supporting family goal-setting and behavior change. They will receive instructions on how to access the Greenlight technology platform (iOTA text messaging and website) Families will consistently receive text messages and goals set for children in the first two years of life	During childs clinic visits from 0 -24 months, parents will the receive the basic Greenlight material (low literacy, age specific education booklet) to promote healthy lifestyle and obesity prevention

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Table 2. Intervention delivery materials and procedures of early intervention studies for the prevention of obesity in infancy (N=29)

Intervention Delivery	Materials							Procedures			
Trial name	Educational handout	Educational handout (image-based)	Educational video	Low literacy educational tool kit	Educational website/app	Educational material mailed out	Feeding supplement	Nutrition and parenting support groups	Phone call consultation	Home Visits	Educational text messages
TOTAL N (%)	**15(52)**	**4(14)**	**27)**	**3(10)**	**5(17)**	**5(17)**	**2(7)**	**7(24)**	**6(21)**	**12(41)**	**4(14)**
Healthy Beginnings	x										
InFANT	x										
NOURISH	x							x			
FYCS	x										
POI.nz	x	x						x		x	
BeeBOFT						x				x	
GREENLIGHT	x			x							
Addressing Health Literacy and Numeracy to Prevent Childhood Obesity	x			x							
INSIGHT						x				x	
Early STOPP	x					x			x	x	
InFANT EXTEND					x	x					
Starting Early Obesity Prevention Program		x	x					x			
HLPP	x								x		
BLISS	x	x								x	
Preventing obesity	x								x	x	

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through early guidance											
PRIMROSE										x	
Early Obesity Prevention:	x				x						
CHAT		x				x			x		x
CHALO	x								x	x	
PROBIT	x										
Samen Happie					x						
Family Spirit Nurture										x	
Baby's first bites			x						x	x	
SPOON-Guatemala							x	x		x	
Strong Futures											x
PROGESPI								x			
SCHeLTI					x			x			x
SPOON-Mexico							x	x		x	
Greenlight plus	x			x	x						x

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Table 3: Intervention delivery agent

Intervention Delivery Agent Trial name	Nurse home visits	Nurse clinic visits	Registered Dietitian	Lactation consultants	Trained Research assistants	Community Health Worker	Community Health Worker Home visits	Nutrition expert	Paediatric residents/ Paediatrician	Psychologist	Family Practitioners	Midwives	Physiotherapist	Trained Sleep Specialists	Multidisciplinary
Total N(%)	**5 (17)**	**5 (17)**	**5 (17)**	**3 (10)**	**4 (13)**	**1 (3)**	**4 (13)**	**2 (7)**	**4 (13)**	**1(3)**	**1(3)**	**1(3)**	**1(3)**	**1(3)**	**2(7)**
Healthy Beginnings	x														
InFANT		x	x												
NOURISH			x							x					
FYCS			x												
POI.nz	x			x										x	
BeeBOFT						x									
GREENLIGHT									x						
Addressing Health Literacy and Numeracy to Prevent Childhood Obesity									x						
INSIGHT	x														
Early STOPP	x	x	x										x		
InFANT EXTEND								x							
Starting Early Obesity Prevention Program				x				x							
HLPP			x												
BLISS				x	x										x
Preventing obesity							x								

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through early guidance															
PRIMROSE		x													
Early Obesity Prevention		x							x						
CHAT	x														
CHALO							x								
PROBIT									x						
Samen Happie															
Family Spirit Nurture					x										
Baby's first bites					x										
SPOON-Guatemala							x								
Strong Futures					x										
PROGESPI		x							x		x	x			
SCHeLTI															x
SPOON-Mexico							x								
Greenlight plus									x						

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Table 4. Intervention components/key messages of early intervention studies for the prevention of obesity in infancy (N=29)

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Trial name/acronym	Breast feeding/Bottle feedng advice	Intro of solids	Limit junk foods (eg sweets)	Repeat food exposure	Healthy dietary behaviours in children	Food serving size	Parenting/ hunger satiety cues	Parent modelling	Fussy eating	Soothe/ Sleep	Sleep promotion	Play/ activity	Tummy time	TV/ screen time	Oral hygiene practices	Growth chart education	HIT technology access education	Health-communication curriculum
Total N (%)	**16 (55)**	**10 (34)**	**6 (21)**	**3 (10)**	**24 (83)**	**5 (17)**	**13 (45)**	**13 (45)**	**5 (17)**	**3 (10)**	**10 (34)**	**20 (69)**	**3 (10)**	**9 (31)**	**1 (3)**	**1 (3)**	**1 (3)**	**2 (7)**
Healthy Beginnings	x	x	x		x		x	x	x	x		x		x				
InFANT					x		x	x	x			x		x				
NOURISH				x	x		x	x										
FYCS	x																	
POI.nz	x	x			x						x	x						
BeeBOFT			x		x							x		x				
GREENLIGHT	x				x			x			x	x		x				x
Addressing Health Literacy and Numeracy to Prevent Childhood Obesity	x				x			x			x	x		x				x
INSIGHT				x	x		x		x	x	x	x				x		
Early STOPP					x						x	x						
InFANT EXTEND					x		x	x	x			x		x				
Starting Early Obesity Prevention Program					x	x	x	x	x	x	x	x						
HLPP					x	x												
BLISS	x	x					x											
Preventing obesity through early guidance	x		x				x					x						
PRIMROSE					x			x				x						
Early Obesity Prevention		x	x		x	x	x	x				x						

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CHAT	x	x			x	x		x				x	x	x				
CHALO	x	x					x					x	x		x			
PROBIT	x	x	x		x	x	x					x						
Samen Happie	x				x						x	x						
Family Spirit Nurture	x		x		x		x	x				x	x	x				
Baby's first bites		x		x			x											
SPOON-Guatemala	x	x			x													
Strong Futures					x						x			x				
PROGESPI	x				x			x			x	x						
SCHeLTI	x				x						x	x						
SPOON-Mexico	x	x			x													
Greenlight plus					x			x									x	

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Table 5. Effect of trial interventions on weight outcomes in early intervention studies for the prevention of obesity in infancy

Study, Author, Year	Sample Size	Primary Outcome	Reported Outcome at End of Follow up		Effect size
			Control Group	Intervention Group	
Healthy Beginnings, Wen 2012	N= 667 *N=497	BMI 2 years	16.82	16.53	Mean difference -0.29 (95% CI 0.02 to 0.55), p=0.04
Wen 2015	*N=415	BMI at 3.5years	16.8	16.74	Mean difference -0.06 (95% CI -0.41 to 0.28) p=0.33
		BMI z score at 3.5 years	0.97	0.89	Mean difference -0.08 (95% CI -30 to 0.16) p=0.44
	*N= 369	BMI 5 years	16.28	16.31	Mean difference 0.3 (95% CI -0.30 to 0.37) p=0.06
		BMI z score at 5 years	0.63	0.65	Mean difference 0.02 (95% CI -0.19 to 0.22) p=0.06
INFANT, Campbell, 2013	N=542 *N=457	BMI (z score) at age 20 months	0.8	0.8	Mean difference -0.01 (95% CI -0.16 to 0.13), p=0.86
INFANT, Hesketh, 2020	*N=361	BMI (z score) at age 3.6 years	-	-	Mean difference 0.05 (95% CI -0.1 to 0.19),
		Waist circumference at 3.6 years	-	-	Mean difference -0.01 (95% CI -0.12 to 0.19),
	*N=337	BMI (z score) at age 5 years	-	-	Mean difference -0.02 (95% CI -0.2 to 0.16),
		Waist circumference at 5 years	-	-	Mean difference 0.01 (95% CI -0.17 to 0.20),

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NOURISH, Daniels, 2013	N=698 *N= 530	BMI z score age 2 years	0.75	0.61			Mean difference -0.14, p= 0.10
Daniels, 2015	*N= 424	BMI z score age 5 years	0.41	0.34			Mean difference 0.07, p =0.06
Feeding Young Children Study, Bonuck, 2013	N=300 *N=135	Reduction in weight for length >85th percentile	-	-			OR 1.01 (95% CI 0.9 to 1.1), p=0.8
POI.nz, Taylor 2017		BMI at 2 years	16.9	FAB 17.1	Sleep 16.8	Both 16.8	P=0.086(overall)
		BMI z score age 2 years	0.77	FAB 0.92	Sleep 0.68	Both 0.72	P= 0.104(overall)
		Waist circumference at 2 years	46.7	FAB 47.0	Sleep 46.6	Both 46.9	P=0.610(overall)
		Prevalence of overweight and obesity at 2 years	68	FAB 73	Sleep 61	Both 70	P= 0.770(overall)
		Prevalence of obesity at 2 years	33	FAB 40	Sleep 19	Both 21	P=0.027(overall) FAB v Sleep group (odds ratio [OR], 0.46 [95% confidence interval (CI), 0.25–0.83]; P = .011 FAB v combination group (OR, 0.51 [95% CI, 0.28–0.90]; P = .022) Sleep and combination v FAB and control (OR, 0.54 [95% CI, 0.35–0.82]; P = .004)
POI.nz, Taylor 2018	N=808 *N= 616	BMI z score at age 3.5years	0.68	FAB 0.81	Sleep 0.54	Both 0.56	p=-0.004 (overall) FAB v Control difference 0.15 (95% CI -0.04 to 0.34) Sleep v Control difference -0.16 (95% CI -0.36 to 0.04) Both v Control difference -0.18 (95% -0.37 to 0.02)

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	*N= 557	BMI z score at age 5 years	0.39	FAB 0.66	Sleep 0.31	Both 0.44	p=0.004 (overall) FAB v Control difference 0.25 (95% 0.04 to 0.47) Sleep v Control difference -0.14 (95% CI -0.36 to 0.09) Both v Control difference 0.06 (95% CI -0.29 to 0.16)
BeeBOFT, Grieken, 2017	N=2102 *N= 1543	BMI (mean) at 36 months	15.66	15.78			Mean difference 0.12, p=0.12
		Prevalence of overweight/obesity (%) at 36 months	3.99%	4.77%			0.78% difference in prevalence, p=0.51
INSIGHT Savage, 2016	N=291 *N=250	Weight-for-length percentile at 1 year of age	64.4%	57.5%			Mean difference 6.9% 95% CI (52.6%-69.0%) p=0.4
INSIGHT Paul, 2018	*N=232	BMI z-score at 3 years of age	0.15	-0.13			Mean difference -0.28 (95% CI -0.53 to 0.01), p=0.04
		Mean BMI percentiles	54th	47th			Difference 6.9 percentile points (95% CI -14.5 to 0.6) p=0.7
BLISS, Taylor, 2017	N=206 *N= 178	BMI z score age 12 months	0.20	0.44			Adjusted difference, 0.21, (95% CI -0.7 to 0.48)
	*N=166	BMI z score age 24 months	0.24	0.39			Adjusted difference 0.16, (95% CI -0.13 to 0.45)
PRIMROSE, Doring, 2016	N=1369 *N=1148	BMI at 4 years of age	16.1	16			Mean change -0.11 (95% CI -0.31 to 0.08), p=0.26
		Waist Circumference (cm) at 4 years of age	53	52.5			Mean change -0.48 (CI -0.99 to 0.04), p= 0.07
		Prevalence of overweight and obesity at 4 years of age	15.5%	14.8%			RR 0.95 (95% CI 0.69 to 1.32) p=0.78

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Early Obesity Prevention: Schroeder 2015 (31)	N=292 *N=278	BMI at baseline	15.03	15.29	Mean difference 0.26
		BMI Z score at baseline	-0.152	-0.283	Mean difference -0.435
		Weight at baseline	4.56	4.91	Mean difference 0.35, P<0.006
	*N= 218	BMI at 12 months	17.29	17.23	Mean difference -0.06
		BMI Z score at 12 months	0.539	0.492	Mean difference -0.047
		Weight at 12 months	9.81	9.85	Mean difference 0.04, P>0.05
	*N=232	BMI at 24 months	16.20	16.34	Mean difference 0.14
		BMI Z score at 24 months	0.218	0.339	Mean difference 0.121
		Weight at 24 months	12.61	12.76	Mean difference 0.15, P>0.05
PROBIT, Morandi, 2019	N=569 *N= 529	Prevalence of overweight/obesity (%) at 2 years of age	26.3%	23.8%	3% difference in prevalence, p=0.49

***Number that completed the study**

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Table 6. Effectiveness of trial intervention on secondary outcomes

Study, Author, Year	Sample size	Outcome	Reported Outcome at End of Follow up		Effect size
			Control Group	Intervention Group	
Healthy Beginnings, Wen 2012, Wen 2015	N=667	Infant feeding practices Vegetable ≥1 serving/day	83%	89%	Difference: 7, CI (1 to 13) p=0.03
		Fruit ≥1 serving/day	93%	90%	Difference: -2, CI (−7 to 3), P=0.43
		Food for reward	72%	62%	Difference: -9,CI (−17 to −1), P=0.03
		Water >3 cups/day	19%	24%	Difference 6, CI (-1 to 13), P=0.12
		Hot chips/French fries	88%	86%	Difference -1, CI (-7 to 5), p=0.65
		Salty snack	70%	65%	Difference -5, CI (-13 to 4), p=0.29
		Sweet snack every day	77%	73%	Difference: -4, CI (-12 to 4) p=0.31
		Soft Drink	26%	24%	Difference: -3, CI (-10 to 5) p=0.48
		Outdoor play ≥120 minutes/day	61%	62%	Difference: 1, CI (-8 to 9) p=0.9
		TV on during meal	76%	66%	Difference: -10,CI (-18 to -2) p=0.02
		Eat dinner in front of TV	68%	56%	Difference:-12, CI (-21 to -3) p=0.01
		Viewing TV >60 minutes/day	22%	14%	Difference: -8,CI (-15 to -1) p=0.02
INFANT, Campbell, 2013	N=457	Child diet at 20 months -Fruit intake (g/d)	152.9	161.2	Mean difference 13.33 (95% CI -2.59 to 29.25), p=0.1

		Vegetable intake (g/d)	80.8	85.3	Mean difference 6.62 (95% CI -2.51 to 15.76), p=0.16
		Water intake (g/d)	338.7	362.9	Mean difference 30.28 (95% CI -3.30 to 63.87), p=0.08
		Noncore drink intake (g/d)	25.4	23.7	Mean difference -5.56 (95% CI -17.48 to 6.36), p=0.36
		Sweet snack intake (g/d)	14.7	11.0	Mean difference -3.60 (95% CI -6.34 to -0.86), p= 0.01
		Savory snack intake (g/d)	5.8	4.8	Mean difference -1.02 (-2.82 to 0.79), p=0.27
		Child physical activity (min/d)	236.8	224.1	Mean difference -2.03 (95% -9.75 to 5.70), p=0.61
		Television viewing (min/d)	60.6	45.5	Mean difference -17.12 (95% CI -26.45 to -7.79), p=<0.001
INFANT, Hesketh, 2020	N=361	Child diet at 3.6 years Fruit intake (g/d)	-	-	Standardised effect size 0.23 (95% CI 0.01 to 0.45)
		Vegetable intake at 3.6 years	-	-	Standardised effect size 0.28 (95% CI 0.05 to 0.51)
		Water intake at 3.6 years	-	-	Standardised effect size 0.41 (95% CI 0.14 to 0.67)
		Fruit variety at 3.6 years	-	-	Standardised effect size 0.13 (95% CI -0.10 to 0.35)
		Vegetable variety at 3.6 years	-	-	Standardised effect size 0.24 (95% CI 0.03 to 0.45)
		Non core drinks at 3.6 years	-	-	Standardised effect size 0.08 (95% CI -0.18 to 0.33)
		Sweet snacks intake at 3.6 years	-	-	Standardised effect size -0.24 (95% CI -0.42 to -0.07)
		Savory snack intake at 3.6 years	-	-	Standardised effect size -0.06 (95% CI -0.23 to 0.12)

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		Television viewing at 3.6 years	-	-	Standardised effect size -0.08 (95% CI -0.25 to 0.09)
		Sitting time at 3.6 years	-	-	Standardised effect size -0.13 (95% CI -0.49 to 0.23)
		Child physical activity at 3.6 years	-	-	Standardised effect size 0 (95% CI -0.26 to 0.27)
		Light intensity PA at 3.6 years	-	-	Standardised effect size 0.17 (95% CI -0.11 to 0.44)
		Moderate to vigorous PA at 3.6 years	-	-	Standardised effect size -0.21 (95% CI -0.50 to 0.08)
	N=337	Child diet at 5 years Fruit intake (g/d)	-	-	Standardised effect size 0.07 (95% CI -0.14 to 0.27)
		Vegetable intake at 5 years	-	-	Standardised effect size 0.11 (95% CI -0.10 to 0.32)
		Water intake at 5 years	-	-	Standardised effect size 0.19 (95% CI -0.03 to 0.40)
		Fruit variety at 5 years	-	-	Standardised effect size 0.12 (95% CI -0.10 to 0.33)
		Vegetable variety at 5 years	-	-	Standardised effect size 0.14 (95% CI -0.06 to 0.34)
		Non core drinks at 5 years	-	-	Standardised effect size -0.17 (95% CI -0.33 to -0.00)
		Sweet snacks intake at 5 years	-	-	Standardised effect size -0.26 (95% CI -0.47 to -0.05)
		Savory snack intake at 5 years	-	-	Standardised effect size 0.00 (95% CI -0.22 to 0.23)
		Television viewing at 5 years	-	-	Standardised effect size -0.15 (95% CI -0.33 to 0.03)

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		Sitting time at 5 years	-	-	Standardised effect size -0.08 (95% CI -0.26 to 0.10)
		Child physical activity at 5 years	-	-	Standardised effect size 0 (95% CI -0.26 to 0.25)
		Light intensity PA at 5 years	-	-	Standardised effect size 0.15 (95% CI -0.09 to 0.38)
		Moderate to vigorous PA at 5 years	-	-	Standardised effect size -0.16 (95% CI -0.42 to 0.18)
NOURISH, Daniels, 2013	N=698 *N= 466	Response to refusal of familiar foods Insist child eats it At 2 years	37(90)	18(39)	P<0.001
	*N= 464	Offer milk drink instead At 2 years	22 (53)	14 (30)	P=0.022
	*N= 465	Offer liked food instead At 2 years	78 (189)	63 (140)	P=0.001
	*N= 466	Encourage to eat: turn mealtime into game At 2 years	57 (139)	21 (47)	P<0.001
	*N= 465	Offer food reward At 2 years	31 (75)	9 (19)	P<0.001
	*N= 464	Encourage to eat: offer nonfood reward At 2 years	27 (65)	18 (39)	P=0.026
	*N= 464	Accept that child may not be hungry; take food away At 2 years	91 (222)	96 (213)	P=0.033
	*N= 457	Response to refusal of unfamiliar foods (neophobia)c Assume child dislikes; do not offer again At 2 years	13 (32)	5 (11)	P=0.033
	*N= 456	Disguise food At 2 years	65 (156	45 (98)	P<0.001
	*N= 462	Offer with liked food At 2 years	94 (229)	94 (206)	P=0.99
	*N= 465	Times offered a food before deciding whether liked ($ 6 times) At 2 years	35 (87)	72 (159)	P<0.001
NOURISH Daniels, 2015	*N=390	Response to refusal of familiar foods Insist child eats it at 5 years	65 (126)	48 (94)	P=0.001
	*N=391	Offer milk drink instead at 5 years	6 (11)	3 (6)	P=0.22

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	*N=389	Offer liked food instead at 5 years	41 (78)	37 (72)	P=0.47
	*N=391	Encourage to eat Feed child with spoon/fork at 5 years	53 (103)	42 (84)	P=0.034
	*N=390	Offer food reward at 5 years	63 (120)	42 (83)	P<0.001
	*N=390	Offer nonfood reward at 5 years	39 (74)	29 (58)	P=0.055
	*N=391	Responsive feeding strategies Offer no food until next usual meal/snack time at 5 years	64 (123)	77 (152)	P=0.006
	*N=389	Accept that child may not be hungry; take food away at 5 years	79 (152)	88 (173)	P=0.014
	*N=382	Response to refusal of unfamiliar foods (neophobia)b Assume child dislikes; do not offer again at 5 years	14 (27)	13 (25)	P=0.88
	*N=382	Disguise food at 5 years	53 (102)	41 (78)	P=0.018
	*N=391	Offer with liked food at 5 years	92 (178)	93 (184)	P=0.85
		Times offered a food before deciding whether liked (#6 times) at 5 years	55 (107)	39 (77)	P=0.002
Feeding Young Children Study, Bonuck, 2013	N=135	Bottle frequency (any use, %)	44%	33%	11% difference in prevalence, p=0.25
POI.nz Fangupo 2015	N= 495	Offered 2 fruits a day (%)	Control + sleep 94%	FAB + Sleep 96%	RR 1.02 (95% CI to 0.98 to 1.06), p=0.455
		Offered 2 vegetables a day (%)	Control + sleep 96%	FAB + Sleep 98%	RR 1.02 (95% CI 0.99 to 1.05), p=0.282
		Used a cup, not bottle (%)	Control + sleep 47%	FAB + Sleep 53%	RR 1.13 (95% CI 0.95 to 1.35), p=0.16

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		Daily breakfast (%)	Control + sleep 91%	FAB + Sleep 93%				RR 1.02 (95% CI 0.97 to 1.08), p-0.375
		Family dinner at the table (%)	Control + sleep 66%	FAB + Sleep 59%				RR 0.9 (95% CI 0.79 to 1.04), p=0.146
		Did not eat meals in front of the TV (%)	Control + sleep 15%	FAB + Sleep 17%				RR 1.16 (95% CI 0.78 to 1.74), p=0.464
	N=502	Household fruit and vegetable availability (mean)	Control + sleep 31	FAB + Sleep 32				RR 0.99 (95% CI -0.5 to 2.48), p=0.194
		Number of obesogenic foods in household (mean number)	Control + sleep 21	FAB + Sleep 21				RR 0.39 (95% CI -0.88 to 1.66), p=0.39
POI.nz Taylor 2018	N=592	Night sleep, duration (hour)	Controls 11.6	FAB 11.5	Sleep 11.6	Combo 11.5		p=0.74
		Night awakenings (number per night)	Controls 1.6	FAB 1.7	Sleep 1.6	Combo 1.5		p=0.66
	N=602	Bedtime resistance score (mean occurrence)	Controls 0.13	FAB 0.15	Sleep 0.11	Combo 0.12		p=0.011
	N=351	Light to vigorous physical activity (mins per day)	Controls 231	FAB 240	Sleep 232	Combo 236		p=0.63
BeeBOFT, Grieken, 2017	N=1543	Health Related Behaviours-Breakfast daily (%)	96.7%	98.3%				1.6% difference, p=0.03
		Activity and outside play (hours/day, mean SD)	2.56	2.68				Mean SD difference 0.12, p=1.9

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		Sweetened sugar beverage consumption (glasses/day, mean)	2.31	2.10	Mean difference -0.21 glasses per day, p=0.003
		Television/computer time (hours/day mean)	1.22	1.05	Mean difference -0.17hours/day, p=<0.001
INSIGHT Adams, 2018	N=279	Met 2012 AAP screen time guidelines -44 weeks -1.5years -2.5years	 30.2 15.9 59.8	 53 23.5 60.9	 P<0.01 P=0.15 P=0.87
		Television on during infant meals -44 weeks -1.5years -2.5years	 45.7% 68.1% 78.4%	 32.5% 48.7% 66.4%	 P=0.04 P<0.01 P=0.05
		Children engagement in daily outdoor play at 2 years	15.1%	30.0%	P=0.01
		Dietary intake of children at 1 year - salty snacks -vegetables daily	 20.3% 89.0%	 9.8% 95.9%	 P=0.03 P=0.049
INSIGHT Savage,2018	N=279	Use of feeding to soothe Context based -8 weeks -16 weeks -32 weeks -44 weeks	 2.83 2.76 2.43 2.56	 2.57 2.50 2.00 2.16	 P=0.008 P=0.009 P<0.0001 P<0.0001
		Emotion based -8 weeks -16 weeks -32 weeks -44 weeks	 2.01 1.90 1.65 1.62	 1.78 1.57 1.36 1.31	 P=0.07 P=0.002 P=0.0003 P=0.0001

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		Adding cereal to bottle -8 weeks -20 weeks -32 weeks	 1.8% 20.0% 14.0%	 5.3% 8.4% 10.2%	 CI [95% 0.6-15.6], P=0.18 CI [95% 0.2-0.8], P=0.01 CI [95% 0.3-1.6], P=0.38
		Put child to bed with bottle/sippy cup -8 weeks -20 weeks -32 weeks -52 weeks	 2.8% 2.8% 7.8% 20.5%	 0% 1.7% 5.3% 10.4%	 P=0.95 CI [95% 0.1-3.6], P=0.56 CI [95% 0.2-1.9], P=0.42 CI [95% 0.2-0.9], P=0.03
		Night time feeds (7pm-7am) -8 weeks -20 weeks -32 weeks	 3.3 2.2 1.7	 3.1 1.8 1.3	 P=0.2 P=0.32 P=0.01
Starting Early Obesity Prevention Program Gross, 2016	N=533 *N=456	Ever breastfed in the hospital	95.3%	95.9%	OR 1.16 (95% CI 0.47 to 2.85), p=0.82
		Exclusive BF in the hospital	31.1%	37.1%	OR 1.31 (95% CI 0.89 to 1.93), p=0.20
		Exclusive BF leaving the Hospital	37.9%	45.7%	OR 1.38 (95% CI 0.95 to 2.01), p=0.11
		Any BM at 3 months	80.4%	83.3%	OR 1.21 (95% CI 0.75 to 1.95), p=0.47
		Exclusive BM at 3 months	23.4%	33.0%	OR 1.61 (95% CI 1.07 to 2.44), p=0.03

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		100% BM on 24 hr diet recall	33%	42.7%	OR 1.51 (95% CI 1.03 to 2.21), p=0.04
		Breastfeeding intensity continuous score (Mean)	59.7	67.7	Mean difference -8.0 (95% CI -15.3 to -0.75), p=0.03
		Ever gave BM and formula at same feed per day	31.1%	22.4%	OR 0.64 (95% CI 0.36 to 1.15), p=0.15
		Introduced tea, water, juice or cereal in bottle at 3 months old	16.7%	6.3%	OR 0.34 (95% CI 0.18 to 0.64), p=0.001
		Total maternal infant feeding knowledge	9.8	10.3	Mean difference 0.51 (95% CI 0.19 to 0.83), p=0.002
Starting Early Obesity Prevention Program Gross,2017	N=533 *N=456	Tummy time (ever)	78.9%	86.4%	OR 1.71 (95% CI 1.04 to 2.8), p=0.04
		Tummy time (daily)	49.6%	50.5%	OR 1.04 (95% CI 0.72 to 1.5), p=0.93
		Tummy time on the floor (ever)	24.1%	40.7%	OR 2.16 (95% CI 1.44 to 3.23), p<0.001
		Tummy time mostly on the floor	5.2%	11.8%	OR 2.44 (95% CI 1.2 to 4.98), p=0.02

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		Mean tummy time per day	1.87	1.96	Mean difference -0.09 (95% CI -0.46 to -0.28), p=0.64
		Mean infant age (weeks) for starting tummy time (SD)	6.90	6.62	Mean difference 0.28 (95% CI -0.75 to 1.31), p=0.60
		Unrestrained floor time (ever	28.9%	40.6%	OR 1.69 (95% CI 1.14 to 2.49), p=0.01
		Restricted time (ever)	85.3%	85.4%	OR 1.00 (95% CI 0.60 to 1.69), p=1.00
		Restricted time (60 min or more)	58.6%	54.3%	OR 0.84 (95% CI 0.58 to 1.22), p=0.39
		Infant bouncy seat (ever)	57.5%	61.2%	OR 0.86 (95% CI 0.59 to 1.25), p=0.45
		Indoor baby swing (ever)	20.7%	20.4%	OR 0.98 (95% CI 0.62 to 1.55), p=1.00
		Car seat when not in a car (ever)	16.4%	9.5%	OR 0.54 (95% CI 0.30 to 0.95), p=0.04
BLISS, Taylor, 2017	N= 160	Energy self-regulation (Mean SD of scale 1-5 based on parental response	4.03	4.01	Mean difference -0.04 (95% CI-0.29 to 0.21)

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		Satiety response (Mean SD of scale 1-5 based on parental response)	3.23	3.01	Mean difference -0.24 (95% CI -0.41 to -0.07)
		Food responsiveness (Mean SD of scale 1-5 based on parental response)	2.41	2.51	Mean difference 0.12 (-0.09 to 0.34)
		Food fussiness (Mean SD of scale 1-5 based on parental response)	2.61	2.43	Mean difference -0.18 (95% CI -0.40 to 0.05)
	N= 113	Child enjoyment of food (Mean SD of scale 1-5 based on parental response)	3.84	4.07	Mean difference 0.24 (95% CI 0.05 to 0.43)
		Energy intake (per day), kj	4084	4026	Mean difference 143 (CI 95% -241 to 526)
PRIMROSE, Doring, 2016	N=1148	Children's eating habits Fruits (t/d)	1.1 (0.03)	1.1(0.03)	0.01(–0.09 to 0.11), P=0.78
		Children's eating habits Vegetables (t/d)	0.9 (0.03)	1.0 (0.03)	0.13 (0.04 to 0.22),P=0.01
		Children's eating habits Fish (t/wk)	1.5 (0.06)	1.6 (0.06)	0.10 (–0.06 to 0.27),P=0.21

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Children's eating habits French fries (t/mo)	1.8 (0.07)	1.5 (0.07)	−0.37 (–0.58 to –0.17), P<0.001
Children's eating habits Sugared drinks (t/wk)	2. 7 (0.15)	2.2 (0.18)	−0.49 (–0.97 to –0.15), P=0.04
Discretionary calories (t/wk)	5.9 (0.12)	5.3 (0.17)	−0.60 (–1.01 to –0.18), p= 0.01
Mothers' eating habits -Fruits (t/d)	1.1 (0.04)	1.2 (0.03)	0.07 (–0.04 to 0.18), P=0.22
Mothers' eating habits -Vegetables (t/d)	1.3 (0.04)	1.3 (0.06)	0.10 (–0.02 to 0.21), P=0.10
Mothers' eating habits -Fish (t/wk)	1.8 (0.07)	2.0 (0.07)	0.18 (–0.01 to 0.38) , P=0.07
Mothers' eating habits -French fries (t/mo)	1.7 (0.10)	1.4 (0.08)	−0.33 (–0.58 to –0.10), P=0.01
Mothers' eating habits Sugared drinks (t/wk)	1.8 (0.11)	1.5 (0.14)	−0.26 (–0.60 to 0.08), P=0.13
Mothers' eating habits Discretionary calories (t/ wk)	5.9(0.12)	5.3(0.17)	−1.00 (–1.72 to –0.28), p=0.01

		Children's physical activity	51 min/day	50.6 min/day	−0.36 (–3.00 to 2.28), P=0.81
		Mothers' physical activity	2.6 (0.04)	2.6 (0.03)	0.07 (–0.02 to 0.16), P=0.13
Early Obesity Prevention: A Randomized Trial of a Practice-Based Intervention in 0–24-Month Infants, 2015	N=232	Tricep skinfold at baseline	7.85	7.94	Mean difference 0.09
		Tricep skinfold at 12 months	8.82	9.70	Mean difference 0.88 P<0.002
		Tricep skinfold at 24 months	8.42	8.83	Mean difference 0.41
		Triceps + subscapular skinfold at baseline	14.45	14.36	Mean difference -0.09
		Triceps + subscapular skinfold at 12 months	15.36	16.46	Mean difference 1.1 P<0.018
		Triceps + subscapular skinfold at 24 months	14.06	14.68	Mean difference 0.62
		Use infant cereal as first complimentary food	-	-	P< 0.001 (INT less likely)

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	Use stage 1 vegetables as first complimentary food	-	-	P<0.05 (INT less likely
	Offered soda	9%	1%	P<0.006
	Sweetened tea	8.2%	1%	P< 0.01
	Punch	5.8%	0%	P<0.02
	Cow's milk	16.2%	2.5%	P<0.001
	Delay introduction of drink and food other than breast milk	-	-	P< 0.05 (INT more likely)
N=186	Perceived feeding responsibility at 24 months	4.45	4.50	Mean difference 0.05 P=0.930
	Perceived parent overweight at 24 months	3.28	3.15	Mean difference -0.13 P=0.409
	Perceived child overweight at 24 months	2.89	2.98	Mean difference 0.09 P=0.194

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		Concerns about child overweight at 24 months	2.06	2.29	Mean difference 0.23 P=0.329
		Dietary restriction at 24 months	3.44	3.77	Mean difference 0.33 P=0.010
		Pressure to eat at 24 months	2.68	2.72	Mean difference 0.04 P=0.939
		Monitoring at 24 months	4.13	4.41	Mean difference 0.28 P=0.046
PROBIT, Morandi, 2019	N= 550	Feeding on demand at 12months (%)	80%	93%	13% difference, p=0.001
	N= 468	Television viewing at age 2 years (>30mins a day, %)	67%	73%	6% difference, p=0.08
	N=468	Sweetened Beverage consumption at age 2 years (any, %)	57%	63%	6% difference, p=0.16

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Appendix table 1: Theoretical Models

Theoretical models used **Trial name**	**Social cognitive theory**	**Social-ecological theories**	**Social learning theory**	**Health beliefs model**	**Behavioural model**	**Attachment theory**	**Transtheoretical model of change**	**Ecological developmental theory**	**Theory of planned behaviour**	**McGuire communication model**	Common Risk/Health Factor Approach (CR/HFA)	**Not listed**
TOTAL N (%)	**10(34)**	**1(3)**	**5(17)**	**3(10)**	**1(3)**	**2(7)**	**1(3)**	**1(3)**	**1(3)**	**1(3)**	**1(3)**	**16(55)**
Healthy Beginnings			x	x								
InFANT	x											
NOURISH	x					x						
FYCS												x
POI.nz												x
BeeBOFT	x	x	x						x	x		
GREENLIGHT	x											
Addressing Health Literacy and Numeracy to Prevent Childhood Obesity	x											
INSIGHT												x
Early STOPP	x				x		x					
InFANT EXTEND												x
Starting Early Obesity Prevention Program	x		x	x								
HLPP												x
BLISS												x
Preventing obesity through early guidance												x
PRIMROSE	x											

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Early Obesity Prevention:												x
CHAT			x	x								
CHALO											x	
PROBIT												x
Samen Happie												x
Family Spirit Nurture	x							x				
Baby's first bites	x		x			x						
SPOON-Guatemala												x
Strong Futures												x
PROGESPI												x
SCHeLTI												x
SPOON-Mexico												x
Greenlight plus												x

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Appendix table 2: Funding Sources

Study	Funding Sources
Healthy Beginnings	Australian National Health and Medical Research Council
INFANT	Australian National Health and Medical Research Council
NOURISH	Australian National Health and Medical Research Council HJ Heinz Meat and Livestock Australia Department of Health South Australia Food standards Australia New Zealand Queensland University of technology Roberta Holmes Transition to contemporary Parenthood Program (La Trobe University)
Feeding Young Children Study	US department of Agriculture National Institute of Food and Agriculture
POI.nz	Health Research Council New Zealand Southern District Health Board
BeeBOFT	ZonMW- Netherlands Organisation of Health Research and Development NOW- Netherlands organisation for scientific research
GREENLIGHT	Eunice Kennedy National Institute of Child Health and Human Development Centers for Disease Control and Prevention Office of Behavioural and Social Science Research National Institutes of Health Robert Wood Johnson Foundation Physician Faculty Scholars Program Health Resources and Services Administration KiDS of the New York University Langone Foundation
Addressing Health Literacy and Numeracy to Prevent Childhood Obesity	NYU Langone Health National Institutes of Health
INSIGHT	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National institute of Health National Center for Advancing Translational Sciences The Children's Miracle Network (Penn State Children's Hospital) US Department of Agriculture Penn State Clinical and Translational Institute
Early STOPP	FAS Vinnova Medical Research Council The Karolinska Institute
INFANT extend	Australian National Health and Medical Research Council National Heart Foundation World Cancer Research Fund International
Starting Early Obesity Prevention Program	National Institute of Food and agriculture National institute of Health/Child Health and Human development
HLPP	Bronx-Lebanon Hospital Center Health Care System United Healthcare Foundation
BLISS	Lottery Health Research Meat and Livestock Australia Karitane Products Society University of Otago Heinz Watties Ltd Perpetual trustees NZ federation of Woman's Institutes
Preventing Childhood Obesity through early guidance	National institute of Health National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

	Arizona State University College of Nursing and Health Innovation
PRIMROSE	Swedish Research Council for Health The Swedish Council for Working Life and Welfare The Swedish Research Council The Research and Development Committee Stockholm, Uppsala and Sormland County Council Regional Research Council of the Uppsala and Orebre Health Care Region The Public Health Committee of Stockholm County Council The Vardal Foundation AFA insurance The foundation of the Swedish Diabetes Society The Karolinska Health Care Sciences Postgraduate School The Karolinska Institute
Early Obesity Prevention:	Dannon Institute (USA)
CHAT	NSW Ministry of Health
CHALO	Grant from the National Institute on Minority Health and Health Disparities
PROBIT	Regione Vento University of Verona
Samen Happie	Behavioural Science Institute, Radbound Univeristy
Family Spirit Nurture	Eunice Kennedy National Institute of Child Health and Human Development Share Our Strength Indian Health service John Hopkins University Discovery Award
Baby's first bites	NWO - Netherlands organisation for scientific research Danone Nutricia research
SPOON Guatemala	Inter-American Developmental Bank The PepsiCo Foundation JPO-JSF Poverty Reduction Program Fundazúcar
Strong futures	University of California Eunice Kennedy National Institute of child health and human development
PROGESPI	FFIS (Fundacion para la Formacion e Investigacion Sanitarias de la Region de Murcia)
SCHeLTI	International Peace Maternity and Child Health Hospital affiliated to Shanghai Jiao Tong University, School of Medicine University of Sherbrooke University of Sherbrooke, Health Campus National Science Foundation of China(NSFC) Canadian Institutes of Health Research (CIHR)
SPOON Mexico	Inter-American Development Bank Hospital Infantil de Mexico Federico Gomez Servicios de Salud de Nayarit The PepsiCo Foundation
Greenlight plus	Vanderbilt University Medical Center Patient-Centered Outcomes Research Institute Duke University University of North Carolina, Chapel Hill Stanford University NYU Langone Health University of Miami

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Appendix table 3. Risk of Bias (RoB 2.0) assessments

Study	Design	Risk of bias
Healthy Beginnings @ 2 years	RCT	High Risk
Healthy Beginnings @ 5 years	RCT	High Risk
Feeding Young Children Study	RCT	Some Concerns
INFANT	RCT	Low Risk
INFANT at 3 and 5	RCT	Low Risk
NOURISH at 2 years	RCT	Low Risk
NOURISH at 5 years	RCT	Low Risk
PRIMROSE	RCT	High Risk
INSIGHT at 1 year	RCT	Low Risk
INSIGHT at 3 years	RCT	Low Risk
BeeBOFT	RCT	Low Risk
BLISS	RCT	Low Risk
POI.nz	RCT	Low Risk
PROBIT	RCT	Low Risk
Early Obesity Prevention	RCT	High Risk

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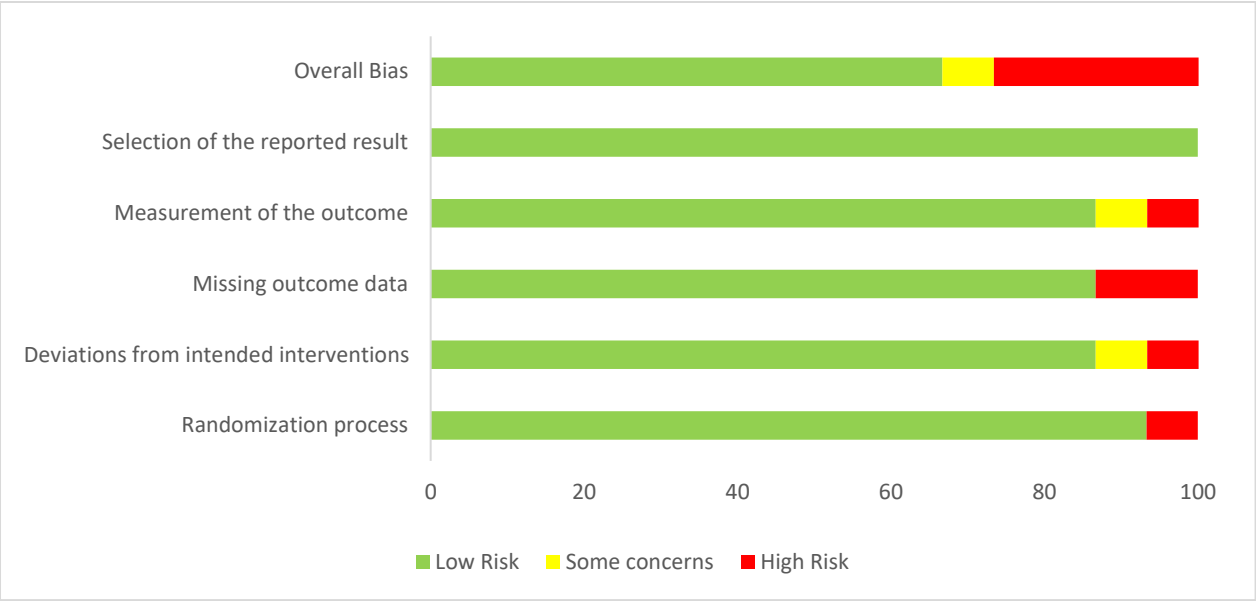
Figure 1: Risk of bias graph



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